Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

Table of Contents
(Rev. 13709; Issued: 04-02-26)

Transmittals for Chapter 32

10- Diagnostic Blood Pressure Monitoring

10.1 - Ambulatory Blood Pressure Monitoring (ABPM) Billing Requirements

11 - Wound Treatments

11.1 – Electrical Stimulation

11.2 – Electromagnetic Therapy

11.3 – Autologous Platelet-Rich Plasma (PRP) for Chronic Non-Healing Wounds

11.3.1 – Policy

11.3.2 – Healthcare Common Procedure Coding System (HCPCS) Codes and Diagnosis Coding

11.3.3 – Types of Bill (TOB)

11.3.5 - Place of Service (POS) for Professional Claims

11.3.6 – Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RARCs), Claim Adjustment Reason Codes (CARCs) and Group Codes

12 - Counseling to Prevent Tobacco Use

12.1 - Counseling to Prevent Tobacco Use HCPCS and Diagnosis Coding

12.2 - Counseling to Prevent Tobacco Use A/B MAC (B) Billing Requirements

12.3 - A/B MAC (A) Billing Requirements

12.4 - Remittance Advice (RA) Notices

12.5 - Medicare Summary Notices (MSNs)

12.6 - Post-Payment Review for Counseling To Prevent Tobacco Use Services

12.7 - Common Working File (CWF) Inquiry

12.8 - Provider Access to Counseling To Prevent Tobacco Use Services Eligibility Data

20 – Billing Requirements for Coverage of Kidney Disease Patient Education Services

20.1 – Additional Billing Requirements Applicable to Claims Submitted to Fiscal Intermediaries (FIs)

20.2 - Healthcare Common Procedure Coding System (HCPCS) Procedure Codes and Applicable Diagnosis Codes

20.3 - Medicare Summary Notices (MSNs) and Claim Adjustment Reason Codes (CARCs)

20.4 - Advance Beneficiary Notice (ABN) Information

30 - Hyperbaric Oxygen (HBO) Therapy

30.1 – Billing Requirements for HBO Therapy for the Treatment of Diabetic Wounds of the Lower Extremities

30.2 Hyperbaric Oxygen (HBO) Therapy (Section C, Topical Application of Oxygen)

40 – Sacral Nerve Stimulation

40.1 – Coverage Requirements

40.2 – Billing Requirements

40.2.1 – Healthcare Common Procedural Coding System (HCPCS)

40.2.2 – Payment Requirements for Test Procedures (HCPCS Codes 64585, 64590 and 64595)
40.2.3 – Payment Requirements for Device Codes A4290, E0752 and E0756
40.2.4 - Payment Requirements for Codes C1767, C1778, C1820, C1883 and C1897
40.3 – Bill Types
40.4 – Revenue Codes
40.5 - Claims Editing
50 – Deep Brain Stimulation for Essential Tremor and Parkinson's Disease
50.1 – Coverage Requirements
50.2 – Billing Requirements
50.2.1 – Part A Intermediary Billing Procedures
50.3 – Payment Requirements
50.3.1 - Part A Payment Methods
50.3.2 – Bill Types
50.3.3 – Revenue Codes
50.4 – Allowable Codes
50.4.1 – Allowable Covered Diagnosis Codes
50.4.2 - Allowable Covered Procedure Codes
50.4.3 – Healthcare Common Procedure Coding System (HCPCS)
50.5 – Ambulatory Surgical Centers
50.6 – Claims Editing for Intermediaries
50.7 – Remittance Advice Notice for A/B MACs (A)
50.8 – Medicare Summary Notices (MSN) Messages for Intermediaries
50.9 – Provider Notification
60 – Coverage and Billing for Home Prothrombin Time (PT/INR) Monitoring for Home Anticoagulation Management
60.1 – Coverage Requirements
60.2 – Intermediary Payment Requirements
60.2.1 – Part A Payment Methods
60.3 – Intermediary Billing Procedures
60.3.1 – Bill Types
60.3.2 – Revenue Codes
60.4 – Intermediary Allowable Codes
60.4.1 – Allowable Covered Diagnosis Codes
60.4.2 – Healthcare Common Procedure Coding System (HCPCS) for Intermediaries
60.5 – Carrier Billing Instructions
60.5.1 - HCPCS for Carriers
60.5.2 – Applicable Diagnosis Codes for A/B MACs (B)
60.6 – Carrier Claims Requirements
60.7 – Carrier Payment Requirements
60.8 – Carrier and Intermediary General Claims Processing Instructions
60.12 - Coverage for PET Scans for Dementia and Neurodegenerative Diseases
60.8.1 – Remittance Advice Notices
60.8.2 – Medicare Summary Notice (MSN) Messages

66 - National Coverage Determination (NCDs) services that are considered a significant cost for Medicare Advantage.

66.1 – Institutional Billing for National Coverage Determination (NCDs) services that are considered a significant cost for Medicare Advantage

66.2 – Services Identified as having Significant Cost for Medicare Advantage

67 - No Cost Claims

67.1 - Practitioner Billing for No Cost Items

67.2 - Institutional Billing for No Cost Items

67.2.1 - Billing No Cost Items Due to Recall, Replacement, or Free Sample

68 - Investigational Device Exemption (IDE) Studies

68.1 - Billing Requirements for Providers Billing for Routine Care Items and Services in Category A IDE Studie

68.2 - Billing Requirements for Providers Billing for Category B IDE Devices and Routine Care Items and Services in Category B IDE Studies

68.4 – Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category B IDE

69 - Qualifying Clinical Trails

69.1 - General

69.2 - Payment for Qualifying Clinical Trial Services

69.3 - Medical Records Documentation Requirements

69.4 - Local Medical Review Policy

69.5 - Billing Requirements - General

69.6 - Requirements for Billing Routine Costs of Clinical Trials

69.7 - Reserved for Future Use

69.8 - Handling Erroneous Denials of Qualifying Clinical Trial Services

69.9 - Billing and Processing Fee for Service Claims for Covered Clinical Trial Services Furnished to Managed Care Enrollees

69.10 - CWF Editing Of Clinical Trial Claims For Managed Care Enrollees

69.11 - Resolution of CWF UR 5232 Rejects

70 - Billing Requirements for Islet Cell Transplantation for Beneficiaries in a National Institutes of Health (NIH) Clinical Trial

70.1 - Healthcare Common Procedure Coding System (HCPCS) Codes for Carriers

70.2 - Applicable Modifier for Islet Cell Transplant Claims for Carriers

70.3 - Special Billing and Payment Requirements for Carriers

70.4 - Special Billing and Payment Requirements for A/B MACs (A)

70.5 - Special Billing and Payment Requirements Medicare Advantage (MA) Beneficiaries

80 – Billing of the Diagnosis and Treatment of Peripheral Neuropathy with Loss of Protective Sensation in People with Diabetes

80.1 - General Billing Requirements

80.2 - Applicable HCPCS Codes

80.3 - Diagnosis Codes

80.4 - Payment

80.5 - Applicable Revenue Codes

80.6 - Editing Instructions for A/B MACs (A)

80.7 - CWF General Information

80.8 - CWF Utilization Edits

90 - Stem Cell Transplantation

90.1 - General
90.2 - HCPCS and Diagnosis Coding - ICD-9-CM Applicable
90.2.1 - HCPCS and Diagnosis Coding for Stem Cell Transplantation - ICD-10-CM Applicable
90.3 - Non-Covered Conditions
90.4 - Edits
90.5 - Suggested MSN and RA Messages
90.6 - Clinical Trials for Allogeneic Hematopoietic Stem Cell Transplantation
(HSCT) for Myelodysplastic Syndrome (MDS)
100 – Billing Requirements for Expanded Coverage of Cochlear Implantation
100.1 –A/B MACs (Part A) Billing Procedures
100.1.1 – Applicable Bill Types
100.1.2 – Special Billing Requirements for A/B MACs (A) for Inpatient Billing
100.2 – A/B MACs (Part A) Payment Requirements
100.3 – A/B MACs (Part B) Billing Procedures
100.4 – Healthcare Common Procedural Coding System (HCPCS)
100.5 – Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages
110 - Coverage and Billing for Ultrasound Stimulation for Nonunion Fracture Healing
110.1 - Coverage Requirements
110.2 - Intermediary Billing Requirements
110.3 - Bill Types
110.4 - Carrier and Intermediary Billing Instructions
110.5 - DMERC Billing Instructions
120 - Presbyopia-Correcting (P-C IOLS) and Astigmatism-Correcting Intraocular Lenses (A-C IOLs) (General Policy Information)
120.1 - Payment for Services and Supplies
120.2 - Coding and General Billing Requirements
120.3 - Provider Notification Requirements
120.4 - Beneficiary Liability
130 - External Counterpulsation (ECP) Therapy
130.1 - Billing and Payment Requirements
130.2 - Special Intermediary Billing and Payment Requirements
140 140 - Cardiac Rehabilitation (CR) Programs, Intensive Cardiac Rehabilitation (ICR) Programs, and Pulmonary Rehabilitation (PR) Programs On or After January 1, 2024
140.1 – CR Program Services Furnished On or Before Dec. 31, 2009
140.1.1 - Coding Requirements for CR Services Furnished On or Before Dec. 31, 2009
140.2 – – CR Program Services Effective for Dates of Service On or After January 1, 2024
140.2.1 – Coding Requirements for CR Services Furnished On or After January 1, 2010
140.2.2 - Claims Processing Requirements for Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Services Furnished On or After January 1, 2010
140.2.2.1 – Correct Place of Service (POS) Codes for CR and ICR Services on Professional Claims
140.2.2.2 – Requirements for CR and ICR Services on Institutional Claims
140.2.2.3 – Frequency Edits for CR and ICR Claims

140.2.2.4 – Edits for CR Services Exceeding 36 Sessions
140.2.2.5 – Edits for ICR Services Exceeding 126 Days and 72 Sessions
140.2.2.6 – Supplier Specialty Code 31 Requirements for ICR Claims
140.3 – ICR Program Services Effective for Dates of Service On or After January 1, 2024
140.3.1 – Coding Requirements for ICR Services Furnished On or After January 1, 2010
140.4 – PR Program Services Effective for Dates of Service On or After January 1, 2024
140.4.1 – Coding Requirements for PR Services Furnished On or After January 1, 2010
140.4.2 - Claims Processing Requirements for Pulmonary Rehabilitation (PR) Services Furnished On or After January 1, 2010
140.4.2.1 – Correct Place of Service (POS) Codes for PR Services on Professional Claims
140.4.2.2 – Requirements for PR Services on Institutional Claims
140.4.2.3 – Daily Frequency Edits for PR Claims
140.4.2.4 – Edits for PR Services Exceeding 36 Sessions
140.4.2.5 – Edits for PR Services Exceeding 72 Sessions
150 - Billing Requirements for Bariatric Surgery for Morbid Obesity
150.1 - General
150.2 - HCPCS Procedure Codes for Bariatric Surgery
150.3 - ICD Procedure Codes for Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity (A/MACs only)
150.4 - ICD Diagnosis Codes for Bariatric Surgery
150.5 - ICD Diagnosis Codes for BMI ≥35
150.5.1 – ICD Codes for Type II Diabetes Mellitus Complication
150.6 - Claims Guidance for Payment
150.7 - Medicare Summary Notices (MSNs) and Claim Adjustment Reason Codes
150.8 - B/MAC Billing Requirements
150.9 - Advance Beneficiary Notice and HINN Information
160 – PTA for Implanting the Carotid Stent
160.1 – Category B Investigational Device Exemption (IDE) Study Coverage
160.2 – Post-Approval Study Coverage
160.2.1 – Carotid Artery Stenting (CAS) Post-Approval Extension Studies
160.3 – Carotid Artery Stenting (CAS) With Embolic Protection Coverage
160.4 – 510k Post-Approval Extension Studies using 510k-Cleared Embolic Protection Devices during Carotid Artery Stenting (CAS) Procedures
161 - Intracranial PTA With Stenting
170 - Billing Requirements for Lumbar Artificial Disc Replacement
170.1 - General
170.2 - Carrier Billing Requirements
170.3 - A/B MAC (A) Billing Requirements
170.4 - Reasons for Denial and Medicare Summary Notice (MSN), Claim Adjustment Reason Code Messages and Remittance Advice Remark Code
170.5 - Advance Beneficiary Notice (ABN and Hospital Issued Notice of Noncoverage (HINN) Information
180 – Cryosurgery of the Prostate Gland
180.1 – Coverage Requirements
180.2 – Billing Requirements
180.3 – Payment Requirements

180.4 - Claim Adjustment Reason Codes, Remittance Advice Remark Codes, Group Codes, and Medicare Summary Notice Messages

180.5 – Additional CWF and Contractor Requirements

190 – Billing Requirements for Extracorporeal Photopheresis

190.1 - Applicable Intermediary Bill Types

190.2 - Healthcare Common Procedural Coding System (HCPCS), Applicable Diagnosis Codes and Procedure Code

190.3 - Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RAs) and Claim Adjustment Reason Coded

190.4 - Advance Beneficiary Notice and Hospital Issued Notice of Noncoverage Information

200 - Billing Requirements for Vagus Nerve Stimulation (VNS)

200.1 - General

200.2 - ICD-9 Diagnosis Codes for Vagus Nerve Stimulation (Covered since DOS on and after July 1, 1999)

200.3 - Carrier/MAC Billing Requirements

200.4 - Fiscal Intermediary Billing Requirements

200.5 - Medicare Summary Notice (MSN), Remittance Advice Remark Code (RARC) and Claims Adjustment Reason Code (CARC) Messages

200.6 - Advance Beneficiary Notice and HINN Information

210 – Billing Requirements for Continuous Positive Airway Pressure (CPAP) for Obstructive Sleep Apnea (OSA)

220 – Billing Requirements for Thermal Intradiscal Procedures (TIPs) Claims

220.1 - General

220.2 - Contractors, A/B Medicare Administrative Contractors (MACs)

220.3 - Medicare Summary Notice (MSN), Claim Adjustment Reason Code (CARC), and Remittance Advise Remark Code (RARC)

220.4 - Advanced Beneficiary Notice (ABN)

230 - Billing Wrong Surgical or Other Invasive Procedures Performed on a Patient, Surgical or Other Invasive Procedures Performed on the Wrong Body Part, and Surgical or Other Invasive Procedures Performed on the Wrong Patient

240 – Special Instructions for Certain Claims with a Gender/Procedure Conflict

240.1 - Billing Instructions for Institutional Providers

240.2 – Billing Instructions for Physicians and Non-Physician Practitioners

250 – Pharmacogenomic Testing for Warfarin Response

250.1 – Coverage Requirements

250.2 – Billing Requirements

250.3 – Payment Requirements

260 – Dermal Injections for Treatment of Facial Lipodystophy Syndrome (FLS)

260.1 – Policy

260.2 – Billing Instructions

260.2.1 – Hospital Billing Instructions

260.2.2. – Practitioner Billing Instructions

260.3 – Claims Processing System Editing

270 - Claims Processing for Implantable Automatic Defibrillators

270.1 - Coding Requirements for Implantable Cardiac Defibrillators (ICDs)

270.2 - Billing Requirements for Patients Enrolled in a Data Collection System

270.3- Messaging

280 – Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer
280.1 - Policy
280.2 – Healthcare Common Procedure Coding System (HCPCS) Codes and Diagnosis Coding
280.3 - Types of Bill (TOB) and Revenue Codes
280.4 - Payment Method
280.5 - Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RARCs), Claims Adjustment Reason Codes (CARCs), and Group Codes
290 - Transcatheter Aortic Valve Replacement (TAVR) Furnished on or After May 1, 2012
290.1 - Coding Requirements for TAVR Furnished on or After May 1, 2012, through December 31, 2012
290.1.1- Coding Requirements for TAVR Services Furnished On or After January 1, 2013
290.2 - Claims Processing Requirements for TAVR Services on Professional Claims
290.3 - Claims Processing Requirements for TAVR Services on Inpatient Hospital Claims
290.4 - Claims Processing Requirements for TAVR Services for Medicare Advantage (MA) Plan Participants
300 - Billing Requirements for Ocular Photodynamic Therapy (OPT) with Verteporfin
300.1 - Coding Requirements for OPT with Verteporfin
300.2 - Claims Processing Requirements for OPT with Verteporfin Services on Professional Claims and Outpatient Facility Claims
300.3 - Claims Processing Requirements for OPT with Verteporfin Services on Inpatient Facility Claims
300.4 - Medicare Summary Notice (MSN) and Remittance Advice (RA)
Messages
310 - Transesophageal Doppler Used for Cardiac Monitoring
310.1 – Coding Requirements for Transesophageal Doppler Cardiac Monitoring Furnished Before October 1, 2012
310.2 – Coding Requirements for Transesophageal Doppler Monitoring Furnished On or After October 1, 2012
310.3 – Correct Place of Service (POS) Code for Transesophageal Doppler Cardiac Monitor Services on Professional Claims
320 - Artificial Hearts and Related Devices
320.1 – Coding Requirements for Artificial Hearts Furnished Before May 1, 2008
320.2 – Coding Requirements for Artificial Hearts Furnished After May 1, 2008
320.3 – Ventricular Assist Devices (VADs)
320.3.1 – Postcardiotomy
320.3.2 – Bridge- to-Transplantation (BTT)
320.3.3 – Other
320.3.4 – Replacement Accessories and Supplies for External VADs or Any VAD
330 – Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS)
330.1 – Claims Processing Requirements for Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) on Professional Claims
330.2 - Claims Processing Requirements for PILD for Outpatient Facilities
340 – Transcatheter Mitral Valve Repair (TMVR)
340.1 – Coding Requirements for TMVR for **Mitral Valve TEER** Claims Furnished on or After August 7, 2014
340.2 – Claims Processing Requirements for **Mitral Valve TEER** Services on Professional Claims

340.3 - Claims Processing Requirements for **Mitral Valve TEER** Services on Inpatient Hospital Claims

340.4 - Claims Processing Requirements for **Mitral Valve TEER** Services for Medicare Advantage (MA) Plan Participants

350 - Emergency and Foreign Hospital Services

350.1 - Services Rendered By Nonparticipating Providers

350.2 - Establishing an Emergency

350.3 - Qualifications of an Emergency Services Hospital

350.4 - Coverage Requirements for Emergency Hospital Services Furnished Outside of the United States

350.5 - Services Furnished in a Foreign Hospital Nearest to Beneficiary's U.S. Residence

350.6 - Coverage of Physician and Ambulance Services Furnished Outside U.S.

350.7 - Claims for Services Furnished in Canada to Qualified Railroad Retirement Beneficiaries

350.8 - Claims from Hospital-Leased Laboratories Not Meeting Conditions of Participation

350.9 - Nonemergency Part B Medical and Other Health Services

350.10 - Elections to Bill for Services Rendered By Nonparticipating Hospitals

350.11 - Processing Claims

350.11.1 - Contractors Designated to Process Foreign Claims

350.11.2 - Contractor Processing Guidelines

350.11.3 - Medicare Approved Charges for Services Rendered in Canada or Mexico

350.11.4 - Accessibility Criteria

350.11.5 - Medical Necessity

350.11.6 - Time Limitation on Emergency and Foreign Claims

350.11.7 - Payment Denial for Medicare Services Furnished to Alien Beneficiaries Who Are Not Lawfully Present in the United States

350.12 - Appeals on Claims for Emergency and Foreign Services

360 - Payment for Services Received By Nonparticipating Providers

360.1 - Payment for Services from Foreign Hospitals

360.1.1 - Attending Physician's Statement and Documentation of Medicare Emergency

360.2 - Designated Contractors

360.3 - Model Letters, Nonparticipating Hospital and Emergency Claims

360.3.1 - Model Letter to Nonparticipating Hospital That Elected to Bill For Current Year

360.3.2 - Model Letter to Nonparticipating Hospital That Did Not Elect to Bill for Current Year

360.3.3 - Model Letter to Nonparticipating Hospital That Requests to Bill the Program

360.3.4 - Full Denial - Hospital-Filed or Beneficiary-Filed Emergency Claim

360.3.5 - Partial Denial - Hospital-Filed or Beneficiary-Filed Emergency Claim

360.3.6 - Denial - Military Personnel/Eligible Dependents

360.3.7 - Full Denial - Shipboard Claim - Beneficiary filed

360.3.8 - Full Denial - Foreign Claim - Beneficiary Filed

370 - Microvolt T-wave Alternans (MTWA)

370.1 - Coding and Claims Processing for MTWA

370.2 - Messaging for MTWA

380--Leadless Pacemakers

380.1 - Leadless Pacemaker Coding and Billing Requirements for Professional Claims

380.1.1 - Leadless Pacemaker Place of Service Restrictions

380.1.2 - Leadless Pacemaker Modifier

380.1.3 - Leadless Pacemaker Additional Claim Billing Information
380.2 - Leadless Pacemaker Claim Adjustment Reason Codes (CARC), Remittance Advice Remark Codes (RARC) and Medicare Summary Notice (MSN) Messages
390 – Supervised exercise therapy (SET) of Symptomatic Peripheral Artery Disease
390.1 - General Billing Requirements
390.2 - Coding Requirements for SET
390.3 - Special Billing Requirements for Institutional Claims
390.4 - Common Working File (CWF) Requirements
390.5 - Applicable Medicare Summary Notice (MSN), Remittance Advice Remark Codes (RARC) and Claim Adjustment Reason Code (CARC) Messaging

400 - Chimeric Antigen Receptor (CAR) T- **cell Therapy**
400.1 - Coverage Requirements
400.2 - Billing Requirements
400.2.1- A/B Medicare Administrative Contractor (MAC) (A) Bill Types
400.2.2 - A/B MAC (A) Revenue Codes
400.2.3 - A/B MAC Billing Healthcare Common Procedural Coding System (HCPCS) Codes
400.2.3.1 – A/B MAC (B) Places of Service (POS)
400.2.4 - A/B MAC Diagnosis Requirements
400.2.5 – Billing Information for Professional Claims
400.3 - Payment Requirements
400.4 - Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs),Group Codes, and Medicare Summary Notice (MSN) Messages
400.5 - Claims Editing
410 - Acupuncture for Chronic Low Back Pain (cLBP)
410.1 - Coverage Requirements
410.2 - Claims Processing General Information
410.3 - Institutional Claims Bill Type and Revenue Coding Information
410.4 – Messaging
410.5 – Common Working File (CWF) Editing

411 – Home Infusion Therapy Services
411.1 – Policy
411.2 – Coverage Requirements
411.3 – Home Infusion Drugs: Healthcare Common Procedural Coding System (HCPCS) Drug Codes
411.4 – Billing and Payment Requirements
411.5 – Return as Un-Processable, Claim Adjustment Reason Codes, Remittance Advice Remark Codes, Group Codes, and Medicare Summary Notice Messages
411.6 – CWF and MCS Editing Requirements
412 - Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD)
412.1 - Coding Information
412.2 - Claim Processing Instructions
412.3 - Messaging
413- Noninvasive Positive Pressure Ventilation (NIPPV) in the Home for the Treatment of Chronic Respiratory Failure (CRF) Consequent to Chronic Obstructive Pulmonary Disease (COPD)
413.1 - Coverage
413.2 - Claims Processing Instructions
414 – Transcatheter Tricuspid Valve Replacement (TTVR)
414.1– Coding Requirements for TTVR
414.2– Claims Processing Instructions for TTVR Professional Claims
414.3– Claims Processing Instructions for TTVR Institutional Claims

414.4– Messages
415 – Transcatheter Edge-to-Edge Repair for Tricuspid Valve Regurgitation (T-TEER)
415.1– Coding Requirements for T-TEER
415.2– Claims Processing Instructions for T-TEER Professional Claims
415.3– Claims Processing Instructions for T-TEER Institutional Claims
415.4– Messages
416- Noninvasive Positive Pressure Ventilation (NIPPV) in the Home for the Treatment of Chronic Respiratory Failure (CRF) Consequent to Chronic Obstructive Pulmonary Disease (COPD)
416.1- Coverage
416.2- Claims Processing Instructions
416.3 Claims Processing Instructions for Cardiac Contractility Modulation (CCM) for Heart Failure (HF) Institutional Claims
416.4 Messages
417 Renal Denervation (RDN) for Uncontrolled Hypertension
417. 1 Coding Requirements
417.2 – Special Intermediary Claims Processing Requirements
417.3 – Special Professional Billing Requirements
417.4 – Messaging
418- Cardiac Contractility Modulation (CCM) for Heart Failure (HF)
418.1 Coding Requirements for Cardiac Contractility Modulation (CCM) for Heart Failure (HF)
418.2 Claims Processing Instructions for Cardiac Contractility Modulation (CCM) for Heart Failure (HF) Professional Claims
418.3 Claims Processing Instructions for Cardiac Contractility Modulation (CCM) for Heart Failure (HF) Institutional Claims
418.4 Messages

10 - Diagnostic Blood Pressure Monitoring
(Rev. 109, 02-27-04)

10.1 - Ambulatory Blood Pressure Monitoring (ABPM) Billing Requirements
(Rev. 11021; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

A. Coding Applicable to A/B MACs (A and B)

Effective April 1, 2002, a National Coverage Decision was made to allow for Medicare coverage of ABPM for those beneficiaries with suspected "white coat hypertension" (WCH). ABPM involves the use of a non-invasive device, which is used to measure blood pressure in 24-hour cycles. These 24-hour measurements are stored in the device and are later interpreted by a physician. Suspected "WCH" is defined as: (1) Clinic/office blood pressure >140/90 mm Hg on at least three separate clinic/office visits with two separate measurements made at each visit; (2) At least two documented separate blood pressure measurements taken outside the clinic/office which are < 140/90 mm Hg; and (3) No evidence of end-organ damage. ABPM is not covered for any other uses. Coverage policy can be found in Medicare National Coverage Determinations Manual, Chapter 1, Part 1, §20.19. (http://www.cms.hhs.gov/manuals/103_cov_determ/ncd103index.asp).

The ABPM must be performed for at least 24 hours to meet coverage criteria. Payment is not allowed for institutionalized beneficiaries, such as those receiving Medicare covered skilled nursing in a facility. In the rare circumstance that ABPM needs to be performed more than once for a beneficiary, the qualifying criteria described above must be met for each subsequent ABPM test.

Effective dates for applicable Common Procedure Coding System (HCPCS) codes for ABPM for suspected WCH and their covered effective dates are as follows:

HCPCS	Definition	Effective Date
93784	ABPM, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; including recording, scanning analysis, interpretation and report.	04/01/2002
93786	ABPM, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; recording only.	04/01/2002
93788	ABPM, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; scanning analysis with report.	01/01/2004

HCPCS	Definition	Effective Date
93790	ABPM, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; physician review with interpretation and report.	04/01/2002

In addition, one of the following diagnosis codes must be present:

	Diagnosis Code	Description
If ICD-10-CM is applicable	R03.0	Elevated blood pressure reading without diagnosis of hypertension

B. A/B MAC (A) Billing Instructions

The applicable types of bills acceptable when billing for ABPM services are 13X, 23X, 71X, 73X, 75X, and 85X. Chapter 25 of this manual provides general billing instructions that must be followed for bills submitted to A/B MACs (A). The A/B MACs (A) pay for hospital outpatient ABPM services billed on a 13X type of bill with HCPCS 93786 and/or 93788 as follows: (1) Outpatient Prospective Payment System (OPPS) hospitals pay based on the Ambulatory Payment Classification (APC); (2) non-OPPS hospitals (Indian Health Services Hospitals, Hospitals that provide Part B services only, and hospitals located in American Samoa, Guam, Saipan and the Virgin Islands) pay based on reasonable cost, except for Maryland Hospitals which are paid based on a percentage of cost. Effective 4/1/06, type of bill 14X is for non-patient laboratory specimens and is no longer applicable for ABPM.

The A/B MACs (A) pay for comprehensive outpatient rehabilitation facility (CORF) ABPM services billed on a 75x type of bill with HCPCS code 93786 and/or 93788 based on the Medicare Physician Fee Schedule (MPFS) amount for that HCPCS code.

The A/B MACs (A) pay for ABPM services for critical access hospitals (CAHs) billed on a 85x type of bill as follows: (1) for CAHs that elected the Standard Method and billed HCPCS code 93786 and/or 93788, pay based on reasonable cost for that HCPCS code; and
(2) for CAHs that elected the Optional Method and billed any combination of HCPCS codes 93786, 93788 and 93790 pay based on reasonable cost for HCPCS 93786 and 93788 and pay 115% of the MPFS amount for HCPCS 93790.

The A/B MACs (A) pay for ABPM services for skilled nursing facility (SNF) outpatients billed on a 23x type of bill with HCPCS code 93786 and/or 93788, based on the MPFS.

The A/B MACs (A) accept independent and provider-based rural health clinic (RHC) bills for visits under the all-inclusive rate when the RHC bills on a 71x type of bill with revenue code 052x for providing the professional component of ABPM services. The A/B MACs
(A) should not make a separate payment to a RHC for the professional component of ABPM services in addition to the all-inclusive rate. RHCs are not required to use ABPM HCPCS codes for professional services covered under the all-inclusive rate.

The A/B MACs (A) accept free-standing and provider-based federally qualified health center (FQHC) bills for visits under the all-inclusive rate when the FQHC bills on a 73x type of bill with revenue code 052x for providing the professional component of ABPM services.

The A/B MACs (A) should not make a separate payment to a FQHC for the professional component of ABPM services in addition to the all-inclusive rate. FQHCs are not required to use ABPM HCPCS codes for professional services covered under the all-inclusive rate.

The A/B MACs (A) pay provider-based RHCs/FQHCs for the technical component of ABPM services when billed under the base provider's number using the above requirements for that particular base provider type, i.e., a OPPS hospital based RHC would be paid for the ABPM technical component services under the OPPS using the APC for code 93786 and/or 93788 when billed on a 13x type of bill.

Independent and free-standing RHC/FQHC practitioners are only paid for providing the technical component of ABPM services when billed to the A/B MAC (B) following the MAC's instructions.

- **A/B MAC (B) Claims**

A/B MACs (B) pay for ABPM services billed with ICD-10-CM diagnosis code R03.0 (if ICD-10 is applicable) and HCPCS codes 93784 or for any combination of 93786, 93788 and 93790, based on the MPFS for the specific HCPCS code billed.

- **Coinsurance and Deductible**

The A/B MACs (A and B) shall apply coinsurance and deductible to payments for ABPM services except for services billed to the A/B MAC (A) by FQHCs. For FQHCs only co-
insurance applies.

11 - Wound Treatments
(Rev 124a, 03-19-04)

11.1 - Electrical Stimulation
(Rev. 371, Issued 11-19-04, Effective: 04-01-05, Implementation: 04-04-05)

A. Coding Applicable to Carriers & Fiscal Intermediaries (FIs)

Effective April 1, 2003, a National Coverage Decision was made to allow for Medicare coverage of Electrical Stimulation for the treatment of certain types of wounds. The type of wounds covered are chronic Stage III or Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers. All other uses of electrical stimulation for the treatment of wounds are not covered by Medicare. Electrical stimulation will not be covered as an initial treatment modality.

The use of electrical stimulation will only be covered after appropriate standard wound care has been tried for at least 30 days and there are no measurable signs of healing. If electrical stimulation is being used, wounds must be evaluated periodically by the treating physician but no less than every 30 days by a physician. Continued treatment with electrical stimulation is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment. Additionally, electrical stimulation must be discontinued when the wound demonstrates a 100% epithelialzed wound bed.

Coverage policy can be found in Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Section 270.1 (http://www.cms.hhs.gov/manuals/103_cov_determ/ncd103index.asp)

The applicable Healthcare Common Procedure Coding System (HCPCS) code for Electrical Stimulation and the covered effective date is as follows:

HCPCS	Definition	Effective Date
G0281	Electrical Stimulation, (unattended), to one or more areas for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care as part of a therapy plan of care.	04/01/2003

Medicare will not cover the device used for the electrical stimulation for the treatment of wounds. However, Medicare will cover the service. Unsupervised home use of electrical stimulation will not be covered.

B. FI Billing Instructions

The applicable types of bills acceptable when billing for electrical stimulation services are 12X, 13X, 22X, 23X, 71X, 73X, 74X, 75X, and 85X. Chapter 25 of this manual provides general billing instructions that must be followed for bills submitted to FIs. FIs pay for electrical stimulation services under the Medicare Physician Fee Schedule for a hospital, Comprehensive Outpatient Rehabilitation Facility (CORF), Outpatient Rehabilitation Facility (ORF), Outpatient Physical Therapy (OPT) and Skilled Nursing Facility (SNF).

Payment methodology for independent Rural Health Clinic (RHC), provider-based RHCs, free-standing Federally Qualified Health Center (FQHC) and provider based FQHCs is made under the all-inclusive rate for the visit furnished to the RHC/FQHC patient to obtain the therapy service. Only one payment will be made for the visit furnished to the RHC/FQHC patient to obtain the therapy service. As of April 1, 2005, RHCs/FQHCs are no longer required to report HCPCS codes when billing for these therapy services.

Payment Methodology for a Critical Access Hospital (CAH) is on a reasonable cost basis unless the CAH has elected the Optional Method and then the FI pays115% of the MPFS amount for the professional component of the HCPCS code in addition to the technical component.

In addition, the following revenues code must be used in conjunction with the HCPCS code identified:

Revenue Code	Description
420	Physical Therapy
430	Occupational Therapy
520	Federal Qualified Health Center *
521	Rural Health Center *
977, 978	Critical Access Hospital- method II CAH professional services only

*** NOTE:** As of April 1, 2005, RHCs/FQHCs are no longer required to report HCPCS codes when billing for these therapy services.

C. Carrier Claims

Carriers pay for Electrical Stimulation services billed with HCPCS codes G0281 based on the MPFS. Claims for Electrical Stimulation services must be billed on Form CMS-1500 or the electronic equivalent following instructions in chapter 12 of this manual (http://www.cms.hhs.gov/manuals/104_claims/clm104c12.pdf).

D. Coinsurance and Deductible

The Medicare contractor shall apply coinsurance and deductible to payments for these therapy services except for services billed to the FI by FQHCs. For FQHCs, only co-insurance applies.

11.2 - Electromagnetic Therapy

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

A. HCPCS Coding Applicable to A/B MACs (A and B)

Effective July 1, 2004, a National Coverage Decision was made to allow for Medicare coverage of electromagnetic therapy for the treatment of certain types of wounds. The type of wounds covered are chronic Stage III or Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers. All other uses of electromagnetic therapy for the treatment of wounds are not covered by Medicare. Electromagnetic therapy will not be covered as an initial treatment modality.

The use of electromagnetic therapy will only be covered after appropriate standard wound care has been tried for at least 30 days and there are no measurable signs of healing. If electromagnetic therapy is being used, wounds must be evaluated periodically by the treating physician but no less than every 30 days. Continued treatment with electromagnetic therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment. Additionally, electromagnetic therapy must be discontinued when the wound demonstrates a 100% epithelialzed wound bed.

Coverage policy can be found in Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1 section 270.1. (http://www.cms.hhs.gov/manuals/103_cov_determ/ncd103index.asp)

The applicable Healthcare Common Procedure Coding System (HCPCS) code for Electrical Stimulation and the covered effective date is as follows:

HCPCS	Definition	Effective Date
G0329	ElectromagneticTherapy, to one or more areas for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care as part of a therapy plan of care.	07/01/2004

Medicare will not cover the device used for the electromagnetic therapy for the treatment of wounds. However, Medicare will cover the service. Unsupervised home use of electromagnetic therapy will not be covered.

B. A/B MAC (A) Billing Instructions

The applicable types of bills acceptable when billing for electromagnetic therapy services are 12X, 13X, 22X, 23X, 71X, 73X, 74X, 75X, and 85X. Chapter 25 of this manual provides general billing instructions that must be followed for bills submitted to A/B MACs (A). A/B MACs (A) pay for electromagnetic therapy services under the Medicare Physician Fee Schedule for a hospital, CORF, ORF, and SNF.

Payment methodology for independent (RHC), provider-based RHCs, free-standing FQHC and provider based FQHCs is made under the all-inclusive rate for the visit furnished to the RHC/FQHC patient to obtain the therapy service. Only one payment will be made for the visit furnished to the RHC/FQHC patient to obtain the therapy service. As of April 1, 2005, RHCs/FQHCs are no longer required to report HCPCS codes when billing for the therapy service.

Payment Methodology for a CAH is payment on a reasonable cost basis unless the CAH has elected the Optional Method and then the A/B MAC (A) pays pay 115% of the MPFS amount for the professional component of the HCPCS code in addition to the technical component.
In addition, the following revenues code must be used in conjunction with the HCPCS code identified:

Revenue Code	**Description**
420	Physical Therapy
430	Occupational Therapy
520	Federal Qualified Health Center *
521	Rural Health Center *
977, 978	Critical Access Hospital- method II CAH professional services only

* **NOTE:** As of April 1, 2005, RHCs/FQHCs are no longer required to report HCPCS codes when billing for the therapy service.

C. A/B MAC (B) Claims

A/B MACs (B) pay for Electromagnetic Therapy services billed with HCPCS codes G0329 based on the MPFS. Claims for electromagnetic therapy services must be billed using the ASC X12 837 professional claim format or Form CMS-1500 following instructions in chapter 12 of this manual (www.cms.hhs.gov/manuals/104_claims/clm104index.asp).

Payment information for HCPCS code G0329 will be added to the July 2004 update of the Medicare Physician Fee Schedule Database (MPFSD).

D. Coinsurance and Deductible

The Medicare contractor shall apply coinsurance and deductible to payments for electromagnetic therapy services except for services billed to the A/B MAC (A) by FQHCs. For FQHCs only co-insurance applies.

11.3 – Autologous Platelet-Rich Plasma (PRP) for Chronic Non-Healing Wounds

(Rev. 11214, Issued: 01-20-22, Effective:04-13-21, Implementation: 01-03-22 Shared Systems Contractors, 02-14-22 MACs)

11.3.1 – Policy

(Rev. 11214, Issued: 01-20-22, Effective:04-13-21, Implementation: 01-03-22 Shared Systems Contractors, 02-14-22 MACs)

Effective for claims with dates of service on or after April 13, 2021, contractors shall accept and pay for autologous platelet-rich plasma (PRP) for the treatment of chronic non-healing diabetic wounds for a duration of 20 weeks, when prepared by devices whose Food and Drug Administration-cleared indications include the management of exuding cutaneous wounds, such as diabetic ulcers, in accordance with the coverage criteria outlined in Publication 100-03, chapter 1, section 270.3, of the National Coverage Determinations (NCD) Manual.

NOTE: Coverage of PRP services for the treatment of chronic non-healing diabetic wounds that are performed more than 20 weeks after the date of the first PRP service shall be determined by the local Medicare Administrative Contractor (MAC).

Coverage of autologous PRP for the treatment of all other chronic non-healing wounds (non-diabetic) will be determined by local MACs under section 1862(a)(1)(A) of the Social Security Act.

11.3.2 – Healthcare Common Procedure Coding System (HCPCS) Codes and Diagnosis Coding

(Rev. 11214, Issued: 01-20-22, Effective:04-13-21, Implementation: 01-03-22 Shared Systems Contractors, 02-14-22 MACs)

Healthcare Common Procedure Coding System (HCPCS) Code

Effective for claims with dates of service on or after April 13, 2021, Medicare providers shall report HCPCS code G0460 for PRP services for the treatment of chronic non-healing non-diabetic wounds.

Effective for claims with dates of service on or after April 13, 2021, Medicare providers shall report HCPCS code G0465 for PRP services for the treatment of chronic non-healing diabetic wounds under the conditions and criteria outlined in NCD Manual Section 270.3.

If ICD-10 Diagnosis coding is applicable

For claims with dates of service on or after April 13, 2021, PRP, for the treatment of chronic non-healing diabetic wounds must be billed reporting both an ICD-10 diagnosis code for diabetes mellitus and an ICD-10 diagnosis code for chronic ulcers.

- Two diagnosis codes are required- Diabetic Mellitus plus Chronic Ulcer

Diabetes Mellitus

E08.621	Diabetes mellitus due to underlying condition with foot ulcer
E08.622	Diabetes mellitus due to underlying condition with other skin ulcer
E09.621	Drug or chemical induced diabetes mellitus with foot ulcer
E09.622	Drug or chemical induced diabetes mellitus with other skin ulcer
E10.621	Type 1 diabetes mellitus with foot ulcer
E10.622	Type 1 diabetes mellitus with other skin ulcer
E11.621	Type 2 diabetes mellitus with foot ulcer
E11.622	Type 2 diabetes mellitus with other skin ulcer
E13.621	Other specified diabetes mellitus with foot ulcer
E13.622	Other specified diabetes mellitus with other skin ulcer

Chronic Ulcer

L97.111	Non-pressure chronic ulcer of right thigh limited to breakdown of skin
L97.112	Non-pressure chronic ulcer of right thigh with fat layer exposed
L97.113	Non-pressure chronic ulcer of right thigh with necrosis of muscle
L97.115	Non-pressure chronic ulcer of right thigh with muscle involvement without evidence of necrosis
L97.116	Non-pressure chronic ulcer of right thigh with bone involvement without evidence of necrosis
L97.118	Non-pressure chronic ulcer of right thigh with other specified severity
L97.114	Non-pressure chronic ulcer of right thigh with necrosis of bone
L97.121	Non-pressure chronic ulcer of left thigh limited to breakdown of skin
L97.122	Non-pressure chronic ulcer of left thigh with fat layer exposed
L97.123	Non-pressure chronic ulcer of left thigh with necrosis of muscle
L97.124	Non-pressure chronic ulcer of left thigh with necrosis of bone
L97.125	Non-pressure chronic ulcer of left thigh with muscle involvement without evidence of necrosis
L97.126	Non-pressure chronic ulcer of left thigh with bone involvement without evidence of necrosis
L97.128	Non-pressure chronic ulcer of left thigh with other specified severity
L97.211	Non-pressure chronic ulcer of right calf limited to breakdown of skin
L97.212	Non-pressure chronic ulcer of right calf with fat layer exposed
L97.213	Non-pressure chronic ulcer of right calf with necrosis of muscle
L97.214	Non-pressure chronic ulcer of right calf with necrosis of bone
L97.215	Non-pressure chronic ulcer of right calf with muscle involvement without evidence of necrosis
L97.216	Non-pressure chronic ulcer of right calf with bone involvement without evidence of necrosis
L97.218	Non-pressure chronic ulcer of right calf with other specified severity
L97.221	Non-pressure chronic ulcer of left calf limited to breakdown of skin
L97.222	Non-pressure chronic ulcer of left calf with fat layer exposed
L97.223	Non-pressure chronic ulcer of left calf with necrosis of muscle
L97.224	Non-pressure chronic ulcer of left calf with necrosis of bone
L97.225	Non-pressure chronic ulcer of left calf with muscle involvement without evidence of necrosis
L97.226	Non-pressure chronic ulcer of left calf with bone involvement without evidence of necrosis
L97.228	Non-pressure chronic ulcer of left calf with other specified severity
L97.315	Non-pressure chronic ulcer of right ankle with muscle involvement without evidence of necrosis
L97.316	Non-pressure chronic ulcer of right ankle with bone involvement without evidence of necrosis
L97.318	Non-pressure chronic ulcer of right ankle with other specified severity
L97.321	Non-pressure chronic ulcer of left ankle limited to breakdown of skin
L97.322	Non-pressure chronic ulcer of left ankle with fat layer exposed
L97.323	Non-pressure chronic ulcer of left ankle with necrosis of muscle

L97.324	Non-pressure chronic ulcer of left ankle with necrosis of bone
L97.325	Non-pressure chronic ulcer of left ankle with muscle involvement without evidence of necrosis
L97.326	Non-pressure chronic ulcer of left ankle with bone involvement without evidence of necrosis
L97.328	Non-pressure chronic ulcer of left ankle with other specified severity
L97.411	Non-pressure chronic ulcer of right heel and midfoot limited to breakdown of skin
L97.412	Non-pressure chronic ulcer of right heel and midfoot with fat layer exposed
L97.413	Non-pressure chronic ulcer of right heel and midfoot with necrosis of muscle
L97.414	Non-pressure chronic ulcer of right heel and midfoot with necrosis of bone
L97.415	Non-pressure chronic ulcer of right heel and midfoot with muscle involvement without evidence of necrosis
L97.416	Non-pressure chronic ulcer of right heel and midfoot with bone involvement without evidence of necrosis
L97.418	Non-pressure chronic ulcer of right heel and midfoot with other specified severity
L97.421	Non-pressure chronic ulcer of left heel and midfoot limited to breakdown of skin
L97.422	Non-pressure chronic ulcer of left heel and midfoot with fat layer exposed
L97.423	Non-pressure chronic ulcer of left heel and midfoot with necrosis of muscle
L97.424	Non-pressure chronic ulcer of left heel and midfoot with necrosis of bone
L97.425	Non-pressure chronic ulcer of left heel and midfoot with muscle involvement without evidence of necrosis
L97.426	Non-pressure chronic ulcer of left heel and midfoot with bone involvement without evidence of necrosis
L97.428	Non-pressure chronic ulcer of left heel and midfoot with other specified severity
L98.411	Non-pressure chronic ulcer of buttock limited to breakdown of skin
L98.412	Non-pressure chronic ulcer of buttock with fat layer exposed
L98.413	Non-pressure chronic ulcer of buttock with necrosis of muscle
L98.414	Non-pressure chronic ulcer of buttock with necrosis of bone
L98.415	Non-pressure chronic ulcer of buttock with muscle involvement without evidence of necrosis
L98.416	Non-pressure chronic ulcer of buttock with bone involvement without evidence of necrosis
L98.418	Non-pressure chronic ulcer of buttock with other specified severity
L98.421	Non-pressure chronic ulcer of back limited to breakdown of skin
L98.422	Non-pressure chronic ulcer of back with fat layer exposed
L98.423	Non-pressure chronic ulcer of back with necrosis of muscle
L98.424	Non-pressure chronic ulcer of back with necrosis of bone
L98.425	Non-pressure chronic ulcer of back with muscle involvement without evidence of necrosis
L98.426	Non-pressure chronic ulcer of back with bone involvement without evidence of necrosis
L98.428	Non-pressure chronic ulcer of back with other specified severity
L98.491	Non-pressure chronic ulcer of skin of other sites limited to breakdown of skin
L98.492	Non-pressure chronic ulcer of skin of other sites with fat layer exposed
L98.493	Non-pressure chronic ulcer of skin of other sites with necrosis of muscle
L98.494	Non-pressure chronic ulcer of skin of other sites with necrosis of bone

Frequency Requirements:

Effective for claims with dates of service on and after April 13, 2021, contractors shall cover PRP services for chronic non-healing diabetic wounds, G0465, for a maximum of 20 weeks beginning with the first week of treatment.

Effective for claims with dates of services on or after April 13, 2021, the local MACs shall have discretion to pay PRP services for chronic non-healing diabetic wounds, G0465, that are performed more than 20 weeks after the date of the first PRP service when the -KX modifier is reported on the claim.

Effective for claims with dates of service on and after April 13, 2021, contractors shall have discretion to cover, and determine frequency for, PRP services for chronic non-healing non-diabetic wounds, G0460.

11.3.3 – Types of Bill (TOB)

(Rev. 11214, Issued: 01-20-22, Effective:04-13-21, Implementation: 01-03-22 Shared Systems Contractors, 02-14-22 MACs)

11.3.4 – Payment Method

(Rev. 11214, Issued: 01-20-22, Effective:04-13-21, Implementation: 01-03-22 Shared Systems Contractors, 02-14-22 MACs)

Payment for PRP services is as follows:

- Hospital outpatient departments TOBs 12X and 13X – based on the Outpatient Prospective Payment System
- Skilled Nursing Facility TOBs 22X and 23X – based on the Medicare Physician Fee Schedule (MPFS)
- TOB 71X – based on the all-inclusive rate
- TOB 75X – based on the MPFS
- TOB 77X – based on the all-inclusive rate
- TOB 85X – based on reasonable cost
- Critical Access Hospitals TOB 85X and revenue codes 096X, 097X, or 098X – based on the MPFS

Local MACs shall pay for PRP services for hospitals in Maryland under the jurisdiction of the Health Services Cost Review Commission on an outpatient basis, TOB 13X, in accordance with the terms of the Maryland waiver.

11.3.5 - Place of Service (POS) for Professional Claims

(Rev. 11214, Issued: 01-20-22, Effective:04-13-21, Implementation: 01-03-22 Shared Systems Contractors, 02-14-22 MACs)

Effective for claims with dates of service on or after August 2, 2012, place of service (POS) codes 11, 22, and 49 shall be used for PRP services.

Effective for claims with dates of service on or after April 13, 2021, POS codes 11, 19, 22, and 49 shall be used for PRP services.

11.3.6 – Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RARCs), Claim Adjustment Reason Codes (CARCs) and Group Codes

(Rev. 11214, Issued: 01-20-22, Effective:04-13-21, Implementation: 01-03-22 Shared Systems Contractors, 02-14-22 MACs)

Contractors shall deny claims for PRP services when provided on other than TOBs 12X, 13X, 22X, 23X, 71X, 75X, 77X, and 85X using:

MSN 21.25 - “This service was denied because Medicare only covers this service in certain settings.”

Spanish Version - “El servicio fue denegado porque Medicare solamente lo cubre en ciertas situaciones.”

CARC 58 - “Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. **NOTE:** Refer to the 832 Healthcare Policy Identification Segment (loop 2110 Service payment Information REF), if present.

RARC N428 - “Service/procedure not covered when performed in this place of service.”

Group Code - CO (Contractual Obligation)

Contractors shall reject claims for PRP services for the treatment of chronic non-healing diabetic wounds, G0465, that are performed more than 20 weeks after the date of the first PRP service when the --KX modifier is NOT included on the claim using the following messages:

CARC 119 – Benefit Maximum for this time period or occurrence has been reached.

RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Medicare Summary Notice (MSN) 20.5 – These services cannot be paid because your benefits are exhausted at this time.

Spanish Version: “Estos servicios no pueden ser pagados porque sus beneficios se han agotado.”

Group Code – CO (Contractual Obligation)

Contractors shall deny/reject claims for PRP services for the treatment of chronic non-healing diabetic wounds, G0465, that don’t contain the appropriate diagnosis codes as noted above and use the following messages:

Claim Adjustment Reason Code (CARC) 50 - These are non-covered services because this is not deemed a 'medical necessity' by the payer.

Remittance Advice Remark Code (RARC) N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at: www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Medicare Summary Notice (MSN) 15.19 - “We used a Local Coverage Determination (LCD) to decide coverage for your claim. To appeal, get a copy of the LCD at www.cms.gov/medicare-coverage-database (use the MSN Billing Code for the CPT/HCPCS Code) and send with information from your doctor."

Spanish Version -Usamos una Determinación de Cobertura Local (LCD) para decidir la cobertura de su reclamo. Para apelar, obtenga una copia del LCD en www.cms.gov/medicare-coverage-database (use el código de facturación de MSN para el código "CPT/HCPCS") y envíela con la información de su médico.

MSN 15.20 - "The following polices were used when we made this decision: NCD 270.3."

Spanish Version – "Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 270.3."

NOTE: Due to system requirement, the Fiscal Intermediary Shared System (FISS) has combined messages 15.19 and 15.20 so that, when used for the same line item, both messages will appear on the same MSN.

Group Code – Contractual Obligation (CO).

12 - Counseling to Prevent Tobacco Use

(Rev.3848, Issued: 08- 25-17, Effective: 09-26-17, Implementation: 09- 26-17)

Background: Effective for services furnished on or after March 22, 2005, a National Coverage Determination (NCD) provided for coverage of smoking and tobacco-use cessation counseling services located at Medicare National Coverage Determinations Manual, Publication 100-03 section 210.4. CMS established a related policy entitled Counseling to Prevent Tobaccos Use at NCD Manual 210.4.1 effective August 25, 2010. However, effective September 30, 2016, the conditions of Medicare Part A and Medicare Part B coverage for smoking and tobacco-use cessation counseling services (210.4) were deleted. The remaining NCD entitled Counseling to Prevent Tobacco Use (210.4.1), remains in effect, along with HCPCS codes 99406 and 99407, specifically payable for counseling to prevent tobacco use effective October 1, 2016.

12.1 - Counseling to Prevent Tobacco Use HCPCS and Diagnosis Coding

(Rev. 13549; Issued: 12-18-25; Effective: 01-20-26; Implementation: 01-20-26)

The following HCPCS codes should be reported when billing for counseling to prevent tobacco use services:

99406 - Smoking and tobacco-use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes

99407 - Smoking and tobacco-use cessation counseling visit; intensive, greater than 10 minutes

Note the above codes were effective for dates of service on or after January 1, 2008, and specifically effective for counseling to prevent tobacco use claims on or after October 1, 2016.

Contractors shall allow payment for a medically necessary E/M service on the same day as the counseling to prevent tobacco use, when it is clinically appropriate. Physicians and qualified non-physician practitioners shall use an appropriate HCPCS code, such as HCPCS 99201–99215, to report an E/M service with modifier 25 to indicate that the E/M service is a separately identifiable service from 99406 or 99407.

Contractors shall only pay for 8 counseling to prevent tobacco use sessions in a 12-month period. The beneficiary may receive another 8 sessions during a second or subsequent year after 11 full months have passed since the first Medicare covered counseling session was performed. To start the count for the second or subsequent 12-month period, begin with the month after the month in which the first Medicare covered counseling session was performed and count until 11 full months have elapsed.

Claims for counseling to prevent tobacco use services shall be submitted with an appropriate diagnosis code.

NOTE: This decision does not modify existing coverage for minimal cessation counseling (defined as 3 minutes or less in duration) which is already considered to be covered as part of each Evaluation and Management (E/M) visit and is not separately billable.

Claims for counseling to prevent tobacco use services shall be submitted with an applicable diagnosis code:

ICD-9-CM (prior to October 1, 2015)

V15.82, personal history of tobacco use, or
305.1, non-dependent tobacco use disorder
989.84, toxic effect of tobacco

ICD-10-CM (effective October 1, 2015)

F17.210, nicotine dependence, cigarettes, uncomplicated,
F17.211, nicotine dependence, cigarettes, in remission,
F17.213 Nicotine dependence, cigarettes, with withdrawal
F17.218 Nicotine dependence, cigarettes, with other nicotine-induced disorders
F17.219 Nicotine dependence, cigarettes, with unspecified nicotine-induced disorders
F17.220, nicotine dependence, chewing tobacco, uncomplicated,
F17.221, nicotine dependence, chewing tobacco, in remission,
F17.223 Nicotine dependence, chewing tobacco, with withdrawal
F17.228 Nicotine dependence, chewing tobacco, with other nicotine-induced disorders
F17.229 Nicotine dependence, chewing tobacco, with unspecified nicotine-induced disorders
F17.290, nicotine dependence, other tobacco product, uncomplicated,
F17.291, nicotine dependence, other tobacco product, in remission, or
F17.293 Nicotine dependence, other tobacco product, with withdrawal
F17.298 Nicotine dependence, other tobacco product, with other nicotine
F17.299 Nicotine dependence, other tobacco product, with unspecified nicotine-induced disorders
Z87.891, personal history of nicotine dependence, unspecified, uncomplicated.
T65.211A, Toxic effect of chewing tobacco, accidental (unintentional), initial encounter
T65.212A, Toxic effect of chewing tobacco, intentional self-harm, initial encounter
T65.213A, Toxic effect of chewing tobacco, assault, initial encounter
T65.214A, Toxic effect of chewing tobacco, undetermined, initial encounter
T65.221A, Toxic effect of tobacco cigarettes, accidental (unintentional), initial encounter
T65.222A, Toxic effect of tobacco cigarettes, intentional self-harm, initial encounter
T65.223A, Toxic effect of tobacco cigarettes, assault, initial encounter
T65.224A, Toxic effect of tobacco cigarettes, undetermined, initial encounter
T65.291A, Toxic effect of other tobacco and nicotine, accidental (unintentional), initial encounter
T65.292A, Toxic effect of other tobacco and nicotine, intentional self-harm, initial encounter
T65.293A, Toxic effect of other tobacco and nicotine, assault, initial encounter
T65.294A, Toxic effect of other tobacco and nicotine, undetermined, initial encounter
Z72.0, Tobacco use effective October 1, 2024

12.2 - Counseling to Prevent Tobacco Use A/B MAC (B) Billing Requirements
(Rev.3848, Issued: 08- 25-17, Effective: 09-26-17, Implementation: 09- 26-17)

A/B MACs (B) shall pay for counseling to prevent tobacco use services billed with codes 99406 and 99407 for dates of service on or after October 1, 2016 A/B MACs (B) shall pay for counseling services billed with codes G0436 and G0437 for dates of service on and after August 25, 2010, through September 30, 2016. The type of service (TOS) for each of the new codes is 1.

A/B MACs (B) pay for these services billed based on the Medicare Physician Fee Schedule (MPFS). Deductible and coinsurance are waived. Claims from physicians or other providers where assignment was not taken are subject to the Medicare limiting charge, which means that charges to the beneficiary may be no more than 115% of the allowed amount.

Physicians or qualified non-physician practitioners shall bill the A/B MAC (B) for counseling to prevent tobacco use services using the ASC X12 837 professional claim format or the Form CMS-1500.

12.3 - A/B MAC (A) Billing Requirements

(Rev. 13549; Issued: 12-18-25; Effective: 01-20-26; Implementation: 01-20-26)

The A/B MACs (A) shall pay for counseling to prevent tobacco use services with codes 99406 and 99407 for dates of service on or after October 1, 2016. A/B MACs (A) shall pay for counseling services billed with codes G0436 and G0437 for dates of service on or after August 25, 2010, through September 30, 2016. Deductible and coinsurance are waived.

A. Claims for counseling to prevent tobacco use services should be submitted using the ASC X12 837 institutional claim format or Form CMS-1450.

The applicable bill types are 12X, 13X, 22X, 23X, 34X, 71X, 77X, 83X, and 85X. Effective April 1, 2006, type of bill 14X is for non-patient laboratory specimens and is no longer applicable for counseling to prevent tobacco use services.

Applicable revenue codes are as follows:

Provider Type	Revenue Code
Rural Health Centers (RHCs)	052X
Federally Qualified Health Centers (FQHCs)	052X, 0519
Indian Health Services (IHS)	0510
Critical Access Hospitals (CAHs) Method II	096X, 097X, 098X
All Other Providers	0942

NOTE: When these services are provided by a clinical nurse specialist in the RHC/FQHC setting, they are considered “incident to” and do not constitute a billable visit.

Payment for outpatient services is as follows:

Type of Facility	Method of Payment
Rural Health Centers (RHCs)	All-inclusive rate (AIR) for the encounter
Federally Qualified Health Centers (FQHCs)	FQHC Prospective Payment System (PPS) for the encounter
Indian Health Service (IHS)/Tribally owned or operated hospitals and hospital-based facilities	AIR
IHS/Tribally owned or operated non-hospital-based facilities	Medicare Physician Fee Schedule (MPFS)
IHS/Tribally owned or operated Critical Access Hospitals (CAHs)	Facility Specific Visit Rate
Hospitals subject to the Outpatient Prospective Payment System (OPPS)	Ambulatory Payment Classification (APC)
Hospitals not subject to OPPS	Payment is made under current methodologies
Skilled Nursing Facilities (SNFs) **NOTE:** Included in Part A PPS for skilled patients.	MPFS
Home Health Agencies (HHAs)	MPFS
Critical Access Hospitals (CAHs)	Method I: Technical services are paid at 101% of reasonable cost. Method II: technical services are paid at 101% of reasonable cost, and Professional services are paid at 115% of the MPFS Data Base
Maryland Hospitals	Payment is based according to the Health Services Cost Review Commission (HSCRC). That is 94% of submitted charges subject to any unmet deductible, coinsurance, and non-covered charges policies.

NOTE: Inpatient claims submitted with counseling to prevent tobacco use services are processed under the current payment methodologies. In addition, payment is not allowed for inpatients whose primary diagnosis is counseling to prevent tobacco use.

12.4 - Remittance Advice (RA) Notices

(Rev.3848, Issued: 08- 25-17, Effective: 09-26-17, Implementation: 09- 26-17)

Contractors shall use the appropriate claim RA(s) when denying payment for counseling to prevent tobacco use services.

The following messages are used where applicable:

- If the counseling services were furnished before August 25, 2010, use an appropriate RA claim adjustment reason code (CARC), such as, 26, "Expenses incurred prior to coverage."

    - If the claim for counseling services is being denied because the coverage criteria are not met, use an appropriate CARC, such as, 272, Coverage/program guidelines were not met.

    - If the claim for counseling services is being denied because the maximum benefit has been reached, use an appropriate CARC, such as, 119, "Benefit maximum for this time period or occurrence has been reached."

12.5 - Medicare Summary Notices (MSNs)

(Rev.3848, Issued: 08- 25-17, Effective: 09-26-17, Implementation: 09- 26-17)

(When denying claims for counseling to prevent tobacco use services that were performed prior to the effective date of coverage, contractors shall use an appropriate MSN, such as, MSN 21.11, "This service was not covered by Medicare at the time you received it."

When denying claims for counseling services on the basis that the coverage criteria were not met, use an appropriate MSN, such as MSN 21.21, "This service was denied because Medicare only covers this service under certain circumstances."

When denying claims for counseling services that have dates of service exceeding the maximum benefit allowed, use an appropriate MSN, such as MSN 17.8, "Payment is denied because the maximum benefit allowance has been reached."

12.6 - Post-Payment Review for Smoking and Tobacco-Use Cessation Counseling Services

(Rev.3848, Issued: 08- 25-17, Effective: 09-26-17, Implementation: 09- 26-17)

As with any claim, Medicare may decide to conduct post-payment reviews to determine that the services provided are consistent with coverage instructions. Providers must keep patient record information on file for each Medicare patient for whom a counseling claim is made. These medical records can be used in any post-payment reviews and must include standard information along with sufficient patient histories to allow determination that the steps required in the coverage instructions were followed.

12.7 - Common Working File (CWF) Inquiry

(Rev. 4203, Issued: 01-18-19, Effective: 02-19-19, Implementation: 02-19-19)

The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.

The Common Working File (CWF) maintains the number of counseling sessions rendered to a beneficiary. By entering the beneficiary's Medicare beneficiary identifier, providers have the capability to view the number of sessions a beneficiary has received for this service via inquiry through CWF.

12.8 - Provider Access to Smoking and Tobacco-Use Cessation Counseling Services Eligibility Data

(Rev.3848, Issued: 08- 25-17, Effective: 09-26-17, Implementation: 09- 26-17)

Providers may access coverage period remaining counseling sessions and a next eligible date, when there are no remaining sessions, through the 270/271 eligibility inquiry and response transaction.

20 – Billing Requirements for Coverage of Kidney Disease Patient Education Services

(Rev. 1876; Issued: 12-18-09; Effective Date: 01-01-10; Implementation Date: 04-05-10)

Effective for claims with dates of service on and after January 1, 2010, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) determines that kidney disease patient education services are covered when provided to patients with stage IV chronic kidney disease (CKD). See Pub. 100-02, chapter 15, section 310, for complete coverage guidelines.

Contractors shall pay for kidney disease education (KDE) services that meet the following conditions:

- No more than 6 sessions of KDE services are provided in a lifetime,
- Is provided in increments of 1 hour. In order to bill for a session, a session must be at least 31 minutes in duration. A session that lasts at least 31 minutes, but less than 1 hour still constitutes 1 session.
- Is provided either individually or in a group setting of 2 to 20 individuals who need not all be Medicare beneficiaries.
- Furnished, upon the referral of the physician managing the beneficiary's kidney condition, by a qualified person meaning a:
    - physician, physician's assistant, nurse practitioner, or clinical nurse specialist;
    - hospital, critical access hospital (CAH), skilled nursing facility (SNF), comprehensive outpatient rehabilitation facility (CORF), home health agency (HHA), or hospice, that is located in a rural area, or
    - hospital or CAH that is paid as if it were located in a rural area (hospital or CAH reclassified as rural under section 42 CFR 412.103).

NOTE: A renal dialysis facility (Type of Bill (TOB) 72x) is precluded from providing KDE services.

20.1 – Additional Billing Requirements Applicable to Claims Submitted to Fiscal Intermediaries (FIs)

(Rev. 1876; Issued: 12-18-09; Effective Date: 01-01-10; Implementation Date: 04-05-10)

The FI will reimburse for KDE services when services are rendered in a rural area and submitted on the following TOBs: 12X, 13X, 22X, 23X, 34X, 75X, 81X, 82X, and 85X.

NOTE: FIs shall use the actual geographic location, core based statistical area (CBSA) to identify facilities located in rural areas. In addition, KDE services are covered when claims containing the above mentioned TOBs are received from section 401 hospitals.

Revenue code 0942 should be reported when billing for KDE services in the following: SNFs, HHAs, CORFs, hospices, and CAHs.

Hospital outpatient departments bill for this service under any valid/appropriate revenue code. They are not required to report revenue code 0942.

Hospices report this service on a separate claim from any hospice services. Hospice claims billed for revenue code 0942 that contain any other services will be returned to the provider. In addition, hospices report value code 61 or G8 when billing for KDE services.

NOTE: KDE services are not covered when services are submitted on TOB 72X.

20.2 - Healthcare Common Procedure Coding System (HCPCS) Procedure Codes and Applicable Diagnosis Codes

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

Effective for services performed on and after January 1, 2010, the following new HCPCS codes have been created for KDE services when provided to patients with stage IV CKD.

- G0420: Face-to-face educational services related to the care of chronic kidney disease; individual, per session, per one hour

- G0421: Face-to-face educational services related to the care of chronic kidney disease; group, per session, per one hour

When billing for KDE services the applicable ICD diagnosis code shall be used:

- If ICD-9-CM is applicable, ICD-9-CM - 585.4 (chronic kidney disease, Stage IV (severe)), or

- If ICD-9-CM is applicable, ICD-10-CM – N18.4 (Chronic Kidney Disease, stage 4.

NOTE: Claims with HCPCS codes G0420 or G0421 and ICD-9 code 585.4, if applicable, or, if ICD -10 is applicable, ICD-10 code N18.4 that are billed for KDE services are not allowed on a professional and institutional claim on the same service date.

20.3 - Medicare Summary Notices (MSNs) and Claim Adjustment Reason Codes (CARCs)

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

The following messages are used by Medicare contractors when denying non-covered services associated with KDE services when provided to patients with stage IV CKD:

When denying claims for KDE services billed without diagnosis code 585.4 contractors shall use:

- MSN 16.10 - Medicare does not pay for this item or service.

- CARC 167 - This (these) diagnosis(es) is (are) not covered. NOTE: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

When denying claims for KDE services when submitted for more than 6 sessions contractors shall use:

- MSN 15.22 - The information provided does not support the need for this many services or items in this period of time so Medicare will not pay for this item or service.

- CARC 119 - Benefit maximum for this time period or occurrence has been reached.

When denying claims for KDE services when two claims are billed (professional and institutional) on the same service date, contractors shall use:

- MSN 15.5 – The information provided does not support the need for similar services by more than one doctor during the same time period.

- CARC 18 – Exact duplicate claim/service (Use only with Group Code OA except where state workers' compensation regulations requires CO).

A/B MACs (A) shall deny KDE services when rendered in an urban area unless:

- The provider is a hospital on the section 401 list or

- The claim is submitted on TOB 85X.

A/B MACs (A) shall deny payment for KDE services when submitted on TOB 72X.
Use the following messages:

- MSN 21.6 – This item or service is not covered when performed, referred or ordered by this provider.

- CARC 170 – Payment is denied when performed/billed by this type of provider in this type of facility. NOTE: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

20.4 - Advance Beneficiary Notice (ABN) Information

(Rev. 1876; Issued: 12-18-09; Effective Date: 01-01-10; Implementation Date: 04-05-10)

If a signed ABN was provided, contractors shall use Group Code PR (Patient Responsibility) and the liability falls to the beneficiary.

If an ABN was not provided, contractors shall use Group Code CO (Contractual Obligation) and the liability falls to the provider.

30 - Hyperbaric Oxygen (HBO) Therapy

(Rev. 187, 05-28-04)

30.1 - Billing Requirements for HBO Therapy for the Treatment of Diabetic Wounds of the Lower Extremities

(Rev. 11021; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

Hyperbaric Oxygen Therapy is a modality in which the entire body is exposed to oxygen under increased atmospheric pressure. Effective April 1, 2003, a National Coverage Decision expanded the use of HBO therapy to include coverage for the treatment of diabetic wounds of the lower extremities. For specific coverage criteria for HBO Therapy, refer to the National Coverage Determinations Manual, Chapter 1, section 20.29.

NOTE: Topical application of oxygen does not meet the definition of HBO therapy as stated above. Also, its clinical efficacy has not been established. Therefore, no Medicare reimbursement may be made for the topical application of oxygen.

- **Billing Requirements for A/B MACs (A)**

Claims for HBO therapy should be submitted using the ASC X12 837 institutional claim format or, in rare cases, on Form CMS-1450.

a. Applicable Bill Types

The applicable hospital bill types are 11X, 13X and 85X.

b. Procedural Coding

- 99183 – Physician attendance and supervision of hyperbaric oxygen therapy, per session.
- G0277 – Hyperbaric oxygen under pressure, full body chamber, per 30-minute interval.

NOTE: Code G0277 is not available for use other than in a hospital outpatient department. In skilled nursing facilities (SNFs), HBO therapy is part of the SNF PPS payment for beneficiaries in covered Part A stays.

For hospital inpatients and critical access hospitals (CAHs) not electing Method I, HBO therapy is reported under revenue code 940 without any HCPCS code. For inpatient services, if ICD-10 is applicable, show ICD-10-PCS code 5A05121.

For CAHs electing Method I, HBO therapy is reported under revenue code 940 along with HCPCS code 99183.

c. Payment Requirements for A/B MACs (A)

Payment is as follows:

A/B MAC (A) payment is allowed for HBO therapy for diabetic wounds of the lower extremities when performed as a physician service in a hospital outpatient setting and for inpatients. Payment is allowed for claims with valid diagnosis codes as shown above with dates of service on or after April 1, 2003. Those claims with invalid codes should be denied as not medically necessary.

For hospitals, payment will be based upon the Ambulatory Payment Classification (APC) or the inpatient Diagnosis Related Group (DRG). Deductible and coinsurance apply.

Payment to Critical Access Hospitals (electing Method I) is made under cost reimbursement. For Critical Access Hospitals electing Method II, the technical component is paid under cost reimbursement and the professional component is paid under the Physician Fee Schedule.

II. A/B MAC (B) Billing Requirements

Claims for this service should be submitted using the ASC X12 837 professional claim format or Form CMS-1500.

The following HCPCS code applies:

- 99183 – Physician attendance and supervision of hyperbaric oxygen therapy, per session.
- G0277 – Hyperbaric oxygen under pressure, full body chamber, per 30-minute interval.

a. Payment Requirements for A/B MACs (B)

Payment and pricing information will occur through updates to the Medicare Physician Fee Schedule Database (MPFSDB). Pay for this service on the basis of the MPFSDB. Deductible and coinsurance apply. Claims from physicians or other practitioners where assignment was not taken, are subject to the Medicare limiting charge.

III. Medicare Summary Notices (MSNs)

Use the following MSN Messages where appropriate:

In situations where the claim is being denied on the basis that the condition does not meet our coverage requirements, use one of the following MSN Messages:

"Medicare does not pay for this item or service for this condition." (MSN Message 16.48)

The Spanish version of the MSN message should read:

"Medicare no paga por este articulo o servicio para esta afeccion."

In situations where, based on the above utilization policy, medical review of the claim results in a determination that the service is not medically necessary, use the following MSN message:

"The information provided does not support the need for this service or item." (MSN Message 15.4)

The Spanish version of the MSN message should read:

"La informacion proporcionada no confirma la necesidad para este servicio o articulo."

IV. Remittance Advice Notices

Use appropriate existing remittance advice remark codes and claim adjustment reason codes at the line level to express the specific reason if you deny payment for HBO therapy for the treatment of diabetic wounds of lower extremities.

30.2 Hyperbaric Oxygen (HBO) Therapy (Section C, Topical Application of Oxygen) (Rev.3921, Issued: 11-17-17, Effective: 04-03-17, 12-18-17)

CMS considers topical oxygen therapy (TOT) to be a method whereby a local supply of oxygen is applied to a wound.

I. Billing Requirements for A/B MACs (A)

Claims for HBO therapy should be submitted using the ASC X12 837 institutional claim format or, in rare cases, on Form CMS-1450.

II. Payment Requirements for A/B MACs (A)

As of April 3, 2017, Medicare coverage of topical oxygen for the treatment of chronic wounds will be determined by the local contractors.
NOTE: Regardless of whether an A/B MAC (A) has made a determination to cover this service, there shall be no coverage for any separate or additional physician's professional services related to this procedure.

III. Billing Requirements for A/B MACs (B)

As of April 3, 2017, Medicare coverage of topical oxygen for the treatment of chronic wounds will be determined by the local contractors.
NOTE: Regardless of whether an A/B MAC (B) has made a determination to cover this service, there shall be no coverage for any separate or additional physician's professional services related to this procedure.

40 – Sacral Nerve Stimulation

(Rev. 125, 03-26-04)

A sacral nerve stimulator is a pulse generator that transmits electrical impulses to the sacral nerves through an implanted wire. These impulses cause the bladder muscles to contract, which gives the patient ability to void more properly.

40.1 – Coverage Requirements

(Rev. 125, 03-26-04)

Effective January 1, 2002, sacral nerve stimulation is covered for the treatment of urinary urge incontinence, urgency-frequency syndrome and urinary retention. Sacral nerve stimulation involves both a temporary test stimulation to determine if an implantable stimulator would be effective and a permanent implantation in appropriate candidates. Both the test and the permanent implantation are covered.

The following limitations for coverage apply to all indications:

- Patient must be refractory to conventional therapy (documented behavioral, pharmacologic and/or surgical corrective therapy) and be an appropriate surgical candidate such that implantation with anesthesia can occur.

- Patients with stress incontinence, urinary obstruction, and specific neurologic diseases (e.g., diabetes with peripheral nerve involvement) that are associated with secondary manifestations of the above three indications are excluded.

- Patient must have had a successful test stimulation in order to support subsequent implantation. Before a patient is eligible for permanent implantation, he/she must demonstrate a 50% or greater improvement through test stimulation. Improvement is measured through voiding diaries.

- Patient must be able to demonstrate adequate ability to record voiding diary data such that clinical results of the implant procedure can be properly evaluated.

40.2 – Billing Requirements

(Rev. 125, 03-26-04)

40.2.1 – Healthcare Common Procedural Coding System (HCPCS)
(Rev. 11789, Issued:01-19-23, Effective Date: 02-21-23, Implementation Date: 02-21-23)

64561 - Percutaneous implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)
64581 - Incision for implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)
64585 - Revision or removal of peripheral neurostimulator electrodes
64590 - Incision and subcutaneous placement of peripheral neurostimulator pulse generator or receiver, direct or inductive coupling
64595 - Revision or removal of peripheral neurostimulator pulse generator or receiver
A4290 - Sacral nerve stimulation test lead, each
C1767 - Generator, neurostimulator (implantable)
C1778 - Lead, neurostimulator (implantable)
C1820 - Generator, neurostimulator (implantable), with rechargeable battery and charging system - effective 01/01/20 for NCD230.18 with CR11655
C1883 - Adaptor/extension, pacing lead or neurostimulator lead (implantable)
C1897 - Lead, neurostimulator test kit (implantable)
E0752 - Implantable neurostimulator electrodes, each
E0756 - Implantable neurostimulator pulse generator

NOTE: The "C" codes listed above are only applicable when billing under the hospital outpatient prospective payment system (OPPS). They should be reported in place of codes A4290, E0752 and E0756.

40.2.2 – Payment Requirements for Test Procedures (HCPCS Codes 64585, 64590 and 64595)
(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

Payment is as follows:

- Hospital outpatient departments – OPPS
- Critical access hospital (CAH) - Reasonable cost
- Comprehensive outpatient rehabilitation facility - Medicare physician fee schedule (MPFS)
- Rural health clinics/federally qualified health centers (RHCs/FQHCs) - All inclusive rate, professional component only. The technical component is outside the scope of the RHC/FQHC benefit. Therefore, the provider of that technical service bills their A/B MAC (B) using the ASC X12 837 professional claim format or Form CMS-1500 and payment is made under the MPFS. For provider-based RHCs/FQHCs payment for the technical component is made as indicated above based on the type of provider the RHC/FQHC is based with.

Deductible and coinsurance apply.

40.2.3 – Payment Requirements for Device Codes A4290, E0752 and E0756
(Rev. 125, 03-26-04)

Payment is made on a reasonable cost basis when these devices are implanted in a CAH.

40.2.4 – Payment Requirements for Codes C1767, C1778, C1820, C1883 and C1897
(Rev. 11789, Issued:01-19-23, Effective Date: 02-21-23, Implementation Date: 02-21-23)

Only hospital outpatient departments report these codes. Payment is made under OPPS.

40.3 – Bill Types
(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

The applicable bill types for test stimulation procedures are 13X, 71X, 73X, 75X and 85X.

The RHCs and FQHCs bill you under bill type 71X and 73X for the professional component. The technical component is outside the scope of the RHC/FQHC benefit. The provider of that technical service bills their A/B MAC (B) using the ASC X12 837 professional claim format or the Form CMS-1500.

The technical component for a provider-based RHC/FQHC is typically furnished by the provider. The provider of that service bills you under bill type 13X, or 85X as appropriate using their outpatient provider number (not the RHC/FQHC provider number since these services are not covered as RHC/FQHC services.) Effective 4/1/06, type of bill 14X is for non-patient laboratory specimens and is no longer applicable for test stimulation procedures.

The applicable bill types for implantation procedures and devices are 11X, 13X, and 85X.

40.4 – Revenue Codes
(Rev.10881; Issued: 08-06-2021; Effective: 09-07-2021; Implementation: 09-07- 2021)

The applicable revenue code for the test procedures is 920 except for RHCs/FQHCs who report these procedures under revenue code 521.

Revenue codes for the implantation can be performed in a number of revenue centers within a hospital such as operating room (360) or clinic (510). Therefore, instruct your hospitals to report these implantation procedures under the revenue center where they are performed.

The applicable revenue code for the device codes C1767, C1778, C1883, C1897, and C1820 provided in a hospital outpatient department is 272, 274, 275, 276, 278, 279, 280, 289, 290 or 624 as appropriate. The applicable revenue code for device codes A4290, E0752 and
E0756 provided in a CAH is 290.

40.5 – Claims Editing
(Rev. 125, 03-26-04)

Nationwide claims processing edits for pre or post payment review of claim(s) for sacral nerve stimulation are not being required at this time. Contractors may develop local medical review policy and edits for such claim(s).

50 – Deep Brain Stimulation for Essential Tremor and Parkinson's Disease
(Rev. 128, 03-26-04)

Deep brain stimulation (DBS) refers to high-frequency electrical stimulation of anatomic regions deep within the brain utilizing neurosurgically implanted electrodes. These DBS electrodes are stereotactically placed within targeted nuclei on one (unilateral) or both (bilateral) sides of the brain. There are currently three targets for DBS -- the thalamic ventralis intermedius nucleus (VIM), subthalamic nucleus (STN) and globus pallidus interna (GPi).

Essential tremor (ET) is a progressive, disabling tremor most often affecting the hands. ET may also affect the head, voice and legs. The precise pathogenesis of ET is unknown. While it may start at any age, ET usually peaks within the second and sixth decades. Beta-adrenergic blockers and anticonvulsant medications are usually the first line treatments for reducing the severity of tremor. Many patients, however, do not adequately respond or cannot tolerate these medications. In these medically refractory ET patients, thalamic VIM DBS may be helpful for symptomatic relief of tremor.

Parkinson's disease (PD) is an age-related progressive neurodegenerative disorder involving the loss of dopaminergic cells in the substantia nigra of the midbrain. The disease is characterized by tremor, rigidity, bradykinesia and progressive postural instability. Dopaminergic medication is typically used as a first line treatment for reducing the primary symptoms of PD. However, after prolonged use, medication can become less effective and can produce significant adverse events such as dyskinesias and other motor function complications. For patients who become unresponsive to medical treatments and/or have intolerable side effects from medications, DBS for symptom relief may be considered.

50.1 – Coverage Requirements
(Rev. 128, 03-26-04)

Effective on or after April 1, 2003, Medicare will cover unilateral or bilateral thalamic VIM DBS for the treatment of ET and/or Parkinsonian tremor and unilateral or bilateral STN or GPi DBS for the treatment of PD only under the following conditions:

1. Medicare will only consider DBS devices to be reasonable and necessary if they are Food and Drug Administration (FDA) approved devices for DBS or devices used in accordance with FDA approved protocols governing Category B Investigational Device Exemption (IDE) DBS clinical trials.

2. For thalamic VIM DBS to be considered reasonable and necessary, patients must meet all of the following criteria:

    a. Diagnosis of essential tremor (ET) based on postural or kinetic tremors of hand(s) without other neurologic signs, or diagnosis of idiopathic PD (presence of at least 2 cardinal PD features (tremor, rigidity or bradykinesia)) which is of a tremor- dominant form.

    b. Marked disabling tremor of at least level 3 or 4 on the Fahn-Tolosa-Marin Clinical Tremor Rating Scale (or equivalent scale) in the extremity intended for treatment, causing significant limitation in daily activities despite optimal medical therapy.

    c. Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

3. For STN or GPi DBS to be considered reasonable and necessary, patients must meet all of the following criteria:

    a. Diagnosis of PD based on the presence of at least 2 cardinal PD features (tremor, rigidity or bradykinesia).

    b. Advanced idiopathic PD as determined by the use of Hoehn and Yahr stage or Unified Parkinson's Disease Rating Scale (UPDRS) part III motor subscale.

    c. L-dopa responsive with clearly defined "on" periods.

    d. Persistent disabling Parkinson's symptoms or drug side effects (e.g., dyskinesias, motor fluctuations, or disabling "off" periods) despite optimal medical therapy.

    e. Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

The DBS is not reasonable and necessary and is not covered for ET or PD patients with any of the following:

1. Non-idiopathic Parkinson's disease or "Parkinson's Plus" syndromes.

2. Cognitive impairment, dementia or depression which would be worsened by or would interfere with the patient's ability to benefit from DBS.

3. Current psychosis, alcohol abuse or other drug abuse.

4. Structural lesions such as basal ganglionic stroke, tumor or vascular malformation as etiology of the movement disorder.

5. Previous movement disorder surgery within the affected basal ganglion.

6. Significant medical, surgical, neurologic or orthopedic co-morbidities contraindicating DBS surgery or stimulation.

Patients who undergo DBS implantation should not be exposed to diathermy (deep heat treatment including shortwave diathermy, microwave diathermy and ultrasound diathermy) or any type of MRI which may adversely affect the DBS system or adversely affect the brain around the implanted electrodes.

The DBS should be performed with extreme caution in patients with cardiac pacemakers or other electronically controlled implants which may adversely affect or be affected by the DBS system.

For DBS lead implantation to be considered reasonable and necessary, providers and facilities must meet all of the following criteria:

1. Neurosurgeons must: (a) be properly trained in the procedure; (b) have experience with the surgical management of movement disorders, including DBS therapy; and (c) have experience performing stereotactic neurosurgical procedures

2. Operative teams must have training and experience with DBS systems, including knowledge of anatomical and neurophysiological characteristics for localizing the targeted nucleus, surgical and/or implantation techniques for the DBS system, and operational and functional characteristics of the device.

3. Physicians specializing in movement disorders must be involved in both patient selection and post-procedure care.

4. Hospital medical centers must have: (a) brain imaging equipment (MRI and/or CT) for pre-operative stereotactic localization and targeting of the surgical site(s); (b) operating rooms with all necessary equipment for stereotactic surgery; and (c) support services necessary for care of patients undergoing this procedure and any potential complications arising intraoperatively or postoperatively.

50.2 – Billing Requirements
(Rev. 128, 03-26-04)

50.2.1 – Part A Intermediary Billing Procedures
(Rev. 128, 03-26-04)

This procedure can be two fold. Implantation of the electrodes is performed in a hospital inpatient setting. Implantation of the pulse generator can be performed in an outpatient department.

50.3 - Payment Requirements
(Rev. 128, 03-26-04)

50.3.1 – Part A Payment Methods
(Rev. 128, 03-26-04)

Payment for the inpatient procedure is under Diagnostic Related Group (DRG). The outpatient procedure is outpatient prospective payment system. For critical access hospitals (CAH), the inpatient stay is on reasonable cost and the outpatient procedures are also based on reasonable cost.

50.3.2 – Bill Types
(Rev. 11021; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

Deep Brain Stimulation may be submitted on institutional claims using the following Types of Bill:

11X, 12X, 13X, and 85X

50.3.3 – Revenue Codes
(Rev. 128, 03-26-04)

Revenue codes for implementation can be performed in a number of revenue centers within a hospital such as operating room (360) or clinic (510). The codes to report the pulse generator and/or electrodes are 270, 278, 279.

For CAHs that choose method II, use revenue code 98X for the professional component only.

50.4 – Allowable Codes
(Rev. 128, 03-26-04)

50.4.1 – Allowable Covered Diagnosis Codes
(Rev. 12435, Issued:12-28-23, Effective:01-29-24, Implementation:01-29-24)

Deep Brain Stimulation is covered for the following diagnosis codes:

If ICD-10-CM is applicable:

- ICD-10-CM G20.A1 - Parkinson's disease without dyskinesia, without mention of fluctuations
- ICD-10-CM G20.A2 - Parkinson's disease without dyskinesia, with fluctuations
- ICD-10-CM G20.B1 - Parkinson's disease with dyskinesia, without mention of fluctuations
- ICD-10 CM G20.B2 - Parkinson's disease with dyskinesia, with fluctuations
- ICD-10-CM G20.C - Parkinsonism, unspecified
- ICD-10-CM G25.0 - Essential tremor
- ICD-10-CM G25.2 - Other specified form of tremor

50.4.2 – Allowable Covered Procedure Codes

(Rev. 11021; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

The following procedure codes may be present:

If ICD-10-PCS is applicable:

ICD-10-PCS Code	Code Description
00H00MZ	Insertion of Neurostimulator Lead into Brain, Open Approach
00H03MZ	Insertion of Neurostimulator Lead into Brain, Percutaneous Approach
00H04MZ	Insertion of Neurostimulator Lead into Brain, Endoscopic Approach
00H60MZ	Insertion of Neurostimulator Lead into Cerebral Ventricle, Open Approach
00H63MZ	Insertion of Neurostimulator Lead into Cerebral Ventricle, Percutaneous Approach
00H64MZ	Insertion of Neurostimulator Lead into Cerebral Ventricle, Percutaneous Endoscopic Approach
00P00MZ	Removal of Neurostimulator Lead from Brain, Open Approach
00P03MZ	Removal of Neurostimulator Lead from Brain, Percutaneous Approach
00P04MZ	Removal of Neurostimulator Lead from Brain, Percutaneous Endoscopic Approach
00P60MZ	Removal of Neurostimulator Lead from Cerebral Ventricle, Open Approach
00P63MZ	Removal of Neurostimulator Lead from Cerebral Ventricle, Percutaneous Approach
00P64MZ	Removal of Neurostimulator Lead from Brain, Open Approach

0H80XZZ	Division of Scalp Skin, External Approach
0HSSXZZ	Reposition Hair, External Approach

Coverage policy may be found in the National Coverage Determinations Manual in Chapter 1, section 160.24: Deep Brain Stimulation, using the following link: (http://www.cms.hhs.gov/manuals/103_cov_determ/ncd103index.asp).

50.4.3 – Healthcare Common Procedure Coding System (HCPCS)

(Rev. 11021; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

The following HCPCS codes are available for use when billing for covered deep brain stimulation:

61880 Revision or removal of intracranial neurostimulator electrodes

61885 Incision and subcutaneous placement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array

61886 Incision and subcutaneous placement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to two or more electrode arrays

61888 Revision or removal of cranial neurostimulator pulse generator or receiver

95961 Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures; initial hour of physician attendance

95962 Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures; each additional hour of physician attendance (List separately in addition to code for primary procedure) (Use 95962 in conjunction with code 95961)

95970 Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming

95971 Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple brain, spinal cord, or peripheral (i.e., peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming.

95983 Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, doe lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional;

with brain neurostimulator pulse generator/ transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional.

95984 Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, doe lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional.

50.5 – Ambulatory Surgical Centers
(Rev. 128, 03-26-04)

The following HCPCS codes are approved for billing in Ambulatory Surgical Centers:

61885 Incision and subcutaneous placement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array - ASC Payment Group 02

61888 Revision or removal of cranial neurostimulator pulse generator or receiver - ASC Payment Group 01

NOTE: Pulse generator is payable in an ASC; implantation of electrodes are not.

50.6 – Claims Editing for Intermediaries
(Rev. 128, 03-26-04)

We do not require nationwide standard system claims processing edits for pre and post payment review of claim(s) at this time. However, carriers and intermediaries may create local claims processing edits for the requirements listed above.

50.7 – Remittance Advice Notice for Intermediaries
(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

Use appropriate existing remittance advice reason and remark codes at the line level to express the specific reason if you deny payment for DBS. If denying services as furnished before April 1, 2003, use existing ASC X 12-835 claim adjustment reason code 26 "Expenses incurred prior to coverage" at the line level.

50.8 - Medicare Summary Notice (MSN) Messages for Intermediaries
(Rev. 128, 03-26-04)

Use the following MSN messages where appropriate:

If a claim for DBS is denied because the service was performed prior to April 1, 2003, use the MSN message:

"This service was not covered by Medicare at the time you received it." (MSN Message 21.11)

The Spanish version of the MSN message should read:

"Este servicio no estaba cubierto por Medicare cuando usted lo recibió." (MSN Message 21.11)

50.9 – Provider Notification
(Rev. 128, 03-26-04)

Contractors should notify providers of this new national coverage in their next regularly scheduled bulletin, on their Web site within 2 weeks, and in routinely scheduled training sessions.

60 – Coverage and Billing for Home Prothrombin Time (PT/INR) Monitoring for Home Anticoagulation Management
(Rev. 1562, Issued: 07-25-08, Effective: 03-19-08, Implementation: 08-25-08)

The prothrombin time (PT) test is an in-vitro test to assess coagulation. PT testing and its normalized correlate, the International Normalized Ratio (INR), are the standard measurements for therapeutic effectiveness of warfarin therapy. Warfarin, Coumadin®, and others, are self-administered, oral anticoagulant, or blood thinner, medications that affect a person's Vitamin K-dependent clotting factors.

Use of the INR allows physicians to determine the level of anticoagulation in a patient independent of the laboratory reagents used. The INR is the ratio of the patient's prothrombin time compared to the mean prothrombin time for a group of normal individuals.

60.1 – Coverage Requirements
(Rev. 1562, Issued: 07-25-08, Effective: 03-19-08, Implementation: 08-25-08)

For services furnished on or after July 1, 2002, Medicare will cover the use of home INR monitoring for anticoagulation management for patients with mechanical heart valves on warfarin. The monitor and the home testing must be prescribed by a physician and the following patient requirements must be met:

- Must have been anticoagulated for at least 3 months prior to use of the home INR device;
- Must undergo an educational program on anticoagulation management and the use of the device prior to its use in the home; and
- Self testing with the device is limited to a frequency of once per week.

For services furnished on or after March 19, 2008, the Centers for Medicare & Medicaid Services revised its national coverage determination (NCD) on PT/INR Monitoring for Home Anticoagulation Management as follows:

Medicare will cover the use of home PT/INR monitoring for chronic, oral anticoagulation management for patients with mechanical heart valves, chronic atrial fibrillation, or venous thromboembolism (inclusive of deep venous thrombosis and pulmonary embolism) on warfarin. The monitor and the home testing must be prescribed by a treating physician as provided at 42 CFR 410.32(a), and all of the following requirements must be met:

1. The patient must have been anticoagulated for at least 3 months prior to use of the home INR device; and,

2. The patient must undergo a face-to-face educational program on anticoagulation management and must have demonstrated the correct use of the device prior to its use in the home; and,

3. The patient continues to correctly use the device in the context of the management of the anticoagulation therapy following the initiation of home monitoring; and,

4. Self-testing with the device should not occur more frequently than once a week.

NOTE: Porcine valves are not included in this NCD, so Medicare will not make payment on home INR monitoring for patients with porcine valves unless covered by local Medicare contractors.

60.2 – Intermediary Payment Requirements
(Rev. 216, 06-25-04)

60.2.1 – Part A Payment Methods
(Rev. 216, 06-25-04)

Payment is as follows:

- Hospital outpatient departments - Outpatient Prospective Payment System (OPPS)
- Critical Access Hospital (CAH) - Reasonable cost or Medicare Physician Fee Schedule (MPFS)

Deductible and coinsurance apply.

60.3 – Intermediary Billing Procedures
(Rev. 216, 06-25-04)

60.3.1 – Bill Types
(Rev. 216, 06-25-04)

The applicable bill types are 13X and 85X.

60.3.2 – Revenue Codes
(Rev. 216, 06-25-04)

Hospitals may report these services under revenue code 920 or they may report HCPCS codes G0248 and G0249 under the revenue center where they are performed.

60.4 – Intermediary Allowable Codes
(Rev. 216, 06-25-04)

60.4.1 – Allowable Covered Diagnosis Codes
(Rev.10881; Issued: 08-06-2021; Effective: 09-07-2021; Implementation: 09-07- 2021)

For services furnished on or after the implementation of ICD-10 the applicable ICD-10-CM diagnosis codes for this benefit are:

ICD-10-CM Code	Code Description
D68.51	Activated protein C resistance
D68.52	Prothrombin gene mutation
D68.59	Other primary thrombophilia
D68.61	Antiphospholipid syndrome
D68.62	Lupus anticoagulant syndrome

I23.6	Thrombosis of atrium, auricular appendage, and ventricle as current complications following acute myocardial infarction
I26.01	Septic pulmonary embolism with acute cor pulmonale
I26.09	Other pulmonary embolism with acute cor pulmonale
I26.90	Septic pulmonary embolism without acute cor pulmonale
I26.93	Single subsegmental pulmonary embolism without acute cor pulmonale
I26.94	Multiple subsegmental pulmonary emboli without acute cor pulmonale
I26.99	Other pulmonary embolism without acute cor pulmonale
I27.24	Chronic thromboembolic pulmonary hypertension
I27.82	Chronic pulmonary embolism
I48.0	Paroxysmal atrial fibrillation
I48.11	Longstanding persistent atrial fibrillation
I48.19	Other persistent atrial fibrillation
I48.21	Permanent atrial fibrillation
I67.6	Nonpyogenic thrombosis of intracranial venous system
I80.11	Phlebitis and thrombophlebitis of right femoral vein
I80.12	Phlebitis and thrombophlebitis of left femoral vein
I80.13	Phlebitis and thrombophlebitis of femoral vein, bilateral
I80.211	Phlebitis and thrombophlebitis of right iliac vein
I80.212	Phlebitis and thrombophlebitis of left iliac vein
I80.213	Phlebitis and thrombophlebitis of iliac vein, bilateral
I80.221	Phlebitis and thrombophlebitis of right popliteal vein
I80.222	Phlebitis and thrombophlebitis of left popliteal vein
I80.223	Phlebitis and thrombophlebitis of popliteal vein, bilateral
I80.231	Phlebitis and thrombophlebitis of right tibial vein
I80.232	Phlebitis and thrombophlebitis of left tibial vein
I80.233	Phlebitis and thrombophlebitis of tibial vein, bilateral
I80.241	Phlebitis and thrombophlebitis of right peroneal vein
I80.242	Phlebitis and thrombophlebitis of left peroneal vein
I80.243	Phlebitis and thrombophlebitis of peroneal vein, bilateral
I80.251	Phlebitis and thrombophlebitis of right calf muscular vein
I80.252	Phlebitis and thrombophlebitis of left calf muscular vein
I80.253	Phlebitis and thrombophlebitis of calf muscular vein, bilateral
I80.291	Phlebitis and thrombophlebitis of other deep vessels of right lower extremity
I80.292	Phlebitis and thrombophlebitis of other deep vessels of left lower extremity
I80.293	Phlebitis and thrombophlebitis of other deep vessels of lower extremity, bilateral
I82.0	Budd-Chiari syndrome
I82.210	Acute embolism and thrombosis of superior vena cava
I82.211	Chronic embolism and thrombosis of superior vena cava
I82.220	Acute embolism and thrombosis of inferior vena cava
I82.221	Chronic embolism and thrombosis of inferior vena cava
I82.290	Acute embolism and thrombosis of other thoracic veins
I82.291	Chronic embolism and thrombosis of other thoracic veins
I82.3	Embolism and thrombosis of renal vein
I82.411	Acute embolism and thrombosis of right femoral vein

I82.412	Acute embolism and thrombosis of left femoral vein
I82.413	Acute embolism and thrombosis of femoral vein, bilateral
I82.421	Acute embolism and thrombosis of right iliac vein
I82.422	Acute embolism and thrombosis of left iliac vein
I82.423	Acute embolism and thrombosis of iliac vein, bilateral
I82.431	Acute embolism and thrombosis of right popliteal vein
I82.432	Acute embolism and thrombosis of left popliteal vein
I82.433	Acute embolism and thrombosis of popliteal vein, bilateral
I82.441	Acute embolism and thrombosis of right tibial vein
I82.442	Acute embolism and thrombosis of left tibial vein
I82.443	Acute embolism and thrombosis of tibial vein, bilateral
I82.451	Acute embolism and thrombosis of right peroneal vein
I82.452	Acute embolism and thrombosis of left peroneal vein
I82.453	Acute embolism and thrombosis of peroneal vein, bilateral
I82.461	Acute embolism and thrombosis of right calf muscular vein
I82.462	Acute embolism and thrombosis of left calf muscular vein
I82.463	Acute embolism and thrombosis of calf muscular vein, bilateral
I82.491	Acute embolism and thrombosis of other specified deep vein of right lower extremity
I82.492	Acute embolism and thrombosis of other specified deep vein of left lower extremity
I82.493	Acute embolism and thrombosis of other specified deep vein of lower extremity, bilateral
I82.511	Chronic embolism and thrombosis of right femoral vein
I82.512	Chronic embolism and thrombosis of left femoral vein
I82.513	Chronic embolism and thrombosis of femoral vein, bilateral
I82.521	Chronic embolism and thrombosis of right iliac vein
I82.522	Chronic embolism and thrombosis of left iliac vein
I82.523	Chronic embolism and thrombosis of iliac vein, bilateral
I82.531	Chronic embolism and thrombosis of right popliteal vein
I82.532	Chronic embolism and thrombosis of left popliteal vein
I82.533	Chronic embolism and thrombosis of popliteal vein, bilateral
I82.541	Chronic embolism and thrombosis of right tibial vein
I82.542	Chronic embolism and thrombosis of left tibial vein
I82.543	Chronic embolism and thrombosis of tibial vein, bilateral
I82.551	Chronic embolism and thrombosis of right peroneal vein
I82.552	Chronic embolism and thrombosis of left peroneal vein
I82.553	Chronic embolism and thrombosis of peroneal vein, bilateral
I82.561	Chronic embolism and thrombosis of right calf muscular vein
I82.562	Chronic embolism and thrombosis of left calf muscular vein
I82.563	Chronic embolism and thrombosis of calf muscular vein, bilateral
I82.591	Chronic embolism and thrombosis of other specified deep vein of right lower extremity
I82.592	Chronic embolism and thrombosis of other specified deep vein of left lower extremity

I82.593	Chronic embolism and thrombosis of other specified deep vein of lower extremity, bilateral
I82.621	Acute embolism and thrombosis of deep veins of right upper extremity
I82.622	Acute embolism and thrombosis of deep veins of left upper extremity
I82.623	Acute embolism and thrombosis of deep veins of upper extremity, bilateral
I82.721	Chronic embolism and thrombosis of deep veins of right upper extremity
I82.722	Chronic embolism and thrombosis of deep veins of left upper extremity
I82.723	Chronic embolism and thrombosis of deep veins of upper extremity, bilateral
I82.890	Acute embolism and thrombosis of other specified veins
I82.891	Chronic embolism and thrombosis of other specified veins
I82.A11	Acute embolism and thrombosis of right axillary vein
I82.A12	Acute embolism and thrombosis of left axillary vein
I82.A13	Acute embolism and thrombosis of axillary vein, bilateral
I82.A21	Chronic embolism and thrombosis of right axillary vein
I82.A22	Chronic embolism and thrombosis of left axillary vein
I82.A23	Chronic embolism and thrombosis of axillary vein, bilateral
I82.B11	Acute embolism and thrombosis of right subclavian vein
I82.B12	Acute embolism and thrombosis of left subclavian vein
I82.B13	Acute embolism and thrombosis of subclavian vein, bilateral
I82.B21	Chronic embolism and thrombosis of right subclavian vein
I82.B22	Chronic embolism and thrombosis of left subclavian vein
I82.B23	Chronic embolism and thrombosis of subclavian vein, bilateral
I82.C11	Acute embolism and thrombosis of right internal jugular vein
I82.C12	Acute embolism and thrombosis of left internal jugular vein
I82.C13	Acute embolism and thrombosis of internal jugular vein, bilateral
I82.C21	Chronic embolism and thrombosis of right internal jugular vein
I82.C22	Chronic embolism and thrombosis of left internal jugular vein
I82.C23	Chronic embolism and thrombosis of internal jugular vein, bilateral
O87.3	Cerebral venous thrombosis in the puerperium
Z79.01	Long term (current) use of anticoagulants
Z86.718	Personal history of other venous thrombosis and embolism
Z95.2	Presence of prosthetic heart valve

Coverage policy can be found in Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, section 190.11 PT/INR. (http://www.cms.hhs.gov/manuals/103_cov_determ/ncd103index.asp

60.4.2 – Healthcare Common Procedure Coding System (HCPCS) for Intermediaries

(Rev. 1562, Issued: 07-25-08, Effective: 03-19-08, Implementation: 08-25-08)

For services furnished on or after July 1, 2002, and prior to March 19, 2008, the applicable HCPCS codes for this benefit are:

G0248: Demonstration, at initial use, of home INR monitoring for patient with mechanical heart valve(s) who meets Medicare coverage criteria, under the direction of a physician; includes: demonstration use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results and documentation of a patient's ability to perform testing.

Short Description: Demonstrate use home INR mon

G0249: Provision of test materials and equipment for home INR monitoring to patient with mechanical heart valve(s) who meets Medicare coverage criteria. Includes provision of materials for use in the home and reporting of test results to physician; per 4 tests.

Short Description: Provide test material, equipm

For services furnished on or after March 19, 2008, the applicable HCPCS codes for this benefit are:

G0248: Demonstration, prior to initial use, of home INR monitoring for patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria, under the direction of a physician; includes: face-to-face demonstration of use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results, and documentation of patient ability to perform testing prior to its use

Short Description: Demonstrate use home INR mon

G0249: Provision of test materials and equipment for home INR monitoring of patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; includes provision of materials for use in the home and reporting of test results to physician; not occurring more frequently than once a week

Short Description: Provide INR test mater/equip

60.5 – Carrier Billing Instructions

(Rev. 1562, Issued: 07-25-08, Effective: 03-19-08, Implementation: 08-25-08)

Effective for claims with dates of service on and after March 19, 2008, the descriptors of HCPCS Codes G0248, G0249, and G0250 were changed to reflect revised coverage policy.

60.5.1 - HCPCS for Carriers

(Rev. 1562, Issued: 07-25-08, Effective: 03-19-08, Implementation: 08-25-08)

For services furnished on or after July 1, 2002, and prior to March 19, 2008, the applicable HCPCS codes for this benefit are:

G0248: Demonstration, at initial use, of home INR monitoring for patient with mechanical heart valve(s) who meets Medicare coverage criteria, under the direction of a physician; includes: demonstration use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results and documentation of a patient's ability to perform testing.

Short Description: Demonstrate use home INR mon

G0249: Provision of test materials and equipment for home INR monitoring to patient with mechanical heart valve(s) who meets Medicare coverage criteria. Includes provision of materials for use in the home and reporting of test results to physician; per 4 tests.

Short Description: Provide test material, equipm

G0250: Physician review; interpretation and patient management of home INR testing for a patient with mechanical heart valve(s) who meets other coverage criteria; per 4 tests (does not require face-to-face).

Short Description: MD review interpret of test

For services furnished on or after March 19, 2008, the applicable HCPCS codes for this benefit are:

G0248: Demonstration, prior to initial use, of home INR monitoring for patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria, under the direction of a physician; includes: face-to-face demonstration of use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results, and documentation of patient ability to perform testing prior to its use

Short Description: Demonstrate use home INR mon

G0249: Provision of test materials and equipment for home INR monitoring of patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; includes provision of materials for use in the home and reporting of test results to physician; not occurring more frequently than once a week

Short Description: Provide INR test mater/equip

G0250: Physician review, interpretation, and patient management of home INR testing for a patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; includes face-to-face verification by the physician that the patient uses the device in the context of the management of the anticoagulation therapy following initiation of the home INR monitoring; not occurring more frequently than once a week

Short Description: MD INR test revie inter mgmt

60.5.2 – Applicable Diagnosis Codes for A/B MACs (B)

(Rev.10881; Issued: 08-06-2021; Effective: 09-07-2021; Implementation: 09-07- 2021)

For services furnished on or after the implementation of ICD-10 the applicable ICD-10-CM diagnosis codes for this benefit are:

ICD-10-CM Code	Code Description
D68.51	Activated protein C resistance
D68.52	Prothrombin gene mutation
D68.59	Other primary thrombophilia
D68.61	Antiphospholipid syndrome
D68.62	Lupus anticoagulant syndrome
I23.6	Thrombosis of atrium, auricular appendage, and ventricle as current complications following acute myocardial infarction
I26.01	Septic pulmonary embolism with acute cor pulmonale
I26.09	Other pulmonary embolism with acute cor pulmonale
I26.90	Septic pulmonary embolism without acute cor pulmonale
I26.93	Single subsegmental pulmonary embolism without acute cor pulmonale

I26.94	Multiple subsegmental pulmonary emboli without acute cor pulmonale
I26.99	Other pulmonary embolism without acute cor pulmonale
I27.24	Chronic thromboembolic pulmonary hypertension
I27.82	Chronic pulmonary embolism
I48.0	Paroxysmal atrial fibrillation
I48.11	Longstanding persistent atrial fibrillation
I48.19	Other persistent atrial fibrillation
I48.21	Permanent atrial fibrillation
I67.6	Nonpyogenic thrombosis of intracranial venous system
I80.11	Phlebitis and thrombophlebitis of right femoral vein
I80.12	Phlebitis and thrombophlebitis of left femoral vein
I80.13	Phlebitis and thrombophlebitis of femoral vein, bilateral
I80.211	Phlebitis and thrombophlebitis of right iliac vein
I80.212	Phlebitis and thrombophlebitis of left iliac vein
I80.213	Phlebitis and thrombophlebitis of iliac vein, bilateral
I80.221	Phlebitis and thrombophlebitis of right popliteal vein
I80.222	Phlebitis and thrombophlebitis of left popliteal vein
I80.223	Phlebitis and thrombophlebitis of popliteal vein, bilateral
I80.231	Phlebitis and thrombophlebitis of right tibial vein
I80.232	Phlebitis and thrombophlebitis of left tibial vein
I80.233	Phlebitis and thrombophlebitis of tibial vein, bilateral
I80.241	Phlebitis and thrombophlebitis of right peroneal vein
I80.242	Phlebitis and thrombophlebitis of left peroneal vein
I80.243	Phlebitis and thrombophlebitis of peroneal vein, bilateral
I80.251	Phlebitis and thrombophlebitis of right calf muscular vein
I80.252	Phlebitis and thrombophlebitis of left calf muscular vein
I80.253	Phlebitis and thrombophlebitis of calf muscular vein, bilateral
I80.291	Phlebitis and thrombophlebitis of other deep vessels of right lower extremity
I80.292	Phlebitis and thrombophlebitis of other deep vessels of left lower extremity
I80.293	Phlebitis and thrombophlebitis of other deep vessels of lower extremity, bilateral
I82.0	Budd-Chiari syndrome
I82.210	Acute embolism and thrombosis of superior vena cava
I82.211	Chronic embolism and thrombosis of superior vena cava
I82.220	Acute embolism and thrombosis of inferior vena cava
I82.221	Chronic embolism and thrombosis of inferior vena cava
I82.290	Acute embolism and thrombosis of other thoracic veins
I82.291	Chronic embolism and thrombosis of other thoracic veins
I82.3	Embolism and thrombosis of renal vein
I82.411	Acute embolism and thrombosis of right femoral vein
I82.412	Acute embolism and thrombosis of left femoral vein
I82.413	Acute embolism and thrombosis of femoral vein, bilateral
I82.421	Acute embolism and thrombosis of right iliac vein
I82.422	Acute embolism and thrombosis of left iliac vein
I82.423	Acute embolism and thrombosis of iliac vein, bilateral
I82.431	Acute embolism and thrombosis of right popliteal vein

I82.432	Acute embolism and thrombosis of left popliteal vein
I82.433	Acute embolism and thrombosis of popliteal vein, bilateral
I82.441	Acute embolism and thrombosis of right tibial vein
I82.442	Acute embolism and thrombosis of left tibial vein
I82.443	Acute embolism and thrombosis of tibial vein, bilateral
I82.451	Acute embolism and thrombosis of right peroneal vein
I82.452	Acute embolism and thrombosis of left peroneal vein
I82.453	Acute embolism and thrombosis of peroneal vein, bilateral
I82.461	Acute embolism and thrombosis of right calf muscular vein
I82.462	Acute embolism and thrombosis of left calf muscular vein
I82.463	Acute embolism and thrombosis of calf muscular vein, bilateral
I82.491	Acute embolism and thrombosis of other specified deep vein of right lower extremity
I82.492	Acute embolism and thrombosis of other specified deep vein of left lower extremity
I82.493	Acute embolism and thrombosis of other specified deep vein of lower extremity, bilateral
I82.511	Chronic embolism and thrombosis of right femoral vein
I82.512	Chronic embolism and thrombosis of left femoral vein
I82.513	Chronic embolism and thrombosis of femoral vein, bilateral
I82.521	Chronic embolism and thrombosis of right iliac vein
I82.522	Chronic embolism and thrombosis of left iliac vein
I82.523	Chronic embolism and thrombosis of iliac vein, bilateral
I82.531	Chronic embolism and thrombosis of right popliteal vein
I82.532	Chronic embolism and thrombosis of left popliteal vein
I82.533	Chronic embolism and thrombosis of popliteal vein, bilateral
I82.541	Chronic embolism and thrombosis of right tibial vein
I82.542	Chronic embolism and thrombosis of left tibial vein
I82.543	Chronic embolism and thrombosis of tibial vein, bilateral
I82.551	Chronic embolism and thrombosis of right peroneal vein
I82.552	Chronic embolism and thrombosis of left peroneal vein
I82.553	Chronic embolism and thrombosis of peroneal vein, bilateral
I82.561	Chronic embolism and thrombosis of right calf muscular vein
I82.562	Chronic embolism and thrombosis of left calf muscular vein
I82.563	Chronic embolism and thrombosis of calf muscular vein, bilateral
I82.591	Chronic embolism and thrombosis of other specified deep vein of right lower extremity
I82.592	Chronic embolism and thrombosis of other specified deep vein of left lower extremity
I82.593	Chronic embolism and thrombosis of other specified deep vein of lower extremity, bilateral
I82.621	Acute embolism and thrombosis of deep veins of right upper extremity
I82.622	Acute embolism and thrombosis of deep veins of left upper extremity
I82.623	Acute embolism and thrombosis of deep veins of upper extremity, bilateral
I82.721	Chronic embolism and thrombosis of deep veins of right upper extremity
I82.722	Chronic embolism and thrombosis of deep veins of left upper extremity

I82.723	Chronic embolism and thrombosis of deep veins of upper extremity, bilateral
I82.890	Acute embolism and thrombosis of other specified veins
I82.891	Chronic embolism and thrombosis of other specified veins
I82.A11	Acute embolism and thrombosis of right axillary vein
I82.A12	Acute embolism and thrombosis of left axillary vein
I82.A13	Acute embolism and thrombosis of axillary vein, bilateral
I82.A21	Chronic embolism and thrombosis of right axillary vein
I82.A22	Chronic embolism and thrombosis of left axillary vein
I82.A23	Chronic embolism and thrombosis of axillary vein, bilateral
I82.B11	Acute embolism and thrombosis of right subclavian vein
I82.B12	Acute embolism and thrombosis of left subclavian vein
I82.B13	Acute embolism and thrombosis of subclavian vein, bilateral
I82.B21	Chronic embolism and thrombosis of right subclavian vein
I82.B22	Chronic embolism and thrombosis of left subclavian vein
I82.B23	Chronic embolism and thrombosis of subclavian vein, bilateral
I82.C11	Acute embolism and thrombosis of right internal jugular vein
I82.C12	Acute embolism and thrombosis of left internal jugular vein
I82.C13	Acute embolism and thrombosis of internal jugular vein, bilateral
I82.C21	Chronic embolism and thrombosis of right internal jugular vein
I82.C22	Chronic embolism and thrombosis of left internal jugular vein
I82.C23	Chronic embolism and thrombosis of internal jugular vein, bilateral
O87.3	Cerebral venous thrombosis in the puerperium
Z79.01	Long term (current) use of anticoagulants
Z86.718	Personal history of other venous thrombosis and embolism
Z95.2	Presence of prosthetic heart valve

Coverage policy can be found in Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, section 190.11 PT/INR. (http://www.cms.hhs.gov/manuals/103_cov_determ/ncd103index.asp

60.6 – Carrier Claims Requirements
(Rev. 1562, Issued: 07-25-08, Effective: 03-19-08, Implementation: 08-25-08)

Note this test is not covered as durable medical equipment. Therefore, claims submitted to DMERCs will not be paid. It is covered under the physician fee schedule. Also note that the cost of the device and supplies is included in the payment for G0249 and therefore not separately billed to Medicare. G0249 continues to include materials for 4 tests. Additionally, G0250 continues to mean per 4 tests and should be billed no more frequently than once every 4 weeks.

60.7 – Carrier Payment Requirements
(Rev. 1562, Issued: 07-25-08, Effective: 03-19-08, Implementation: 08-25-08)

Payment and pricing information will be in the Medicare Physician Fee Schedule Database (MPFSDB). Pay for INR on the basis of the MPFS. Deductible and coinsurance apply.

60.8 – Carrier and Intermediary General Claims Processing Instructions
(Rev. 216, 06-25-04)

60.8.1 – Remittance Advice Notices

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

Use appropriate existing remittance advice reason and remark codes at the line level to express the specific reason for denying payment for PT/INR:

Remittance Advice Remark Code N386, "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at http://www.cms.hhs.gov/mcd/search.asp. If you do not have Web access, you may contact the contractor to request a copy of the NCD."

If denying services furnished after July 1, 2002, use ASC X 12-835 claim adjustment reason code 50, "These are non-covered services because this is not deemed a 'medical necessity' by the payer."

60.8.2 - Medicare Summary Notice (MSN) Messages

(Rev. 1562, Issued: 07-25-08, Effective: 03-19-08, Implementation: 08-25-08)

If denying services furnished after July 1, 2002, use MSN message:

"The following policies [190.11] were used when we made this decision." (MSN Message 15.20)

60.12 - Coverage for PET Scans for Dementia and Neurodegenerative Diseases

(Rev. 11021; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

Effective for dates of service on or after September 15, 2004, Medicare will cover FDG PET scans for a differential diagnosis of fronto-temporal dementia (FTD) and Alzheimer's disease OR; its use in a CMS-approved practical clinical trial focused on the utility of FDG-PET in the diagnosis or treatment of dementing neurodegenerative diseases. Refer to Pub. 100-03, NCD Manual, section 220.6.13, for complete coverage conditions and clinical trial requirements and section 60.15 of this manual for claims processing information.

A. A/B MAC (A and B) Billing Requirements for PET Scan Claims for FDG-PET for the Differential Diagnosis of Fronto-temporal Dementia and Alzheimer's Disease:

CPT Code for PET Scans for Dementia and Neurodegenerative Diseases

Contractors shall advise providers to use the appropriate CPT code from section 60.3.1 for dementia and neurodegenerative diseases for services performed on or after January 28, 2005.

Diagnosis Codes for PET Scans for Dementia and Neurodegenerative Diseases

The contractor shall ensure one of the following appropriate diagnosis codes is present on claims for PET Scans for AD:

- ICD-10-CM is applicable, ICD-10 codes are: F03.90, F03.90 plus F05, G30.9, G31.01, G31.9, R41.2 or R41.3

Medicare contractors shall deny claims when submitted with an appropriate CPT code from section 60.3.1 and with a diagnosis code other than the range of codes listed above.

Medicare contractors shall instruct providers to issue an Advanced Beneficiary Notice to beneficiaries advising them of potential financial liability prior to delivering the service if one of the appropriate diagnosis codes will not be present on the claim.

The contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Three.

Group Code: PR (if claim is received with a GA modifier) otherwise CO
CARC: 11
RARC: N/A
MSN: 16.48

Provider Documentation Required with the PET Scan Claim

Medicare contractors shall inform providers to ensure the conditions mentioned in the NCD Manual, section 220.6.13, have been met. The information must also be maintained in the beneficiary's medical record:

- Date of onset of symptoms;
- Diagnosis of clinical syndrome (normal aging, mild cognitive impairment or MCI: mild, moderate, or severe dementia);
- Mini mental status exam (MMSE) or similar test score;
- Presumptive cause (possible, probably, uncertain AD);
- Any neuropsychological testing performed;
- Results of any structural imaging (MRI, CT) performed;
- Relevant laboratory tests (B12, thyroid hormone); and,
- Number and name of prescribed medications.

B. Billing Requirements for Beta Amyloid Positron Emission Tomography (PET) in Dementia and Neurodegenerative Disease:

Effective for claims with dates of service on and after September 27, 2013, Medicare will only allow coverage with evidence development (CED) for Positron Emission Tomography (PET) beta amyloid (also referred to as amyloid-beta (Aβ)) imaging (HCPCS A9586) or (HCPCS Q9982) or (HCPCS Q9983) (one PET Aβ scan per patient).

Note: Please note that effective January 1, 2014 the following code A9599 will be updated in the IOCE and HCPCS update. This code will be contractor priced.

Note: Please note that effective January 1, 2018 the following code A9599 is end-date.

Medicare Summary Notices, Remittance Advice Remark Codes, and Claim Adjustment Reason Codes

Effective for dates of service on or after September 27, 2013, contractors shall return as unprocessable/return to provider claims for PET Aβ imaging, through CED during a clinical trial, not containing the following:

- Condition code 30, and value code D4 (FI only)
- Modifier Q0 as appropriate
- CD-10 dx code Z00.6 (in either the primary/secondary position)
- A PET HCPCS code (78811 or78814)
- At least, one Dx code from the table below,

And one of these additional diagnoses is required in addition to Z00.6

F03.90	Unspecified dementia without behavioral disturbance
F03.91	Unspecified dementia with behavioral disturbance
F01.50	Vascular dementia without behavioral disturbance
F01.51	Vascular dementia with behavioral disturbance
F02.80	Dementia in other diseases classified elsewhere without behavioral disturbance
F02.81	Dementia in other diseases classified elsewhere with behavioral disturbance
G31.01	Pick's disease
G31.09	Other frontotemporal dementia
G31.85	Corticobasal degeneration
G31.83	Dementia with Lewy bodies
G31.84	Mild cognitive impairment, so stated
R41.1	Anterograde amnesia
R41.2	Retrograde amnesia
R41.3	Other amnesia (amnesia NOS, memory loss NOS)

and

- Aβ HCPCS code A9586 or Q9982 or Q9983)

Contractors shall return as unprocessable claims for PET Aβ imaging using the following messages:

-Claim Adjustment Reason Code 4 – the procedure code is inconsistent with the modifier used or a required modifier is missing.

Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

Remittance Advice Remark Code N519 - Invalid combination of HCPCS modifiers. Contractors shall line-item deny claims for PET Aβ , HCPCS code A9586 or Q9982 or Q9983, where a previous PET Aβ, HCPCS code A9586 or Q9982 or Q9983 is paid in history using the following messages:

- CARC 149: “Lifetime benefit maximum has been reached for this service/benefit category.”
- RARC N587: “Policy benefits have been exhausted”.
- MSN 20.12: “This service was denied because Medicare only covers this service once a lifetime.”
- Spanish Version: “Este servicio fue negado porque Medicare sólo cubre este servicio una vez en la vida.”

- Group Code: PR, if a claim is received with a GA modifier

- Group Code: CO, if a claim is received with a GZ modifier

66 - National Coverage Determination (NCDs) services that are considered a significant cost for Medicare Advantage Plans

(Rev. 10229, Issued: 07-21-20 Effective: 10-01-20, Implementation: 10-05-20)

CMS is streamlining the editing for MA plans' claims when it is determined that certain services are being disallowed on MA plans that are considered a significant cost under section 422.109(a)(2) of title 42 of the Code of Federal Regulations. Original fee-for-service Medicare will pay for services obtained by beneficiaries enrolled in Medicare Advantage (MA) plans in this circumstance.

Consistent with §1862 (t)(2) of the Social Security Act, Medicare Administrative Contractors will pay for identified significant cost services for Medicare beneficiaries enrolled in MA plans. In addition 42 CFR §422.109, the Medicare payment for the services or benefit is made directly by the A/B MAC to the provider furnishing the service or benefit in accordance with original Medicare payment, rules, methods, and requirements**.**

Beneficiaries are liable for any applicable coinsurance amounts.
Cost for NCD services legislative changes in benefits for which CMS A/B MACs will not make payment and are the responsibility of the M+C organization are:

I. Services necessary to diagnose a condition covered by the NCD or legislative changes in benefits;
II. Most services furnished as follow up care to the NCD services or legislative changes in benefits;
III. Any services that is already a Medicare-covered service and included in the annual M+C capitation rate or previously, adjusted payments; and
IV. Any services, including costs of the NCD service or legislative change in benefits, to the extent the M+C organization is already obligated to cover it as an additional benefit under 42CFR §422.312 or supplemental benefit under 42 CFR §422.102.

66.1 – Institutional Billing for National Coverage Determination (NCDs) services that are considered a significant cost for Medicare Advantage

(Rev. 10229, Issued: 07-21-20 Effective: 10-01-20, Implementation: 10-05-20)

A. Institutional Inpatient Billing for National Coverage Determination (NCDs) services that are considered a significant cost for Medicare Advantage.
The Medicare contractors shall allow Condition Code (CC) 78 on any inpatient institutional claims for Medicare Advantage beneficiaries when it is determined that certain services are being disallowed on MA plans that are considered a significant cost under section 422.109(a)(2) of title 42 of the Code of Federal Regulations. Any current editing that doesn't allow this shall be updated to allow this scenario, unless there has been previous instructions excluding certain conditions.

Note: Condition Code 78 = Newly covered Medicare service for which an HMO doesn't pay.
B. Institutional Outpatient Billing for National Coverage Determination (NCDs) services that are considered a significant cost for Medicare Advantage
The Medicare contractors shall allow Condition Code (CC) 78 on any outpatient institutional claims for Medicare Advantage beneficiaries when it is determined that certain services are being disallowed on MA plans that are considered a significant cost under section 422.109(a)(2) of title 42 of the Code of Federal Regulations. Any current editing that doesn't allow this shall be updated to allow this scenario, unless there has been previous instructions excluding certain conditions.

Note: Condition Code 78 = Newly covered Medicare service for which an HMO doesn't pay.

66.2 – Services Identified as having Significant Cost for Medicare Advantage

(Rev. 10229, Issued: 07-21-20 Effective: 10-01-20, Implementation: 10-05-20)

Services Identified as having Significant cost under section 422.109(a)(2) of title 42 of the Code of Federal Regulations Providers may bill the A/B MAC for these NCD services provided to a MA beneficiary.

Services Identified as having Significant cost					
Service/Benefit	Revenue Code	HCPCS	ICD-10-PCS Procedure	Significant Cost Start	Significant Cost End
CAR-T	0891	Q2041, Q2042	XW033C3 or XW043C3	08/07/2019	12/31/2020

67 – No Cost Items

(Rev. 1147, Issued: 01-05-07, Effective: 11-06-06, Implementation: 02-05-07)

On occasion, providers may receive an item (such as a device or drug) that is offered by a manufacturer/supplier free of charge. Such items, for purposes of these instructions, are considered "no cost items." Providers are not to seek reimbursement for no cost items as noted in Section 1862(a)(2) of the Social Security Act.

67.1 – Practitioner Billing for No Cost Items

(Rev. 1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)

Practitioners typically should not bill for no cost items as there is no non-covered charges field on the claim and there are also no system edits in place to require providers to do so. However, practitioners are required to report Category A IDE devices received at no cost on claims as specified in §68.3 of this chapter (although they will not receive payment).

67.2 – Institutional Billing for No Cost Items

(Rev. 4013, Issued: 03-30-18, Effective: 01-01-09, Implementation: 06-29-18)

Generally speaking, institutional, providers should not have to report the usage of a no cost item. However, for some claims (e.g., hospital Outpatient Prospective Payment System (OPPS) claims), providers may be required to bill a no cost item due to claims processing edits that require an item (even if received at no cost) to be billed along with an associated service (e.g., a specified device must be reported along with a specified implantation procedure).

For OPPS claims, when a drug is provided at no cost, claims processing edits prevent drug administration charges from being billed when the claim does not contain a covered/billable drug charge. Therefore, for drugs provided at no cost in the hospital outpatient department, providers must report the applicable drug HCPCS code and appropriate units with a token charge of less than $1.01 for the item in the covered charge field and mirror this less than $1.01 amount reported in the noncovered charge field. Providers must also bill the corresponding drug administration charge with the appropriate drug administration CPT or HCPCS code.

For OPPS claims, providers must report a token charge of less than $1.01 for the item in the covered charge field, along with the applicable HCPCS modifier (i.e., modifier –FB) appended to the procedure code that reports the service requiring

a device. For more information on billing no cost items under the OPPS, refer to Chapter 4, §20.6.9 and 61.3.1 of this manual.

By billing in this way, the provider is accomplishing four things:

1) Communicating to the contractor that the provider is not seeking payment for the no cost item;

2) Reflecting, with completeness and accuracy, all services provided to the patient;

3) Preventing the line item or claim from being rejected/denied by system edits that require an item to be billed in conjunction with an associated procedure (such as implantation or administration procedures);

4) Assuring that the patient and provider are not held liable for any charges for the no cost item.

Future updates will be issued in a Recurring Update Notification.

67.2.1 – Billing No Cost Items Due to Recall, Replacement, or Free Sample
(Rev. 3181, Issued: 01-30-15, Effective: 07-01-15, Implementation: 07-06-15)

Currently, institutional providers that use the Healthcare Common Procedural Coding System (HCPCS) bill device HCPCS codes for no cost or full credit items with token charges in order for claims to pass OPPS claims processing edits that require certain devices to be billed with their associated procedures so that payment can be made.

Effective January 1, 2006, modifier –FB is used to indicate that an item used in a procedure was furnished without cost to the provider, and, therefore, it is not being charged to Medicare or the beneficiary. More information on billing HCPCS modifier –FB can be located in Chapter 4, §20.6.9 and 61.3.1 of this manual.

Effective April 1, 2006, two new condition codes were created for institutional use: 49 and 50 (Table 1). These new codes are used to identify and track medical devices that are provided by a manufacturer at no cost or with full credit to the hospital due to warranty for a malfunction or recall.

Table 1: New Condition Codes and Descriptions

Condition Code		**Description**
49	Product Replacement within Product Lifecycle	Replacement of a product earlier than the anticipated lifecycle.
50	Product Replacement for Known Recall of a Product	Manufacturer or FDA has identified the product for recall and therefore replacement.

- Providers must use these condition codes to identify medical devices that are provided by a manufacturer at no cost or with full credit due to warranty or recall. These condition codes will be used to track no cost/full credit devices replaced due to recall or warranty.

- Providers must report these condition codes on any inpatient or outpatient institutional claim that includes a no cost/full credit replacement device when conditions of warranty or recall are met.

NOTE: OPPS hospitals billing no cost/full credit devices must append modifier –FB to the procedure code for implanting the no cost/full credit device, along with the appropriate condition code if applicable (in Table 1 above), in instances when claims processing edits require that certain devices be billed with their associated procedures. The modifier identifies the procedure code line for the no cost/full credit device, while the condition code explains if the device was provided free of cost due to warranty or recall.

Effective January 1, 2014, an additional new condition code was created for institutional use: 53 (Table 2). This new code is used to identify and track medical devices that are provided by a manufacturer at no cost or with full credit to the hospital due a clinical trial or a free sample.

Table 2: New Condition Codes and Descriptions		
Condition Code		**Description**
49	Product Replacement within Product Lifecycle	Replacement of a product earlier than the anticipated lifecycle.
50	Product Replacement for Known Recall of a Product	Manufacturer or FDA has identified the product for recall and therefore replacement.
53	Initial placement of a medical device provided as part of a clinical trial or free sample	Code is for outpatient claims that have received a device credit upon initial medical device placement in a clinical trial or a free sample.

- Providers must use these condition codes to identify medical devices that are provided by a manufacturer at no cost or with full credit due to warranty, recall, or free sample. These condition codes will be used to track no cost/full credit devices replaced due to recall, warranty, or free sample.

- Providers must report these condition codes on any inpatient or outpatient institutional claim that includes a no cost/full credit replacement device when conditions of warranty, recall, or free sample are met.

NOTE: OPPS hospitals billing no cost/full credit devices are no longer required to append modifier –FB to the procedure code for implanting the no cost/full credit device, along with the appropriate condition code if applicable (in Table 2 above), in instances when claims processing edits require that certain devices be billed with their associated procedures.

68 – Investigational Device Exemption (IDE) Studies
(Rev. 3105, Issued: 11-06-14, Effective: 01-01-15, Implementation: 01-05-15)

See Pub. 100-02, Medicare Benefit Policy Manual, Chapter 14 for complete Medicare coverage requirements for items and services in Category A and B IDE studies, related to these billing requirements.

NOTE: For information regarding Medicare coverage related to IDEs in Medicare Advantage plans, refer to Pub. 100-16, Medicare Managed Care Manual, chapter 4, section 10.7.2.

68.1 – Billing Requirements for Providers Billing for Routine Care Items and Services in Category A IDE Studies
(Rev. 3105, Issued: 11-06-14, Effective: 01-01-15, Implementation: 01-05-15)

A. Institutional Inpatient and Outpatient Billing in Category A IDE Studies

Routine Care Items and Services

Institutional providers shall submit claims only for routine care items and services in Category A IDE device studies approved by CMS (or its designated entity) and listed on the CMS Coverage Website, by billing according to the clinical trial billing instructions found in §69.6 of this chapter, and as described below under subsection C ("General

Billing Requirements"). The Category A IDE device shall not be reported on institutional claims since Category A IDE devices are not eligible for payment under Medicare.

B. Practitioner Billing in Category A IDE Studies

Routine Care Items and Services

Practitioners shall submit claims for the routine care items and services in Category A IDE studies approved by CMS (or its designated entity) and listed on the CMS Coverage Website, by billing according to the clinical trial billing instructions found in §69.6 of this chapter, and as described below under subsection C ("General Billing Requirements"). The Category A IDE device shall not be reported on practitioner claims since Category A IDE devices are not eligible for payment under Medicare.

C. General Billing Requirements

Effective for claims with dates of service on or after January 1, 2014, it is **mandatory** to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under coverage with evidence development (CED). This is the number assigned by the National Library of Medicine (NLM) ClinicalTrials.gov Website when a new study appears in the NLM Clinical Trials data base. This number is listed prominently on each specific study's page and is always preceded by the letters "NCT." Contractors verify the validity of a trial/study/registry by consulting CMS's Coverage Website at: http://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center.html?redirect=/center/coverage.asp. Providers report the 8-digit number on the following claims locators:

CMS-1500 paper form-place in Field 19 (preceded by 'CT'); or
837 P—Loop 2300, REF02, REF01=P4 (do not use 'CT' on the electronic claim)

In addition to the clinical trial number, claims shall include:

ICD-9 diagnosis code V70.7/ICD-10 diagnosis code Z00.6 (in either the primary/secondary positions)

HCPCS modifier Q0 or Q1 as appropriate

Claims submitted without a clinical trial number shall be returned as unprocessable reporting the following messages:

CARC 16: "Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.)"

RARC MA50: "Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services."

RARC MA130: "Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information."

Group Code - Contractual Obligation (CO)

Effective for dates of service on or before December 31, 2007, practitioners must place a QV modifier (Item or service provided as routine care in a Medicare qualifying clinical trial) on the line for the device along with the IDE number.

Effective for dates of service on or after January 1, 2008, practitioners will no longer bill a QV modifier to identify the device. Instead, practitioners will bill a Q0 (numeral 0 versus the letter O) modifier (Investigational clinical service provided in a clinical research study that is in an approved clinical research study) along with the IDE number.

The following table shows the designated field locations to report the Category A IDE number on practitioner claims:

Data	CMS-1500	837i and 837p
IDE #	Item 23	Segment 2300, REF02(REF01=LX)

Contractors will validate the IDE number for the Category A device when modifier Q0 is submitted on the claim along with the IDE number. Claims containing an invalid IDE number will be returned to the provider using the following messages:

RARC MA50: "Missing/incomplete/invalid Investigational Device Exemption Number for FDA approved clinical trial services."

CARC 16: "Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT)."

68.2 – Billing Requirements for Providers Billing for Category B IDE Devices and Routine Care Items and Services in Category B IDE Studies

(Rev. 3105, Issued: 11-06-14, Effective: 01-01-15, Implementation: 01-05-15)

Payment for the device may not exceed the Medicare-approved amount for a comparable device that has been already FDA-approved.

A. Institutional Inpatient Billing for Items and Services in Category B IDE Studies

Routine Care Items and Services

Institutional providers shall submit claims for the routine care items and services in Category B IDE studies approved by CMS (or its designated entity) and listed on the CMS Coverage Website, by billing according to the clinical trial billing instructions found in §69.6 of this chapter, and as described below under subsection D ("General Billing Requirements").

Category B Device

Institutional providers must bill the Category B IDE number on a 0624 revenue code line with charges in the covered charges field. Hospital inpatient providers should not bill for the Category B IDE device if receiving the device free-of-charge.

B. Institutional Outpatient Billing for Items and Services in Category B IDE Studies

Routine Care Items and Services

Institutional providers shall submit claims for the routine care items and services in Category B IDE studies approved by CMS (or its designated entity) and listed on the CMS Coverage Website, by billing according to the clinical trial

billing instructions found in section 69.6 of this chapter, and as described below under subsection D ("General Billing Requirements").

Category B Device

On a 0624 revenue code line, institutional providers must bill the following for Category B IDE devices for which they incur a cost:

- Category B IDE device HCPCS code, if applicable
- Appropriate HCPCS modifier:
    - Q0 or Q1 as appropriate for claims with dates of service on or after January 1, 2014; or
    - Q0 (numeral 0 versus the letter O) modifier for claims with dates of service on or after January 1, 2008; or,
    - QA modifier for claims with dates of service prior to January 1, 2008.
- Category B IDE number
- Charges for the device billed as covered charges

NOTE: If the Category B IDE device is provided at no cost, outpatient prospective payment system (OPPS) providers must report a token charge in the covered charge field along with the applicable HCPCS modifier (i.e., modifier – FB) appended to the procedure code that reports the service to furnish the device, in instances when claims processing edits require that certain devices be billed with their associated procedures. For more information on billing 'no cost items' under the OPPS, refer to chapter 4, §§20.6.9 and 61.3.1 of this manual.

C. Practitioner Billing for Items and Services in Category B IDE Studies

Routine Care Items and Services

Practitioners shall submit claims for routine care items and services in Category B IDE studies approved by CMS (or its designated entity) and listed on the CMS Coverage Website, by billing according to the clinical trial billing instructions found in section 69.6 of this chapter, and as described below under subsection D ("General Billing Requirements").

Category B Device

Effective for dates of service on or before December 31, 2007, practitioners must bill the Category B IDE device on a line with a QA modifier (FDA IDE) along with the IDE number. However, effective for dates of service on or after January 1, 2008, practitioners will no longer bill a QA modifier to identify a Category B device. Instead, practitioners will bill a Q0 modifier (numeral 0 versus the letter O) (Investigational clinical service provided in a clinical research study that is in an approved clinical research study) along with the IDE number.

The following table shows the designated field locations to report the Category B IDE number on institutional and practitioner claims:

Data	CMS-1450	CMS-1500	837i and 837p

IDE #	FL 43	Item 23	Segment 2300, REF02(REF01=LX)

Contractors will validate the IDE number for the Category B device when modifier Q0 is submitted on the claim along with the IDE number. Claims containing an invalid IDE number will be returned to the provider using the following messages:

RARC MA50: "Missing/incomplete/invalid Investigational Device Exemption Number for FDA approved clinical trial services."

CARC 16: "Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT."

D. General Billing Requirements

Effective for claims with dates of service on or after January 1, 2014, it is mandatory to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under CED. This is the number assigned by the NLM ClinicalTrials.gov Website when a new study appears in the NLM Clinical Trials data base. This number is listed prominently on each specific study's page and is always preceded by the letters "NCT." Contractors verify the validity of a trial/study/registry by consulting CMS's Coverage Website at: http://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center.html?redirect=/center/coverage.asp. Providers report the 8-digit number on the following claims locators:

- CMS-1500 paper form-place in Field 19 (preceded by 'CT'); or
- 837 P—Loop 2300, REF02, REF01=P4 (do not use 'CT' on the electronic claim).

In addition to the clinical trial number, claims shall include:

- ICD-9 diagnosis code V70.7/ICD-10 diagnosis code Z00.6 (in either the primary/secondary positions)
- HCPCS modifier Q0 or Q1 as appropriate

Claims submitted without a clinical trial number shall be returned as unprocessable reporting the following messages:

- CARC 16: "Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.)"
- RARC MA50: "Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services."
- RARC MA130: "Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information."

Group Code-Contractual Obligation (CO)

68.4 – Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category B IDE

(Rev. 12571; Issued: 04-11-24) Effective: 10-11-23; Implementation: 05-13-24)

As noted above in section 68.2, of this chapter, providers shall first notify their contractor of the IDE device trial before submitting claims for Category B IDE devices and the routine costs of clinical trials involving Category B IDE devices. Once the contractor notifies the provider that all required information for the IDE has been furnished, the provider may bill Category B IDE claims.

When billing for Category B IDEs, providers shall bill for the device and all related procedures. The Category B IDE device and the routine costs associated with its use are eligible for payment under Medicare. (Payment for the device may not exceed the Medicare-approved amount for a comparable device that has been already FDA-approved.)

Institutional Inpatient Billing

Routine Costs

Institutional providers shall submit claims for the routine costs of a clinical trial involving a Category B IDE device by billing according to the clinical trial billing instructions found in §69.6 of this chapter.

Category B Device

Institutional providers must bill the Category B IDE number on a 0624 revenue code line with charges in the covered charges field. Hospital inpatient providers should not bill for the Category B IDE device if receiving the device free-of-charge.

Institutional Outpatient Billing

Routine Costs

Institutional providers shall submit claims for the routine costs of a clinical trial involving a Category B IDE device by billing according to the clinical trial billing instructions found in section 69.6 of this chapter.

Category B Device

On a 0624 revenue code line, institutional providers must bill the following for Category B IDE devices for which they incur a cost:

- Category B IDE device HCPCS code, if applicable.
- Appropriate HCPCS modifier:
    - Q0 or Q1 as appropriate for claims with dates of service on or after January 1, 2014; or
    - Q0 (numeral 0 versus the letter O) modifier for claims with dates of service on or after January 1, 2008; or
    - QA modifier for claims with dates of service prior to January 1, 2008.
- Category B IDE number
- Charges for the device billed as covered charges

NOTE: For claims prior to January 1, 2014, if the Category B IDE device is provided at no cost, outpatient prospective payment system (OPPS) providers must report a token charge in the covered charge field along with the applicable HCPCS modifier (i.e., modifier –FB) appended to the procedure code that reports the service to furnish the device, in instances when claims processing edits require that certain devices be billed with their associated procedures. For more information on billing 'no cost items' under the OPPS, refer to Chapter 4, §§20.6.9 and 61.3.1 of this manual.

Effective January 1, 2014, if the Category B IDE device is provided at no cost, outpatient prospective payment system (OPPS) providers must report a token charge in the covered charge field along with condition code "53" and Value Code "FD". For more information on billing 'no cost items' under the OPPS, refer to Chapter 4, §§20.6.9 and 61.3.1 of this manual.

Practitioner Billing

Routine Costs

Practitioners shall submit claims for the routine costs of a clinical trial involving a Category B IDE device by billing according to the clinical trial billing instructions found in section 69.6 of this chapter.

Category B Device

Effective for claims with dates of service on or after January 1, 2014, it is **mandatory** to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under CED. Providers report the 8-digit number on the following claims locators:

- 837 professional claim format (do not use 'CT' on the electronic claim) or,
- CMS-1500 paper form-place in Field 19 (preceded by 'CT').

In addition to the clinical trial number, claims shall include (in either the primary/secondary positions):

- If ICD-9-CM is applicable, ICD-9 diagnosis code V70.7
- If ICD-10-CM is applicable, ICD-10 diagnosis code Z00.6
- HCPCS modifier Q0 or Q1 as appropriate

Claims submitted without a clinical trial number shall be returned as unprocessable reporting the following messages:

CARC 16: "Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.)"

RARC MA50: "Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services."

RARC MA130: "Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information."

Group Code-Contractual Obligation (CO)

Effective for dates of service on or before December 31, 2007, practitioners must bill the Category B IDE device on a line with a QA modifier (FDA IDE) along with the IDE number. However, effective for dates of service on or after January 1, 2008, practitioners will no longer bill a QA modifier to identify a Category B device. Instead, practitioners will bill a Q0 modifier (numeral 0 versus the letter O) (Investigational clinical service provided in a clinical research study that is in an approved clinical research study) along with the IDE number.

The following table shows the designated field locations to report the Category B IDE number on institutional and practitioner claims:

Data	**CMS-1450**	**CMS-1500**	**837 institutional claim format and 837 professional claim format**
IDE #	Revenue Code Description field	Item 23	Segment 2300, REF02(REF01=LX)

Contractors will validate the IDE number for the Category B device when modifier Q0 is submitted on the claim along with the IDE number. Claims containing an invalid IDE number will be returned to the provider using the following messages:

RARC MA50: "Missing/incomplete/invalid Investigational Device Exemption Number for FDA approved clinical trial services."

CARC 16: "Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT."

Claims that are submitted without the 'Q0' modifier will be returned with the following messages:

CARC 16 - Claim/service lacks information or has submission/billing error(s). Usage: Do not use this code for claims attachment(s)/other documentation. At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.) Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC N822 – Missing procedure modifier(s).

69 - Qualifying Clinical Trials

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

69.1 – General

(Rev. 13551; Issued: 12-19-25; Effective: 01-21-26; Implementation: 01-21-26)

The CMS has issued a National Coverage Determination (NCD) which allows Medicare coverage for the routine costs of qualifying clinical trial services as well as reasonable, necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. The coverage requirements for routine costs of qualifying clinical trial services are contained in the National Coverage Determinations Manual, Section 310.1, www.cms.gov/regulations-and-

guidance/guidance/manuals/downloads/ncd103c1_part4.pdf

69.2 - Payment for Qualifying Clinical Trial Services

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

For dates of service on or after September 19, 2000, pay for covered services furnished to beneficiaries participating in qualifying clinical trials. Payment is based on the payment methodology applicable for the service that was furnished (e.g., physician fee schedule, lab fee schedule, durable medical equipment fee schedule, reasonable charge, etc.). With the exception of managed care enrollees, applicable deductibles and coinsurance rules apply to clinical trial items and services. The Part A and Part B deductibles are assumed to be met for covered clinical trial services billed on a fee service basis for managed care enrollees.

NOTE: Effective for claims with dates of service on or after January 1, 2014, it is **mandatory** to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under CED. This is the number assigned by the National Library of Medicine (NLM) ClinicalTrials.gov Web site when a new study appears in the NLM Clinical Trials data base. This number is listed prominently on each specific study's page and is always preceded by the letters "NCT." Contractors verify the validity of a trial/study/registry by consulting CMS's clinical trials/registry web site at: http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/index.html.

NOTE: Contractors shall ensure value code 'D4'/amount data from their internal claims processing is mapped/populated to the 837 institutional claim format for a coordination of benefits 837 institutional claim.

69.3 - Medical Records Documentation Requirements

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

The billing provider must include in the beneficiary's medical record the following information: trial name, sponsor, and sponsor-assigned protocol number. This information does not need to be submitted with the claim but must be provided if requested for medical review.

69.4 - Local Medical Review Policy

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

Do not develop new or revised LMRPs for clinical trial services. Clinical trial services that meet the requirements of the NCD are considered reasonable and necessary.

69.5 - Billing Requirements – General

(Rev. 2955, Issued: 05-14-14, Effective, 01-01-14, Implementation, 01- 06-14)

Instruct practitioners and institutional providers to enter clinical trial and non-clinical trial services on separate line items when billing both types of services on the same claim. For services that require a Certificate of Medical Necessity (CMN), continue to require CMNs. Items and services provided free-of-charge by research sponsors generally may not be billed to be paid by Medicare, and providers are not required to submit the charge to Medicare. If it is necessary for a provider to show the items and services that are provided free-of-charge in order to receive payment for the covered routine costs (e.g. administration of a non-covered chemotherapeutic agent), providers are instructed to submit such charges as non-covered at the time of entry, while also assuring that the beneficiary is not held liable. This instruction applies to all hospitals including hospitals located in Maryland under the jurisdiction of the Health Services Cost Review Commission (HSCRC).

For OPPS claims, providers must report a token charge for a 'no cost' item in the covered charge field along with the applicable HCPCS modifier (i.e., modifier –FB) appended to the procedure code that reports the service provided to furnish the 'no cost' item, in instances when claims processing edits require that certain devices be billed with their associated procedures. For more information on billing 'no cost' items under the OPPS, refer to Chapter 4, §§20.6.9 and 61.3.1 of this manual.

NOTE: Effective for claims with dates of service on or after January 1, 2014, it is **mandatory** to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under CED.

Future updates will be issued in a Recurring Update Notification.

69.6 - Requirements for Billing Routine Costs of Clinical Trials
(Rev. 13551; Issued: 12-19-25; Effective: 01-21-26; Implementation: 01-21-26)

Routine Costs Submitted by Practitioners/Suppliers

Claims with dates of service on or after January 1, 2008:

- HCPCS modifier 'Q1' (numeral 1 instead of the letter i); and,
- ICD-10 diagnosis code Z00.6 (in either the primary or secondary positions)

CMS covers the cost of healthy volunteers in a qualified clinical trial if it meets the following conditions:

- The trial is not designed exclusively to test toxicity or disease pathophysiology.
- The trial must have therapeutic intent.
- If the trial has therapeutic interventions, it must enroll patients with a diagnosed disease rather than healthy volunteers.
- If the trial is studying diagnostic interventions, it may enroll healthy patients to have a proper control group.

Claims submitted with modifier Q1 shall be returned as unprocessable if ICD-10-CM code Z00.6 is not submitted on the claim.

Contractors shall return the following messages:

Claims Adjustment Reason Code (CARC) 16: "Claim/service lacks information which is needed for adjudication. As least one Remark Code must be provided (may be comprised of either the Remittance Advice Code or NCPDP Reject Reason Code)."

Remittance Advice Remark Code (RARC) M76: "Missing/incomplete/invalid diagnosis or condition."

Effective for claims with dates of service on or after January 1, 2014, it is mandatory to report a

clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under Coverage with Evidence Development (CED.) Providers must report the 8-digit number on clinical trial number on the following claims locators:

- 837 professional claim format Loop 2300 REF02 (REF01=P4) (do not use 'CT' on the electronic claim); or

- CMS-1500 paper form place in Field 19 (preceded by 'CT').

In addition to the clinical trial number, claims should also include:

- ICD-10 diagnosis code Z00.6 (in either the primary or secondary positions)

- HCPCS modifier Q0 or Q1 as appropriate

Practitioner claims submitted without a clinical trial number shall be returned as unprocessable using the following messages:

CARC 16: "Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.)"

RARC MA50: "Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services."

RARC MA130: "Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information."

Group Code-Contractual Obligation (CO)

<u>Routine Costs Submitted by Institutional Providers</u>

All Institutional Clinical Trial Claims

Regardless of the date of service, clinical trial claims received after April 1, 2008, providers must report the 8-digit clinical trial number. To bill the 8-digit clinical trial number, institutional providers shall use value code 'D4'where the value code amount equals the 8-digit clinical trial number. Below are the claim locators in which to bill the 8-digit clinical trial number:

- 837 institutional claim format Loop 2300 REF02 (REF01=P4)

- Paper CMS-1450 value code 'D4'

NOTE: Value code 'D4'/amount data from the internal claims processing is mapped/populated to the 837 institutional claim formats for a coordination of benefits 837 institutional claim

NOTE: It is mandatory to report a clinical trial number on claims for items or services provided in clinical trials, studies or registries. Institutional claims submitted without a clinical trial number shall be returned to providers.

NOTE: Modifier Q0 is used for services defined as an investigational clinical service provided in an approved clinical research study. Append this modifier on a Category B Investigational Device Exemption (IDE) code along with IDE number on the claim.

The modifier Q1 is a line item specific and must be used to identify items and services that constitute medically necessary routine patient care or treatment of complications arising from a Medicare beneficiary's participation in a Medicare covered clinical trial. Items and services that are provided solely to:

- Satisfy data collection and analysis needs; and
- That are not used in the clinical management of the patient

are not covered and may not be billed using modifier Q1. Items and services that are not covered by Medicare by virtue of a statutory exclusion or lack of a benefit category also may not be billed using modifier Q1. When billed in conjunction with the Z00.6 diagnosis code, modifier Q1 will serve as the provider's attestation that the service meets the Medicare coverage criteria (i.e., was furnished to a beneficiary who is participating in a Medicare qualifying clinical trial and represents routine patient care, including complications associated with qualifying clinical trial participation).

Inpatient Clinical Trial Claims

Institutional providers billing clinical trial service(s) must report ICD-10 diagnosis code Z00.6 in either the primary or secondary position and condition code 30 regardless of whether all services are related to the clinical trial or not.

NOTE: HCPCS codes are not reported on inpatient claims. Therefore, the HCPCS modifier requirements (i.e., Q0/Q1) as outlined in the outpatient clinical trial section below, are not applicable to inpatient clinical trial claims.

Outpatient Clinical Trial Claims

On all outpatient clinical trial claims, providers must do the following:

- Report condition code 30,
- Report ICD-10 diagnosis code Z00.6, in the primary or secondary position; and
- The 8-digit clinical trial identifier number in the 837I Loop 2300 REF02 (REF01=P4) or as value code 'D4' on paper only CMS-1450.
- Identify all lines that contain an investigational item/service with HCPCS modifier Q0 for dates of services on or after 01/01/08.
- Identify all lines that contain a routine service with HCPCS modifier Q1 for dates of service on or after 1/1/08.

For clinical trial billing requirements for patients enrolled in a managed care plan/MAO, please refer to Section 69.9 of this chapter.

69.7 - Reserved for Future Use
(Rev. 1418, Issued: 01-18-08, Effective: 01-01-08, Implementation: 04-07-08)

69.8 - Handling Erroneous Denials of Qualifying Clinical Trial Services
(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

If a service Medicare covers was billed with the appropriate clinical trial coding but was inadvertently denied (e.g., for medical necessity or utilization) and is subsequently brought to your attention, adjust the denied claim. If the denied services weren't properly coded as clinical trial services, instruct the provider to resubmit the service on a new claim with appropriate clinical trial coding.

69.9 - Billing and Processing Fee for Service Claims for Covered Clinical Trial Services Furnished to Managed Care Enrollees
(Rev. 13551; Issued: 12-19-25; Effective: 01-21-26; Implementation: 01-21-26)

Payment for Investigational Device Exemption (IDE) Studies
Medicare Advantage Organizations (MAOs) are responsible for payment of claims related to the enrollees' participation in both Category A and B IDE studies that are covered by the Medicare Administrative Contractor (MAC) with jurisdiction over the MA plan's service area. The MAO is responsible for payment of routine care items and services in Centers for Medicare & Medicaid (CMS) approved Category A and Category B IDE studies. The MAO is also responsible for CMS approved Category B devices. CMS will not approve Category A devices because they are statutorily excluded from coverage.

Payment for Clinical Studies Approved Under Coverage with Evidence Development (CED)
In National Coverage Determinations (NCDs) requiring CED, Medicare covers items and services in CMS approved CED studies. MAOs are responsible for

payment of items and services in CMS approved CED studies unless CMS determines that the significant cost threshold is exceeded for that item or service (see 42 CFR 422.109).

Payment for Clinical Trial Services
Per Publication 100-16, Chapter 4, Section 10.7.1- 10.7.3, Medicare Advantage Organizations (MAOs) are responsible for payment of services. For additional information regarding MAO benefits refer to:
https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c04.pdf

The clinical trial coding requirements for MAO claims are the same as those for regular Medicare fee for service claims. However, for beneficiaries enrolled in a MAO plan, institutional providers must not bill outpatient clinical trial services and non-clinical trial services on the same claim. If covered outpatient services unrelated to the clinical trial are rendered during the same day/stay, the provider must split bill submitting only the clinical trial services on a single claim and billed as fee-for-service. (This allows the Medicare claims processing system to not apply the deductible when the patient is found to be in a MAO plan). Any outpatient services unrelated to the clinical trial should be billed to the MAO plan

69.10 - CWF Editing Of Clinical Trial Claims For Managed Care Enrollees
(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

Submit clinical trial services for managed care enrollees to CWF for payment approval. CWF will not reject clinical trial claims for managed care enrollees when all services on the claim transaction record are coded as clinical trial services and the date(s) of service is (are) on or after September 19, 2000. In addition, CWF will not apply Part B deductible to clinical trial claims for managed care enrollees (i.e., CWF will process clinical trial services for managed care enrollees as if the Part B deductible has already been met).

69.11 - Resolution of CWF UR 5232 Rejects
(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

If you send a claim transaction to CWF that includes both clinical and non-clinical trial services for a managed care enrollee, the entire claim will be rejected with the UR 5232 error code. When you receive a UR 5232 error code split the claim and resubmit the clinical trial portion to CWF. Process the non-clinical trial portion of the rejected claims in the same manner that other non-clinical trial fee for service claims for managed care enrollees are handled.

70 - Billing Requirements for Islet Cell Transplantation for Beneficiaries in a National Institutes of Health (NIH) Clinical Trial
(Rev. 986, Issued: 06-16-06, Effective: 05-01-06, Implementation: 07-31-06)

For services performed on or after October 1, 2004, Medicare will cover islet cell transplantation for patients with Type I diabetes who are participating in an NIH sponsored clinical trial. See Pub 100-04 (National Coverage Determinations Manual) section 260.3.1 for complete coverage policy.

The islet cell transplant may be done alone or in combination with a kidney transplant. Islet recipients will also need immunosuppressant therapy to prevent rejection of the transplanted islet cells. Routine follow-up care will be necessary for each trial patient. See Pub 100-04,

section 310 for further guidance relative to routine care. All other uses for islet cell services will remain non-covered.

70.1 - Healthcare Common Procedure Coding System (HCPCS) Codes for Carriers

(Rev. 261, Issued: 07-30-04, Effective: 10-01-04, Implementation: 10-04-04)

G0341: Percutaneous islet cell transplant, includes portal vein catheterization and infusion

Short Descriptor: Percutaneous islet cell trans

Type of Service: 2

G0342: Laparoscopy for islet cell transplant, includes portal vein catheterization and infusion

Short Descriptor: Laparoscopy islet cell trans

Type of Service: 2

G0343: Laparotomy for islet cell transplant, includes portal vein catheterization and infusion

Short Descriptor: Laparotomy islet cell transp

Type of Service: 2

70.2 - Applicable Modifier for Islet Cell Transplant Claims for Carriers

(Rev. 986, Issued: 06-16-06, Effective: 05-01-06, Implementation: 07-31-06)

Carriers shall instruct physicians to bill using the above procedure code(s) with modifier QR (Item or service provided in a Medicare-specified study) for all claims for islet cell transplantation and routine follow-up care related to this service.

70.3 - Special Billing and Payment Requirements for Carriers

(Rev. 261, Issued: 07-30-04, Effective: 10-01-04, Implementation: 10-04-04)

Payment and pricing information will be on the October 2004 update of the Medicare Physician Fee Schedule Database (MPFSDB). Pay for islet cell transplants on the basis of the MPFS. Deductible and coinsurance apply for fee-for-service beneficiaries.

70.4 - Special Billing and Payment Requirements for A/B MACs (A)

(Rev. 11021; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

If ICD-10 is applicable, ICD-10-PCS codes for the clinical trial are:

ICD-10-PCS Code	Code Description
3E030U1	Introduction of Nonautologous Pancreatic Islet Cells into Peripheral Vein, Open Approach

3E033U1	Introduction of Nonautologous Pancreatic Islet Cells into Peripheral Vein, Percutaneous Approach
3E0J3U1	Introduction of Nonautologous Pancreatic Islet Cells into Biliary and Pancreatic Tract, Percutaneous Approach
3E0J7U1	Introduction of Nonautologous Pancreatic Islet Cells into Biliary and Pancreatic Tract, Via Natural or Artificial Opening
3E0J8U1	Introduction of Nonautologous Pancreatic Islet Cells into Biliary and Pancreatic Tract, Via Natural or Artificial Opening Endoscopic

E10.9	Type 1 diabetes mellitus without complications
E10.65	Type 1 diabetes mellitus with hyperglycemia
E10.10	Type 1 diabetes mellitus with ketoacidosis without coma
E10.69	Type 1 diabetes mellitus with other specified complication
E10.21	Type 1 diabetes mellitus with diabetic nephropathy
E10.22	Type 1 diabetes mellitus with diabetic chronic kidney disease
E10.29	Type 1 diabetes mellitus with other diabetic kidney complication
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E10.319	Type 1 diabetes mellitus with unspecified diabetic retinopathy without macular edema
E10.3211	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
E10.3212	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E10.3213	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E10.3291	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye
E10.3292	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye
E10.3293	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral
E10.3311	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E10.3312	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E10.3313	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E10.3391	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye
E10.3392	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye
E10.3393	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral
E10.3411	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye
E10.3412	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye
E10.3413	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E10.3491	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye
E10.3492	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye
E10.3493	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral
E10.3511	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E10.3512	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E10.3513	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral

E10.3521 Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye
E10.3522 Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye
E10.3523 Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral
E10.3531 Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye
E10.3532 Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye
E10.3533 Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral
E10.3541 Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye
E10.3542 Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye
E10.3543 Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral
E10.3551 Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, right eye
E10.3552 Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, left eye
E10.3553 Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral
E10.3591 Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye
E10.3592 Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye
E10.3593 Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral
E10.37x1 Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye
E10.37x2 Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye
E10.37x3 Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral
E10.36 Type 1 diabetes mellitus with diabetic cataract
E10.39 Type 1 diabetes mellitus with other diabetic ophthalmic complication
E10.40 Type 1 diabetes mellitus with diabetic neuropathy, unspecified
E10.41 Type 1 diabetes mellitus with diabetic mononeuropathy
E10.42 Type 1 diabetes mellitus with diabetic polyneuropathy
E10.43 Type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy
E10.44 Type 1 diabetes mellitus with diabetic amyotrophy
E10.49 Type 1 diabetes mellitus with other diabetic neurological complication
E10.610 Type 1 diabetes mellitus with diabetic neuropathic arthropathy
E10.51 Type 1 diabetes mellitus with diabetic peripheral angiopathy without gangrene
E10.52 Type 1 diabetes mellitus with diabetic peripheral angiopathy with gangrene
E10.59 Type 1 diabetes mellitus with other circulatory complications
E10.618 Type 1 diabetes mellitus with other diabetic arthropathy
E10.620 Type 1 diabetes mellitus with diabetic dermatitis
E10.621 Type 1 diabetes mellitus with foot ulcer
E10.622 Type 1 diabetes mellitus with other skin ulcer
E10.628 Type 1 diabetes mellitus with other skin complications
E10.630 Type 1 diabetes mellitus with periodontal disease
E10.638 Type 1 diabetes mellitus with other oral complications

E10.649 Type 1 diabetes mellitus with hypoglycemia without coma
E10.8 Type 1 diabetes mellitus with unspecified complications

If ICD-10 is applicable, ICD-10-CM codes for the clinical trial are:

Secondary ICD-10-CM Diagnosis requirement for Clinical Trial:

Z00.6 Encounter for examination for normal comparison and control in clinical research program

The applicable TOB is 11X. A secondary diagnosis (diagnoses positions 2 – 9) of ICD-10- CM code Z00.6 (examination of participant or control in clinical research) must be present along with condition code 30 (qualifying clinical trial) Z00.6 and condition code 30 alerts the claims processing system that this is a clinical trial. The procedure is paid under inpatient prospective payment system for hospitals with patients in the trial. Deductible and coinsurance apply for fee-for-service beneficiaries.

Inpatient hospitals participating in this trial are entitled to an add-on payment of $18,848.00 for islet isolation services. This amount is in addition to the final IPPS payment made to the hospital. Should two infusions occur during the same hospital stay, Medicare will pay for two add-ons for isolation of the islet cells, but never for more than two add-ons for a hospital stay.

Inpatient hospitals shall report charges for organ acquisition in Revenue Code 0810, 0811, 0812, 0813, or 0819. This includes charges for the pre-transplant items and services related to the acquisition and delivery of the pancreatic islet cell transplants. As is Medicare's policy with other organ transplants, Medicare contractors deduct acquisition charges prior to processing through the IPPS Pricer. Pancreata procured for islet cell transplant are not included in the prospective payment. They are paid on a reasonable cost basis. This is a pass-through cost for which interim payments may be made.

Effective for services on or after May 1, 2006, contractors shall accept the QR modifier for islet cell transplantation follow up care when performed in an outpatient department of a hospital when the transplant was done in conjunction with an NIH-sponsored clinical trial, and when billed on type of bill 13X or 85X.

All other normal inpatient billing practices apply.

70.5 - Special Billing and Payment Requirements Medicare Advantage (MA) Beneficiaries

(Rev. 261, Issued: 07-30-04, Effective: 10-01-04, Implementation: 10-04-04)

CMS will make payment directly on a fee-for service basis for the routine costs of pancreatic islet cell transplants as well as transplantation and appropriate related items and services, for MA beneficiaries participating in an NIH-sponsored clinical trial. MA organizations will not be liable for payment for routine costs of this new clinical trial until MA payments can be appropriately adjusted to take into account the cost of this national coverage decision. Medicare contractors shall make payment on behalf of MA organizations directly to providers of these islet cell transplants in accordance with Medicare payment rules, except that beneficiaries are not responsible for the Part A and Part B deductibles. MA enrollees will be liable for any applicable coinsurance amounts MA organizations have in place for clinical trial benefits.

80 - Billing of the Diagnosis and Treatment of Peripheral Neuropathy with Loss of Protective Sensation in People with Diabetes

(Rev. 498, Issued: 03-11-05, Effective/Implementation: N/A)

Coverage Requirements - Peripheral neuropathy is the most common factor leading to amputation in people with diabetes. In diabetes, peripheral neuropathy is an anatomically diffuse process primarily affecting sensory and autonomic fibers; however, distal motor findings may be present in advanced cases. Long nerves are affected first, with symptoms typically beginning insidiously in the toes and then advancing proximally. This leads to loss of protective sensation (LOPS), whereby a person is unable to feel minor trauma from mechanical, thermal, or chemical sources. When foot lesions are present, the reduction in autonomic nerve functions may also inhibit wound healing.

Peripheral neuropathy with LOPS, secondary to diabetes, is a localized illness of the feet and falls within the regulation's exception to the general exclusionary rule (see 42 C.F.R. §411.15(l)(l)(i)). Foot exams for people with diabetic peripheral neuropathy with LOPS are reasonable and necessary to allow for early intervention in serious complications that typically afflict diabetics with the disease.

Effective for services furnished on or after July 1, 2002, Medicare covers, as a physician service, an evaluation (examination and treatment) of the feet no more often than every 6 months for individuals with a documented diagnosis of diabetic sensory neuropathy and LOPS, as long as the beneficiary has not seen a foot care specialist for some other reason in the interim. LOPS shall be diagnosed through sensory testing with the 5.07 monofilament using established guidelines, such as those developed by the National Institute of Diabetes and Digestive and Kidney Diseases guidelines. Five sites should be tested on the plantar surface of each foot, according to the National Institute of Diabetes and Digestive and Kidney Diseases guidelines. The areas must be tested randomly since the loss of protective sensation may be patchy in distribution, and the patient may get clues if the test is done rhythmically. Heavily callused areas should be avoided. As suggested by the American Podiatric Medicine Association, an absence of sensation at two or more sites out of 5 tested on either foot when tested with the 5.07 Semmes-Weinstein monofilament must be present and documented to diagnose peripheral neuropathy with loss of protective sensation.

80.1 - General Billing Requirements

(Rev. 2783, Issued: 09-10-13, Effective: 09-30-13, Implementation: 09-30-13)

The following providers of service may bill you for these services:

Hospitals;
Critical Access Hospitals
Rural Health Clinics; and
Free-Standing Federally Qualified Health Clinics (FQHC).

80.2 - Applicable HCPCS Codes

(Rev. 498, Issued: 03-11-05, Effective/Implementation: N/A)

G0245 - Initial physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) which must include:

1. The diagnosis of LOPS;

2. A patient history;

3. A physical examination that consists of at least the following elements:

   (a) visual inspection of the forefoot, hindfoot, and toe web spaces,

   (b) evaluation of a protective sensation,

   (c) evaluation of foot structure and biomechanics,

   (d) evaluation of vascular status and skin integrity,

   (e) evaluation and recommendation of footwear, and

4. Patient education.

G0246 - Follow-up physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include at least the following:

1. a patient history;

2. a physical examination that includes:

   (a) visual inspection of the forefoot, hindfoot, and toe web spaces,

   (b) evaluation of protective sensation,

   (c) evaluation of foot structure and biomechanics,

   (d) evaluation of vascular status and skin integrity,

   (e) evaluation and recommendation of footwear, and

3. patient education.

G0247 - Routine foot care by a physician of a diabetic patient with diabetic sensory neuropathy resulting in a LOPS to include if present, at least the following:

(1) local care of superficial (i.e., superficial to muscle and fascia) wounds;

(2) debridement of corns and calluses; and

(3) trimming and debridement of nails.

NOTE: Code G0247 must be billed on the same date of service with either G0245 or G0246 in order to be considered for payment.

The short descriptors for the above HCPCS codes are as follows:

G0245 – INITIAL FOOT EXAM PTLOPS

G0246 – FOLLOWUP EVAL OF FOOT PT LOP

G0247 – ROUTINE FOOTCARE PT W LOPS

80.3 - Diagnosis Codes

(Rev. 11021; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

If ICD-10-CM is applicable--Providers should report one of the following diagnosis codes in conjunction with this benefit:

ICD-10-CM	ICD-10 DX Description
E08.40	Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified
E08.42	Diabetes mellitus due to underlying condition with diabetic polyneuropathy
E09.40	Drug or chemical induced diabetes mellitus with neurological complications with diabetic n
E09.42	Drug or chemical induced diabetes mellitus with neurological complications with diabetic p
E10.40	Type 1 diabetes mellitus with diabetic neuropathy, unspecified
E10.41	Type 1 diabetes mellitus with diabetic mononeuropathy
E10.42	Type 1 diabetes mellitus with diabetic polyneuropathy
E10.43	Type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy
E10.44	Type 1 diabetes mellitus with diabetic amyotrophy
E10.49	Type 1 diabetes mellitus with other diabetic neurological complication
E10.610	Type 1 diabetes mellitus with diabetic neuropathic arthropathy
E11.40	Type 2 diabetes mellitus with diabetic neuropathy, unspecified
E11.41	Type 2 diabetes mellitus with diabetic mononeuropathy
E11.42	Type 2 diabetes mellitus with diabetic polyneuropathy
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy
E11.44	Type 2 diabetes mellitus with diabetic amyotrophy
E11.49	Type 2 diabetes mellitus with other diabetic neurological complication
E11.610	Type 2 diabetes mellitus with diabetic neuropathic arthropathy
E13.40	Other specified diabetes mellitus with diabetic neuropathy, unspecified
E13.41	Other specified diabetes mellitus with diabetic mononeuropathy
E13.42	Other specified diabetes mellitus with diabetic polyneuropathy
E13.43	Other specified diabetes mellitus with diabetic autonomic (poly)neuropathy
E13.44	Other specified diabetes mellitus with diabetic amyotrophy
E13.49	Other specified diabetes mellitus with other diabetic neurological complication
E13.610	Other specified diabetes mellitus with diabetic neuropathic arthropathy

Coverage policy can be found in Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, section 70.2.1 Diabetic neuropathy w/ LOPs.
(http://www.cms.hhs.gov/manuals/103_cov_determ/ncd103index.asp

80.4 – Payment

(Rev. 2783, Issued: 09-10-13, Effective: 09-30-13, Implementation: 09-30-13)

- Hospital outpatient departments – OPPS
- Critical Access Hospital (CAH) - Method I -- Reasonable cost; Method II -- Technical - reasonable cost, Professional -- 115 percent of the fee schedule
- Rural Health Clinics/Federally Qualified Health Centers (RHCs/FQHCs) - All inclusive rate.

Deductible and coinsurance apply.

While these physician services may be appropriately provided to patients of Comprehensive Outpatient Rehabilitation Facilities (CORFs), the CORF does not bill. The services are billed by the physician on a professional claim.

Examples of Payment calculation:

Part B Deductible Met: $900 (MPFS allowed amount) x 20 percent (co-insurance) = $720 (Medicare reimbursement). Beneficiary is responsible for $180.

Part B Deductible Not met: $900 (MPFS allowed amount) - $100 (Part B deductible) = $800 x 20 percent (co-insurance) = $640 (Medicare reimbursement). Beneficiary is responsible for $260.

Part B Deductible Met: $800 (actual charged amount) x 20 percent (co-insurance) = $640 (Medicare Reimbursement), beneficiary is responsible for $160 co-insurance.

Part B Deductible Not Met: $800 (actual charged amount) - $100 (Part B deductible) = $700 x 20 percent (co-insurance) = $560 (Medicare reimbursement). Beneficiary is responsible for $240, ($100 Part B deductible and $140 co-insurance).

Services are paid at 80 percent of the lesser of the fee schedule amount or the actual charges.

This service, when furnished in an RHC/FQHC by a physician or non-physician, is considered an RHC/FQHC service. RHCs/FQHCs bill you under bill type 71X or 73X with revenue code 940 and HCPCS G0245, G0246, and G0247.

Payment should not be made for this service unless the claim contains a related visit code. Therefore, install an edit in your system to assure payment is not made for revenue code 940 unless the claim also contains a visit revenue code (520 or 521).

Applicable Revenue Codes

The applicable revenue code is 940, except for hospitals.

This service can be performed in other revenue centers such as a clinic (510) for hospitals. Therefore, instruct your hospitals to report these procedures under the revenue center where they are performed.

80.5 - Applicable Revenue Codes

(Rev. 498, Issued: 03-11-05, Effective/Implementation: N/A)

The applicable revenue code is 940, except for hospitals.

This service can be performed in other revenue centers such as a clinic (510) for hospitals. Therefore, instruct your hospitals to report these procedures under the revenue center where they are performed.

80.6 - Editing Instructions for A/B MACs (A)

(Rev. 11021; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

Edit 1 - Implement diagnosis to procedure code edits to allow payment only for the LOPS codes, G0245, G0246, and G0247 when submitted with one of the following ICD-10-CM diagnosis codes

If ICD-10-CM is applicable:

ICD-10-CM	ICD-10 DX Description
E08.40	Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified
E08.42	Diabetes mellitus due to underlying condition with diabetic polyneuropathy
E09.40	Drug or chemical induced diabetes mellitus with neurological complications with diabetic n
E09.42	Drug or chemical induced diabetes mellitus with neurological complications with diabetic p
E10.40	Type 1 diabetes mellitus with diabetic neuropathy, unspecified
E10.41	Type 1 diabetes mellitus with diabetic mononeuropathy
E10.42	Type 1 diabetes mellitus with diabetic polyneuropathy
E10.43	Type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy
E10.44	Type 1 diabetes mellitus with diabetic amyotrophy
E10.49	Type 1 diabetes mellitus with other diabetic neurological complication
E10.610	Type 1 diabetes mellitus with diabetic neuropathic arthropathy
E11.40	Type 2 diabetes mellitus with diabetic neuropathy, unspecified
E11.41	Type 2 diabetes mellitus with diabetic mononeuropathy
E11.42	Type 2 diabetes mellitus with diabetic polyneuropathy
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy
E11.44	Type 2 diabetes mellitus with diabetic amyotrophy
E11.49	Type 2 diabetes mellitus with other diabetic neurological complication
E11.610	Type 2 diabetes mellitus with diabetic neuropathic arthropathy
E13.40	Other specified diabetes mellitus with diabetic neuropathy, unspecified
E13.41	Other specified diabetes mellitus with diabetic mononeuropathy
E13.42	Other specified diabetes mellitus with diabetic polyneuropathy
E13.43	Other specified diabetes mellitus with diabetic autonomic (poly)neuropathy
E13.44	Other specified diabetes mellitus with diabetic amyotrophy
E13.49	Other specified diabetes mellitus with other diabetic neurological complication
E13.610	Other specified diabetes mellitus with diabetic neuropathic arthropathy

Deny these services when submitted without one of the appropriate diagnoses. Use the same

messages you currently use for procedure to diagnosis code denials. Edit 2 – Deny G0247 if it is

not submitted on the same claim as G0245 or G0246.

Use MSN 21.21 - This service was denied because Medicare only covers this service under certain circumstances.
Use RA claim adjustment reason code 107 - The related or qualifying claim/service was not identified on this claim. NOTE: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

80.7 - CWF General Information

(Rev. 4203, Issued: 01-18-19, Effective: 02-19-19, Implementation: 02-19-19)

The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.

Though G0245 and G0246 have no technical or professional components, for these codes, CWF will post institutional claims with type of bill 13X as technical, and professional claims as professional. For bill type 85X with revenue code 940, CWF will post as technical. For 85X bill type with revenue code 98X, (Method II), CWF will post as technical and professional. This will allow both the facility and professional service payments to be approved by CWF for payment when the code and date of service match. Therefore, should a claim be received with the same code and same date of service for the same beneficiary, the second claim submitted will not be rejected as a duplicate.

Due to the billing and payment methodology of Rural Health Clinics - bill type 71X and Federally Qualified Health Centers - bill type 73X, CWF will post these claims as usual, which will correctly allow claims from these entities that are billed on institutional claims to reject as duplicates when the HCPCS code, date of service, and Medicare beneficiary identifier are an exact match with a claim billed on a professional claim.

Medicare contractors must react to these duplicate claims as they currently do for any other duplicates.

80.8 - CWF Utilization Edits

(Rev. 1742, Issued: 05-22-09, Effective: 06-08-09, Implementation: 06-08-09)

Edit 1 - Should CWF receive a claim from an FI for G0245 or G0246 and a second claim from a contractor for either G0245 or G0246 (or vice versa) and they are different dates of service and less than 6 months apart, the second claim will reject. CWF will edit to allow G0245 or G0246 to be paid no more than every 6 months for a particular beneficiary, regardless of who furnished the service. If G0245 has been paid, regardless of whether it was posted as a facility or professional claim, it must be 6 months before G0245 can be paid again or G0246 can be paid. If G0246 has been paid, regardless of whether it was posted as a facility or professional claim, it must be 6 months before G0246 can be paid again or G0245 can be paid. CWF will not impose limits on how many times each code can be paid for a beneficiary as long as there has been 6 months between each service.

The CWF will return a specific reject code for this edit to the contractors and FIs that will be identified in the CWF documentation. Based on the CWF reject code, the contractors and FIs must deny the claims and return the following messages:

> MSN 18.4 -- This service is being denied because it has not been __ months since your last examination of this kind (NOTE**:** Insert 6 as the appropriate number of months.)

RA claim adjustment reason code 96 – Non-covered charges, along with remark code M86 – Service denied because payment already made for same/similar procedure within set time frame.

Edit 2

The CWF will edit to allow G0247 to pay only if either G0245 or G0246 has been submitted and accepted as payable on the same date of service. CWF will return a specific reject code for this edit to the contractors and FIs that will be identified in the CWF documentation. Based on this reject code, contractors and FIs will deny the claims and return the following messages:

MSN 21.21 - This service was denied because Medicare only covers this service under certain circumstances.

RA claim adjustment reason code 107 – The related or qualifying claim/service was not identified on this claim.

Edit 3

Once a beneficiary's condition has progressed to the point where routine foot care becomes a covered service, payment will no longer be made for LOPS evaluation and management services. Those services would be considered to be included in the regular exams and treatments afforded to the beneficiary on a routine basis. The physician or provider must then just bill the routine foot care codes, per Pub 100-02, Chapter 15, §290.

The CWF will edit to reject LOPS codes G0245, G0246, and/or G0247 when on the beneficiary's record it shows that one of the following routine foot care codes were billed and paid within the prior 6 months: 11055, 11056, 11057, 11719, 11720, and/or 11721.

The CWF will return a specific reject code for this edit to the contractors and FIs that will be identified in the CWF documentation. Based on the CWF reject code, the contractors and FIs must deny the claims and return the following messages:

MSN 21.21 - This service was denied because Medicare only covers this service under certain circumstances.

The RA claim adjustment reason code 96 – Non-covered charges, along with remark code M86 – Service denied because payment already made for same/similar procedure within set time frame.

90 - Stem Cell Transplantation

(Rev.12533; Issued: 03-07-24 Effective: 04-08-24; Implementation:04-08-24)

A. General

Stem cell transplantation is a process in which stem cells are harvested from either a patient's (autologous) or donor's (allogeneic) bone marrowor peripheral blood for intravenous infusion.

Allogeneic and autologous stem cell transplants are covered under Medicare for specific diagnoses. See Pub. 100-03, National Coverage Determinations Manual, section 110.23, for a complete description of covered and noncovered conditions. For Part A hospital inpatient claims processing instructions, refer to Pub. 100-04, chapter 3, section 90. The following sections contain claims processing instructions for all other claims.

B. Nationally Covered Indications

C. Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

ICD-10-PCS Procedure Codes

30230G2	Transfusion of Allogeneic Related Bone Marrow into Peripheral Vein, Open Approach
30230G3	Transfusion of Allogeneic Unrelated Bone Marrow into Peripheral Vein, Open Approach
30233U2	Transfusion of Allogeneic Related T-cell Depleted Hematopoietic Stem Cells into Peripheral Vein, Percutaneous Approach
30233U3	Transfusion of Allogeneic Unrelated T-cell Depleted Hematopoietic Stem Cells into Peripheral Vein, Percutaneous Approach
30230Y2	Transfusion of Allogeneic Related Hematopoietic Stem Cells into Peripheral Vein, Open Approach
30230Y3	Transfusion of Allogeneic Unrelated Hematopoietic Stem Cells into Peripheral Vein, Open Approach
30233G2	Transfusion of Allogeneic Related Bone Marrow into Peripheral Vein, Percutaneous Approach
30233G3	Transfusion of Allogeneic Unrelated Bone Marrow into Peripheral Vein, Percutaneous Approach
30243U2	Transfusion of Allogeneic Related T-cell Depleted Hematopoietic Stem Cells into Central Vein, Percutaneous Approach
30243U3	Percutaneous Approach
30233Y2	Transfusion of Allogeneic Related Hematopoietic Stem Cells into Peripheral Vein, Percutaneous Approach
30233Y3	Transfusion of Allogeneic Unrelated Hematopoietic Stem Cells into Peripheral Vein, Percutaneous Approach

30240G2	Transfusion of Allogeneic Related Bone Marrow into Central Vein, Open Approach
30240G3	Transfusion of Allogeneic Unrelated Bone Marrow into Central Vein, Open Approach
30240Y2	Transfusion of Allogeneic Related Hematopoietic Stem Cells into Central Vein, Open Approach
30240Y3	Transfusion of Allogeneic Unrelated Hematopoietic Stem Cells into Central Vein, Open Approach
30243G2	Transfusion of Allogeneic Related Bone Marrow into Central Vein, Percutaneous Approach
30243G3	Transfusion of Allogeneic Unrelated Bone Marrow into Central Vein, Percutaneous Approach
30243Y2	Transfusion of Allogeneic Related Hematopoietic Stem Cells into Central Vein, Percutaneous Approach
30243Y3	Transfusion of Allogeneic Unrelated Hematopoietic Stem Cells into Central Vein, Percutaneous Approach

HCPCS Code 38240

See below table for ICD-10-DX Codes:

a. **Effective for services performed on or after August 1, 1978:**

a. For the treatment of leukemia, leukemia in remission; see table below for ICD-10-CM codes:

C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.01	Acute lymphoblastic leukemia, in remission
C91.02	Acute lymphoblastic leukemia, in relapse
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.11	Chronic lymphocytic leukemia of B-cell type in remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
C91.30	Prolymphocytic leukemia of B-cell type not having achieved remission
C91.31	Prolymphocytic leukemia of B-cell type, in remission
C91.32	Prolymphocytic leukemia of B-cell type, in relapse
C91.50	Adult T-cell lymphoma/leukemia (HTLV-1-associated) not having achieved remission
C91.51	Adult T-cell lymphoma/leukemia (HTLV-1-associated), in remission
C91.52	Adult T-cell lymphoma/leukemia (HTLV-1-associated), in relapse
C91.60	Prolymphocytic leukemia of T-cell type not having achieved remission
C91.61	Prolymphocytic leukemia of T-cell type, in remission
C91.62	Prolymphocytic leukemia of T-cell type, in relapse
C91.90	Lymphoid leukemia, unspecified not having achieved remission
C91.91	Lymphoid leukemia, unspecified, in remission
C91.92	Lymphoid leukemia, unspecified, in relapse
C91.A0	Mature B-cell leukemia Burkitt-type not having achieved remission

C91.A1	Mature B-cell leukemia Burkitt-type, in remission
C91.A2	Mature B-cell leukemia Burkitt-type, in relapse
C91.Z0	Other lymphoid leukemia not having achieved remission
C91.Z1	Other lymphoid leukemia, in remission
C91.Z2	Other lymphoid leukemia, in relapse
C92.00	Acute myeloblastic leukemia, not having achieved remission
C92.01	Acute myeloblastic leukemia, in remission
C92.02	Acute myeloblastic leukemia, in relapse
C92.10	Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission
C92.11	Chronic myeloid leukemia, BCR/ABL-positive, in remission
C92.12	Chronic myeloid leukemia, BCR/ABL-positive, in relapse
C92.20	Atypical chronic myeloid leukemia, BCR/ABL-negative, not having achieved remission
C92.21	Atypical chronic myeloid leukemia, BCR/ABL-negative, in remission
C92.22	Atypical chronic myeloid leukemia, BCR/ABL-negative, in relapse
C92.30	Myeloid sarcoma, not having achieved remission
C92.31	Myeloid sarcoma, in remission
C92.32	Myeloid sarcoma, in relapse
C92.40	Acute promyelocytic leukemia, not having achieved remission
C92.41	Acute promyelocytic leukemia, in remission
C92.42	Acute promyelocytic leukemia, in relapse
C92.50	Acute myelomonocytic leukemia, not having achieved remission
C92.51	Acute myelomonocytic leukemia, in remission
C92.52	Acute myelomonocytic leukemia, in relapse
C92.60	Acute myeloid leukemia with 11q23-abnormality not having achieved remission
C92.61	Acute myeloid leukemia with 11q23-abnormality in remission
C92.62	Acute myeloid leukemia with 11q23-abnormality in relapse
C92.90	Myeloid leukemia, unspecified, not having achieved remission
C92.91	Myeloid leukemia, unspecified in remission
C92.92	Myeloid leukemia, unspecified in relapse
C92.A0	Acute myeloid leukemia with multilineage dysplasia, not having achieved remission
C92.A1	Acute myeloid leukemia with multilineage dysplasia, in remission
C92.A2	Acute myeloid leukemia with multilineage dysplasia, in relapse
C92.Z0	Other myeloid leukemia not having achieved remission
C92.Z1	Other myeloid leukemia, in remission
C92.Z2	Other myeloid leukemia, in relapse
C93.00	Acute monoblastic/monocytic leukemia, not having achieved remission
C93.01	Acute monoblastic/monocytic leukemia, in remission
C93.02	Acute monoblastic/monocytic leukemia, in relapse
C93.10	Chronic myelomonocytic leukemia not having achieved remission
C93.11	Chronic myelomonocytic leukemia, in remission
C93.12	Chronic myelomonocytic leukemia, in relapse
C93.30	Juvenile myelomonocytic leukemia, not having achieved remission
C93.31	Juvenile myelomonocytic leukemia, in remission
C93.32	Juvenile myelomonocytic leukemia, in relapse
C93.90	Monocytic leukemia, unspecified, not having achieved remission

C93.91	Monocytic leukemia, unspecified in remission
C93.92	Monocytic leukemia, unspecified in relapse
C93.Z0	Other monocytic leukemia, not having achieved remission
C93.Z1	Other monocytic leukemia, in remission
C93.Z2	Other monocytic leukemia, in relapse
C94.00	Acute erythroid leukemia, not having achieved remission
C94.01	Acute erythroid leukemia, in remission
C94.02	Acute erythroid leukemia, in relapse
C94.20	Acute megakaryoblastic leukemia not having achieved remission
C94.21	Acute megakaryoblastic leukemia, in remission
C94.22	Acute megakaryoblastic leukemia, in relapse
C94.30	Mast cell leukemia not having achieved remission
C94.31	Mast cell leukemia, in remission
C94.32	Mast cell leukemia, in relapse
C94.80	Other specified leukemias not having achieved remission
C94.81	Other specified leukemias, in remission
C94.82	Other specified leukemias, in relapse
C95.00	Acute leukemia of unspecified cell type not having achieved remission
C95.01	Acute leukemia of unspecified cell type, in remission
C95.02	Acute leukemia of unspecified cell type, in relapse
C95.10	Chronic leukemia of unspecified cell type not having achieved remission
C95.11	Chronic leukemia of unspecified cell type, in remission
C95.12	Chronic leukemia of unspecified cell type, in relapse
C95.90	Leukemia, unspecified not having achieved remission
C95.91	Leukemia, unspecified, in remission
C95.92	Leukemia, unspecified, in relapse
D45	Polycythemia vera

ii. For the treatment of aplastic anemia; see table below for ICD-10-CM codes)

ICD-10	**Description**
D60.0	Chronic acquired pure red cell aplasia
D60.1	Transient acquired pure red cell aplasia
D60.8	Other acquired pure red cell aplasias
D60.9	Acquired pure red cell aplasia, unspecified
D61.01	Constitutional (pure) red blood cell aplasia
D61.09	Other constitutional aplastic anemia
D61.1	Drug-induced aplastic anemia
D61.2	Aplastic anemia due to other external agents
D61.3	Idiopathic aplastic anemia
D61.810	Antineoplastic chemotherapy induced pancytopenia
D61.811	Other drug-induced pancytopenia
D61.818	Other pancytopenia
D61.82	Myelophthisis

D61.89	Other specified aplastic anemias and other bone marrow failure syndromes
D61.9	Aplastic anemia, unspecified

b. **Effective for services performed on or after June 3, 1985:**

c. For the treatment of severe combined immunodeficiency disease (SCID) (ICD-10-CM codes D81.0, D81.1, D81.2, D81.6, D81.7, D81.89, and D81.9)

d. For the treatment of Wiskott-Aldrich syndrome (ICD-10- CM code D82.0)

c. Effective for services performed on or after August 4, 2010:

For the treatment of Myelodysplastic Syndromes (MDS) (ICD-10-CM codes D46.A, D46.B, D46.C, D46.Z, D46.0, D46.1, D46.4, D46.9, D46.20, D46.21, D46.22, and Z00.6) pursuant to Coverage with Evidence Development (CED) in the context of a Medicare- approved, prospective clinical study. Refer to Pub. 100-03, NCD Manual, chapter 1, section 110.23, for further information about thispolicy. See section F below for billing instructions.

d. **Effective for services performed on or after January 27, 2016:**

b. Allogeneic HSCT for multiple myeloma (ICD-10-CM codes C90.00, C90.01, C90.02, and Z00.6) is covered by Medicareonly for beneficiaries with Durie-Salmon Stage II or III multiple myeloma, or International Staging

System (ISS) Stage II or Stage III multiple myeloma, and participating in an approved prospective clinical study. Refer to Pub. 100-03, NCD Manual, chapter 1, section 110.23, for furtherinformation about this policy. See section F below for billing instructions.

e. Allogeneic HSCT for myelofibrosis (MF) (ICD-10-CM codes C94.40, C94.41, C94.42, D47.1, D47.4, D75.81, and Z00.6) is covered by Medicare only for beneficiaries with Dynamic International Prognostic Scoring System (DIPSSplus) intermediate-2 or High primary or secondary MF and participating in an approved prospective clinical study. Refer to Pub. 100- 03, NCD Manual, chapter 1, section 110.23, for further information about this policy. See section F below for billing instructions.

f. Allogeneic HSCT for sickle cell disease (SCD) (ICD-10-CM codes D57.00, D57.01, D57.02, D57.03, D57.09, D57.1, D57.20, D57.211, D57.212, D57.213, D57.218, D57.219, D57.40, D57.411, D57.412, D57.413, D57.418, D57.419, D57.42, D57.431, D57.432, D57.433, D57.438, D57.439, D57.44, D57.451, D57.452, D57.453, D57.458, D57.459, D57.80, D57.811,D57.812, D57.813, D57.818, D57.819, and Z00.6) is covered by Medicare only for beneficiaries with severe, symptomatic SCD who participate in an

approved prospective clinical study. Refer to Pub.100-03, NCD Manual, chapter 1, section 110.23, for further information about this policy. See section F below for billing instructions.

II. Autologous Stem Cell Transplantation (AuSCT)

HCPCS Code 38241

ICD-10-PCS Procedure Codes:

30230C0	Transfusion of Autologous Hematopoietic Stem/Progenitor Cells, Genetically Modified into Peripheral Vein, Open Approach
30230G0	Transfusion of Autologous Bone Marrow into Peripheral Vein, Open Approach
30230Y0	Transfusion of Autologous Hematopoietic Stem Cells into Peripheral Vein, Open Approach
30233G0	Transfusion of Autologous Bone Marrow into Peripheral Vein, Percutaneous Approach
30233C0	Transfusion of Autologous Hematopoietic Stem/Progenitor Cells, Genetically Modified into Peripheral Vein, Percutaneous Approach
30233Y0	Transfusion of Autologous Hematopoietic Stem Cells into Peripheral Vein, Percutaneous Approach
30240C0	Transfusion of Autologous Hematopoietic Stem/Progenitor Cells, Genetically Modified into Central Vein, Open Approach
30240G0	Transfusion of Autologous Bone Marrow into Central Vein, Open Approach
30240Y0	Transfusion of Autologous Hematopoietic Stem Cells into Central Vein, Open Approach
30243C0	Transfusion of Autologous Hematopoietic Stem/Progenitor Cells, Genetically Modified into Central Vein, Percutaneous Approach
30243G0	Transfusion of Autologous Bone Marrow into Central Vein, Percutaneous Approach
30243Y0	Transfusion of Autologous Hematopoietic Stem Cells into Central Vein, Percutaneous Approach

Below ICD-10 CM codes Cover autologous SCT (38241) no trial for acute leukemia in remission, resistant non-Hodgkins lymphomas, recurrent/refractory neuroblastoma, advanced Hodgkins Disease on or after 4/28/89, and Cover autologous SCT (38241) no trial for Durie-Salmon stage II/III responsive multiplemyeloma and responsive relapse on or after 10/1/00 over autologous SCT (38241) together with high dose melphalan (HDMI) no trial for primary amyloid light chain (AL) amyloidosis on or after 3/15/05

C81.01	Nodular lymphocyte predominant Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.02	Nodular lymphocyte predominant Hodgkin lymphoma, intrathoracic lymph nodes
C81.03	Nodular lymphocyte predominant Hodgkin lymphoma, intra-abdominal lymph nodes
C81.04	Nodular lymphocyte predominant Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.05	Nodular lymphocyte predominant Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.06	Nodular lymphocyte predominant Hodgkin lymphoma, intrapelvic lymph nodes
C81.07	Nodular lymphocyte predominant Hodgkin lymphoma, spleen
C81.08	Nodular lymphocyte predominant Hodgkin lymphoma, lymph nodes of multiple sites
C81.09	Nodular lymphocyte predominant Hodgkin lymphoma, extranodal and solid organ sites
C81.11	Nodular sclerosis Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.12	Nodular sclerosis Hodgkin lymphoma, intrathoracic lymph nodes
C81.13	Nodular sclerosis Hodgkin lymphoma, intra-abdominal lymph nodes
C81.14	Nodular sclerosis Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.15	Nodular sclerosis Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.16	Nodular sclerosis Hodgkin lymphoma, intrapelvic lymph nodes
C81.17	Nodular sclerosis Hodgkin lymphoma, spleen
C81.18	Nodular sclerosis Hodgkin lymphoma, lymph nodes of multiple sites
C81.19	Nodular sclerosis Hodgkin lymphoma, extranodal and solid organ sites
C81.21	Mixed cellularity Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.22	Mixed cellularity Hodgkin lymphoma, intrathoracic lymph nodes
C81.23	Mixed cellularity Hodgkin lymphoma, intra-abdominal lymph nodes

C81.24	Mixed cellularity Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.25	Mixed cellularity Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.26	Mixed cellularity Hodgkin lymphoma, intrapelvic lymph nodes
C81.27	Mixed cellularity Hodgkin lymphoma, spleen
C81.28	Mixed cellularity Hodgkin lymphoma, lymph nodes of multiple sites
C81.29	Mixed cellularity Hodgkin lymphoma, extranodal and solid organ sites
C81.31	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.32	Lymphocyte depleted Hodgkin lymphoma, intrathoracic lymph nodes
C81.33	Lymphocyte depleted Hodgkin lymphoma, intra-abdominal lymph nodes
C81.34	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.35	Lymphocyte depleted Hodgkin lymphoma, lymph nodes ofinguinal region and lower limb
C81.36	Lymphocyte depleted Hodgkin lymphoma, intrapelvic lymph nodes
C81.37	Lymphocyte depleted Hodgkin lymphoma, spleen
C81.38	Lymphocyte depleted Hodgkin lymphoma, lymph nodes ofmultiple sites
C81.39	Lymphocyte depleted Hodgkin lymphoma, extranodal and solid organ sites
C81.41	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.42	Lymphocyte-rich Hodgkin lymphoma, intrathoracic lymph nodes
C81.43	Lymphocyte-rich Hodgkin lymphoma, intra-abdominal lymph nodes
C81.44	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.45	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.46	Lymphocyte-rich Hodgkin lymphoma, intrapelvic lymph nodes
C81.47	Lymphocyte-rich Hodgkin lymphoma, spleen
C81.48	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of multiplesites
C81.49	Lymphocyte-rich Hodgkin lymphoma, extranodal and solid organ sites
C81.71	Other Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.72	Other Hodgkin lymphoma, intrathoracic lymph nodes
C81.73	Other Hodgkin lymphoma, intra-abdominal lymph nodes

C81.74	Other Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.75	Other Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.76	Other Hodgkin lymphoma, intrapelvic lymph nodes
C81.77	Other Hodgkin lymphoma, spleen
C81.78	Other Hodgkin lymphoma, lymph nodes of multiple sites
C81.91	Hodgkin lymphoma, unspecified, lymph nodes of head, face, and neck
C81.92	Hodgkin lymphoma, unspecified, intrathoracic lymph nodes
C81.93	Hodgkin lymphoma, unspecified, intra-abdominal lymph nodes
C81.94	Hodgkin lymphoma, unspecified, lymph nodes of axilla and upper limb
C81.95	Hodgkin lymphoma, unspecified, lymph nodes of inguinal region and lower limb
C81.96	Hodgkin lymphoma, unspecified, intrapelvic lymph nodes
C81.97	Hodgkin lymphoma, unspecified, spleen
C81.98	Hodgkin lymphoma, unspecified, lymph nodes of multiple sites
C81.99	Hodgkin lymphoma, unspecified, extranodal and solid organ sites
C82.01	Follicular lymphoma grade I, lymph nodes of head, face, and neck
C82.02	Follicular lymphoma grade I, intrathoracic lymph nodes
C82.03	Follicular lymphoma grade I, intra-abdominal lymph nodes
C82.04	Follicular lymphoma grade I, lymph nodes of axilla and upper limb
C82.05	Follicular lymphoma grade I, lymph nodes of inguinal region and lower limb
C82.06	Follicular lymphoma grade I, intrapelvic lymph nodes
C82.07	Follicular lymphoma grade I, spleen
C82.08	Follicular lymphoma grade I, lymph nodes of multiple sites
C82.09	Follicular lymphoma grade I, extranodal and solid organ sites
C82.11	Follicular lymphoma grade II, lymph nodes of head, face, and neck
C82.12	Follicular lymphoma grade II, intrathoracic lymph nodes
C82.13	Follicular lymphoma grade II, intra-abdominal lymph nodes
C82.14	Follicular lymphoma grade II, lymph nodes of axilla and upper limb
C82.15	Follicular lymphoma grade II, lymph nodes of inguinal region and lower limb
C82.16	Follicular lymphoma grade II, intrapelvic lymph nodes
C82.17	Follicular lymphoma grade II, spleen
C82.18	Follicular lymphoma grade II, lymph nodes of multiple sites
C82.19	Follicular lymphoma grade II, extranodal and solid organ sites
C82.21	Follicular lymphoma grade III, unspecified, lymph nodes of head, face, and neck

C82.22	Follicular lymphoma grade III, unspecified, intrathoracic lymph nodes
C82.23	Follicular lymphoma grade III, unspecified, intra-abdominal lymph nodes
C82.24	Follicular lymphoma grade III, unspecified, lymph nodes of axilla and upper limb
C82.25	Follicular lymphoma grade III, unspecified, lymph nodes of inguinal region and lower limb
C82.26	Follicular lymphoma grade III, unspecified, intrapelvic lymph nodes
C82.27	Follicular lymphoma grade III, unspecified, spleen
C82.28	Follicular lymphoma grade III, unspecified, lymph nodes of multiple sites
C82.29	Follicular lymphoma grade III, unspecified, extranodal and solid organ sites
C82.31	Follicular lymphoma grade IIIa, lymph nodes of head, face, and neck
C82.32	Follicular lymphoma grade IIIa, intrathoracic lymph nodes
C82.33	Follicular lymphoma grade IIIa, intra-abdominal lymph nodes
C82.34	Follicular lymphoma grade IIIa, lymph nodes of axilla and upper limb
C82.35	Follicular lymphoma grade IIIa, lymph nodes of inguinal region and lower limb
C82.36	Follicular lymphoma grade IIIa, intrapelvic lymph nodes
C82.37	Follicular lymphoma grade IIIa, spleen
C82.38	Follicular lymphoma grade IIIa, lymph nodes of multiple sites
C82.39	Follicular lymphoma grade IIIa, extranodal and solid organ sites
C82.41	Follicular lymphoma grade IIIb, lymph nodes of head, face, and neck
C82.42	Follicular lymphoma grade IIIb, intrathoracic lymph nodes
C82.43	Follicular lymphoma grade IIIb, intra-abdominal lymph nodes
C82.44	Follicular lymphoma grade IIIb, lymph nodes of axilla and upper limb
C82.45	Follicular lymphoma grade IIIb, lymph nodes of inguinal region and lower limb
C82.46	Follicular lymphoma grade IIIb, intrapelvic lymph nodes
C82.47	Follicular lymphoma grade IIIb, spleen
C82.48	Follicular lymphoma grade IIIb, lymph nodes of multiple sites
C82.49	Follicular lymphoma grade IIIb, extranodal and solid organ sites
C82.51	Diffuse follicle center lymphoma, lymph nodes of head, face, and neck
C82.52	Diffuse follicle center lymphoma, intrathoracic lymph nodes
C82.53	Diffuse follicle center lymphoma, intra-abdominal lymph nodes
C82.54	Diffuse follicle center lymphoma, lymph nodes of axilla and upper limb

C82.55	Diffuse follicle center lymphoma, lymph nodes of inguinal region and lower limb
C82.56	Diffuse follicle center lymphoma, intrapelvic lymph nodes
C82.57	Diffuse follicle center lymphoma, spleen
C82.58	Diffuse follicle center lymphoma, lymph nodes of multiple sites
C82.59	Diffuse follicle center lymphoma, extranodal and solid organ sites
C82.61	Cutaneous follicle center lymphoma, lymph nodes of head, face, and neck
C82.62	Cutaneous follicle center lymphoma, intrathoracic lymph nodes
C82.63	Cutaneous follicle center lymphoma, intra-abdominal lymph nodes
C82.64	Cutaneous follicle center lymphoma, lymph nodes of axilla and upper limb
C82.65	Cutaneous follicle center lymphoma, lymph nodes of inguinal region and lower limb
C82.66	Cutaneous follicle center lymphoma, intrapelvic lymph nodes
C82.67	Cutaneous follicle center lymphoma, spleen
C82.68	Cutaneous follicle center lymphoma, lymph nodes of multiple sites
C82.69	Cutaneous follicle center lymphoma, extranodal and solid organ sites
C82.81	Other types of follicular lymphoma, lymph nodes of head, face, and neck
C82.82	Other types of follicular lymphoma, intrathoracic lymph nodes
C82.83	Other types of follicular lymphoma, intra-abdominal lymph nodes
C82.84	Other types of follicular lymphoma, lymph nodes of axilla and upper limb
C82.85	Other types of follicular lymphoma, lymph nodes of inguinal region and lower limb
C82.86	Other types of follicular lymphoma, intrapelvic lymph nodes
C82.87	Other types of follicular lymphoma, spleen
C82.88	Other types of follicular lymphoma, lymph nodes of multiple sites
C82.89	Other types of follicular lymphoma, extranodal and solid organ sites
C82.91	Follicular lymphoma, unspecified, lymph nodes of head, face, and neck
C82.92	Follicular lymphoma, unspecified, intrathoracic lymph nodes
C82.93	Follicular lymphoma, unspecified, intra-abdominal lymph nodes
C82.94	Follicular lymphoma, unspecified, lymph nodes of axilla and upper limb
C82.95	Follicular lymphoma, unspecified, lymph nodes of inguinal region and lower limb
C82.96	Follicular lymphoma, unspecified, intrapelvic lymph nodes

C82.97	Follicular lymphoma, unspecified, spleen
C82.98	Follicular lymphoma, unspecified, lymph nodes of multiple sites
C82.99	Follicular lymphoma, unspecified, extranodal and solid organ sites
C83.01	Small cell B-cell lymphoma, lymph nodes of head, face, and neck
C83.02	Small cell B-cell lymphoma, intrathoracic lymph nodes
C83.03	Small cell B-cell lymphoma, intra-abdominal lymph nodes
C83.04	Small cell B-cell lymphoma, lymph nodes of axilla and upper limb
C83.05	Small cell B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.06	Small cell B-cell lymphoma, intrapelvic lymph nodes
C83.07	Small cell B-cell lymphoma, spleen
C83.08	Small cell B-cell lymphoma, lymph nodes of multiple sites
C83.09	Small cell B-cell lymphoma, extranodal and solid organ sites
C83.11	Mantle cell lymphoma, lymph nodes of head, face, and neck
C83.12	Mantle cell lymphoma, intrathoracic lymph nodes
C83.13	Mantle cell lymphoma, intra-abdominal lymph nodes
C83.14	Mantle cell lymphoma, lymph nodes of axilla and upper limb
C83.15	Mantle cell lymphoma, lymph nodes of inguinal region and lower limb
C83.16	Mantle cell lymphoma, intrapelvic lymph nodes
C83.17	Mantle cell lymphoma, spleen
C83.18	Mantle cell lymphoma, lymph nodes of multiple sites
C83.19	Mantle cell lymphoma, extranodal and solid organ sites
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma, intrathoracic lymph nodes
C83.33	Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.36	Diffuse large B-cell lymphoma, intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites
C83.39	Diffuse large B-cell lymphoma, extranodal and solid organ sites
C83.51	Lymphoblastic (diffuse) lymphoma, lymph nodes of head, face, and neck
C83.52	Lymphoblastic (diffuse) lymphoma, intrathoracic lymph nodes
C83.53	Lymphoblastic (diffuse) lymphoma, intra-abdominal lymph nodes
C83.54	Lymphoblastic (diffuse) lymphoma, lymph nodes of axilla and upper limb
C83.55	Lymphoblastic (diffuse) lymphoma, lymph nodes of inguinal region and lower limb

C83.56	Lymphoblastic (diffuse) lymphoma, intrapelvic lymph nodes
C83.57	Lymphoblastic (diffuse) lymphoma, spleen
C83.58	Lymphoblastic (diffuse) lymphoma, lymph nodes of multiple sites
C83.59	Lymphoblastic (diffuse) lymphoma, extranodal and solid organ sites
C83.71	Burkitt lymphoma, lymph nodes of head, face, and neck
C83.72	Burkitt lymphoma, intrathoracic lymph nodes
C83.73	Burkitt lymphoma, intra-abdominal lymph nodes
C83.74	Burkitt lymphoma, lymph nodes of axilla and upper limb
C83.75	Burkitt lymphoma, lymph nodes of inguinal region and lower limb
C83.76	Burkitt lymphoma, intrapelvic lymph nodes
C83.77	Burkitt lymphoma, spleen
C83.78	Burkitt lymphoma, lymph nodes of multiple sites
C83.79	Burkitt lymphoma, extranodal and solid organ sites
C83.81	Other non-follicular lymphoma, lymph nodes of head, face, and neck
C83.82	Other non-follicular lymphoma, intrathoracic lymph nodes
C83.83	Other non-follicular lymphoma, intra-abdominal lymph nodes
C83.84	Other non-follicular lymphoma, lymph nodes of axilla and upper limb
C83.85	Other non-follicular lymphoma, lymph nodes of inguinal region and lower limb
C83.86	Other non-follicular lymphoma, intrapelvic lymph nodes
C83.87	Other non-follicular lymphoma, spleen
C83.88	Other non-follicular lymphoma, lymph nodes of multiple sites
C83.89	Other non-follicular lymphoma, extranodal and solid organ sites
C83.91	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of head, face, and neck
C83.92	Non-follicular (diffuse) lymphoma, unspecified, intrathoracic lymph nodes
C83.93	Non-follicular (diffuse) lymphoma, unspecified, intra-abdominal lymph nodes
C83.94	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of axilla and upper limb
C83.95	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of inguinal region and lower limb
C83.96	Non-follicular (diffuse) lymphoma, unspecified, intrapelvic lymph nodes
C83.97	Non-follicular (diffuse) lymphoma, unspecified, spleen
C83.98	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of multiple sites
C83.99	Non-follicular (diffuse) lymphoma, unspecified, extranodal and solid organ sites
C84.01	Mycosis fungoides, lymph nodes of head, face, and neck

C84.02	Mycosis fungoides, intrathoracic lymph nodes
C84.03	Mycosis fungoides, intra-abdominal lymph nodes
C84.04	Mycosis fungoides, lymph nodes of axilla and upper limb
C84.05	Mycosis fungoides, lymph nodes of inguinal region and lower limb
C84.06	Mycosis fungoides, intrapelvic lymph nodes
C84.07	Mycosis fungoides, spleen
C84.08	Mycosis fungoides, lymph nodes of multiple sites
C84.09	Mycosis fungoides, extranodal and solid organ sites
C84.11	Sezary disease, lymph nodes of head, face, and neck
C84.12	Sezary disease, intrathoracic lymph nodes
C84.13	Sezary disease, intra-abdominal lymph nodes
C84.14	Sezary disease, lymph nodes of axilla and upper limb
C84.15	Sezary disease, lymph nodes of inguinal region and lower limb
C84.16	Sezary disease, intrapelvic lymph nodes
C84.17	Sezary disease, spleen
C84.18	Sezary disease, lymph nodes of multiple sites
C84.19	Sezary disease, extranodal and solid organ sites
C84.41	Peripheral T-cell lymphoma, not classified, lymph nodes of head, face, and neck
C84.42	Peripheral T-cell lymphoma, not classified, intrathoracic lymph nodes
C84.43	Peripheral T-cell lymphoma, not classified, intra-abdominal lymph nodes
C84.44	Peripheral T-cell lymphoma, not classified, lymph nodes of axilla and upper limb
C84.45	Peripheral T-cell lymphoma, not classified, lymph nodes of inguinal region and lower limb
C84.46	Peripheral T-cell lymphoma, not classified, intrapelvic lymph nodes
C84.47	Peripheral T-cell lymphoma, not classified, spleen
C84.48	Peripheral T-cell lymphoma, not classified, lymph nodes of multiple sites
C84.49	Peripheral T-cell lymphoma, not classified, extranodal and solid organ sites
C84.61	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of head, face, and neck
C84.62	Anaplastic large cell lymphoma, ALK-positive, intrathoracic lymph nodes
C84.63	Anaplastic large cell lymphoma, ALK-positive, intra-abdominal lymph nodes
C84.64	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of axilla and upper limb
C84.65	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of inguinal region and lower limb

C84.66	Anaplastic large cell lymphoma, ALK-positive, intrapelvic lymph nodes
C84.67	Anaplastic large cell lymphoma, ALK-positive, spleen
C84.68	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of multiple sites
C84.69	Anaplastic large cell lymphoma, ALK-positive, extranodal and solid organ sites
C84.71	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of head, face, and neck
C84.72	Anaplastic large cell lymphoma, ALK-negative, intrathoracic lymph nodes
C84.73	Anaplastic large cell lymphoma, ALK-negative, intra-abdominal lymph nodes
C84.74	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of axilla and upper limb
C84.75	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of inguinal region and lower limb
C84.76	Anaplastic large cell lymphoma, ALK-negative, intrapelvic lymph nodes
C84.77	Anaplastic large cell lymphoma, ALK-negative, spleen
C84.78	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of multiple sites
C84.79	Anaplastic large cell lymphoma, ALK-negative, extranodal and solid organ sites
C84.91	Mature T/NK-cell lymphomas, unspecified, lymph nodes of head, face, and neck
C84.92	Mature T/NK-cell lymphomas, unspecified, intrathoracic lymph nodes
C84.93	Mature T/NK-cell lymphomas, unspecified, intra-abdominal lymph nodes
C84.94	Mature T/NK-cell lymphomas, unspecified, lymph nodes of axilla and upper limb
C84.95	Mature T/NK-cell lymphomas, unspecified, lymph nodes of inguinal region and lower limb
C84.96	Mature T/NK-cell lymphomas, unspecified, intrapelvic lymph nodes
C84.97	Mature T/NK-cell lymphomas, unspecified, spleen
C84.98	Mature T/NK-cell lymphomas, unspecified, lymph nodes of multiple sites
C84.99	Mature T/NK-cell lymphomas, unspecified, extranodal and solid organ sites
C84.A1	Cutaneous T-cell lymphoma, unspecified lymph nodes of head, face, and neck
C84.A2	Cutaneous T-cell lymphoma, unspecified, intrathoracic lymph nodes

C84.A3	Cutaneous T-cell lymphoma, unspecified, intra-abdominal lymph nodes
C84.A4	Cutaneous T-cell lymphoma, unspecified, lymph nodes of axilla and upper limb
C84.A5	Cutaneous T-cell lymphoma, unspecified, lymph nodes of inguinal region and lower limb
C84.A6	Cutaneous T-cell lymphoma, unspecified, intrapelvic lymph nodes
C84.A7	Cutaneous T-cell lymphoma, unspecified, spleen
C84.A8	Cutaneous T-cell lymphoma, unspecified, lymph nodes of multiple sites
C84.A9	Cutaneous T-cell lymphoma, unspecified, extranodal and solid organ sites
C84.Z1	Other mature T/NK-cell lymphomas, lymph nodes of head, face, and neck
C84.Z2	Other mature T/NK-cell lymphomas, intrathoracic lymph nodes
C84.Z3	Other mature T/NK-cell lymphomas, intra-abdominal lymph nodes
C84.Z4	Other mature T/NK-cell lymphomas, lymph nodes of axilla and upper limb
C84.Z5	Other mature T/NK-cell lymphomas, lymph nodes of inguinal region and lower limb
C84.Z6	Other mature T/NK-cell lymphomas, intrapelvic lymph nodes
C84.Z7	Other mature T/NK-cell lymphomas, spleen
C84.Z8	Other mature T/NK-cell lymphomas, lymph nodes of multiple sites
C84.Z9	Other mature T/NK-cell lymphomas, extranodal and solid organ sites
C85.11	Unspecified B-cell lymphoma, lymph nodes of head, face, and neck
C85.12	Unspecified B-cell lymphoma, intrathoracic lymph nodes
C85.13	Unspecified B-cell lymphoma, intra-abdominal lymph nodes
C85.14	Unspecified B-cell lymphoma, lymph nodes of axilla and upper limb
C85.15	Unspecified B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.16	Unspecified B-cell lymphoma, intrapelvic lymph nodes
C85.17	Unspecified B-cell lymphoma, spleen
C85.18	Unspecified B-cell lymphoma, lymph nodes of multiple sites
C85.19	Unspecified B-cell lymphoma, extranodal and solid organ sites
C85.21	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of head, face, and neck
C85.22	Mediastinal (thymic) large B-cell lymphoma, intrathoracic lymph nodes

C85.23	Mediastinal (thymic) large B-cell lymphoma, intra-abdominal lymph nodes
C85.24	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of axilla and upper limb
C85.25	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.26	Mediastinal (thymic) large B-cell lymphoma, intrapelvic lymph nodes
C85.27	Mediastinal (thymic) large B-cell lymphoma, spleen
C85.28	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of multiple sites
C85.29	Mediastinal (thymic) large B-cell lymphoma, extranodal and solid organ sites
C85.81	Other specified types of non-Hodgkin lymphoma, lymph nodes of head, face, and neck
C85.82	Other specified types of non-Hodgkin lymphoma, intrathoracic lymph nodes
C85.83	Other specified types of non-Hodgkin lymphoma, intra-abdominal lymph nodes
C85.84	Other specified types of non-Hodgkin lymphoma, lymph nodes of axilla and upper limb
C85.85	Other specified types of non-Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C85.86	Other specified types of non-Hodgkin lymphoma, intrapelvic lymph nodes
C85.87	Other specified types of non-Hodgkin lymphoma, spleen
C85.88	Other specified types of non-Hodgkin lymphoma, lymph nodes of multiple sites
C85.89	Other specified types of non-Hodgkin lymphoma, extranodal and solid organ sites
C85.91	Non-Hodgkin lymphoma, unspecified, lymph nodes of head, face, and neck
C85.92	Non-Hodgkin lymphoma, unspecified, intrathoracic lymph nodes
C85.93	Non-Hodgkin lymphoma, unspecified, intra-abdominal lymph nodes
C85.94	Non-Hodgkin lymphoma, unspecified, lymph nodes of axilla and upper limb
C85.95	Non-Hodgkin lymphoma, unspecified, lymph nodes of inguinal region and lower limb
C85.96	Non-Hodgkin lymphoma, unspecified, intrapelvic lymph nodes
C85.97	Non-Hodgkin lymphoma, unspecified, spleen
C85.98	Non-Hodgkin lymphoma, unspecified, lymph nodes of multiple sites
C85.99	Non-Hodgkin lymphoma, unspecified, extranodal and solid organ sites

C86.0	Extranodal NK/T-cell lymphoma, nasal type
C86.1	Hepatosplenic T-cell lymphoma
C86.2	Enteropathy-type (intestinal) T-cell lymphoma
C86.3	Subcutaneous panniculitis-like T-cell lymphoma
C86.4	Blastic NK-cell lymphoma
C86.5	Angioimmunoblastic T-cell lymphoma
C86.6	Primary cutaneous CD30-positive T-cell proliferations
C88.0	Waldenstrom macroglobulinemia
C88.2	Heavy chain disease
C88.3	Immunoproliferative small intestinal disease
C88.4	Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue [MALT-lymphoma]
C88.8	Other malignant immunoproliferative diseases
C88.9	Malignant immunoproliferative disease, unspecified
C90.00	Multiple myeloma not having achieved remission
C90.01	Multiple myeloma in remission
C90.02	Multiple myeloma in relapse
C90.10	Plasma cell leukemia not having achieved remission
C90.11	Plasma cell leukemia in remission
C90.20	Extramedullary plasmacytoma not having achieved remission
C90.21	Extramedullary plasmacytoma in remission
C90.22	Extramedullary plasmacytoma in relapse
C90.30	Solitary plasmacytoma not having achieved remission
C90.31	Solitary plasmacytoma in remission
C90.32	Solitary plasmacytoma in relapse
C91.01	Acute lymphoblastic leukemia, in remission
C91.11	Chronic lymphocytic leukemia of B-cell type in remission
C91.31	Prolymphocytic leukemia of B-cell type, in remission
C91.51	Adult T-cell lymphoma/leukemia (HTLV-1-associated), in remission
C91.61	Prolymphocytic leukemia of T-cell type, in remission
C91.91	Lymphoid leukemia, unspecified, in remission
C91.A1	Mature B-cell leukemia Burkitt-type, in remission
C91.Z1	Other lymphoid leukemia, in remission
C92.01	Acute myeloblastic leukemia, in remission
C92.11	Chronic myeloid leukemia, BCR/ABL-positive, in remission
C92.21	Atypical chronic myeloid leukemia, BCR/ABL-negative, inremission
C92.31	Myeloid sarcoma, in remission
C92.41	Acute promyelocytic leukemia, in remission
C92.51	Acute myelomonocytic leukemia, in remission
C92.61	Acute myeloid leukemia with 11q23-abnormality in remission
C92.91	Myeloid leukemia, unspecified in remission
C92.A1	Acute myeloid leukemia with multilineage dysplasia, in remission
C92.Z1	Other myeloid leukemia, in remission

C93.01	Acute monoblastic/monocytic leukemia, in remission
C93.11	Chronic myelomonocytic leukemia, in remission
C93.31	Juvenile myelomonocytic leukemia, in remission
C93.91	Monocytic leukemia, unspecified in remission
C93.Z1	Other monocytic leukemia, in remission
C94.01	Acute erythroid leukemia, in remission
C94.21	Acute megakaryoblastic leukemia, in remission
C94.31	Mast cell leukemia, in remission
C94.81	Other specified leukemias, in remission
C95.01	Acute leukemia of unspecified cell type, in remission
C95.11	Chronic leukemia of unspecified cell type, in remission
C95.91	Leukemia, unspecified, in remission
C96.0	Multifocal and multisystemic (disseminated) Langerhans-cell histiocytosis
C96.20	Malignant mast cell neoplasm, unspecified
C96.21	Aggressive systemic mastocytosis
C96.22	Mast cell sarcoma
C96.29	Other malignant mast cell neoplasm
C96.4	Sarcoma of dendritic cells (accessory cells)
C96.5	Multifocal and unisystemic Langerhans-cell histiocytosis
C96.6	Unifocal Langerhans-cell histiocytosis
C96.9	Malignant neoplasm of lymphoid, hematopoietic and related tissue, unspecified
C96.A	Histiocytic sarcoma
C96.Z	Other specified malignant neoplasms of lymphoid, hematopoietic and related tissue
D45	Polycythemia vera
D47.Z9	Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
E85.4	Organ-limited amyloidosis
E85.81	Light chain (AL) amyloidosis
E85.89	Other amyloidosis
E85.9	Amyloidosis, unspecified

a. Effective for services performed on or after April 28, 1989:

Acute leukemia in remission who have a high probability of relapse and who have no human leucocyte antigens (HLA)- matched (ICD-10-CM diagnosis codes C91.01, C92.01, C92,41, C92.51, C92.61, C92.A1, C93.01, C94.01, C94.21, C94.41, C95.01);

Resistant non-Hodgkin's lymphomas or those presenting withpoor prognostic features following an initial response (ICD-

10-CM diagnosis codes C82.01-C85.29, C85.81-C86.6, C96.4,and C96.Z-C96.9);

Recurrent or refractory neuroblastoma (see ICD-10-CM codesNeoplasm by site, malignant for the appropriate diagnosis code) following ranges are reported: C00 - C96, and D00 - D09 Resistant non- Hodgkin's lymphomas); or, Advanced Hodgkin's disease who have failed conventional therapy and have no HLA-matched donor (ICD-10-CM codes C81.01 - C81.99).

a. Effective for services performed on or after October 1, 2000:

Single AuSCT is only covered for Durie-Salmon Stage II orIII multiple myeloma patients (ICD-10-CM codes C90.00, C90.01, C90.02 and D47.Z9) that fit the following requirements:

- Newly diagnosed or responsive multiple myeloma. This includes those patients with previously untreated disease,those with at least a partial response to prior chemotherapy (defined as a 50% decrease either in measurable paraprotein [serum and/or urine] or in bone marrow infiltration, sustained for at least 1 month), and those in responsive relapse; and

- Adequate cardiac, renal, pulmonary, and hepatic function.

b. Effective for services performed on or after March 15, 2005:

When recognized clinical risk factors are employed to select patients for transplantation, high dose melphalan(HDM) together with AuSCT is reasonable and necessary for Medicare beneficiaries of any age group with primary amyloid light chain (AL) amyloidosis (ICD-10-CM codes E85.4, E85.81, E85.89 and E85.9)
who meet the following criteria:

- Amyloid deposition in 2 or fewer organs; and,

- Cardiac left ventricular ejection fraction (EF) greater than 45%.

E85.4 Organ-limited amyloidosis
E85.81 Light chain (AL) amyloidosis

E85.89 Other amyloidosis

E85.9 Amyloidosis, unspecified

As the applicable ICD-10 CM codes E85.4, E85.81, E85.9, and E85.89 for amyloidosis do not differentiate between primary and non- primary, A/B MACs (B) should perform prepayreviews on all claims with a diagnosis of ICD- 10-CM code E85.4, E85.81, E85.9, and E85.89
to determine whether payment is appropriate.

C. Nationally Non-Covered Indications

I. Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

Effective for claims with dates of service on or after May 24, 1996, through January 27, 2016, allogeneic HSCT is not covered as treatment for multiple myeloma (if ICD-10-CM is applicable, ICD- 10-CM codes C90.00, C90.01, C90.02 and D47.Z9).

II. Autologous Stem Cell Transplantation (AuSCT)

AuSCT is not considered reasonable and necessary within the meaning of §1862(a)(1)(A) of the Act and is not covered under Medicarefor the following conditions:

- Acute leukemia not in remission prior to October 1, 2000 (if ICD-10-CM is applicable, ICD-10-CM codes C91.00, C92.00, C93.00, C94.00, and C95.00)

- Chronic granulocytic leukemia prior to October 1, 2000 (if ICD-10-CM is applicable, ICD-10-CM code C92.10);

1. Solid tumors prior to October 1, 2000 (other than neuroblastoma) (if ICD-10-CM is applicable, ICD-10-CM codes C00.0 – C80.2 and D00.0 – D09.9);

2. Multiple myeloma prior to October 1, 2000 (if ICD-10-CMis applicable, ICD-10-CM codes C90.00, C90.01, C90.02and D47.Z9);

3. Tandem transplantation, on or after October 1, 2000 (ifICD-10-CM is applicable, ICD-10-CM codes C90.00,C90.01, C90.02, and D47.Z9) ;

4. Non- primary amyloidosis on or after 10/01/00, for all Medicare beneficiaries

5. Primary AL amyloidosis effective October 1, 2000, through March 14, 2005 for Medicare beneficiaries age 64. (if ICD-10-CM is applicable, ICD-10-CM codes E85.4, E85.81, E85.9, and E85.89);

As the ICD-10-CM is applicable, as the applicable ICD-10 CM codes E85.4, E85.81, E85.9, and E85.89 for amyloidosis do not differentiate between primary and non-primary, A/B MACs (B) should perform prepay reviews on all claims witha diagnosis of ICD-10-CM code E85.4, E85.81, E85.9, and E85.89 to determine whether payment is appropriate.

2. Other

All other indications for stem cell transplantation not otherwise notedabove as covered or non-covered remain at local Medicare Administrative Contractor discretion.

3. Suggested MSN and RA Messages

The contractor shall use an appropriate MSN and CARC messagesuch as the following:

MSN - 15.4, The information provided does not support the need forthis service or item;

CARC - 150, Payment adjusted because the payer deems the information submitted does not support this level of service.

4. Clinical Trials for Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndrome (MDS), Multiple Myeloma, Myelofibrosis (MF), and for Sickle Cell Disease (SCD)

- **Background**

Effective for services performed on or after August 4, 2010, contractors shall pay for claims for allogeneic HSCT for the treatmentof Myelodysplastic Syndromes (MDS) pursuant to Coverage with Evidence Development (CED) in the context of a Medicare-approved,prospective clinical study.

Effective for services performed on or after January 27, 2016, contractors shall pay for claims for allogeneic HSCT for the treatmentof multiple myeloma, myelofibrosis (MF), and for sickle cell disease (SCD) pursuant to CED, in the context of a Medicare-approved, prospective clinical study.

Refer to Pub.100-03, National Coverage Determinations Manual, Chapter 1, section 110.23, for more information about this policy,and Pub. 100-04, Medicare Claims Processing Manual, Chapter 3, section 90.3, for information on inpatient billing of this CED.

- **Adjudication Requirements**

Payable Conditions. **For claims with dates of service on and after August 4, 2010**, contractors shall pay for claims for allogeneic HSCT for MDS when the service was provided pursuant to a Medicare-approved clinical study under CED; these services are paidonly in the inpatient setting (Type of Bill (TOB) 11X), as outpatient Part B (TOB 13X), and in Method II critical access hospitals (TOB 85X).

Contractors shall require the following coding in order to pay for these claims:

- Existing Medicare-approved clinical trial coding conventions, as required in Pub. 100-04, Medicare Claims Processing Manual, Chapter 32, section 69, and inpatient billing requirements regarding acquisition of stem cells in Pub. 100- 04, Medicare Claims Processing Manual, Chapter 3, section 90.3.1.

- If ICD-10-CM is applicable, ICD-10-PCS, procedure codes 30230G2, 30230G3, 30230Y2, 30230Y3, 30233G2, 30233G3, 30233Y2, 30233Y3, 30240G2, 30240G3, 30240Y2, 30240Y3, 30243G2, 30243G3, 30243Y2, and 30243Y3.

- If Outpatient Hospital or Professional Claims: HCPCS procedure code 38240

- If ICD-10-CM is applicable, ICD-10-CM codes D46.A, D46.B, D46.C, D46.Z, D46.0, D46.1, D46.4, D46.9, D46.20, D46.21, D46.22, and Z00.6.

- Professional claims only: place of service codes 19, 21, or 22.

Payable Conditions. **For claims with dates of service on and after January 27, 2016**, contractors shall pay for claims for allogeneic HSCT for multiple myeloma, myelofibrosis (MF), andfor sickle cell disease (SCD) when the service was provided pursuant to a Medicare-approved clinical study under CED; theseservices are paid only in the inpatient setting (Type of Bill (TOB) 11X), as outpatient Part B (TOB 13X), and in Method II critical access hospitals (TOB 85X).

Contractors shall require the following coding in order to pay for these claims:

- Existing Medicare-approved clinical trial coding conventions, as required in Pub. 100-04, Medicare Claims Processing Manual, Chapter 32, section 69, and inpatient billing requirements regarding acquisition of stem cells in Pub. 100- 04, Medicare Claims Processing Manual, Chapter 3, section 90.3.1.

- ICD-10-PCS codes 30230G2, 30230G3, 30230Y2, 30230Y3, 30233G2, 30233G3, 30233Y2, 30233Y3, 30240G2, 30240G3, 30240Y2, 30240Y3, 30243G2, 30243G3, 30243Y2, and 30243Y3.

- ICD-10-CM diagnosis codes C90.00, C90.01, C90.02, C94.40, C94.41, C94.42, D47.1, D47.4, D75.81, D57.00, D57.01, D57.02, D57.03, D57.09, D57.1, D57.20, D57.211, D57.212, D57.213, D57.218, D57.219, D57.40, D57.411, D57.412, D57.413, D57.418, D57.419, D57.42, D57.431, D57.432, D57.433, D57.438, D57.439, D57.44, D57.451, D57.452, D57.453, D57.458, and D57.459, D57.80, D57.811, D57.812, D57.813, D57.818, D57.819, and Z00.6.

- If Outpatient Hospital or Professional Claims: HCPCS procedure code 38240

- Professional claims only: place of service codes 19, 21, or 22.

Denials. Contractors shall deny claims failing to meet any ofthe above criteria. In addition, contractors shall apply the following requirements:

□ Providers shall issue a hospital issued notice of non- coverage (HINN) or advance beneficiary notice (ABN) to the beneficiary if the services performed are not providedin accordance with CED.

□ Contractors shall deny claims that do not meet the criteriafor coverage with the following messages:

CARC 50 - These are non-covered services because this is notdeemed a 'medical necessity' by the payer.

NOTE: Refer to the 835 Healthcare Policy Identification Segment (loop 2110Service Payment Information REF), if present.

RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determinationas to whether a particular item or service is covered. A copy of this policy is available a http:www.cms.hhs.gov/mcd/search.asp. If youdo not have web access, you may contact the contractor to request acopy of the NCD.

Group Code – Patient Responsibility (PR) if HINN/ABN issued,otherwise Contractual Obligation (CO)

MSN 16.77 – This service/item was not covered because it was not provided as part of a qualifying trial/study. (Este servicio/artículo no fue cubierto porque no estaba incluido comoparte de un ensayo clínico/estudio calificado.)

MSN 15.20 – The following policies [NCD 110.23] were usedwhen we made this decision. (Las siguientes políticas [NCD 110.23] fueron utilizadas cuando se tomó esta decisión.)

90.1 - General

(Rev. 486, Issued: 03-04-05, Effective Date/Implementation Date: N/A)

Allogeneic Stem Cell Transplantation.

Allogeneic stem cell transplantation is a procedure in which a portion of a healthy donor’s stem cells is obtained and prepared for intravenous infusion to restore normal hematopoietic function in recipients having an inherited or acquired hematopoietic deficiency or defect.

Expenses incurred by a donor are a covered benefit to the recipient/beneficiary but, except for physician services, are not paid separately. Services to the donor include physician services, hospital care in connection with screening the stem cell, and ordinary follow-up care.

Autologous Stem Cell Transplantation

Autologous stem cell transplantations is a technique for restoring stem cells using the patient’s own previously stored cells. Autologous stem cell transplants are covered for certain specified diagnoses for services rendered on or after April 28, 1989.

90.2 - HCPCS and Diagnosis Coding – ICD-9-CM Applicable
(Rev.11035, Issued:10-13-21, Effective: 11-17-21; Implementation: 11-21)

Allogeneic Stem Cell Transplantation

- Effective for services performed on or after August 1, 1978:

For the treatment of leukemia or leukemia in remission,providers shall use appropriate ICD-10 diagnosis codes noted in section 90 and HCPCS code 38240.

For the treatment of aplastic anemia, providers shall use appropriate ICD-10 diagnosis codes noted in section 90 andHCPCS code 38240.

- Effective for services performed on or after June 3, 1985:

For the treatment of severe combined immunodeficiency disease, providers shall use appropriate ICD-10 diagnosiscodes noted in section 90 and HCPCS code 38240.

For the treatment of Wiskott-Aldrich syndrome, providers shall use appropriate ICD-10-CM code D82.0 and HCPCScode 38240.

Autologous Stem Cell Transplantation.--Is covered under thefollowing circumstances effective for services performed on orafter April 28, 1989:

For the treatment of patients with acute leukemia in remission who have a high probability of relapse and who have no humanleucocyte antigens (HLA) matched, providers shall use appropriate ICD-10 diagnosis codes noted in section 90 for lymphoid; myeloid; monocytic; acute erythremia; erythroleukemia; unspecified cell type and HCPCS code 38241.

For the treatment of resistant non-Hodgkin's lymphomas for thosepatients presenting with poor prognostic features following an initial response, providers shall use appropriate ICD-10 diagnosiscodes noted in section 90 and HCPCS code 38241.

For the treatment of recurrent or refractory neuroblastoma, providers shall use ICD- 10-CM codes Neoplasm by site, malignant, the appropriate HCPCS code and HCPCS code 38241.

For the treatment of advanced Hodgkin's disease for patients whohave failed conventional therapy and have no HLA-matched donor, providers shall use appropriate ICD-10 diagnosis codes and HCPCS code 38241

Autologous Stem Cell Transplantation.--Is covered under thefollowing circumstances effective for services furnished on or after October 1, 2000:

For the treatment of multiple myeloma (only for beneficiaries whoare less than age 78, have Durie-Salmon stage II or III newly diagnosed or responsive multiple myeloma, and have adequate cardiac, renal, pulmonary and hepatic functioning), providers shalluse appropriate ICD-10-CM code and HCPCS code 38241.

For the treatment of recurrent or refractory neuroblastoma,providers shall use appropriate code (see ICD-10-CM neoplasm by site, malignant) and HCPCS code 38241.

Effective for services performed on or after March 15, 2005, when recognized clinical risk factors are employed to select patients for transplantation, high-dose melphalan (HDM) togetherwith autologous stem cell transplantation (HDM/AuSCT) is reasonable and necessary for Medicare beneficiaries of any age group for the treatment of primary amyloid light chain (AL) amyloidosis, ICD-10- CM codes E85.4, E85.81, E85.9, and E85.89 who meet the following criteria:

Amyloid deposition in 2 or fewer organs; and,

Cardiac left ventricular ejection fraction (EF) greater than 45%.

90.2.1 - HCPCS and Diagnosis Coding for Stem Cell Transplantation - ICD-10-CM Applicable

(Rev. 11035, Issued:10-13-21, Effective: 11-17-21; Implementation: 11-17-21)

ICD-10 is applicable to services on and after the implementation of ICD-.

For services provided use the appropriate code from the ICD-10 CM codes the table below..
See §90.2 for a list of covered conditions

ICD-10	Description
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.01	Acute lymphoblastic leukemia, in remission
C91.02	Acute lymphoblastic leukemia, in relapse
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.11	Chronic lymphocytic leukemia of B-cell type in remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse

C91.30	Prolymphocytic leukemia of B-cell type not having achieved remission
C91.31	Prolymphocytic leukemia of B-cell type, in remission
C91.32	Prolymphocytic leukemia of B-cell type, in relapse
C91.50	Adult T-cell lymphoma/leukemia (HTLV-1-associated) not having achieved remission
C91.51	Adult T-cell lymphoma/leukemia (HTLV-1-associated), in remission
C91.52	Adult T-cell lymphoma/leukemia (HTLV-1-associated), in relapse
C91.60	Prolymphocytic leukemia of T-cell type not having achieved remission
C91.61	Prolymphocytic leukemia of T-cell type, in remission
C91.62	Prolymphocytic leukemia of T-cell type, in relapse
C91.90	Lymphoid leukemia, unspecified not having achieved remission
C91.91	Lymphoid leukemia, unspecified, in remission
C91.92	Lymphoid leukemia, unspecified, in relapse
C91.A0	Mature B-cell leukemia Burkitt-type not having achieved remission
C91.A1	Mature B-cell leukemia Burkitt-type, in remission
C91.A2	Mature B-cell leukemia Burkitt-type, in relapse
C91.Z0	Other lymphoid leukemia not having achieved remission
C91.Z1	Other lymphoid leukemia, in remission
C91.Z2	Other lymphoid leukemia, in relapse
C92.00	Acute myeloblastic leukemia, not having achieved remission
C92.01	Acute myeloblastic leukemia, in remission
C92.02	Acute myeloblastic leukemia, in relapse
C92.10	Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission
C92.11	Chronic myeloid leukemia, BCR/ABL-positive, in remission
C92.12	Chronic myeloid leukemia, BCR/ABL-positive, in relapse
C92.20	Atypical chronic myeloid leukemia, BCR/ABL-negative, not having achieved remission
C92.21	Atypical chronic myeloid leukemia, BCR/ABL-negative, in remission
C92.22	Atypical chronic myeloid leukemia, BCR/ABL-negative, in relapse
C92.30	Myeloid sarcoma, not having achieved remission
C92.31	Myeloid sarcoma, in remission
C92.32	Myeloid sarcoma, in relapse
C92.40	Acute promyelocytic leukemia, not having achieved remission
C92.41	Acute promyelocytic leukemia, in remission
C92.42	Acute promyelocytic leukemia, in relapse
C92.50	Acute myelomonocytic leukemia, not having achieved remission
C92.51	Acute myelomonocytic leukemia, in remission
C92.52	Acute myelomonocytic leukemia, in relapse
C92.60	Acute myeloid leukemia with 11q23-abnormality not having achieved remission
C92.61	Acute myeloid leukemia with 11q23-abnormality in remission
C92.62	Acute myeloid leukemia with 11q23-abnormality in relapse
C92.90	Myeloid leukemia, unspecified, not having achieved remission
C92.91	Myeloid leukemia, unspecified in remission
C92.92	Myeloid leukemia, unspecified in relapse
C92.A0	Acute myeloid leukemia with multilineage dysplasia, not having achieved

C92.Z0	Other myeloid leukemia not having achieved remission
C92.Z1	Other myeloid leukemia, in remission
C92.Z2	Other myeloid leukemia, in relapse
C93.00	Acute monoblastic/monocytic leukemia, not having achieved remission
C93.01	Acute monoblastic/monocytic leukemia, in remission
C93.02	Acute monoblastic/monocytic leukemia, in relapse
C93.10	Chronic myelomonocytic leukemia not having achieved remission
C93.11	Chronic myelomonocytic leukemia, in remission
C93.12	Chronic myelomonocytic leukemia, in relapse
C93.30	Juvenile myelomonocytic leukemia, not having achieved remission
C93.31	Juvenile myelomonocytic leukemia, in remission
C93.32	Juvenile myelomonocytic leukemia, in relapse
C93.90	Monocytic leukemia, unspecified, not having achieved remission
C93.91	Monocytic leukemia, unspecified in remission
C93.92	Monocytic leukemia, unspecified in relapse
C93.Z0	Other monocytic leukemia, not having achieved remission
C93.Z1	Other monocytic leukemia, in remission
C93.Z2	Other monocytic leukemia, in relapse
C94.00	Acute erythroid leukemia, not having achieved remission
C94.01	Acute erythroid leukemia, in remission
C94.02	Acute erythroid leukemia, in relapse
C94.20	Acute megakaryoblastic leukemia not having achieved remission
C94.21	Acute megakaryoblastic leukemia, in remission
C94.22	Acute megakaryoblastic leukemia, in relapse
C94.30	Mast cell leukemia not having achieved remission
C94.31	Mast cell leukemia, in remission
C94.32	Mast cell leukemia, in relapse
C94.80	Other specified leukemias not having achieved remission
C94.81	Other specified leukemias, in remission
C94.82	Other specified leukemias, in relapse
C95.00	Acute leukemia of unspecified cell type not having achieved remission
C95.01	Acute leukemia of unspecified cell type, in remission
C95.02	Acute leukemia of unspecified cell type, in relapse
C95.10	Chronic leukemia of unspecified cell type not having achieved remission
C95.11	Chronic leukemia of unspecified cell type, in remission
C95.12	Chronic leukemia of unspecified cell type, in relapse
C95.90	Leukemia, unspecified not having achieved remission
C95.91	Leukemia, unspecified, in remission
C95.92	Leukemia, unspecified, in relapse
D45	Polycythemia vera

III. For the treatment of aplastic anemia; see table below for ICD-10-CM codes)

ICD-10	Description
D60.0	Chronic acquired pure red cell aplasia
D60.1	Transient acquired pure red cell aplasia
D60.8	Other acquired pure red cell aplasias
D60.9	Acquired pure red cell aplasia, unspecified
D61.01	Constitutional (pure) red blood cell aplasia
D61.09	Other constitutional aplastic anemia
D61.1	Drug-induced aplastic anemia
D61.2	Aplastic anemia due to other external agents
D61.3	Idiopathic aplastic anemia
D61.810	Antineoplastic chemotherapy induced pancytopenia
D61.811	Other drug-induced pancytopenia
D61.818	Other pancytopenia
D61.82	Myelophthisis
D61.89	Other specified aplastic anemias and other bone marrow failure syndromes
D61.9	Aplastic anemia, unspecified

If ICD-10-CM is applicable, the following ranges of ICD-10-CM codes are also covered for AuSCT:

- Resistant non-Hodgkin's lymphomas, ICD-10-CM diagnosis codes C82.01-C85.29, C85.81- C86.6, C96.4, and C96.Z-C96.9.

- Tandem transplantation (multiple rounds of autologous stem cell transplantation) for patients with multiple myeloma, ICD-10-CM codes C90.00, C90.01, C90.02 and D47.Z9

NOTE: The following conditions are not covered:

- Acute leukemia not in remission
- Chronic granulocytic leukemia
- Solid tumors (other than neuroblastoma)
- Multiple myeloma
- For Medicare beneficiaries age 64 or older, all forms of amyloidosis, primary and non-primary
- Non-primary amyloidosis

Also coverage for conditions other than those specifically designated as covered in §90.2 or specifically designated as non-covered in this section or in §90.3will be at the discretion of the individual contractor.

90.3 - Non-Covered Conditions

(Rev.11035, Issued:10-13-21, Effective: 11-17-21; Implementation: 11-17-21)

Autologous stem cell transplantation is not covered for the following conditions:

a) Acute leukemia not in remission prior to October 1, 2000 (if ICD-10-CM is applicable, ICD-10-CM codes C91.00, C92.00, C93.00, C94.00, and C95.00)

b) Chronic granulocytic leukemia prior to October 1, 2000 (if ICD-10-CM is applicable, ICD-10-CM code C92.10);

c) Solid tumors prior to October 1, 2000 (other than neuroblastoma) (if ICD-10-CM is applicable, ICD-10-CM codes C00.0 – C80.2 and D00.0 – D09.9);

d) Multiple myeloma prior to October 1, 2000 (if ICD-10-CM is applicable, ICD-10-CM codes C90.00, C90.01, C90.02 and D47.Z9);

e) Tandem transplantation, on or after October 1, 2000 (if ICD-10-CM is applicable, ICD-10-CM codes C90.00, C90.01, C90.02, and D47.Z9) ;

f) Non- primary amyloidosis on or after 10/01/00, for all Medicare beneficiaries

g) Primary AL amyloidosis effective October 1, 2000, through March 14, 2005 for Medicare beneficiaries age 64. (if ICD-10-CM is applicable, ICD-10-CM codes E85.4, E85.81, E85.9, and E85.89);

NOTE: Coverage for conditions other than those specifically designated ascovered in 90.2 or 90.2.1 or specifically designated as non-covered in thissection will be at the discretion of the individual A/B MAC (B).

90.4 - Edits

(Rev.11035, Issued:10-13-21, Effective: 11-17-21; Implementation: 11-17-21)

NOTE: Coverage for conditions other than those specifically designated as covered in 80.2 or specifically designated as non-covered in this section will be atthe discretion of the individual A/B MAC (B).

Appropriate diagnosis to procedure code edits should be implemented for the non-covered conditions and services in 90.290.2.1, and 90.3 as applicable

As the ICD-10-CM codes E85.4, E85.81, E85.89, and E85.9
amyloidosis does not differentiate between primary and non-primary,A/B MACs (B) should perform prepay reviews on all claims with a diagnosis **of ICD-10-CM codes E85.4, E85.81, E85.89, and E85.9** and a HCPCS procedure code of 38241 to determine whether payment is appropriate.

90.5 - Suggested MSN and RA Messages

(Rev.11035, Issued:10-13-21, Effective: 11-17-21; Implementation: 11-17-21)

The contractor shall use an appropriate MSN and CARC messagesuch as the following:

MSN - 15.4, The information provided does not support the needfor this service or item;

CARC - 150, Payment adjusted because the payer deems theinformation submitted does not support this level of service.

90.6 - Clinical Trials for Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndrome (MDS)

(Rev. 11035, Issued:10-13-21, Effective: 11-17-21; Implementation: 11-21)

Myelodysplastic Syndrome (MDS) refers to a group of diverse blood disorders in which the bone marrow does not produce enoughhealthy, functioning blood cells. These disorders are varied with regard to clinical characteristics, cytologic and pathologic features, and cytogenetics.

On August 4, 2010, the Centers for Medicare & Medicaid Services (CMS) issued a national coverage determination (NCD) stating that

CMS believes that the evidence does not demonstrate that the use ofallogeneic hematopoietic stem cell transplantation (HSCT) improveshealth outcomes in Medicare beneficiaries with MDS. Therefore, allogeneic HSCT for MDS is not reasonable and necessary under §1862(a)(1)(A) of the Social Security Act (the Act). However,allogeneic HSCT for MDS is reasonable and necessary under §1862(a)(1)(E) of the Act and therefore covered by Medicare ONLYif provided pursuant to a Medicare-approved clinical study under Coverage with Evidence Development (CED). Refer to Pub.100-03, National Coverage Determinations Manual, Chapter 1, section 110.8.1, for more information about this policy, and Pub. 100-04, Medicare Claims Processing Manual, Chapter 3, section 90.3.1, for information on CED.

B Adjudication Requirements

Payable Conditions. For claims with dates of service on and after August 4, 2010, contractors shall pay for claims for HSCT for MDSwhen the service was provided pursuant to a Medicare-approved clinical study under CED; these services are paid only in the inpatient setting (Type of Bill (TOB) 11X), as outpatient Part B (TOB 13X), and in Method II critical access hospitals (TOB 85X). Contractors shall require the following coding in order to pay for these claims:

- Existing Medicare-approved clinical trial coding conventions, as required in Pub. 100-04, Medicare Claims Processing Manual, Chapter 32, section 69, and inpatient billing requirements regarding acquisition of stem cells in Pub. 100-04, Medicare Claims Processing Manual, Chapter 3, section 90.3.3.

- If ICD-10-CM is applicable, ICD-10-PCS, procedure codes 30230C0, 30230G0, 30230Y0, 30233G0, 30233C0, 30233Y0,30240C0, 30240G0, 30240Y0, 30243C0, 30243G0, and30243Y0

- If Outpatient Hospital or Professional Claims: HCPCS procedure code 38240

- If ICD-10-CM is applicable, ICD-10-CM diagnosis codes, D46.A, D46.B, D46.C, D46.Z, D46.0, D46.1, D46.20, D46.21, D46.22, D46.4, D46.9, and Z00.6

- Professional claims only: place of service codes 21 or 22.

Denials. Contractors shall deny claims failing to meet any of theabove criteria. In addition, contractors shall apply the following requirements:

- Providers shall issue a hospital issued notice of non-coverage (HINN) or advance beneficiary notice (ABN) to the beneficiary if the services performed are not provided in accordance with CED.

- Contractors shall deny claims that do not meet the criteria for coverage with the following messages:

CARC 50 - These are non-covered services because this is notdeemed a 'medical necessity' by the payer.

NOTE: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), ifpresent.

RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determinationas to whether a particular item or service is covered. A copy of thispolicy is available at http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Group Code – Patient Responsibility (PR) if HINN/ABNissued, otherwise Contractual Obligation (CO)

MSN 16.77 – This service/item was not covered because it wasnot provided as part of a qualifying trial/study. (Este servicio/artículo no fue cubierto porque no estaba incluido como parte de un ensayo clínico/estudio calificado.)

100 – Billing Requirements for Expanded Coverage of Cochlear Implantation

(Rev. 11875; Issued:02-23-23; Effective: 09-26-22; Implementation: 03-24-23)

Effective for dates of services on and after September 26, 2022, the Centers for Medicare & Medicaid Services (CMS) has expanded the coverage for cochlear implantation to cover bilateral pre- or post- linguistic, sensorineural, moderate-to-profound hearing loss in individuals with hearing test scores equal to or less than 60% correct in the best aided listening condition on recorded tests of open-set sentence recognition and who demonstrate limited benefit from amplification. (See Publication 100-03, Chapter 1, Section 50.3, for complete coverage criteria).

In addition, CMS is covering cochlear implants for beneficiaries not meeting the coverage criteria listed under Publication 100-03, Chapter 1, Section 50.3 when performed in context with:

- A Food and Drug Administration (FDA)-approved category B investigational device exemption (IDE) clinical trial as defined at 42 CFR 405.201; or

- As a routine cost in a clinical trial under the CMS clinical trial policy (see Pub. 100-03, section 310.1).

100.1 – A/B MACs (Part A) Billing Procedures
(Rev. 11875; Issued:02-23-23; Effective: 09-26-22; Implementation: 03-24-23)

There are no special payment methods. Existing payment methods shall apply.

100.1.1 – Applicable Bill Types
(Rev. 601, Issued: 07-01-05; Effective: 04-04-05; Implementation: 07-25-05)

11X, 12X (see note below), 13X, 83X, 85X

NOTE: Surgical procedures are not acceptable on 12x bill types.

100.1.2 – Special Billing Requirements for A/B MACs (A) for Inpatient Billing
(Rev. 11875; Issued:02-23-23; Effective: 09-26-22; Implementation: 03-24-23)

- The second or subsequent diagnosis code must be ICD-10-CM Z00.6 (Encounter for exam for normal comparison and control in clinical research program). These diagnoses alert the claims processing system that this is a clinical trial.

- For patients in an FDA-approved category B IDE clinical trial the -Q0 modifier must be reported with the cochlear implantation device and all other related costs or; (see note below)

- For patients in an approved clinical trial under the clinical trial policy the -Q1 modifier must be billed for routine costs and not for the device itself

NOTE: The -Q0/-Q1 modifiers do not need to be applied to these services (92601-92604, 92507 & 92521-92524).

100.2 – Intermediary Payment Requirements
(Rev. 601, Issued: 07-01-05; Effective: 04-04-05; Implementation: 07-25-05)

There are no special payment methods. Existing payment methods shall apply.

100.3 – A/B MACs (Part B) Billing Procedures
(Rev. 11875; Issued:02-23-23; Effective: 09-26-22; Implementation: 03-24-23)

Effective for dates of service performed on and after September 26, 2022, the following applies:

A/B MACs (Part B) shall accept claims for cochlear implantation devices and services for beneficiaries meeting the coverage criteria listed under Publication 100-03, Chapter 1, section 50.3.

A/B MACs (Part B) shall accept claims for cochlear implantation devices and all related costs for beneficiaries not meeting the coverage criteria listed under Publication 100-03, Chapter 1, Section 50.3 provided in an FDA-approved category B IDE clinical trial or a trial under the CMS Clinical Trial policy, that is billed with the -Q0 modifier. The definition of the -Q0 modifier is, “Item or service provided in a Medicare specified study.”

A/B MACs (Part B) shall accept claims for routine costs pertaining to beneficiaries not meeting the coverage criteria listed under Publication 100-03, Chapter 1, Section 50.3 who are in a clinical trial under the clinical

trial policy that is billed with the -Q1 modifier. The definition of the -Q1 modifier is, "Routine clinical service provided in a clinical research study that is in an approved clinical research study"

A/B MACs (Part B) shall accept claims for evaluation and therapeutic services related to cochlear implantation.

NOTE: The -Q0/-Q1 modifier does not need to be applied to these services (92601-92604, 92507 & 92521-92524).

These services should be billed on an approved electronic claim form or a paper CMS Form 1500.

100.4 – Healthcare Common Procedural Coding System (HCPCS)

(Rev. 11875; Issued:02-23-23; Effective: 09-26-22; Implementation: 03-24-23)

The following HCPCS codes are some of those available for use when billing for cochlear implantation services and devices provided by audiologists or physicians, and for the service of 92507, by speech language pathologists.

69930 – Cochlear device implantation, with or without mastoidectomy

L8614 – Cochlear Device includes all internal and external components

L8619 – Cochlear implant external speech processor and controller, integrated system, replacement

L7510 – Repair of prosthetic device, repair or replace minor parts

92507 – Treatment of speech, language, voice, communication, and/or auditory processing disorder (includes aural rehabilitation); individual

92521 – Evaluation of speech fluency (e.g. stuttering, cluttering)

92522 – Evaluation of speech sound production (e.g. articulation, phonological process, apraxia, dysarthria)

92523 – Evaluation of speech sound production (e.g. articulation, phonological process, apraxia, dysarthria) with evaluation of language comprehension and expression (e.g. receptive and expressive language).

92524 – Behavioral and qualitive analysis of voice and resonance

92601 – Diagnostic analysis of cochlear implant, patient under 7 years of age; with programming

(Codes 92601 and 92603 describe post-operative analysis and fitting of previously placed external devices, connection to the cochlear implant, and programming of the stimulator. Codes 92602 and 92604 describe subsequent sessions for measurements and adjustment of the external transmitter and re-programming of the internal stimulator.)

92602 – Diagnostic analysis of cochlear implant, patient under 7 years of age; subsequent programming. (Do not report 92602 in addition to 92601.)

92603 – Diagnostic analysis of cochlear implant, age 7 years or older; with programming

92604 – Diagnostic analysis of cochlear implant, age 7 years or older; subsequent reprogramming

A complete list of audiology codes can be found in Pub 100-4, chapter12, section 30.3.

100.5 - Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages

(Rev. 11875; Issued:02-23-23; Effective: 09-26-22; Implementation: 03-24-23)

Contractors shall use the appropriate claim adjustment reason codes (CARCs), remittance advice remark codes (RARCs), group codes, or Medicare summary notice (MSN) messages when denying payment for cochlear implantation devices and services for beneficiaries with moderate-to-profound hearing loss in patients with hearing test scores ≤ 40% through 9/25/22; ≤ 60% effective 9/26/22.

Use the following messages when denying services on claims:

- submitted on a TOB other than 11X, 12X (except surgical procedures), 13X or 85X (For Part A only); or
- submitted without the Q0/Q1; or
- submitted without diagnostic code Z000.6 or
- submitted without one of the CPT/HCPCs listed (92521-92524, 92507, 92601- 92604, L7510, L8614, L8619, 69930)

CARC 50 - "These are non-covered services because this is not deemed a 'medical necessity' by the payer"

RARC N386 - "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD."

MSN 15.20 = "The following policies were used when we made this decision:
NCD 50. 3"

Spanish translation: "Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 50.3")

Contractors processing institutional claims shall use the following MSN message in addition to MSN 15.20:

MSN 15.19 - Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD.

Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800-MEDICARE (1-800-633-4227).

NOTE: Due to system requirement, FISS has combined messages 15.19 and 15.20 so that, when used for the same line item, both messages will appear on the same MSN.

Group Code: CO (Contractual Obligation) assigning financial liability to the provider

A/B MACs (Part A) shall deny for any covered dx audiology/therapy services related to cochlear implantation with the following messages:

Use the following messages when denying services on claims:

- Submitted on a TOB other than 11X, 12X (except surgical procedures), 13X or 85X (Part A only), or
- submitted without diagnostic code Z00.6
- submitted without one of the CPT/HCPCs listed (92521-92524, 92507, 92601- 92604, L7510, L8614, L8619, 69930)

CARC 50 - "These are non-covered services because this is not deemed a 'medical necessity' by the payer"

RARC N386 - "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD."

MSN 15.20 = "The following policies were used when we made this decision:
NCD 50. 3"

Spanish translation: "Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 50.3")

Contractors processing institutional claims shall use the following MSN message in addition to MSN 15.20:

MSN 15.19 - Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD.

Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800-MEDICARE (1-800-633-4227).

NOTE: Due to system requirement, FISS has combined messages 15.19 and 15.20 so that, when used for the same line item, both messages will appear on the same MSN.

Group Code: CO (Contractual Obligation) assigning financial liability to the provider

A/B/MACs (Part B) shall deny claims for evaluation and therapeutic services related to cochlear implantation. NOTE: Modifiers -Q0/-Q1 do not need to be applied to these services (92601– 92604, 92521-92524 or any applicable audiology codes).

Use the following messages when denying services on claims:

- Submitted without one of the CPT/HCPCs listed (92521-92524, 92507, 92601- 92604).

  CARC 50 - "These are non-covered services because this is not deemed a 'medical necessity' by the payer"

  RARC N386 - "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD."

  MSN 15.20 - "The following policies were used when we made this decision: NCD 50. 3"

    Spanish translation: "Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 50.3")

  Group Code - CO (Contractual Obligation) assigning financial liability to the provider

110 – Coverage and Billing for Ultrasound Stimulation for Nonunion Fracture Healing
(Rev. 597, Issued: 06-24-05, Effective: 04-27-05, Implementation: 08-01-05)

An ultrasonic osteogenic stimulator is a non-invasive device that emits low intensity, pulsed ultrasound. This device is applied to the surface of the skin at the fracture site and ultrasound waves are emitted via a conductive coupling gel to stimulate fracture healing. The ultrasonic osteogenic stimulators are not to be used concurrently with other non-invasive osteogenic devices.

110.1 – Coverage Requirements
(Rev. 597, Issued: 06-24-05, Effective: 04-27-05, Implementation: 08-01-05)

Effective for dates of service on and after April 27, 2005, ultrasonic osteogenic stimulators are covered as medically reasonable and necessary for the treatment of nonunion bone fractures prior to surgical intervention. In demonstrating nonunion fractures, CMS expects:

- A minimum of 2 sets of radiographs, obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days. Each radiograph set must include multiple views of the fracture site accompanied with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the 2 sets of radiographs.

For further coverage information, please refer to the National Coverage Determinations Manual, Pub. 100-03, chapter 1, section 150.2.

110.2 – Intermediary Billing Requirements
(Rev. 597, Issued: 06-24-05, Effective: 04-27-05, Implementation: 08-01-05)

The RHHIs will pay for ultrasonic osteogenic stimulators only when services are submitted on type of bills (TOBs) listed under Pub. 100-04, Medicare Claims Processing Manual, chapter 32, section 100.3.

Fiscal intermediaries (FIs) must educate hospitals that there are no covered services for Ultrasonic Osteogenic Stimulation for which hospitals can be paid by the FI.

NOTE: Hospitals can not bill for Ultrasonic Osteogenic Stimulators.

110.3 – Bill Types
(Rev. 597, Issued: 06-24-05, Effective: 04-27-05, Implementation: 08-01-05)

Only the following TOBs can bill for Ultrasonic Osteogenic Stimulators: 32X, 33X, 34X, which is payable under the DMEPOS Fee Schedule.

NOTE: Ultrasonic Osteogenic Stimulators must be in the patient's home health plan of care if billed on TOBs 32X or 33X.

110.4 – Carrier and Intermediary Billing Instructions
(Rev. 597, Issued: 06-24-05, Effective: 04-27-05, Implementation: 08-01-05)

Effective for dates of service on or after April 27, 2005, contractors shall allow payment for ultrasonic osteogenic stimulators with the following current procedural terminology (CPT) code:

- 20979 - Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)

110.5 – DMERC Billing Instructions
(Rev. 816, Issued: 01-20-06, Effective: 04-27-05, Implementation: 04-03-06)

Effective for dates of service on or after April 27, 2005, DMERCs shall allow payment for ultrasonic osteogenic stimulators with the following HCPCS codes:

E0760 for low intensity ultrasound (include modifier "KF"), or;
E1399 for other ultrasound stimulation (include modifier "KF")

120 - Presbyopia-Correcting (P-C IOLS) and Astigmatism-Correcting Intraocular Lenses (A-C IOLs) (General Policy Information)
(Rev. 1228; Issued: 04-27-07; Effective: 01-22-07; Implementation: 05-29-07)

Per CMS Ruling 05-01, issued May 3, 2005, Medicare will allow beneficiaries to pay additional charges associated with insertion of a P-C IOL following cataract surgery.

- Presbyopia is a type of age-associated refractive error that results in progressive loss of the focusing power of the lens of the eye, causing difficulty seeing objects at near distance, or close-up. Presbyopia occurs as the natural lens of the eye becomes thicker and less flexible with age.

- A presbyopia-correcting IOL is indicated for primary implantation in the capsular bag of the eye for the visual correction of aphakia (absence of the lens of the eye) following cataract extraction that is intended to provide near, intermediate and distance vision without the need for eyeglasses or contact lenses.

Per CMS-1536-Ruling, effective for services on and after January 22, 2007, Medicare will allow beneficiaries to pay additional charges (which are non-covered by Medicare as these additional charges are not part of a Medicare benefit category) for insertion of an A-C IOL.

- Regular astigmatism is a visual condition where part of an image is blurred due to uneven corneal curvature. A normal cornea has the same curvature at all axes, whereas the curvature of an astigmatic cornea differs in two primary axes, resulting in vision that is distorted at all distances.

- The A-C IOL is intended to provide what is otherwise achieved by two separate items; an implantable conventional IOL (one that is not astigmatism-correcting) that is covered by Medicare, and the surgical correction, eyeglasses or contact lenses that are not covered by Medicare.

A list of A-C IOLs and P-C IOLs can be accessed online at
http://www.cms.hhs.gov/HospitalOutpatientPPS/01_overview.asp

120.1 - Payment for Services and Supplies

(Rev. 1430; Issued: 02-01-08; Effective: 01-01-08; Implementation: 03-03-08)

For an IOL inserted following removal of a cataract in a hospital, on either an outpatient or inpatient basis, that is paid under the hospital Outpatient Prospective Payment System (OPPS) or the Inpatient Prospective Payment System (IPPS), respectively; or in a Medicare-approved ambulatory surgical center (ASC) that is paid under the ASC fee schedule:

- Medicare does not make separate payment to the hospital or ASC for an IOL inserted subsequent to extraction of a cataract. Payment for the IOL is packaged into the payment for the surgical cataract extraction/lens replacement procedure.

- Any person or ASC, who presents or causes to be presented a bill or request for payment for an IOL inserted during or subsequent to cataract surgery for which payment is made under the ASC fee schedule, is subject to a civil money penalty.

- For a P-C IOL or A-C IOL inserted subsequent to removal of a cataract in a hospital, on either an outpatient or inpatient basis, that is paid under the OPPS or the IPPS, respectively; or in a Medicare-approved ASC that is paid under the ASC fee schedule:

- The facility shall bill for the removal of a cataract with insertion of a conventional IOL, regardless of whether a conventional, P-C IOL, or A-C IOL is inserted. When a beneficiary receives a P-C or A-C IOL following removal of a cataract, hospitals and ASCs shall report the same CPT code that is used to report removal of a cataract with insertion of a conventional IOL. Physicians, hospitals and ASCs may also report an additional HCPCS code, V2788, to indicate any additional charges that accrue when a P-C IOL or A-C IOL is inserted in lieu of a conventional IOL until January 1, 2008. Effective for A-C IOL insertion services on or after January 1, 2008, physicians, hospitals and ASCs should use V2787 to report any additional charges that accrue. On or after January 1, 2008, physicians, hospitals, and ASCs should continue to report HCPCS code V2788 to indicate any additional charges that accrue for insertion of a P-C IOL. See Section 120.2 for coding guidelines.

- There is no Medicare benefit category that allows payment of facility charges for services and supplies required to insert and adjust a P-C or A-C IOL following removal of a cataract that exceed the facility charges for services and supplies required for the insertion and adjustment of a conventional IOL.

- There is no Medicare benefit category that allows payment of facility charges for subsequent treatments, services and supplies required to examine and monitor the beneficiary who receives a P-C or A-C IOL following removal of a cataract that exceeds the facility charges for subsequent treatments, services and supplies required to examine and monitor a beneficiary after cataract surgery followed by insertion of a conventional IOL.

A - For a P-C IOL or A-C IOL inserted in a physician's office

- A physician shall bill for a conventional IOL, regardless of a whether a conventional, P-C IOL, or A-C IOL is inserted (see section 120.2, General Billing Requirements)

- There is no Medicare benefit category that allows payment of physician charges for services and supplies required to insert and adjust a P-C or A-C IOL following removal of a cataract that exceed the physician charges for services and supplies for the insertion and adjustment of a conventional IOL.

- There is no Medicare benefit category that allows payment of physician charges for subsequent treatments, service and supplies required to examine and monitor a beneficiary following removal of a cataract with insertion of a P-C or A-C IOL that exceed physician charges for services and supplies to examine and monitor a beneficiary following removal of a cataract with insertion of a conventional IOL.

B - For a P-C IOL or A-C IOL inserted in a hospital

- A physician may not bill Medicare for a P-C or A-C IOL inserted during a cataract procedure performed in a hospital setting because the payment for the lens is included in the payment made to the facility for the surgical procedure.

- There is no Medicare benefit category that allows payment of physician charges for services and supplies required to insert and adjust a P-C or A-C IOL following removal of a cataract that exceed the physician charges for services and supplies required for the insertion of a conventional IOL.

C - For a P-C IOL or A-C IOL inserted in an Ambulatory Surgical Center

- Refer to Chapter 14, Section 40.3 for complete guidance on payment for P-C IOL or A-C IOL in Ambulatory Surgical Centers.

120.2 - Coding and General Billing Requirements

(Rev. 1430; Issued: 02-01-08; Effective: 01-01-08; Implementation: 03-03-08)

Physicians and hospitals must report one of the following Current Procedural Terminology (CPT) codes on the claim:

66982 - Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic development stage.

- 66983 - Intracapsular cataract with insertion of intraocular lens prosthesis (one stage procedure)

- 66984 - Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification)

- 66985 - Insertion of intraocular lens prosthesis (secondary implant), not associated with concurrent cataract extraction

- 66986 - Exchange of intraocular lens

In addition, physicians inserting a P-C IOL or A-C IOL in an office setting may bill code V2632 (posterior chamber intraocular lens) for the IOL. Medicare will make payment for the lens based on reasonable cost for a conventional IOL. Place of Service (POS) = 11.

Effective for dates of service on and after January 1, 2006, physician, hospitals and ASCs may also bill the non-covered charges related to the P-C function of the IOL using HCPCS code V2788. Effective for dates of service on and after January 22, 2007 through January 1, 2008, non-covered charges related to A-C function of the IOL can be billed using HCPCS code V2788. The type of service indicator for the non-covered billed charges is Q. (The type of service is applied by the Medicare carrier and not the provider). Effective for A-C IOL insertion services on or after January 1, 2008, physicians, hospitals and ASCs should use V2787 rather than V2788 to report any additional charges that accrue.

When denying the non-payable charges submitted with V2787 or V2788, contractors shall use an appropriate Medical Summary Notice (MSN) such as 16.10 (Medicare does not pay for this item or service) and an appropriate claim adjustment reason code such as 96 (non-covered charges) for claims submitted with the non-payable charges.

Hospitals and physicians may use the proper CPT code(s) to bill Medicare for evaluation and management services usually associated with services following cataract extraction surgery, if appropriate.

A - Applicable Bill Types

The hospital applicable bill types are 12X, 13X, 83X and 85X.

B - Other Special Requirements for Hospitals

Hospitals shall continue to pay CAHs method 2 claims under current payment methodologies for conditional IOLs.

120.3 - Provider Notification Requirements

(Rev. 1228; Issued: 04-27-07; Effective: 01-22-07; Implementation: 05-29-07)

When a beneficiary requests insertion of a P-C or A-C IOL instead of a conventional IOL following removal of a cataract:

- Prior to the procedure to remove a cataractous lens and insert a P-C or A-C lens, the facility and the physician must inform the beneficiary that Medicare will not make payment for services that are specific to the insertion, adjustment or other subsequent treatments related to the P-C or A-C functionality of the IOL.

- The P-C or A-C functionality of a P-C or A-C IOL does not fall into a Medicare benefit category, and, therefore, is not covered. Therefore, the facility and physician are not required to provide an Advanced Beneficiary Notice to beneficiaries who request a P-C or A-C IOL.

- Although not required, CMS strongly encourages facilities and physicians to issue a Notice of Exclusion from Medicare Benefits to beneficiaries in order to clearly identify the non-payable aspects of a P-C or A-C IOL insertion. This notice may be found in English at http:\\cms.hhs.gov/medicare/bni/20007_English.pdf

- Spanish language at: http://cms.hhs.gov/medicare/bni/20007_Spanish.pdf.

120.4 - Beneficiary Liability
(Rev. 1228; Issued: 04-27-07; Effective: 01-22-07; Implementation: 05-29-07)

When a beneficiary requests insertion of a P-C or A-C IOL instead of a conventional IOL following removal of a cataract and that procedure is performed, the beneficiary is responsible for payment of facility and physician charges for services and supplies attributable to the P-C or A-C functionality of the P-C or A-C IOL:

- In determining the beneficiary's liability, the facility and physician may take into account any additional work and resources required for insertion, fitting, vision acuity testing, and monitoring of the P-C or A-C IOL that exceed the work and resources attributable to insertion of a conventional IOL.

- The physician and the facility may not charge for cataract extraction with insertion of a P-C or A-C IOL unless the beneficiary requests this service.

    - The physician and the facility may not require the beneficiary to request a P-C or A-C IOL as a condition of performing a cataract extraction with IOL insertion.

130 - External Counterpulsation (ECP) Therapy
(Rev. 898, Issued: 03-31-06; Effective/Implementation Dates: 03-31-06)

Commonly referred to as enhanced external counterpulsation, is a non-invasive outpatient treatment for coronary artery disease refractory medical and/or surgical therapy. Effective for dates of service July 1, 1999, and after, Medicare will cover ECP when its use is in patients with stable angina (Class III or Class IV, Canadian Cardiovascular Society Classification or equivalent classification) who, in the opinion of a cardiologist or cardiothoracic surgeon, are not readily amenable to surgical intervention, such as PTCA or cardiac bypass, because:

- Their condition is inoperable, or at high risk of operative complications or post-operative failure;

- Their coronary anatomy is not readily amenable to such procedures; or

- They have co-morbid states that create excessive risk.

(Refer to Publication 100-03, section 20.20 for further coverage criteria.)

130.1 - Billing and Payment Requirements
(Rev. 12109; Issued:06-29-23; Effective: 10-02-23; Implementation: 10-02-23)

Effective for dates of service on or after January 1, 2000, use HCPCS code G0166 (External counterpulsation, per session) to report ECP services. The codes for external cardiac assist (92971), ECG rhythm strip and report (93040 or 93041), pulse oximetry (94760 or 94761) and plethysmography (93922 or 93923) or other monitoring tests for examining the effects of this treatment are not clinically necessary with this service and

should not be paid on the same day, unless they occur in a clinical setting not connected with the delivery of the ECP. Daily evaluation and management service, e.g., 99201- 99205, 99211-99215, 99217-99220, 99241-99245, and G0463 cannot be billed with the ECP treatments. Any evaluation and management service must be justified with adequate documentation of the medical necessity of the visit. Deductible and coinsurance apply.

Note: Please note that effective December 31, 2020 evaluation and management service code 99201 is end-dated. Effective December 31, 2022 codes 99217,99218,99219,99220 and 99241 are end dated. For Part A, remove CPT codes 99202-99215, 99242-99245 and replace with G0463 (the OPPS equivalent of E/M codes) effective retroactive to 10/1/2015.

130.2 - Special Intermediary Billing and Payment Requirements
(Rev. 898, Issued: 03-31-06; Effective/Implementation Dates: 03-31-06)

Payment is made to hospitals for the facility costs it incurs under Part B on a reasonable cost basis. Payment is also made to PPS-exempt hospitals for the facility costs it incurs on a reasonable cost basis. Deductible and coinsurance apply.

Applicable bill types are 12X, 13X, 83X or 85X.

140 - Cardiac Rehabilitation (CR) Programs, Intensive Cardiac Rehabilitation (ICR) Programs, and Pulmonary Rehabilitation (PR) Programs On or After January 1, 2024
(Rev. 12497; Issued: 02-08-24; Effective: 01-01-24; Implementation: 03-12-24)

Cardiac rehabilitation (CR) means a physician or nonphysician practitioner supervised program that furnishes physician prescribed exercise; cardiac risk factor modification, including education, counseling, and behavioral intervention; psychosocial assessment; and outcomes assessment. Intensive cardiac rehabilitation (ICR) program means a physician or nonphysician practitioner supervised program that furnishes CR and has shown, in peer-reviewed published research, that it improves patients' cardiovascular disease through specific outcome measurements described in 42 CFR 410.49(c). Nonphysician practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as those terms are defined in section 1861(aa)(5)(A) of the Social Security Act (the Act).

Effective January 1, 2024, Medicare Part B pays for CR/ICR if specific criteria are met by the Medicare beneficiary, the CR/ICR program itself, the setting in which it is administered, and the physician administering the program.

Pulmonary rehabilitation (PR) means a physician or nonphysician practitioner supervised program for chronic obstructive pulmonary disease (COPD) and certain other chronic respiratory diseases designed to optimize physical and social performance and autonomy. Nonphysician practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as those terms are defined in section 1861(aa)(5)(A) of the Act.

Effective January 1, 2024, Medicare Part B pays for PR if specific criteria are met by the Medicare beneficiary, the PR program itself, the setting in which it is administered, and the physician administering the program, as outlined below.

140.1 – CR Program Services Furnished On or Before December 31, 2009
(Rev. 11426; Issued: 05-20-22; Effective: 01-01-22; Implementation: 07-05-22)

Medicare covers CR exercise programs for patients who meet the following criteria:

- Have a documented diagnosis of acute myocardial infarction (MI) within the preceding 12 months; or
- Have had coronary bypass surgery; or,
- Have stable angina pectoris; or,
- Have had heart valve repair/replacement; or,
- Have had percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting; or,
- Have had a heart or heart-lung transplant.

Effective for dates of services on or after March 22, 2006, services provided in connection with a CR exercise program may be considered reasonable and necessary for up to 36 sessions. Patients generally receive 2 to 3 sessions per week for 12 to 18 weeks. The contractor has discretion to cover CR beyond 18 weeks. Coverage must not exceed a total of 72 sessions for 36 weeks.

CR programs shall be performed incident to physician's services in outpatient hospitals, or outpatient settings such as clinics or offices. Follow the policies for services incident to the services of a physician as they apply in each setting. For example, see Pub. 100-02, Chapter 6, §2.4.1, and Pub. 100-02, Chapter 15, §60.1. (Refer to Publication 100-03, §20.10 for further coverage guidelines.)

140.1.1 - Coding Requirements for Cardiac Rehabilitation Services Furnished On or Before Dec. 31, 2009

(Rev. 12497; Issued: 02-08-24; Effective: 01-01-24; Implementation: 03-12-24)

The following are the applicable Healthcare Common Procedure Coding System (HCPCS) codes:

93797 - Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous
ECG monitoring (per session); and

93798 - Physician or other qualified health care professional services for outpatient cardiac rehabilitation; with continuous ECG
monitoring (per session).
Note: The above HCPCS descriptors are effective January 1, 2013.

Effective for dates of service on or after January 1, 2008, and before January 1, 2010, providers and practitioners may report more than one unit of CPT code 93797 or 97398 for a date of service if more than one CR session lasting at least 1 hour each is provided on the same day. In order to report more than one session for a given date of service, each session must last a minimum of 60 minutes. For example, if the CR provided on a given day total 1 hour and 50 minutes, then only one session should be billed to report the CR provided on that day.

140.2 – Cardiac Rehabilitation Program Services Effective for Dates of Service On or After January 1, 2024

(Rev. 12497; Issued: 02-08-24; Effective: 01-01-24; Implementation: 03-12-24)

As specified at 42 CFR 410.49, Medicare Part B covers CR for beneficiaries who have experienced one or more of the following:

• An acute MI within the preceding 12 months;
• A coronary artery bypass surgery;
• Current stable angina pectoris;
• Heart valve repair or replacement;
• PTCA or coronary stenting;
• A heart or heart-lung transplant;
• Stable, chronic heart failure defined as patients with left ventricular ejection fraction
of 35% or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks, on or after February 18, 2014; or,
• Other cardiac conditions as specified through a national coverage determination (NCD).

CR must include all of the following components:

• Physician prescribed exercise each day CR items and services are furnished.
• Cardiac risk factor modification, including education, counseling, and behavioral intervention, tailored to the individual's needs.
• Psychosocial assessment.
• Outcomes assessment.
• An individualized treatment plan detailing how components are utilized for each patient. The individualized treatment plan must be established, reviewed, and signed by a physician every 30 days.

Medicare Part B pays for CR in a physician's office or a hospital outpatient setting. All settings must have a physician or nonphysician practitioner immediately available and accessible for medical consultations and emergencies at all times when items and services are being furnished under the program. This provision is satisfied if the physician or nonphysician practitioner meets the requirements for direct supervision for physician office services, at 42 CFR 410.26, and for hospital outpatient services at 42 CFR 410.27.
Note: Nonphysician practitioners are eligible to supervise CR effective January 1, 2024.

As specified at 42 CFR 410.49(f)(1), the number of CR sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions over up to 36 weeks with the option for an additional 36 sessions over an extended period of time if approved by the Medicare Administrative Contractor (MAC).

140.2.1 – Coding Requirements for CR Services Furnished On or After January 1, 2010

(Rev. 12497; Issued: 02-08-24; Effective: 01-01-24; Implementation: 03-12-24)

The following are the applicable Current Procedural Technology (CPT) codes for CR services:

93797 Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ECG monitoring (Per Session)

93798 Physician or other qualified care health professional services for outpatient cardiac rehabilitation; with continuous ECG monitoring (Per Session)
Note: The above HCPCS descriptors are effective January 1, 2013.

Effective for dates of service on or after January 1, 2010, hospitals and practitioners may report a maximum of 2 1-hour sessions per day. In order to report one session of CR in a day, the duration of treatment must be at least 31 minutes. Two sessions of CR may only be reported in the same day if the duration of treatment is at least 91 minutes. In other words, the first session would account for 60 minutes and the second session would account for at least 31 minutes if two sessions are reported. If several shorter periods of CR are furnished on a given day, the minutes of service during those periods must be added together for reporting in 1-hour session increments.

Example: If the patient receives 20 minutes of CR in the day, no CR session may be reported because less than 31 minutes of services were furnished.

Example: If a patient receives 20 minutes of CR in the morning and 35 minutes of CR in the afternoon of a single day, the hospital or practitioner would report 1 session of CR under 1 unit of the appropriate CPT code for the total duration of 55 minutes of CR on that day.

Example: If the patient receives 70 minutes of CR in the morning and 25 minutes of CR in the afternoon of a single day, the hospital or practitioner would report two sessions of CR under the appropriate CPT code(s) because the total duration of CR on that day of 95 minutes exceeds 90 minutes.

Example: If the patient receives 70 minutes of CR in the morning and 85 minutes of CR in the afternoon of a single day, the hospital or practitioner would report two sessions of CR under the appropriate CPT code(s) for the total duration of CR of 155 minutes. A maximum of two sessions per day may be reported, regardless of the total duration of CR.

sessions after 36 (to include completed ICR sessions prior to switch). In these cases, and consistent with the information above, the -KX modifier must be included on the claim should the beneficiary participate in more than 36 CR sessions following the switch.

See Pub. 100-06, Medicare Financial Management Manual, chapter 6, section 420, and Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, section 232, and Pub. 100-08, Medicare Program Integrity Manual, chapter 10, section 10.2.2.5 for detailed information regarding CR and ICR policy and claims processing.

140.2.2 – Claims Processing Requirements for Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Services Furnished On or After January 1, 2010

(Rev. 11426; Issued: 05-20-22; Effective: 01-01-22; Implementation: 07-05-22)

NOTE: A beneficiary may switch from an ICR program to a CR program. The beneficiary is limited to a one-time switch, multiple switches are not allowable. Once the beneficiary switches from ICR to CR he or she will be limited to the number of sessions remaining in the program. For example, a beneficiary who switches from ICR to CR after 12 sessions will have 24 sessions of CR remaining, (i.e., 12 sessions of ICR + 24 sessions of CR = total of 36 sessions). Should a beneficiary experience more than one indication simultaneously, he or she may participate in a single series of CR or ICR sessions (i.e., a patient who had a MI within 12 months and currently experiences stable angina is entitled to one series of CR sessions, up to 36 1-hour sessions with contractor discretion for an additional 36 sessions; or one series of ICR sessions, up to 72 1-hour sessions over a period up to 18 weeks). Beneficiaries may not switch from CR to ICR. Upon completion of a CR or ICR program, beneficiaries must experience another indication in order to be eligible for coverage of more CR or ICR.

Contractors shall accept the inclusion of the -KX modifier on the claim line(s) as an attestation by the provider of the service that documentation is on file verifying that further treatment beyond 36 sessions of CR up to a total of 72 sessions meets the requirements of the medical policy or, for ICR, that any further sessions beyond 72 sessions within a 126-day period counting from the date of the first session, or for any sessions provided after 126 days from the date of the first session, meet the requirements of the medical policy. Beneficiaries who switch from ICR to CR may also be eligible for up to 72 combined sessions with contractor discretion for CR sessions after 36 (to include completed ICR sessions prior to switch). In these cases, and consistent with the information above, the -KX modifier must be included on the claim should the beneficiary participate in more than 36 CR sessions following the switch.

See Pub. 100-06, Medicare Financial Management Manual, chapter 6, section 420, and Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, section 232, and Pub. 100-08, Medicare Program Integrity Manual, chapter 10, section 10.2.2.5 for detailed information regarding CR and ICR policy and claims processing.

140.2.2.1 – Correct Place of Service (POS) Code for CR and ICR Services on Professional Claims

(Rev. 3058, Issued: 08-29-14, Effective: 02-18-14, Implementation: 08-18-14)

Effective for claims with dates of service on and after January 1, 2010, place of service (POS) code 11 shall be used for CR and ICR services provided in a physician's office and POS 22 shall be used for services provided in a hospital outpatient setting. All other POS codes shall be denied. Contractors shall adjust their prepayment procedure edits as appropriate.

The following messages shall be used when contractors deny CR and ICR claims for POS:

Claim Adjustment Reason Code (CARC) 171 – Payment is denied when performed/billed by this type of provider in this type of facility.

NOTE: Refer to the 832 Healthcare Policy Identification Segment (loop 2110 Service payment Information REF), if present.

Remittance Advice Remark Code (RARC) N428 - Service/procedure not covered when performed in this place of service.

Medicare Summary Notice (MSN) 21.25 - This service was denied because Medicare only covers this service in certain settings.

Group Code PR (Patient Responsibility) - Where a claim is received with the GA modifier indicating that a signed ABN is on file.

Group Code CO (Contractor Responsibility) – Where a claim is received with the GZ modifier indicating that no signed ABN is on file.

140.2.2.2 – Requirements for CR and ICR Services on Institutional Claims

(Rev. 3084, Issued: 10-03-14, Effective: 05-06-14, Implementation: 11-04-14)

Effective for claims with dates of service on and after January 1, 2010, contractors shall pay for CR and ICR services when submitted on Types of Bill (TOBs) 13X and 85X only. All other TOBs shall be denied.

The following messages shall be used when contractors deny CR and ICR claims for TOBs other than 13X and 85X:

Claim Adjustment Reason Code (CARC) 171 – Payment is denied when performed/billed by this type of provider in this type of facility. NOTE: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

Remittance Advice Remark Code (RARC) N428 - Service/procedure not covered when performed in this place of service.

Medicare Summary Notice (MSN) 21.25 - This service was denied because Medicare only covers this service in certain settings.

Group Code PR (Patient Responsibility) – Where a claim is received with the GA modifier indicating that a signed ABN is on file.

Group Code CO (Contractor Responsibility) – Where a claim is received with the GZ modifier indicating that no signed ABN is on file.

140.2.2.3 – Frequency Edits for CR and ICR Claims
(Rev. 11426; Issued: 05-20-22; Effective: 01-01-22; Implementation: 07-05-22)

Effective for claims with dates of service on or after January 1, 2010, contractors shall deny all CR claims (both professional and institutional claims) that exceed 2 units per date of service for CR and 6 units per date of service for ICR.

The following messages shall be used when contractors deny CR and ICR claims for exceeding units per date of service:

CARC 119 - Benefit maximum for this time period or occurrence has been reached.

RARC N362 - The number of days or units of service exceeds our acceptable maximum.

MSN 20.5 - These services cannot be paid because your benefits are exhausted at this time.

Spanish Version - Estos servicios no pueden ser pagados porque sus beneficios se han agotado.

Group Code PR – Where a claim is received with the GA modifier indicating that a signed ABN is on file.

Group Code CO – Where a claim is received with the GZ modifier indicating that no signed ABN is on file.

Contractors shall not research and adjust CR claims (HCPCS 93797 and 93798) paid for more than 2 units on the same date of service processed prior to the implementation of edits. However, contractors may adjust claims brought to their attention.

Contractors shall not research and adjust ICR claims (HCPCS G0422 and G0423) paid for more than 6 units on the same date of service processed prior to the implementation of edits. However, contractors may adjust claims brought to their attention.

140.2.2.4 – Edits for CR Services Exceeding 36 Sessions
(Rev. 11426; Issued: 05-20-22; Effective: 01-01-22; Implementation: 07-05-22)

Effective for claims with dates of service on or after January 1, 2010, contractors shall deny all claims with HCPCS 93797 and 93798 (both professional and institutional claims) that exceed 36 CR sessions when a -KX modifier is not included on the claim line.

The following messages shall be used when contractors deny CR claims that exceed 36 sessions, when a -KX modifier is not included on the claim line:

-CARC-) 119 – Benefit maximum for this period or occurrence has been reached.

RARC N435 - Exceeds number/frequency approved/allowed within time period without support documentation.
MSN 23.17- Medicare won’t cover these services because they are not considered medically necessary.

Spanish Version - Medicare no cubrirá estos servicios porque no son considerados necesarios por razones médicas.

Group Code PR – Where a claim is received with the GA modifier indicating that a signed ABN is on file.

Group Code CO – Where a claim is received with the GZ modifier indicating that no signed ABN is on file.

Contractors shall not research and adjust CR claims paid for more than 36 sessions processed prior to the implementation of Common Working File (CWF) edits. However, contractors may adjust claims brought to their attention.

140.2.2.5 – Edits for ICR Services Exceeding 126 Days and 72 Sessions
(Rev. 1974, Issued: 05-21-10, Effective: 01-10-10, Implementation: 10-04-10)

Effective for claims with dates of service on and after January 1, 2010, CWF shall reject ICR claims (G0422 and G0423) that exceed 72 sessions or where any billed sessions were provided after126 days from the date of the first session and a KX modifier is not included on the claim line.

The following messages shall be used when contractors deny ICR claims that exceed 72 sessions or where any billed sessions were received after the 126 days from the date of the first session:

Claim Adjustment Reason Code (CARC) 119 - Benefit maximum for this time period or occurrence has been reached.

RARC N435 - Exceeds number/frequency approved/allowed within time period without support documentation.

MSN 20.5 - These services cannot be paid because your benefits are exhausted at this time.

Spanish Version - Estos servicios no pueden ser pagados porque sus beneficios se han agotado.

Group Code PR (Patient Responsibility) – Where a claim is received with the GA modifier indicating that a signed ABN is on file.

Group Code CO (Contractor Responsibility) – Where a claim is received with the GZ modifier indicating that no signed ABN is on file.

Contractors shall not research and adjust ICR claims paid for more than 72 sessions or where any billed sessions were received after 126 days from the date of the first session that were processed prior to the implementation of CWF edits. However, contractors may adjust claims brought to their attention.

140.2.2.6 – Supplier Specialty Code 31 Requirements for ICR Claims
(Rev. 1974, Issued: 05-21-10, Effective: 01-10-10, Implementation: 10-04-10)

Effective for claims with dates of service on and after January 1, 2010, contractors shall pay for ICR services when submitted by providers enrolled as the new supplier specialty code 31 for ICR. ICR services submitted by providers enrolled as other than the new supplier specialty code 31 for ICR are to be denied using the following messages:

CARC 8: “The procedure code is inconsistent with the provider type/specialty (taxonomy). **NOTE:** Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”

RARC N95: “This provider type may not bill this service.”

MSN 21.18 – "This item or service is not covered when performed or ordered by this provider."

Spanish Version: Este servicio no está cubierto cuando es ordenado o rendido por este proveedor.

Group Code PR (Patient Responsibility) – Where a claim is received with the GA modifier indicating that a signed ABN is on file.

Group Code CO (Contractor Responsibility) – Where a claim is received with the GZ modifier indicating that no signed ABN is on file.

140.3 – ICR Program Services Effective for Dates of Service On or After January 1, 2024

(Rev. 12497; Issued: 02-08-24; Effective: 01-01-24; Implementation: 03-12-24)

As specified at 42 CFR 410.49, Medicare Part B covers ICR for beneficiaries who have experienced one or more of the following:

• An acute MI within the preceding 12 months;
• A coronary artery bypass surgery;
• Current stable angina pectoris;
• Heart valve repair or replacement;
• PTCA or coronary stenting;
• A heart or heart-lung transplant;
• Stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35% or less and NYHA class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks, on or after February 9, 2018; or,
• Other cardiac conditions as specified through an NCD. The NCD process may also be used to specify non-coverage of a cardiac condition for ICR if coverage is not supported by clinical evidence.

ICR must include all of the following components:

• Physician prescribed exercise each day CR items and services are furnished.
• Cardiac risk factor modification, including education, counseling, and behavioral intervention, tailored to the individual's needs.
• Psychosocial assessment.
• Outcomes assessment.
• An individualized treatment plan detailing how components are utilized for each patient. The individualized treatment plan must be established, reviewed, and signed by a physician every 30 days.

A list of approved ICR programs, identified through the NCD process, will be listed in the Federal Register and is available on the CMS website at https://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/ICR. In order to be approved, a program must demonstrate through peer-reviewed, published research that it has accomplished one or more of the following for its patients:

• Positively affected the progression of coronary heart disease.
• Reduced the need for coronary bypass surgery.
• Reduced the need for percutaneous coronary interventions.

An ICR program must also demonstrate through peer-reviewed published research that it accomplished a statistically significant reduction in 5 or more of the following measures for patients from their levels before CR services to after CR services:

• Low density lipoprotein.

• Triglycerides.
• Body mass index.
• Systolic blood pressure.
• Diastolic blood pressure.
• The need for cholesterol, blood pressure, and diabetes medications.

Medicare Part B pays for ICR in a physician's office or a hospital outpatient setting. All settings must have a physician or nonphysician practitioner immediately available and accessible for medical consultations and emergencies at all times when items and services are being furnished under the program. This provision is satisfied if the physician or nonphysician practitioner meets the requirements for direct supervision for physician office services, at 42 CFR 410.26, and for hospital outpatient services at 42 CFR 410.27.
Note: Nonphysician practitioners are eligible to supervise ICR effective January 1, 2024.

As specified at 42 CFR 410.49(f)(2), ICR sessions are limited to 72 1-hour sessions (as defined in section 1848(b)(5) of the Act), up to 6 sessions per day, over a period of up to 18 weeks.

140.3.1 – Coding Requirements for ICR Services Furnished On or After January 1, 2010
(Rev. 11426; Issued: 05-20-22; Effective: 01-01-22; Implementation: 07-05-22)

The following are the applicable HCPCS codes for ICR:

G0422 (Intensive cardiac rehabilitation; with or without continuous ECG monitoring, with exercise, per hour, per session)

G0423 (Intensive cardiac rehabilitation; with or without continuous ECG monitoring, without exercise, per hour, per session)

Effective for dates of service on or after January 1, 2010, hospitals and practitioners may report a maximum of 6 1-hour sessions per day. In order to report one session of ICR in a day, the duration of treatment must be at least 31 minutes. Additional sessions of ICR beyond the first session may only be reported in the same day if the duration of treatment is 31 minutes or greater beyond the hour increment. In other words, in order to report 6 sessions of ICR on a given date of service, the first five sessions would account for 60 minutes each and the sixth session would account for at least 31 minutes. If several shorter periods of ICR are furnished on a given day, the minutes of service during those periods must be added together for reporting in 1-hour session increments.

Example: If the patient receives 20 minutes of ICR in the day, no ICR session may be reported because less than 31 minutes of services were furnished.

Example: If a patient receives 20 minutes of ICR in the morning and 35 minutes of ICR in the afternoon of a single day, the hospital or practitioner would report 1 session of ICR under 1 unit of the appropriate HCPCS code for the total duration of 55 minutes of ICR on that day.

Example: If the patient receives 70 minutes of ICR in the morning and 25 minutes of ICR in the afternoon of a single day, the hospital or practitioner would report two sessions of ICR under the appropriate HCPCS code(s) because the total duration of ICR on that day of 95 minutes exceeds 90 minutes.

Example: If the patient receives 70 minutes of ICR in the morning and 85 minutes of ICR in the afternoon of a single day, the hospital or practitioner would report three sessions of ICR under the appropriate HCPCS code(s) because the total duration of ICR on that day is 155 minutes, which exceeds 150 minutes and is less than 211 minutes.

140.4 – PR Program Services Effective for Dates of Service On or After January 1, 2024
(Rev. 12497; Issued: 02-08-24; Effective: 01-01-24; Implementation: 03-12-24)

As specified in 42 CFR 410.47, Medicare Part B covers PR for beneficiaries:

- With moderate to very severe COPD (defined as GOLD classification II, III and IV), when referred by the physician treating the chronic respiratory disease;
- Who have had confirmed or suspected COVID-19 and experience persistent symptoms that include respiratory dysfunction for at least four weeks (effective January 1, 2022);
- Additional medical indications for coverage for PR may be established through an NCD.

PR must include all of the following components:

• Physician prescribed exercise during each pulmonary rehabilitation session.
• Education or training that is closely and clearly related to the individual's care and treatment which is tailored to the individual's needs and assists in achievement of goals toward independence in activities of daily living, adaptation to limitations and improved quality of life. Education must include information on respiratory problem management and, if appropriate, brief smoking cessation counseling.
• Psychosocial assessment.
• Outcomes assessment.
• An individualized treatment plan detailing how components are utilized for each patient. The individualized treatment plan must be established, reviewed, and signed by a physician every 30 days.

Medicare Part B pays for PR in a physician's office or a hospital outpatient setting. All settings must have the following: (i) A physician or nonphysician practitioner immediately available and accessible for medical consultations and emergencies at all times when items and services are being furnished under the program. This provision is satisfied if the physician or nonphysician practitioner meets the requirements for direct supervision for physician office services, at 42 CFR 410.26, and for hospital outpatient services at 42 CFR 410.27, and, (ii) The necessary cardio-pulmonary, emergency, diagnostic, and therapeutic life-saving equipment accepted by the medical community as medically necessary (for example, oxygen, cardiopulmonary resuscitation equipment, and defibrillator) to treat chronic respiratory disease.
Note: Nonphysician practitioners are eligible to supervise PR effective January 1, 2024.

As specified at 42 CFR 410.47(e), the number of PR sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions over up to 36 weeks with the option for an additional 36 sessions over an extended period of time if approved by the MACs.

140.4.1 – Coding Requirements for PR Services Furnished On or After January 1, 2010
(Rev. 11426; Issued: 05-20-22; Effective: 01-01-22; Implementation: 07-05-22)

The following are the applicable HCPCS codes for PR:

Effective January 1, 2010 through December 31, 2021

G0424 (Pulmonary rehabilitation, including exercise (includes monitoring), per hour, per session)

Effective January 1, 2022

94625 (Physician or other qualified health care professional services for outpatient pulmonary rehabilitation; without continuous oximetry monitoring (per session))

94626 (Physician or other qualified health care professional services for outpatient pulmonary rehabilitation; with continuous oximetry monitoring (per session)

Effective for dates of service on or after January 1, 2010, hospitals and practitioners may report a maximum of 2 1-hour sessions per day. In order to report one session of PR in a day, the duration of treatment must be at least 31 minutes. Two sessions of PR may only be reported in the same day if the duration of treatment is at least 91 minutes. In other words, the first session would account for 60 minutes and the second session would account for at least 31 minutes, if two sessions are reported. If several shorter periods of PR are furnished on a given day, the minutes of service during those periods must be added together for reporting in 1-hour session increments.

Example: If the patient receives 20 minutes of PR in the day, no PR session may be reported because less than 31 minutes of services were furnished.

Example: If a patient receives 20 minutes of PR in the morning and 35 minutes of PR in the afternoon of a single day, the hospital or practitioner would report 1 session of PR under 1 unit of HCPCS code/CPT code for the total duration of 55 minutes of PR on that day.

Example: If the patient receives 70 minutes of pulmonary rehabilitation services in the morning and 25 minutes of pulmonary rehabilitation services in the afternoon of a single day, the hospital or practitioner would report two sessions of pulmonary rehabilitation services under the HCPCS G-code/CPT codes because the total duration of pulmonary rehabilitation services on that day of 95 minutes exceeds 90 minutes.

Example: If the patient receives 70 minutes of pulmonary rehabilitation services in the morning and 85 minutes of pulmonary rehabilitation services in the afternoon of a single day, the hospital or practitioner would report two sessions of pulmonary rehabilitation services under the HCPCS G-code/CPT codes for the total duration of pulmonary rehabilitation services of 155 minutes. A maximum of two sessions per day may be reported, regardless of the total duration of pulmonary rehabilitation services.

140.4.2 – Claims Processing Requirements for Pulmonary Rehabilitation (PR) Services Furnished On or After January 1, 2010

(Rev. 1966, Issued: 05-07-10, Effective: 01-01-10, Implementation: 10-04-10)

140.4.2.1 – Correct Place of Service (POS) Code for PR Services on Professional Claims

(Rev. 11021; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

Effective for claims with dates of service on and after January 1, 2010, place of service (POS) code 11 shall be used for pulmonary rehabilitation (PR) services provided in a physician's office and POS 22 shall be used for services provided in a hospital outpatient setting. All other POS codes shall be denied. Medicare contractors shall adjust their prepayment procedure edits as appropriate.

The following messages shall be used when Medicare contractors deny PR claims for POS:

CARC 96: "Non-covered charge(s)."

RARC N428: "Service/procedure not covered when performed in this place of service."

Medicare Summary Notice (MSN) 21.25: “This service was denied because Medicare only covers this service in certain settings.”

Spanish Version: El servicio fue denegado porque Medicare solamente lo cubre en ciertas situaciones."

NOTE: This is a new MSN message.

Contractors shall use Group Code PR (Patient `Responsibility) assigning financial liability to the beneficiary, if a claim is received with a GA modifier indicating a signed ABN is on file.

Contractors shall use Group Code CO (Contractual Obligation) assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.

140.4.2.2 – Requirements for PR Services on Institutional Claims
(Rev. 11021; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

Effective for claims with dates of service on and after January 1, 2010, Medicare contractors shall pay for PR services when submitted on a type of bill (TOB) 13X and 85X only, along with revenue code 0948. All other TOBs shall be denied.

The following messages shall be used when Medicare contractors deny PR claims for TOB:

CARC 96: “Non-covered charge(s).”

RARC N428: “Service/procedure not covered when performed in this place of service.”

Medicare Summary Notice (MSN) 21.25: “This service was denied because Medicare only covers this service in certain settings.”

Spanish Version: El servicio fue denegado porque Medicare solamente lo cubre en ciertas situaciones."

NOTE: This is a new MSN message.

Contractors shall use Group Code PR (Patient `Responsibility) assigning financial liability to the beneficiary, if a claim is received with a GA modifier indicating a signed ABN is on file.

Contractors shall use Group Code CO (Contractual Obligation) assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.

140.4.2.3 – Daily Frequency Edits for PR Claims
(Rev. 1966, Issued: 05-07-10, Effective: 01-01-10, Implementation: 10-04-10)

Effective for claims with dates of service on or after January 1, 2010, Medicare contractors shall deny all PR claims (both professional and institutional claims) that exceed two units on the same date of service.

The following messages shall be used when Medicare contractors deny PR claims for exceeding the daily frequency limit:

CARC 119: “Benefit maximum for this time period or occurrence has been reached.”

RARC N362: “The number of days or units of service exceeds our acceptable maximum.”

MSN 20.5: “These services cannot be paid because your benefits are exhausted at this time.”

Spanish Version: “Estos servicios no pueden ser pagados porque sus beneficios se han agotado.”

Contractors shall use Group Code PR (Patient Responsibility) assigning financial liability to the beneficiary, if a claim is received with a GA modifier indicating a signed ABN is on file.

Contractors shall use Group Code CO (Contractual Obligation) assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.

140.4.2.4 – Edits for PR Services Exceeding 36 Sessions

(Rev. 1966, Issued: 05-07-10, Effective: 01-01-10, Implementation: 10-04-10)

When a beneficiary has reached 37 PR sessions, CWF shall reject the claims to the contractors if the KX modifier is not included on the claim line. Effective for claims with dates of service on or after January 1, 2010, Medicare contractors shall deny all claims (both professional and institutional claims) that exceed 36 PR sessions without a KX modifier included on the claim line.

The following messages shall be used when Medicare contractors deny PR claims that exceed 36 sessions, without the KX modifier on the claim line:

CARC 151: “Payment adjusted because the payer deems the information submitted does not support this many/frequency of services.”

MSN 23.17: “Medicare won’t cover these services because they are not considered medically necessary.”

Spanish Version: “Medicare no cubrirá estos servicios porque no son considerados necesarios por razones médicas.”

Contractors shall use Group Code PR (Patient Responsibility) assigning financial liability to the beneficiary, if a claim is received with a GA modifier indicating a signed ABN is on file.

Contractors shall use Group Code CO (Contractual Obligation) assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.

140.4.2.5 – Edits for PR Services Exceeding 72 Sessions

(Rev. 12497; Issued: 02-08-24; Effective: 01-01-24; Implementation: 03-12-24)

Effective for claims with dates of service on and after January 1, 2010, through December 31, 2021, CWF shall reject PR claims that exceed 72 sessions. Medicare contractors shall deny PR claims that exceed 72 sessions regardless of whether the -KX modifier is submitted on the claim line.

The following messages shall be used when Medicare contractors deny PR claims that exceed 72 sessions:

CARC 119: “Benefit maximum for this time period or occurrence has been reached.”

RARC N362: “The number of days or units of service exceeds our acceptable maximum.”

MSN 20.5: “These services cannot be paid because your benefits are exhausted at this time.”

Spanish Version: “Estos servicios no pueden ser pagados porque sus beneficios se han agotado.”

Contractors shall use Group Code PR assigning financial liability to the beneficiary, if a claim is received with a GA modifier indicating a signed ABN is on file.

Contractors shall use Group Code CO assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.

Effective for claims with dates of service on and after January 1, 2022, Medicare Contractors shall deny PR claims that exceed 72 sessions only when the -KX modifier is not submitted on the claim line.

150 - Billing Requirements for Bariatric Surgery for Treatment of Morbid Obesity

(Rev. 931, Issued: 04-28-06, Effective: 02-21-06, Implementation: 05-30-06 Carrier/10-02-06 FI)

150.1 - General

(Rev. 2841, Issued: 12-23-13, Effective: 09-24-13, Implementation: 12-17-13)

Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity

Effective for services on or after February 21, 2006, Medicare has determined that the following bariatric surgery procedures are reasonable and necessary under certain conditions for the treatment of morbid obesity. The patient must have a body-mass index (BMI) ≥35, have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity. This medical information must be documented in the patient's medical record. In addition, the procedure must be performed at an approved facility. A list of approved facilities may be found at http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/Bariatric-Surgery.html

Effective for services performed on and after February 12, 2009, Medicare has determined that Type 2 diabetes mellitus is a co-morbidity for purposes of processing bariatric surgery claims.

Effective for dates of service on and after September 24, 2013, the Centers for Medicare & Medicaid Services (CMS) has removed the certified facility requirements for Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity.

Please note the additional national coverage determinations related to bariatric surgery will be consolidated and subsumed into Publication 100-03, Chapter 1, section 100.1. These include sections 40.5, 100.8, 100.11 and 100.14.

Open Roux-en-Y gastric bypass (RYGBP)

Laparoscopic Roux-en-Y gastric bypass (RYGBP)

Laparoscopic adjustable gastric banding (LAGB)

Open biliopancreatic diversion with duodenal switch (BPD/DS) or gastric reduction duodenal switch (BPD/GRDS)

Laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS) or gastric reduction duodenal switch (BPD/GRDS)

Laparoscopic sleeve gastrectomy (LSG) (Effective June 27, 2012, covered at Medicare Administrative Contractor (MAC) discretion.

150.2 - HCPCS Procedure Codes for Bariatric Surgery

(Rev. 2641, Issued: 01-29-13, Effective: 06-27-12, Implementation: 02-28-13)

A. Covered HCPCS Procedure Codes

For services on or after February 21, 2006, the following HCPCS procedure codes are covered for bariatric surgery:

43770 - Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric band (gastric band and subcutaneous port components).

43644 - Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less).

43645 - Laparoscopy with gastric bypass and small intestine reconstruction to limit absorption. (Do not report 43645 in conjunction with 49320, 43847.)

43845 - Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch).

43846 - Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less Roux-en-Y gastroenterostomy. (For greater than 150 cm, use 43847.) (For laparoscopic procedure, use 43644.)

43847 - With small intestine reconstruction to limit absorption.

43775- Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy) (Effective June 27, 2012, covered at contractor’s discretion.)

B. Non-Covered HCPCS Procedure Codes

For services on or after February 21, 2006, the following HCPCS procedure codes are non-covered for bariatric surgery:

43842 - Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical banded gastroplasty NOC code 43999 used to bill for:

Laparoscopic vertical banded gastroplasty
Open sleeve gastrectomy
Laparoscopic sleeve gastrectomy (for contractor non-covered instances)
Open adjustable gastric banding

150.3 - ICD Procedure Codes for Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity (A/MACs only)

(Rev. 12683 Issued: 06-13-24; Effective: 01-01-20; Implementation: 07-15-24)

Covered ICD Procedure Codes

For services on or after October 1, 2015, the following independent ICD-10 procedure codes are covered for bariatric surgery:

0D16479	Bypass Stomach to Duodenum with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0D1647A	Bypass Stomach to Jejunum with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0D1647B	Bypass Stomach to Ileum with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0D1647L	Bypass Stomach to Transverse Colon with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0D164J9	Bypass Stomach to Duodenum with Synthetic Substitute, Percutaneous Endoscopic Approach
0D164JA	Bypass Stomach to Jejunum with Synthetic Substitute, Percutaneous Endoscopic Approach
0D164JB	Bypass Stomach to Ileum with Synthetic Substitute, Percutaneous Endoscopic Approach
0D164JL	Bypass Stomach to Transverse Colon with Synthetic Substitute, Percutaneous Endoscopic Approach
0D164K9	Bypass Stomach to Duodenum with Non-autologous Tissue Substitute, Percutaneous Endoscopic Approach
0D164KA	Bypass Stomach to Jejunum with Non-autologous Tissue Substitute, Percutaneous Endoscopic Approach
0D164KB	Bypass Stomach to Ileum with Non-autologous Tissue Substitute, Percutaneous Endoscopic Approach
0D164KL	Bypass Stomach to Transverse Colon with Non-autologous Tissue Substitute, Percutaneous Endoscopic Approach
0D164Z9	Bypass Stomach to Duodenum, Percutaneous Endoscopic Approach
0D164ZA	Bypass Stomach to Jejunum, Percutaneous Endoscopic Approach
0D164ZB	Bypass Stomach to Ileum, Percutaneous Endoscopic Approach

0D164ZL Bypass Stomach to Transverse Colon, Percutaneous Endoscopic Approach

0D16079 Bypass Stomach to Duodenum with Autologous Tissue Substitute, Open Approach

0D1607A Bypass Stomach to Jejunum with Autologous Tissue Substitute, Open Approach

0D1607B Bypass Stomach to Ileum with Autologous Tissue Substitute, Open Approach

0D1607L Bypass Stomach to Transverse Colon with Autologous Tissue Substitute, Open Approach

0D160J9 Bypass Stomach to Duodenum with Synthetic Substitute, Open Approach

0D160JA Bypass Stomach to Jejunum with Synthetic Substitute, Open Approach

0D160JB Bypass Stomach to Ileum with Synthetic Substitute, Open Approach

0D160JL Bypass Stomach to Transverse Colon with Synthetic Substitute, Open Approach

0D160K9 Bypass Stomach to Duodenum with Non-autologous Tissue Substitute, Open Approach

0D160KA Bypass Stomach to Jejunum with Non-autologous Tissue Substitute, Open Approach

0D160KB Bypass Stomach to Ileum with Non-autologous Tissue Substitute, Open Approach

0D160KL Bypass Stomach to Transverse Colon with Non-autologous Tissue Substitute, Open Approach

0D160Z9 Bypass Stomach to Duodenum, Open Approach

0D160ZA Bypass Stomach to Jejunum, Open Approach

0D160ZB Bypass Stomach to Ileum, Open Approach

0D160ZL Bypass Stomach to Transverse Colon, Open Approach

0D16879 Bypass Stomach to Duodenum with Autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic

0D1687A Bypass Stomach to Jejunum with Autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic

0D1687B Bypass Stomach to Ileum with Autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic

0D1687L	Bypass Stomach to Transverse Colon with Autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic
0D168J9	Bypass Stomach to Duodenum with Synthetic Substitute, Via Natural or Artificial Opening Endoscopic
0D168JA	Bypass Stomach to Jejunum with Synthetic Substitute, Via Natural or Artificial Opening Endoscopic
0D168JB	Bypass Stomach to Ileum with Synthetic Substitute, Via Natural or Artificial Opening Endoscopic
0D168JL	Bypass Stomach to Transverse Colon with Synthetic Substitute, Via Natural or Artificial Opening Endoscopic
0D168K9	Bypass Stomach to Duodenum with Non-autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic
0D168KA	Bypass Stomach to Jejunum with Non-autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic
0D168KB	Bypass Stomach to Ileum with Non-autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic
0D168KL	Bypass Stomach to Transverse Colon with Non-autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic
0D168Z9	Bypass Stomach to Duodenum, Via Natural or Artificial Opening Endoscopic
0D168ZA	Bypass Stomach to Jejunum, Via Natural or Artificial Opening Endoscopic
0D168ZB	Bypass Stomach to Ileum, Via Natural or Artificial Opening Endoscopic
0D168ZL	Bypass Stomach to Transverse Colon, Via Natural or Artificial Opening Endoscopic
0DV64CZ	Restriction of Stomach with Extraluminal Device, Percutaneous Endoscopic Approach

To describe either laparoscopic or open BPD with DS or GRDS, one code from each of the following three groups must be on the claim:

Group 1:

0DB60Z3	Excision of Stomach, Open Approach, Vertical
0DB60ZZ	Excision of Stomach, Open Approach
0DB63Z3	Excision of Stomach, Percutaneous Approach, Vertical
0DB63ZZ	Excision of Stomach, Percutaneous Approach

0DB67Z3 Excision of Stomach, Via Natural or Artificial Opening, Vertical
0DB67ZZ Excision of Stomach, Via Natural or Artificial Opening
0DB68Z3 Excision of Stomach, Via Natural or Artificial Opening Endoscopic, Vertical

Group 2:
(Note: One code from A-C below is required for a correct equivalent)
0DB80ZZ Excision of Small Intestine, Open Approach – A
0DB84ZZ Excision of Small Intestine, Perc Endo Approach – A (Effective 01-01-20)
0DB90ZZ Excision of Duodenum, Open Approach – A
0DB93ZZ Excision of Duodenum, Percutaneous Approach – A (Effective 01-01-20)
0DBB0ZZ Excision of Ileum, Open Approach – A
0DBB3ZZ Excision of Ileum, Percutaneous Approach – A (Effective 01-01-20)
0D160ZB Bypass Stomach to Ileum, Open Approach – B
0D164ZB Bypass Stomach to Ileum, Percutaneous Endoscopic Approach – B (Effective 01-01-20)
0F190Z3 Bypass Common Bile Duct to Duodenum, Open Approach – C
0F194Z3 Bypass Common Bile Duct to Duodenum, Perc Endo Approach – C (Effective 01-01-20)

Group 3:

0D19079 Bypass Duodenum to Duodenum with Autologous Tissue Substitute, Open Approach

0D1907A Bypass Duodenum to Jejunum with Autologous Tissue Substitute, Open Approach

0D1907B Bypass Duodenum to Ileum with Autologous Tissue Substitute, Open Approach

0D190J9 Bypass Duodenum to Duodenum with Synthetic Substitute, Open Approach
0D190JA Bypass Duodenum to Jejunum with Synthetic Substitute, Open Approach
0D190JB Bypass Duodenum to Ileum with Synthetic Substitute, Open Approach

0D190K9 Bypass Duodenum to Duodenum with Non-autologous Tissue Substitute, Open Approach

0D190KA Bypass Duodenum to Jejunum with Non-autologous Tissue Substitute, Open Approach

0D190KB Bypass Duodenum to Ileum with Non-autologous Tissue Substitute, Open Approach
0D190Z9 Bypass Duodenum to Duodenum, Open Approach

0D190ZA Bypass Duodenum to Jejunum, Open Approach

0D190ZB Bypass Duodenum to Ileum, Open Approach

0D19479 Bypass Duodenum to Duodenum with Autologous Tissue Substitute, Percutaneous Endoscopic Approach

0D1947A Bypass Duodenum to Jejunum with Autologous Tissue Substitute, Percutaneous Endoscopic Approach

0D1947B Bypass Duodenum to Ileum with Autologous Tissue Substitute, Percutaneous Endoscopic Approach

0D194J9 Bypass Duodenum to Duodenum with Synthetic Substitute, Percutaneous Endoscopic Approach

0D194JA Bypass Duodenum to Jejunum with Synthetic Substitute, Percutaneous Endoscopic Approach

0D194JB Bypass Duodenum to Ileum with Synthetic Substitute, Percutaneous Endoscopic Approach

0D194K9 Bypass Duodenum to Duodenum with Non-autologous Tissue Substitute, Percutaneous Endoscopic Approach

0D194KA Bypass Duodenum to Jejunum with Non-autologous Tissue Substitute, Percutaneous Endoscopic Approach

0D194KB Bypass Duodenum to Ileum with Non-autologous Tissue Substitute, Percutaneous Endoscopic Approach

0D194Z9 Bypass Duodenum to Duodenum, Percutaneous Endoscopic Approach

0D194ZA Bypass Duodenum to Jejunum, Percutaneous Endoscopic Approach

0D194ZB Bypass Duodenum to Ileum, Percutaneous Endoscopic Approach

0D19879 Bypass Duodenum to Duodenum with Autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic

0D1987A Bypass Duodenum to Jejunum with Autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic

0D1987B Bypass Duodenum to Ileum with Autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic

0D198J9 Bypass Duodenum to Duodenum with Synthetic Substitute, Via Natural or Artificial Opening Endoscopic

0D198JA Bypass Duodenum to Jejunum with Synthetic Substitute, Via Natural or Artificial Opening Endoscopic

0D198JB Bypass Duodenum to Ileum with Synthetic Substitute, Via Natural or Artificial Opening Endoscopic

0D198K9 Bypass Duodenum to Duodenum with Non-autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic

0D198KA Bypass Duodenum to Jejunum with Non-autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic

0D198KB Bypass Duodenum to Ileum with Non-autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic

0D198Z9 Bypass Duodenum to Duodenum, Via Natural or Artificial Opening Endoscopic

0D198ZA Bypass Duodenum to Jejunum, Via Natural or Artificial Opening Endoscopic

0D198ZB Bypass Duodenum to Ileum, Via Natural or Artificial Opening Endoscopic

0D1A07A Bypass Jejunum to Jejunum with Autologous Tissue Substitute, Open Approach

0D1A07B Bypass Jejunum to Ileum with Autologous Tissue Substitute, Open Approach

0D1A0JA Bypass Jejunum to Jejunum with Synthetic Substitute, Open Approach

0D1A0JB Bypass Jejunum to Ileum with Synthetic Substitute, Open Approach

0D1A0KA Bypass Jejunum to Jejunum with Non-autologous Tissue Substitute, Open Approach

0D1A0KB Bypass Jejunum to Ileum with Non-autologous Tissue Substitute, Open Approach

0D1A0ZA Bypass Jejunum to Jejunum, Open Approach

0D1A0ZB Bypass Jejunum to Ileum, Open Approach

0D1A47A Bypass Jejunum to Jejunum with Autologous Tissue Substitute, Percutaneous Endoscopic Approach

0D1A47B Bypass Jejunum to Ileum with Autologous Tissue Substitute, Percutaneous Endoscopic Approach

0D1A4JA Bypass Jejunum to Jejunum with Synthetic Substitute, Percutaneous Endoscopic Approach

0D1A4JB Bypass Jejunum to Ileum with Synthetic Substitute, Percutaneous Endoscopic Approach

0D1A4KA Bypass Jejunum to Jejunum with Non-autologous Tissue Substitute, Percutaneous Endoscopic Approach

0D1A4KB Bypass Jejunum to Ileum with Non-autologous Tissue Substitute, Percutaneous Endoscopic Approach

0D1A4ZA Bypass Jejunum to Jejunum, Percutaneous Endoscopic Approach

0D1A4ZB Bypass Jejunum to Ileum, Percutaneous Endoscopic Approach

0D1A87A Bypass Jejunum to Jejunum with Autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic

0D1A87B	Bypass Jejunum to Ileum with Autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic
0D1A8JA	Bypass Jejunum to Jejunum with Synthetic Substitute, Via Natural or Artificial Opening Endoscopic
0D1A8JB	Bypass Jejunum to Ileum with Synthetic Substitute, Via Natural or Artificial Opening Endoscopic
0D1A8KA	Bypass Jejunum to Jejunum with Non-autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic
0D1A8KB	Bypass Jejunum to Ileum with Non-autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic
0D1A8ZA	Bypass Jejunum to Jejunum, Via Natural or Artificial Opening Endoscopic
0D1A8ZB	Bypass Jejunum to Ileum, Via Natural or Artificial Opening Endoscopic
0D1A8ZH	Bypass Jejunum to Cecum, Via Natural or Artificial Opening Endoscopic
0D1B07B	Bypass Ileum to Ileum with Autologous Tissue Substitute, Open Approach
0D1B0JB	Bypass Ileum to Ileum with Synthetic Substitute, Open Approach
0D1B0KB	Bypass Ileum to Ileum with Non-autologous Tissue Substitute, Open Approach
0D1B0ZB	Bypass Ileum to Ileum, Open Approach
0D1B47B	Bypass Ileum to Ileum with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0D1B4JB	Bypass Ileum to Ileum with Synthetic Substitute, Percutaneous Endoscopic Approach
0D1B4KB	Bypass Ileum to Ileum with Non-autologous Tissue Substitute, Percutaneous Endoscopic Approach
0D1B4ZB	Bypass Ileum to Ileum, Percutaneous Endoscopic Approach
0D1B87B	Bypass Ileum to Ileum with Autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic
0D1B8JB	Bypass Ileum to Ileum with Synthetic Substitute, Via Natural or Artificial Opening Endoscopic

0D1B8KB Bypass Ileum to Ileum with Non-autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic

0D1B8ZB Bypass Ileum to Ileum, Via Natural or Artificial Opening Endoscopic

0D1B8ZH Bypass Ileum to Cecum, Via Natural or Artificial Opening Endoscopic

NOTE: There is no distinction between open and laparoscopic BPD with DS or GRDS for the inpatient setting. For either approach, one code from each of the above three groups must appear on the claim to be covered.

Effective October 1, 2015, the following ICD-10 procedure code is covered for bariatric surgery at contractor discretion:

0DB64Z3 Excision of stomach, percutaneous endoscopic approach, vertical.

150.4 - ICD Diagnosis Codes for Bariatric Surgery

(Rev. 13608; Issued: 01-29-26; Effective: 08-25-25; Implementation: 08-25-25)

For services on or after October 1, 2015, the following ICD-10 diagnosis code is covered for bariatric surgery if certain other conditions are met:

E66.01 - Morbid (severe) obesity due to excess calories

E66.812 - Obesity, class 2, effective October 1, 2024

E66.813 – Obesity, class 3, effective October 1, 2024

Effective for services performed on and after February 12, 2009, type 2 diabetes mellitus (T2DM) is considered a comorbid condition related to morbid obesity for covered bariatric surgery procedures in Medicare beneficiaries with a BMI ≥35. When T2DM is the comorbid condition related to morbid obesity, the claim must include a covered ICD procedure code, ICD diagnosis code E66.01, E66.812 or E66.813 as a primary diagnosis, a covered ICD diagnosis code indicating T2DM as a secondary diagnosis, and an ICD diagnosis code indicating a BMI ≥ 35 as a secondary diagnosis.

150.5 - ICD Diagnosis Codes for BMI ≥35

(Rev. 11021; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

The following ICD-10 diagnosis codes identify BMI ≥35:

Z68.35 - Body Mass Index 35.0-35.9, adult
Z68.36 - Body Mass Index 36.0-36.9, adult
Z68.37 - Body Mass Index 37.0-37.9, adult
Z68.38 - Body Mass Index 38.0-38.9, adult
Z68.39 - Body Mass Index 39.0-39.9, adult
Z68.41 - Body Mass Index 40.0-44.9, adult
Z68.42 - Body Mass Index 45.0-49.9, adult
Z68.43 - Body Mass Index 50.0-59.9, adult
Z68.44 - Body Mass Index 60.0-69.9, adult
Z68.45 - Body Mass Index 70.0 and over, adult

150.5.1 – ICD Codes for Type II Diabetes Mellitus Complication

(Rev. 11021; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

E11.9	Type 2 diabetes mellitus without complications
E13.9	Other specified diabetes mellitus without complications
E11.65	Type 2 diabetes mellitus with hyperglycemia
E13.10	Other specified diabetes mellitus with ketoacidosis without coma
E11.69	Type 2 diabetes mellitus with other specified complication
	Note: E11.69 with E11.65 are a cluster BUT since each code on its own justifies the service, the combination is not required together for this policy.
E11.00	Type 2 diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)
E11.01	Type 2 diabetes mellitus with hyperosmolarity with coma
E13.00	Other specified diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)
E13.01	Other specified diabetes mellitus with hyperosmolarity with coma
	Note: E11.00 with E11.65 are a cluster BUT since each code on its own justifies the service, the combination is not required together for this policy.
E11.641	Type 2 diabetes mellitus with hypoglycemia with coma
E13.11	Other specified diabetes mellitus with ketoacidosis with coma
E13.641	Other specified diabetes mellitus with hypoglycemia with coma
	Note: E11.01 with E11.65 are a cluster BUT since each code on its own justifies the service, the combination is not required together for this policy.
E11.21	Type 2 diabetes mellitus with diabetic nephropathy
E11.22	Type 2 diabetes mellitus with diabetic chronic kidney disease
E11.29	Type 2 diabetes mellitus with other diabetic kidney complication
E13.21	Other specified diabetes mellitus with diabetic nephropathy
E13.22	Other specified diabetes mellitus with diabetic chronic kidney disease
E13.29	Other specified diabetes mellitus with other diabetic kidney complication
	Note: E11.21 with E11.65 are a cluster BUT since each code on its own justifies the service, the combination is not required together for this policy.
E11.3211	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
E11.3212	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E11.3213	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E11.3591	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye
E11.3592	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye
E11.3593	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral
E11.37X1	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye
E11.37X2	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye

E11.37X3	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral
E11.3291	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye
E11.3292	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye
E11.3293	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral
E11.3311	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E11.3312	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E11.3313	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E11.3391	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye
E11.3392	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye
E11.3393	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral
E11.3411	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye
E11.3412	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye
E11.3413	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E11.3491	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye
E11.3492	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye
E11.3493	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral
E11.3511	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E11.3512	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E11.3513	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral
E11.3521	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye
E11.3522	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye
E11.3523	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral
E11.3531	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye
E11.3532	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye
E11.3533	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral

E11.3591	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye
E11.3592	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye
E11.3593	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral
E11.37X1	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye
E11.37X2	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye
E11.37X3	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral
E13.311	Other specified diabetes mellitus with unspecified diabetic retinopathy with macular edema
E13.319	Other specified diabetes mellitus with unspecified diabetic retinopathy without macular edema
E13.3211	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
E13.3212	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E13.3213	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E13.3291	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye
E13.3292	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye
E13.3293	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral
E13.3311	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E13.3312	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E13.3313	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E13.3391	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye
E13.3392	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye
E13.3393	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral
E13.3411	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye
E13.3412	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye
E13.3413	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E13.3491	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye
E13.3492	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye

E13.3493	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral
E13.3511	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E13.3512	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E13.3513	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral
E13.3521	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye
E13.3522	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye
E13.3523	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral
E13.3531	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye
E13.3532	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye
E13.3533	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral
E13.3541	Other specified diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye
E13.3542	Other specified diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye
E13.3543	Other specified diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral
E13.3551	Other specified diabetes mellitus with stable proliferative diabetic retinopathy, right eye
E13.3552	Other specified diabetes mellitus with stable proliferative diabetic retinopathy, left eye
E13.3553	Other specified diabetes mellitus with stable proliferative diabetic retinopathy, bilateral
E13.3591	Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye
E13.3592	Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye
E13.3593	Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral
E13.36	Other specified diabetes mellitus with diabetic cataract
E13.39	Other specified diabetes mellitus with other diabetic ophthalmic complication
E11.311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema OR
E11.319	Type 2 diabetes mellitus with unspecified diabetic retinopathy without macular edema OR
E11.36	Type 2 diabetes mellitus with diabetic cataract OR
E11.39	Type 2 diabetes mellitus with other diabetic ophthalmic complication AND

	Note: E11.39 with E11.65 are a cluster BUT since each code on its own justifies the service, the combination is not required together for this policy
E13.37X1	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye
E13.37X2	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye
E13.37X3	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral
E11.40	Type 2 diabetes mellitus with diabetic neuropathy, unspecified
E11.41	Type 2 diabetes mellitus with diabetic mononeuropathy
E11.42	Type 2 diabetes mellitus with diabetic polyneuropathy
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy
E11.44	Type 2 diabetes mellitus with diabetic amyotrophy
E11.49	Type 2 diabetes mellitus with other diabetic neurological complication
E11.610	Type 2 diabetes mellitus with diabetic neuropathic arthropathy
E13.40	Other specified diabetes mellitus with diabetic neuropathy, unspecified
E13.41	Other specified diabetes mellitus with diabetic mononeuropathy
E13.42	Other specified diabetes mellitus with diabetic polyneuropathy
E13.43	Other specified diabetes mellitus with diabetic autonomic (poly)neuropathy
E13.44	Other specified diabetes mellitus with diabetic amyotrophy
E13.49	Other specified diabetes mellitus with other diabetic neurological complication
E13.610	Other specified diabetes mellitus with diabetic neuropathic arthropathy
	Note: E11.40 with E11.65 are a cluster BUT since each code on its own justifies the service, the combination is not required together for this policy.
E11.51	Type 2 diabetes mellitus with diabetic peripheral angiopathy without gangrene
E11.52	Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene
E11.59	Type 2 diabetes mellitus with other circulatory complications
E13.51	Other specified diabetes mellitus with diabetic peripheral angiopathy without gangrene
E13.52	Other specified diabetes mellitus with diabetic peripheral angiopathy with gangrene
E13.59	Other specified diabetes mellitus with other circulatory complications
	Note: E11.51 with E11.65 are a cluster BUT since each code on its own justifies the service, the combination is not required together for this policy.
E11.618	Type 2 diabetes mellitus with other diabetic arthropathy
E11.620	Type 2 diabetes mellitus with diabetic dermatitis
E11.621	Type 2 diabetes mellitus with foot ulcer
E11.622	Type 2 diabetes mellitus with other skin ulcer
E11.628	Type 2 diabetes mellitus with other skin complications
E11.630	Type 2 diabetes mellitus with periodontal disease
E11.638	Type 2 diabetes mellitus with other oral complications
E11.649	Type 2 diabetes mellitus with hypoglycemia without coma
E13.618	Other specified diabetes mellitus with other diabetic arthropathy
E13.620	Other specified diabetes mellitus with diabetic dermatitis

E13.621	Other specified diabetes mellitus with foot ulcer
E13.622	Other specified diabetes mellitus with other skin ulcer
E13.628	Other specified diabetes mellitus with other skin complications
E13.630	Other specified diabetes mellitus with periodontal disease
E13.638	Other specified diabetes mellitus with other oral complications
E13.649	Other specified diabetes mellitus with hypoglycemia without coma
E13.65	Other specified diabetes mellitus with hyperglycemia
E13.69	Other specified diabetes mellitus with other specified complication
	Note: E11.69 with E11.65 are a cluster BUT since each code on its own justifies the service, the combination is not required together for this policy.
E13.8	Other specified diabetes mellitus with unspecified complications
E11.8	Type 2 diabetes mellitus with unspecified complications
	Note: E11.8 with E11.65 are a cluster BUT since each code on its own justifies the service, the combination is not required together for this policy.

150.6 - Claims Guidance for Payment

(Rev. 13608; Issued: 01-29-26; Effective: 08-25-25; Implementation: 08-25-25)

Covered Bariatric Surgery Procedures for Treatment of Co-Morbid Conditions Related to Morbid Obesity

Contractors shall process covered bariatric surgery claims as follows:

C. Identify bariatric surgery claims.

Contractors identify inpatient bariatric surgery claims by the presence of ICD-10 diagnosis code E66.01, E66.812 or E66.813 as the primary diagnosis (for morbid obesity) and one of the covered ICD-10 procedure codes listed in §150.3.

Contractors identify practitioner bariatric surgery claims by the presence of ICD-10 diagnosis code E66.01, E66.812 or E66.813 as the primary diagnosis (for morbid obesity) and one of the covered HCPCS procedure codes listed in §150.2.

D. Perform facility certification validation for all bariatric surgery claims on a pre-pay basis up to and including date of service September 23, 2013.

A list of approved facilities is found at the link noted in section 150.1, section A, above.

E. Review bariatric surgery claims data and determine whether a pre- or post-pay sample of bariatric surgery claims needs further review to assure that the beneficiary has a BMI ≥35 (Z68.35-Z68.45) (see ICD-10 equivalents above in section 150.5), and at least one co-morbidity related to obesity.

The A/B MAC medical director may define the appropriate method for addressing the obesity-related co-morbid requirement.

Effective for dates of service on and after September 24, 2013, CMS has removed the certified facility requirements for Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity.

NOTE: If ICD-10 diagnosis code E66.01, E66.812 or E66.813 is present, but a covered procedure code (listed in §150.2 or §150.3) is/are not present, the claim is not for bariatric surgery and should be processed under normal procedures.

150.7 - Medicare Summary Notices (MSNs) and Claim Adjustment Reason Codes

(Rev. 11021; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

When rejecting/denying claims because bariatric surgery procedures were performed in an unapproved facility use:

- MSN 16.2 - "This service cannot be paid when provided in this location/facility."

- Claim Adjustment Reason Code 58 - "Payment adjusted because treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service."
- Remittance Advice Remark Code N386 - “This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.”

When rejecting/denying claims for non-covered bariatric surgery procedures use:

- MSN16.10 - Medicare does not pay for this item or service.

- Claim Adjustment Reason Code 50 - "These are non-covered services because this is not deemed a “medical necessity” by the payer."
- Remittance Advice Remark Code N386 - “This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.”
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When rejecting/denying claims for covered bariatric surgery procedures because the patient did not meet the conditions for coverage use:

- MSN 15.4 - “The information provided does not support the need for this service or item.”

- Claim Adjustment Reason Code 167 - "This (these) diagnosis(es) is (are) not covered”

- Remittance Advice Remark Code N386 - “This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.”

- Group Code CO – Contractual Obligation

In addition to the codes listed above, afford appeal rights to all denied parties.

150.8 - A/MAC Billing Requirements

(Rev. 2841, Issued: 12-23-13, Effective: 09-24-13, Implementation: 12-17-13)

The A/MAC billing requirements will pay for bariatric surgery only when the services are submitted on the following type of bill (TOB): 11X. Type of facility and setting determines the basis of payment:

- For services performed in Indian Health Services inpatient hospitals, TOB 11X under the inpatient prospective payment system (IPPS) is based on the diagnosis-related group (DRG).

- For services performed in inpatient hospitals, TOB 11X under IPPS is based on the DRG.

- For services performed in IHS critical access hospitals (CAHs), TOB 11X, payment is based on 101% facility specific per diem rate.

- For services performed in CAH inpatient hospitals, TOB 11X, payment is based on 101% of reasonable cost.

150.9 - Advance Beneficiary Notice and HINN Information
(Rev. 1233, Issued: 04-27-07, Effective: 02-21-06, Implementation: 05-29-07)

Physicians must be advised that the physician is liable for charges if the surgery is performed in an unapproved facility, unless the beneficiary was informed that he or she would be financially responsible prior to performance for the procedure. The provider must have the beneficiary sign an advance beneficiary notice (ABN) if the bariatric surgery is performed in an unapproved facility. Note that the ABN is the appropriate notice for Part B services.

The HINN model language should be adapted to this situation in the sections addressing: description of the care at issue if the surgery is performed on an inpatient basis, in an unapproved facility, to avoid being liable, the provider must issue a HINN. Other content requirements of HINN still apply. Use the HINN letter most appropriate to the overall situation.

160 – PTA for Implanting the Carotid Stent
(Rev. 1042, Issued: 08-25-06; Effective: 03-17-05; Implementation: 10-02-06)

160.1 – Category B Investigational Device Exemption (IDE) Study Coverage
(Rev. 12571; Issued: 04-11-24) Effective: 10-11-23; Implementation: 05-13-24)

Effective July 1, 2001, Medicare covers percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with stent placement when furnished in accordance with the Food and Drug Administration (FDA) protocols governing Category B Investigational Device Exemption (IDE) studies.

The billing for this procedure is based upon how the service is delivered. There are several CPT codes that may be billed depending upon how the procedure is performed. Contractor medical directors should consider what provider education information is needed to assist providers on the billing for this service.

Contractors must review their local coverage determinations to ensure that payment is provided for claims for PTA in an FDA-approved clinical study.

As a requirement for Category B IDE coverage, providers must bill a six-digit IDE Number that begins with a "G" (i.e., G123456). To identify the line as an IDE line, institutional providers must bill this IDE Number on a 0624 Revenue Code line while practitioners must bill this IDE Number along with a Q0 modifier.

160.2 – Post-Approval Study Coverage
(Rev. 12571; Issued: 04-11-24) Effective: 10-11-23; Implementation: 05-13-24)

Effective October 12, 2004, under section B3 of NCD 20.7, Medicare covers PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent and an FDA-approved or –cleared embolic protection device (effective December 9, 2009) for an FDA-approved indication when furnished in accordance with FDA-approved protocols governing post-approval studies. Also included in the currently covered population of patients participating in FDA-approved post-approval studies are patients participating in post-approval extension studies and patients participating in studies following FDA 510k approval of these devices.

Billing post-approval studies is similar to normal Category B IDE billing procedures, except that under post-approval coverage, providers must bill the Pre-Market Approval (PMA) number assigned to the stent system by the FDA. PMA numbers are like typical IDE Numbers in that they have six-digits, but they begin with a "P" (i.e., P123456) instead of a "G."

160.2.1 – Carotid Artery Stenting (CAS) for Post-Approval Studies
(Rev. 11021; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

A. Background

As the post-approval studies began to end, CMS received requests to extend coverage for the post-approval studies. CMS has reviewed the extension requests and has determined that patients participating in post-approval extension studies are also included in the currently covered population of patients participating in FDA-approved post-approval studies.

B. Policy

To grant approval for post-approval studies, the FDA reviews each study protocol. Once approval is granted, the FDA issues a formal approval letter to the study sponsor.
Extensions of post-approval studies are not subject to approval by the FDA because they surpass the post-approval study requirements identified in the conditions of approval for post-approval studies. Since the FDA cannot approve these extension studies, individual Post-Market Approval (PMA) numbers cannot be issued to separately identify each study. Currently, in order to receive reimbursement for procedures performed as part of a carotid artery stenting post-approval study, providers must include the FDA-issued PMA number on each claim to indicate participation in a specific study.

CMS has determined that all extension studies must be reviewed by the FDA. The FDA will issue an acknowledgement letter stating that the extension study is scientifically valid and will generate clinically relevant post-market data. Upon receipt of this letter and review of the extension study protocol, CMS will issue a letter to the study sponsor indicating that the study under review will be covered by Medicare. Since an individual PMA number cannot be assigned by the FDA to each extension study, these studies will use the PMA number assigned to the original FDA-approved post-approval study (i.e., CAPTURE 2 shall use the PMA number assigned to CAPTURE 1).

C. Billing

In order to receive Medicare coverage for patients participating in post-approval extension studies, providers shall submit both the FDA acknowledgement letter and the CMS letter providing coverage for the extension study to their contractor. Additionally, providers shall submit any other materials contractors would require for FDA-approved post- approval studies.

In response, contractors will issue a letter assigning an effective date for each facility's participation in the extension study. Providers may bill for procedures performed in the extension study for dates of service on and after the assigned effective date. Providers billing A/B MACs (A) must bill using the most current ICD-10-CM is applicable, Indications for PTA of the Carotid Artery Concurrent with Stenting (must bill one of these primary codes to meet coverage under 20.7B2, 20.7B3, 20.7B4)

I63.031	Cerebral infarction due to thrombosis of right carotid artery
I63.032	Cerebral infarction due to thrombosis of left carotid artery
I63.033	Cerebral infarction due to thrombosis of bilateral carotid arteries
I63.131	Cerebral infarction due to embolism of right carotid artery
I63.132	Cerebral infarction due to embolism of left carotid artery
I63.133	Cerebral infarction due to embolism of bilateral carotid arteries
I63.231	Cerebral infarction due to unspecified occlusion or stenosis of right carotid arteries
I63.232	Cerebral infarction due to unspecified occlusion or stenosis of left carotid arteries
I63.233	Cerebral infarction due to unspecified occlusion or stenosis of bilateral carotid arteries
I65.21	Occlusion and stenosis of right carotid artery
I65.22	Occlusion and stenosis of left carotid artery
I65.23	Occlusion and stenosis of bilateral carotid arteries

ICD-10-PCS codes may be used.

037G34Z	Dilation of Intracranial Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
037G35Z	Dilation of Intracranial Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Appro
037G36Z	Dilation of Intracranial Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Appr
037G37Z	Dilation of Intracranial Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneo Approach
037G3DZ	Dilation of Intracranial Artery with Intraluminal Device, Percutaneous Approach
037G3EZ	Dilation of Intracranial Artery with Two Intraluminal Devices, Percutaneous Approach
037G3FZ	Dilation of Intracranial Artery with Three Intraluminal Devices, Percutaneous Approach
037G3GZ	Dilation of Intracranial Artery with Four or More Intraluminal Devices, Percutaneous Approach
037G44Z	Dilation of Intracranial Artery with Drug-eluting Intraluminal Device, Percutaneous Endoscopic Approach
037G45Z	Dilation of Intracranial Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Endos Approach
037G46Z	Dilation of Intracranial Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037G47Z	Dilation of Intracranial Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneo Endoscopic Approach
037G4DZ	Dilation of Intracranial Artery with Intraluminal Device, Percutaneous Endoscopic Approach
037G4EZ	Dilation of Intracranial Artery with Two Intraluminal Devices, Percutaneous Endoscopic Approa
037G4FZ	Dilation of Intracranial Artery with Three Intraluminal Devices, Percutaneous Endoscopic Appro

037G4GZ	Dilation of Intracranial Artery with Four or More Intraluminal Devices, Percutaneous Endoscopi Approach
037H34Z	Dilation of Right Common Carotid Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
037H35Z	Dilation of Right Common Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutar Approach
037H36Z	Dilation of Right Common Carotid Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach
037H37Z	Dilation of Right Common Carotid Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
037H3DZ	Dilation of Right Common Carotid Artery with Intraluminal Device, Percutaneous Approach
037H3EZ	Dilation of Right Common Carotid Artery with Two Intraluminal Devices, Percutaneous Approa
037H3FZ	Dilation of Right Common Carotid Artery with Three Intraluminal Devices, Percutaneous Appro
037H3GZ	Dilation of Right Common Carotid Artery with Four or More Intraluminal Devices, Percutaneou Approach
037H44Z	Dilation of Right Common Carotid Artery with Drug-eluting Intraluminal Device, Percutaneous Endoscopic Approach
037H45Z	Dilation of Right Common Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutar Endoscopic Approach
037H46Z	Dilation of Right Common Carotid Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037H47Z	Dilation of Right Common Carotid Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037H4DZ	Dilation of Right Common Carotid Artery with Intraluminal Device, Percutaneous Endoscopic Approach
037H4EZ	Dilation of Right Common Carotid Artery with Two Intraluminal Devices, Percutaneous Endosc Approach
037H4FZ	Dilation of Right Common Carotid Artery with Three Intraluminal Devices, Percutaneous Endos Approach
037H4GZ	Dilation of Right Common Carotid Artery with Four or More Intraluminal Devices, Percutaneou Endoscopic Approach
037J34Z	Dilation of Left Common Carotid Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
037J35Z	Dilation of Left Common Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutane Approach
037J36Z	Dilation of Left Common Carotid Artery with Three Drug-eluting Intraluminal Devices, Percutar Approach
037J37Z	Dilation of Left Common Carotid Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
037J3DZ	Dilation of Left Common Carotid Artery with Intraluminal Device, Percutaneous Approach
037J3EZ	Dilation of Left Common Carotid Artery with Two Intraluminal Devices, Percutaneous Approach
037J3FZ	Dilation of Left Common Carotid Artery with Three Intraluminal Devices, Percutaneous Approa
037J3GZ	Dilation of Left Common Carotid Artery with Four or More Intraluminal Devices, Percutaneous Approach
037J44Z	Dilation of Left Common Carotid Artery with Drug-eluting Intraluminal Device, Percutaneous Endoscopic Approach
037J45Z	Dilation of Left Common Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutane Endoscopic Approach
037J46Z	Dilation of Left Common Carotid Artery with Three Drug-eluting Intraluminal Devices, Percutar Endoscopic Approach

037J47Z	Dilation of Left Common Carotid Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037J4DZ	Dilation of Left Common Carotid Artery with Intraluminal Device, Percutaneous Endoscopic Approach
037J4EZ	Dilation of Left Common Carotid Artery with Two Intraluminal Devices, Percutaneous Endoscop Approach
037J4FZ	Dilation of Left Common Carotid Artery with Three Intraluminal Devices, Percutaneous Endosc Approach
037J4GZ	Dilation of Left Common Carotid Artery with Four or More Intraluminal Devices, Percutaneous Endoscopic Approach
037K34Z	Dilation of Right Internal Carotid Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
037K35Z	Dilation of Right Internal Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutane Approach
037K36Z	Dilation of Right Internal Carotid Artery with Three Drug-eluting Intraluminal Devices, Percutar Approach
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037K3EZ	Dilation of Right Internal Carotid Artery with Two Intraluminal Devices, Percutaneous Approach
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037K3GZ	Dilation of Right Internal Carotid Artery with Four or More Intraluminal Devices, Percutaneous Approach
037K44Z	Dilation of Right Internal Carotid Artery with Drug-eluting Intraluminal Device, Percutaneous Endoscopic Approach
037K45Z	Dilation of Right Internal Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutane Endoscopic Approach
037K46Z	Dilation of Right Internal Carotid Artery with Three Drug-eluting Intraluminal Devices, Percutar Endoscopic Approach
037K47Z	Dilation of Right Internal Carotid Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037K4DZ	Dilation of Right Internal Carotid Artery with Intraluminal Device, Percutaneous Endoscopic Approach
037K4EZ	Dilation of Right Internal Carotid Artery with Two Intraluminal Devices, Percutaneous Endoscop Approach
037K4FZ	Dilation of Right Internal Carotid Artery with Three Intraluminal Devices, Percutaneous Endosc Approach
037K4GZ	Dilation of Right Internal Carotid Artery with Four or More Intraluminal Devices, Percutaneous Endoscopic Approach
037L34Z	Dilation of Left Internal Carotid Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
037L35Z	Dilation of Left Internal Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutaneo Approach
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037L37Z	Dilation of Left Internal Carotid Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
037L3DZ	Dilation of Left Internal Carotid Artery with Intraluminal Device, Percutaneous Approach
037L3EZ	Dilation of Left Internal Carotid Artery with Two Intraluminal Devices, Percutaneous Approach
037L3FZ	Dilation of Left Internal Carotid Artery with Three Intraluminal Devices, Percutaneous Approach

037L3GZ	Dilation of Left Internal Carotid Artery with Four or More Intraluminal Devices, Percutaneous Approach
037L44Z	Dilation of Left Internal Carotid Artery with Drug-eluting Intraluminal Device, Percutaneous Endoscopic Approach
037L45Z	Dilation of Left Internal Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutaneo Endoscopic Approach
037L46Z	Dilation of Left Internal Carotid Artery with Three Drug-eluting Intraluminal Devices, Percutane Endoscopic Approach
037L47Z	Dilation of Left Internal Carotid Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037L4DZ	Dilation of Left Internal Carotid Artery with Intraluminal Device, Percutaneous Endoscopic App
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037L4FZ	Dilation of Left Internal Carotid Artery with Three Intraluminal Devices, Percutaneous Endoscop Approach
037L4GZ	Dilation of Left Internal Carotid Artery with Four or More Intraluminal Devices, Percutaneous Endoscopic Approach
037M34Z	Dilation of Right External Carotid Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
037M35Z	Dilation of Right External Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutan Approach
037M36Z	Dilation of Right External Carotid Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach
037M37Z	Dilation of Right External Carotid Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
037M3DZ	Dilation of Right External Carotid Artery with Intraluminal Device, Percutaneous Approach
037M3EZ	Dilation of Right External Carotid Artery with Two Intraluminal Devices, Percutaneous Approac
037M3FZ	Dilation of Right External Carotid Artery with Three Intraluminal Devices, Percutaneous Approa
037M3GZ	Dilation of Right External Carotid Artery with Four or More Intraluminal Devices, Percutaneous Approach
037M44Z	Dilation of Right External Carotid Artery with Drug-eluting Intraluminal Device, Percutaneous Endoscopic Approach
037M45Z	Dilation of Right External Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutan Endoscopic Approach
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037M47Z	Dilation of Right External Carotid Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
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037M4EZ	Dilation of Right External Carotid Artery with Two Intraluminal Devices, Percutaneous Endosco Approach
037M4FZ	Dilation of Right External Carotid Artery with Three Intraluminal Devices, Percutaneous Endosc Approach
037M4GZ	Dilation of Right External Carotid Artery with Four or More Intraluminal Devices, Percutaneous Endoscopic Approach
037N34Z	Dilation of Left External Carotid Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
037N35Z	Dilation of Left External Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutane Approach

037N36Z	Dilation of Left External Carotid Artery with Three Drug-eluting Intraluminal Devices, Percutan Approach
037N37Z	Dilation of Left External Carotid Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
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037N3EZ	Dilation of Left External Carotid Artery with Two Intraluminal Devices, Percutaneous Approach
037N3FZ	Dilation of Left External Carotid Artery with Three Intraluminal Devices, Percutaneous Approac
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037N44Z	Dilation of Left External Carotid Artery with Drug-eluting Intraluminal Device, Percutaneous Endoscopic Approach
037N45Z	Dilation of Left External Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutane Endoscopic Approach
037N46Z	Dilation of Left External Carotid Artery with Three Drug-eluting Intraluminal Devices, Percutan Endoscopic Approach
037N47Z	Dilation of Left External Carotid Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037N4DZ	Dilation of Left External Carotid Artery with Intraluminal Device, Percutaneous Endoscopic Approach
037N4EZ	Dilation of Left External Carotid Artery with Two Intraluminal Devices, Percutaneous Endoscop Approach
037N4FZ	Dilation of Left External Carotid Artery with Three Intraluminal Devices, Percutaneous Endosco Approach
037N4GZ	Dilation of Left External Carotid Artery with Four or More Intraluminal Devices, Percutaneous Endoscopic Approach

160.3 – Carotid Artery Stenting (CAS) With Embolic Protection Coverage

(Rev. 12571; Issued: 04-11-24) Effective: 10-11-23; Implementation: 05-13-24)

On October 11, 2023, CMS issued a reconsideration of NCD 20.7. The updated NCD covers PTA of the carotid artery concurrent with stenting with the placement of an FDA-approved carotid stent with an FDA-approved or cleared embolic protection device, for Medicare beneficiaries with symptomatic carotid artery stenosis ≥50% and asymptomatic carotid artery stenosis ≥70%. The NCD also sets forth requirements regarding neurological assessments, imaging, shared decision-making, and retains institutional and physician standards but removes the requirement that facilities that perform CAS procedures must be approved by CMS. Additionally, CMS revised section D of NCD 20.7 to allow MACs to make reasonable and necessary determinations under section 1862(a)(1)(A) for any other beneficiary seeking coverage for PTA of the carotid artery concurrent with stenting.

A. Billing

Effective for claims with dates of services on or after October 11, 2023, contractors shall cover PTA of the carotid artery concurrent with stenting with the placement of an FDA-approved carotid stent with an FDA-approved or cleared embolic protection device, for Medicare beneficiaries under the following conditions:
A. Patients with symptomatic carotid artery stenosis- ≥50%; and,
B. Patients with asymptomatic carotid artery stenosis ≥70%.

Also effective for claims with dates of service on or after October 11, 2023, beneficiaries no longer have to be enrolled in a clinical trial for this service. Contractors may also pay for claims for PTA of the carotid artery

concurrent with stenting not otherwise addressed in The National Coverage Determinations Manual, Chapter 1, part 1, section 20.7 at local discretion.

Effective March 17, 2005, through October 10, 2023, Medicare covered PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent with embolic protection under specific patient indications found in Pub. 100-03, Medicare National Coverage Determinations Manual, part 1, section 20.7. Coverage was limited to procedures performed using FDA-approved CAS systems and FDA-approved or –cleared (effective December 9, 2009) embolic protection devices (EPDs). If deployment of the EPD was not technically possible, and not performed, then the procedure was not covered.

In addition to the specific patient indications, CMS determined that CAS with embolic protection was reasonable and necessary only if performed in facilities that had been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. CMS created a list of minimum standards modeled in part on professional society statements on competency. All facilities were required to at least meet CMS's standards in order to receive coverage for CAS for high-risk patients. Facilities were required to recertify every 2 years in order to maintain coverage of CAS procedures.

161 - Intracranial Percutaneous Transluminal Angioplasty (PTA) With Stenting

(Rev. 11021; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

A. Background

In the past, PTA to treat obstructive lesions of the cerebral arteries was non-covered by Medicare because the safety and efficacy of the procedure had not been established. This national coverage determination (NCD) meant that the procedure was also non-covered for beneficiaries participating in Food and Drug Administration (FDA)-approved investigational device exemption (IDE) clinical trials.

B. Policy

On February 9, 2006, a request for reconsideration of this NCD initiated a national coverage analysis. CMS reviewed the evidence and determined that intracranial PTA with stenting is reasonable and necessary under §1862(a)(1)(A) of the Social Security Act for the treatment of cerebral vessels (as specified in The National Coverage Determinations Manual, Chapter 1, part 1, section 20.7) only when furnished in accordance with FDA- approved protocols governing Category B IDE clinical trials. All other indications for intracranial PTA with stenting remain non-covered.

- **Billing**

Providers of covered intracranial PTA with stenting shall use Category B IDE billing requirements, as listed above in section 68.4. In addition to these requirements, providers must bill the appropriate procedure and diagnosis codes for the date of service to receive payment.

See the below ICD-10-CM diagnosis codes list applies, depending on the date of service. Indications for PTA and Stenting of Intracranial Arteries (must bill I67.2 and one of these primary codes to meet coverage under 20.7B5)

If ICD-10-CM is applicable:

I67.2 Cerebral atherosclerosis

I66.01 Occlusion and stenosis of right middle cerebral artery
I66.02 Occlusion and stenosis of left middle cerebral artery
I66.03 Occlusion and stenosis of bilateral middle cerebral arteries
I66.11 Occlusion and stenosis of right anterior cerebral artery
I66.12 Occlusion and stenosis of left anterior cerebral artery
I66.13 Occlusion and stenosis of bilateral anterior cerebral arteries
I66.21 Occlusion and stenosis of right posterior cerebral artery
I66.22 Occlusion and stenosis of left posterior cerebral artery
I66.23 Occlusion and stenosis of bilateral posterior cerebral arteries
I66.8 Occlusion and stenosis of other cerebral arteries
I63.59 Cerebral infarction due to unspecified occlusion or stenosis of other cerebral artery

If ICD-10-PCS is applicable, ICD-10-PCS procedure codes.
That is, under Part A, providers must bill intracranial PTA using if ICD-10-PCS procedure codes is applicable.

037G34Z	Dilation of Intracranial Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
037G35Z	Dilation of Intracranial Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach
037G36Z	Dilation of Intracranial Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach
037G37Z	Dilation of Intracranial Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
037G3DZ	Dilation of Intracranial Artery with Intraluminal Device, Percutaneous Approach
037G3EZ	Dilation of Intracranial Artery with Two Intraluminal Devices, Percutaneous Approach
037G3FZ	Dilation of Intracranial Artery with Three Intraluminal Devices, Percutaneous Approach
037G3GZ	Dilation of Intracranial Artery with Four or More Intraluminal Devices, Percutaneous Approach
037G44Z	Dilation of Intracranial Artery with Drug-eluting Intraluminal Device, Percutaneous Endoscopic Approach
037G45Z	Dilation of Intracranial Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037G46Z	Dilation of Intracranial Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037G47Z	Dilation of Intracranial Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037G4DZ	Dilation of Intracranial Artery with Intraluminal Device, Percutaneous Endoscopic Approach
037G4EZ	Dilation of Intracranial Artery with Two Intraluminal Devices, Percutaneous Endoscopic Approach
037G4FZ	Dilation of Intracranial Artery with Three Intraluminal Devices, Percutaneous Endoscopic Approach
037G4GZ	Dilation of Intracranial Artery with Four or More Intraluminal Devices, Percutaneous Endoscopic Approach
037H34Z	Dilation of Right Common Carotid Artery with Drug-eluting Intraluminal Device, Percutaneous Approach

037H35Z	Dilation of Right Common Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach
037H36Z	Dilation of Right Common Carotid Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach
037H37Z	Dilation of Right Common Carotid Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
037H3DZ	Dilation of Right Common Carotid Artery with Intraluminal Device, Percutaneous Approach
037H3EZ	Dilation of Right Common Carotid Artery with Two Intraluminal Devices, Percutaneous Approach
037H3FZ	Dilation of Right Common Carotid Artery with Three Intraluminal Devices, Percutaneous Approach
037H3GZ	Dilation of Right Common Carotid Artery with Four or More Intraluminal Devices, Percutaneous Approach
037H44Z	Dilation of Right Common Carotid Artery with Drug-eluting Intraluminal Device, Percutaneous Endoscopic Approach
037H45Z	Dilation of Right Common Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037H46Z	Dilation of Right Common Carotid Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037H47Z	Dilation of Right Common Carotid Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037H4DZ	Dilation of Right Common Carotid Artery with Intraluminal Device, Percutaneous Endoscopic Approach
037H4EZ	Dilation of Right Common Carotid Artery with Two Intraluminal Devices, Percutaneous Endoscopic Approach
037H4FZ	Dilation of Right Common Carotid Artery with Three Intraluminal Devices, Percutaneous Endoscopic Approach
037H4GZ	Dilation of Right Common Carotid Artery with Four or More Intraluminal Devices, Percutaneous Endoscopic Approach
037J34Z	Dilation of Left Common Carotid Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
037J35Z	Dilation of Left Common Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach
037J36Z	Dilation of Left Common Carotid Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach
037J37Z	Dilation of Left Common Carotid Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
037J3DZ	Dilation of Left Common Carotid Artery with Intraluminal Device, Percutaneous Approach
037J3EZ	Dilation of Left Common Carotid Artery with Two Intraluminal Devices, Percutaneous Approach
037J3FZ	Dilation of Left Common Carotid Artery with Three Intraluminal Devices, Percutaneous Approach
037J3GZ	Dilation of Left Common Carotid Artery with Four or More Intraluminal Devices, Percutaneous Approach
037J44Z	Dilation of Left Common Carotid Artery with Drug-eluting Intraluminal Device, Percutaneous Endoscopic Approach
037J45Z	Dilation of Left Common Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach

037J46Z	Dilation of Left Common Carotid Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037J47Z	Dilation of Left Common Carotid Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037J4DZ	Dilation of Left Common Carotid Artery with Intraluminal Device, Percutaneous Endoscopic Approach
037J4EZ	Dilation of Left Common Carotid Artery with Two Intraluminal Devices, Percutaneous Endoscopic Approach
037J4FZ	Dilation of Left Common Carotid Artery with Three Intraluminal Devices, Percutaneous Endoscopic Approach
037J4GZ	Dilation of Left Common Carotid Artery with Four or More Intraluminal Devices, Percutaneous Endoscopic Approach
037K34Z	Dilation of Right Internal Carotid Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
037K35Z	Dilation of Right Internal Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach
037K36Z	Dilation of Right Internal Carotid Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach
037K37Z	Dilation of Right Internal Carotid Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
037K3DZ	Dilation of Right Internal Carotid Artery with Intraluminal Device, Percutaneous Approach
037K3EZ	Dilation of Right Internal Carotid Artery with Two Intraluminal Devices, Percutaneous Approach
037K3FZ	Dilation of Right Internal Carotid Artery with Three Intraluminal Devices, Percutaneous Approach
037K3GZ	Dilation of Right Internal Carotid Artery with Four or More Intraluminal Devices, Percutaneous Approach
037K44Z	Dilation of Right Internal Carotid Artery with Drug-eluting Intraluminal Device, Percutaneous Endoscopic Approach
037K45Z	Dilation of Right Internal Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037K46Z	Dilation of Right Internal Carotid Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037K47Z	Dilation of Right Internal Carotid Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037K4DZ	Dilation of Right Internal Carotid Artery with Intraluminal Device, Percutaneous Endoscopic Approach
037K4EZ	Dilation of Right Internal Carotid Artery with Two Intraluminal Devices, Percutaneous Endoscopic Approach
037K4FZ	Dilation of Right Internal Carotid Artery with Three Intraluminal Devices, Percutaneous Endoscopic Approach
037K4GZ	Dilation of Right Internal Carotid Artery with Four or More Intraluminal Devices, Percutaneous Endoscopic Approach
037L34Z	Dilation of Left Internal Carotid Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
037L35Z	Dilation of Left Internal Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach
037L36Z	Dilation of Left Internal Carotid Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach

037L37Z	Dilation of Left Internal Carotid Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
037L3DZ	Dilation of Left Internal Carotid Artery with Intraluminal Device, Percutaneous Approach
037L3EZ	Dilation of Left Internal Carotid Artery with Two Intraluminal Devices, Percutaneous Approach
037L3FZ	Dilation of Left Internal Carotid Artery with Three Intraluminal Devices, Percutaneous Approach
037L3GZ	Dilation of Left Internal Carotid Artery with Four or More Intraluminal Devices, Percutaneous Approach
037L44Z	Dilation of Left Internal Carotid Artery with Drug-eluting Intraluminal Device, Percutaneous Endoscopic Approach
037L45Z	Dilation of Left Internal Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037L46Z	Dilation of Left Internal Carotid Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037L47Z	Dilation of Left Internal Carotid Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037L4DZ	Dilation of Left Internal Carotid Artery with Intraluminal Device, Percutaneous Endoscopic Approach
037L4EZ	Dilation of Left Internal Carotid Artery with Two Intraluminal Devices, Percutaneous Endoscopic Approach
037L4FZ	Dilation of Left Internal Carotid Artery with Three Intraluminal Devices, Percutaneous Endoscopic Approach
037L4GZ	Dilation of Left Internal Carotid Artery with Four or More Intraluminal Devices, Percutaneous Endoscopic Approach
037M34Z	Dilation of Right External Carotid Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
037M35Z	Dilation of Right External Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach
037M36Z	Dilation of Right External Carotid Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach
037M37Z	Dilation of Right External Carotid Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
037M3DZ	Dilation of Right External Carotid Artery with Intraluminal Device, Percutaneous Approach
037M3EZ	Dilation of Right External Carotid Artery with Two Intraluminal Devices, Percutaneous Approach
037M3FZ	Dilation of Right External Carotid Artery with Three Intraluminal Devices, Percutaneous Approach
037M3GZ	Dilation of Right External Carotid Artery with Four or More Intraluminal Devices, Percutaneous Approach
037M44Z	Dilation of Right External Carotid Artery with Drug-eluting Intraluminal Device, Percutaneous Endoscopic Approach
037M45Z	Dilation of Right External Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037M46Z	Dilation of Right External Carotid Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037M47Z	Dilation of Right External Carotid Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach

037M4DZ	Dilation of Right External Carotid Artery with Intraluminal Device, Percutaneous Endoscopic Approach
037M4EZ	Dilation of Right External Carotid Artery with Two Intraluminal Devices, Percutaneous Endoscopic Approach
037M4FZ	Dilation of Right External Carotid Artery with Three Intraluminal Devices, Percutaneous Endoscopic Approach
037M4GZ	Dilation of Right External Carotid Artery with Four or More Intraluminal Devices, Percutaneous Endoscopic Approach
037N34Z	Dilation of Left External Carotid Artery with Drug-eluting Intraluminal Device, Percutaneous Approach
037N35Z	Dilation of Left External Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Approach
037N36Z	Dilation of Left External Carotid Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Approach
037N37Z	Dilation of Left External Carotid Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Approach
037N3DZ	Dilation of Left External Carotid Artery with Intraluminal Device, Percutaneous Approach
037N3EZ	Dilation of Left External Carotid Artery with Two Intraluminal Devices, Percutaneous Approach
037N3FZ	Dilation of Left External Carotid Artery with Three Intraluminal Devices, Percutaneous Approach
037N3GZ	Dilation of Left External Carotid Artery with Four or More Intraluminal Devices, Percutaneous Approach
037N44Z	Dilation of Left External Carotid Artery with Drug-eluting Intraluminal Device, Percutaneous Endoscopic Approach
037N45Z	Dilation of Left External Carotid Artery with Two Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037N46Z	Dilation of Left External Carotid Artery with Three Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037N47Z	Dilation of Left External Carotid Artery with Four or More Drug-eluting Intraluminal Devices, Percutaneous Endoscopic Approach
037N4DZ	Dilation of Left External Carotid Artery with Intraluminal Device, Percutaneous Endoscopic Approach
037N4EZ	Dilation of Left External Carotid Artery with Two Intraluminal Devices, Percutaneous Endoscopic Approach
037N4FZ	Dilation of Left External Carotid Artery with Three Intraluminal Devices, Percutaneous Endoscopic Approach
037N4GZ	Dilation of Left External Carotid Artery with Four or More Intraluminal Devices, Percutaneous Endoscopic Approach

Under Part B, providers must bill HCPCS procedure code 37799. If above ICD-10-CM is applicable.

NOTE: ICD- codes are subject to modification. Providers must always ensure they are using the latest and most appropriate codes.

170 - Billing Requirements for Lumbar Artificial Disc Replacement

(Rev. 992, Issued: 06-23-06, Effective: 05-16-06, Implementation: Carriers 07-17-06/FIs 10-01-06)

170.1 - General
(Rev. 1340, Issued: 09-21-07, Effective: 08-14-07, Implementation: 10-01-07)

Effective for services performed from May 16, 2006 through August 13, 2007, the Centers for Medicare & Medicaid Services (CMS) made the decision that lumbar artificial disc replacement (LADR) with the Charite™ lumbar artificial disc is non-covered for Medicare beneficiaries over 60 years of age. See Pub. 100-03, Medicare National Coverage Determinations Manual, section 150.10, for more information about the non-covered determination.

Effective for services performed on or after August 14, 2007, CMS made the decision that LADR with any lumbar artificial disc is non-covered for Medicare beneficiaries over 60 years of age, (i.e., on or after a beneficiary's 61st birthday).

For Medicare beneficiaries 60 years of age and younger, there is no national coverage determination for LADR, leaving such determinations to continue to be made by the local contractors.

170.2 - Carrier Billing Requirements
(Rev. 11902; Issued:03-16-23; Effective: 04-17-23; Implementation: 04-17-23)

Effective for services performed on or after May 16, 2006 through December 31, 2006, carriers shall deny claims, for Medicare beneficiaries over 60 years of age, submitted with the following Category III Codes:

- 0091T Single interspace, lumbar; and

- 0092T Each additional interspace (List separately in addition to code for primary procedure.)

Effective for services performed on or after January 1, 2007 through August 13, 2007, for Medicare beneficiaries over 60 years of age, LADR with the Charite™ lumbar artificial disc, carriers shall deny claims submitted with the following codes:

- 22857 Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), lumbar, single interspace

- 0163T Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), lumbar, each additional interspace. NOTE: Effective December 31, 2022, code 0163T is end dated.

Carriers shall continue to follow their normal claims processing criteria for IDEs for LADR performed with an implant eligible under the IDE criteria.

For dates of service May 16, 2006 through August 13, 2007, Medicare coverage under the investigational device exemption (IDE) for LADR with a disc other than the Charite™ lumbar disc in eligible clinical trials is not impacted.

Effective for services performed on or after August 14, 2007, carriers shall deny claims for LADR surgery, for Medicare beneficiaries over 60 years of age, (i.e., on or after a beneficiary's 61st birthday) submitted with the following codes:

- 22857 Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), lumbar, single interspace

- 0163T Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), lumbar, each additional interspace NOTE: Effective December 31, 2022, code 0163T is end dated.
- 22860 Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar. Effective 01/01/23

170.3 - A/B MAC (A) Billing Requirements

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

The A/B MAC (A) will pay for LADR when approved under the IDE/clinical trial criteria only when submitted with ICD-9-CM procedure code 84.65 if ICD-9 is applicable, with condition code 30 and if ICD-9-CM is applicable, ICD-9-CM diagnosis code V70.7 when submitted on type of bill (TOB) 11X from May 16, 2006 through August 13, 2007.

Special Billing instructions:

For services performed on TOB 11X in critical access hospitals (CAH), the payment will be 101% of reasonable cost.

For services performed on TOB 11X Indian Health Services (IHS) inpatient hospitals will pay under the inpatient prospective payment system (IPPS) based on the DRG.

For services performed on TOB 11X, IHS CAHs will pay under 101% facility specific per diem rate.

NOTE: The ICD-9-CM procedure code 84.65 is not payable for beneficiaries over 60 years of age, with the Charite™ lumbar artificial disc, which is the only one that is FDA approved for any diagnosis. If a different manufacture's disc is used in an approved clinical trials or is an approved IDE, then condition code 30 and ICD-9-CM diagnosis code V70.7 must be on the claim for it to be payable.

Effective for discharges on or after August 14, 2007, CMS has found that LADR is not reasonable and necessary for the Medicare population over 60 years of age. Therefore, LADR is non-covered for Medicare beneficiaries over 60 years of age as identified in section 150.10, of Pub.100-03, the NCD Manual. A/B MACS (A) shall deny claims with ICD-9-CM procedure code 84.65 for Medicare beneficiaries over 60 years of age.

For Medicare beneficiaries 60 years of age and younger, there is no NCD, leaving such determinations to continue to be made by the local contractors.

170.4 – Reasons for Denial and Medicare Summary Notice (MSN), Claim Adjustment Reason Code Messages, and Remittance Advice Remark Code

(Rev. 1340, Issued: 09-21-07, Effective: 08-14-07, Implementation: 10-01-07)

Contractors shall use the following messages when denying claims for Medicare beneficiaries over 60 years of age (i.e. on or after a beneficiary's 61st birthday).

21.24 "This service is not covered for patients over age 60."

"Este servicio no está cubierto en pacientes mayores de 60 años."

Use an appropriate Claim Adjustment Reason Code:

96 "Non-covered charge(s)."

Use an appropriate Remittance Advice Remark Code:

N386 "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at http://www.cms.hhs.gov/mcd/search.asp. If you do not have Web access, you may contact the contractor to request a copy of the NCD."

170.5 - Advance Beneficiary Notice (ABN) and Hospital Issued Notice of Noncoverage (HINN) Information

(Rev. 1340, Issued: 09-21-07, Effective: 08-14-07, Implementation: 10-01-07)

Providers must be advised that the provider is liable for charges if the lumbar artificial disc replacement is used in the surgery, unless the beneficiary was informed that he/she would be financially responsible prior to performance of the procedure. To avoid this liability the provider should have the beneficiary sign an ABN.

The HINN model language should be adapted to this situation in the sections addressing description of the care at issue if the surgery is performed on an inpatient basis. Unless the beneficiary was informed prior to the admission that he/ she would be financially liable for the admission, the provider is liable. To avoid this liability the provider must issue a HINN. Other content requirements of a HINN still apply. Use the HINN letter most appropriate to the overall situation.

180 – Cryosurgery of the Prostate Gland

(Rev. 1111, Issued: 11-09-06, Effective: 04-01-07, Implementation: 04-02-07)

Cryosurgery of the prostate gland, also known as cryosurgical ablation of the prostate (CAP), destroys prostate tissue by applying extremely cold temperatures in order to reduce the size of the prostate gland.

180.1 - Coverage Requirements

(Rev. 1111, Issued: 11-09-06, Effective: 04-01-07, Implementation: 04-02-07)

Medicare covers cryosurgery of the prostate gland effective for claims with dates of service on or after July 1, 1999. The coverage is for:

1. Primary treatment of patients with clinically localized prostate cancer, Stages T1 – T3 (diagnosis code is 185 – malignant neoplasm of prostate).

2. Salvage therapy (effective for claims with dates of service on or after July 1, 2001 for patients:

    a. Having recurrent, localized prostate cancer;

    b. Failing a trial of radiation therapy as their primary treatment; and

    c. Meeting one of these conditions: State T2B or below; Gleason score less than 9 or; PSA less than 8 ng/ml.

180.2 - Billing Requirements

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

Claims for cryosurgery for the prostate gland are to be submitted on the ASC X12 837, or, in exceptional circumstances, on a hard copy Form CMS – 1450. This procedure can be rendered in an inpatient or outpatient hospital setting (types of bill (TOBs) 11x 13x, 83x, and 85x).

The A/B MAC (A) will look for the following when processing claims with cryosurgery services:

- If ICD-9-CM is applicable, ICD-9 CM diagnosis code 185 or
- If ICD-10-CM is applicable, ICD-10 CM diagnosis code C61 must be on all cryosurgical claims;
- For outpatient claims HCPCS 55873 and revenue codes 0360, 0361, or 0369 Cryosurgery ablation of localized prostate cancer, stages T1- T3 (includes ultrasonic guidance for interstitial cryosurgery probe placement, postoperative irrigations and aspiration of sloughing tissue included) must be on all outpatient claims; and
- For inpatient claims correct procedure codes are:
    - If ICD-9-CM is applicable, ICD-9-CM procedure code 60.62 (perineal prostatectomy- the definition includes cryoablation of prostate, cryostatectomy of prostate, and radical cryosurgical ablation of prostate)
    - If ICD-10 is applicable,ICD-10-PCS procedure code 0V500ZZ (Destruction of Prostate, Open Approach), or 0V503ZZ (Destruction of Prostate, Percutaneous Approach), or 0V504ZZ (Destruction of Prostate, Percutaneous Endoscopic Approach).

180.3 – Payment Requirements

(Rev. 1111, Issued: 11-09-06, Effective: 04-01-07, Implementation: 04-02-07)

This service may be paid as a primary treatment for patients with clinically localized prostate cancer, Stages T1 – T3. The ultrasonic guidance associated with this procedure will not be paid for separately, but is bundled into the payment for the surgical procedure. When one provider has furnished the cryosurgical ablation and another the ultrasonic guidance, the provider of the ultrasonic guidance must seek compensation from the provider of the cryosurgical ablation.

Effective July 1, 2001, cryosurgery performed as salvage therapy, will be paid only according to the coverage requirements described above.

Type of facility and setting determines the basis of payment:

- For services performed on an inpatient or outpatient basis in a CAH, TOBs 11x and 85x: the FI will pay 101 percent of reasonable cost minus any applicable deductible and coinsurance.
- For services performed on an inpatient basis in short term acute care hospitals, (including those in Guam, America Samoa, Virgin Islands, Saipan, and Indian Health Services Hospitals) TOB 11x: the FI will pay the DRG payment minus any applicable deductible and coinsurance.

- For services performed on an outpatient basis in hospitals subject to the Outpatient PPS, TOB 13x: the FI will pay the assigned APC minus any applicable deductible and coinsurance.

- For outpatient services in hospitals that are exempt from OPPS (such as in American Samoa, Virgin Islands, Guam, and Saipan) TOBs 13x: the FI will pay reasonable cost, minus any applicable deductible and coinsurance.

- For outpatient services in Indian Health Service hospitals TOBs 13x and 83x: the FI will pay the ASC payment amount for TOB 83x. minus any applicable deductible and coinsurance.

- For inpatient or outpatient services in hospitals in Maryland, make payment according to the State Cost Containment system.

For services performed on an inpatient basis: the hospitals exempt from inpatient acute care PPS shall be paid on reasonable cost basis, minus any applicable deductible and coinsurance.

180.4 - Claim Adjustment Reason Codes, Remittance Advice Remark Codes, Group Codes, and Medicare Summary Notice Messages

(Rev 2544, Issued: 09-13-2012, Effective: 10-01-2012, Implementation: 10-01-2012)

Contractors shall use the appropriate claim adjustment reason codes (CARCs), remittance advice remark codes (RARCs), group codes, or Medicare summary notice (MSN) messages when denying payment for alcohol misuse screening and alcohol misuse behavioral counseling sessions:

- For RHC and FQHC claims that contain screening for alcohol misuse HCPCS code G0442 and alcohol misuse counseling HCPCS code G0443 with another encounter/visit with the same line item date of service, use group code CO and reason code:

    - Claim Adjustment Reason Code (CARC) 97 – The benefit for this service is included in the payment/allowance for another service/procedure that has already been adjudicated. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF) if present

- Denying claims containing HCPCS code G0442 and HCPCS code G0443 submitted on a TOB other than 13X, 71X, 77X, and 85X:

    - Claim Adjustment Reason Code (CARC) 5 - The procedure code/bill type is inconsistent with the place of service. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF) if present

    - Remittance Advice Remark Code (RARC) M77 – Missing/incomplete/invalid place of service

    - Group Code PR (Patient Responsibility) assigning financial liability to the beneficiary, if a claim is received with a GA modifier indicating a signed ABN is on file.

    - Group Code CO (Contractual Obligation) assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.

    NOTE: For modifier GZ, use CARC 50 and MSN 8.81 per instructions in CR 7228/TR 2148.

- Denying claims that contains more than one alcohol misuse behavioral counseling session G0443 on the same date of service:

    - Medicare Summary Notice (MSN) 15.6 – The information provided does not support the need for this many services or items within this period of time.

    - Claim Adjustment Reason Code (CARC) 151 – Payment adjusted because the payer deems the information submitted does not support this many/frequency of services.

    - Remittance Advice Remark Code (RARC) M86 – Service denied because payment already made for same/similar procedure within set time frame.

    - Group Code PR (Patient Responsibility) assigning financial liability to the beneficiary, if a claim is received with a GA modifier indicating a signed ABN is on file.

    - Group Code CO (Contractual Obligation) assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.

    NOTE: For modifier GZ, use CARC 50 and MSN 8.81 per instructions in CR 7228/TR 2148.

- Denying claims that are not submitted from the appropriate provider specialties:

    - Medicare Summary Notice (MSN) 21.18 – This item or service is not covered when performed or ordered by this provider.

    - Claim Adjustment Reason Code (CARC) 185 - The rendering provider is not eligible to perform the service billed. NOTE: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

    - Remittance Advice Remark Code (RARC) N95 - This provider type/provider specialty may not bill this service.

    - Group Code PR (Patient Responsibility) assigning financial liability to the beneficiary, if a claim is received with a GA modifier indicating a signed ABN is on file.

    - Group Code CO (Contractual Obligation) assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.

    NOTE: For modifier GZ, use CARC 50 and MSN 8.81 per instructions in CR 7228/TR 2148.

- Denying claims without the appropriate POS code:

    - Medicare Summary Notice (MSN) 21.25 – This service was denied because Medicare only covers this service in certain settings.

    - Claim Adjustment Reason Code (CARC) 58 – Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF) if present.

    - Remittance Advice Remark Code (RARC) N428 – Not covered when performed in this place of service.

- Group Code PR (Patient Responsibility) assigning financial liability to the beneficiary, if a claim is received with a GA modifier indicating a signed ABN is on file.

- Group Code CO (Contractual Obligation) assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.

NOTE: For modifier GZ, use CARC 50 and MSN 8.81 per instructions in CR 7228/TR 2148.

- Denying claims for alcohol misuse screening HCPCS code G0442 more than once in a 12-month period, and denying alcohol misuse counseling sessions HCPCS code G0443 more than four times in the same 12-month period:

  - Medicare Summary Notice (MSN) 20.5 – These services cannot be paid because your benefits are exhausted at this time.

  - Claim Adjustment Reason Code (CARC) 119 – Benefit maximum for this time period or occurrence has been reached.

  - Remittance Advice Remark Code (RARC) N362 – The number of Days or Units of service exceeds our acceptable maximum.

  - Group Code PR (Patient Responsibility) assigning financial liability to the beneficiary, if a claim is received with a GA modifier indicating a signed ABN is on file.

  - Group Code CO (Contractual Obligation) assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.

  NOTE: For modifier GZ, use CARC 50 and MSN 8.81 per instructions in CR 7228/TR 2148.

- Denying claims for alcohol misuse counseling session HCPCS code G0443 when there is no claim in history for the screening service HCPCS code G0442 in the prior 12 months:

    - Medicare Summary Notice (MSN) 16.26 – Medicare does not pay for services or items related to a procedure that has not been approved or billed.

    - Claim Adjustment Reason Code (CARC) B15 – This service/procedure requires that a qualifying service/procedure be received and covered. The qualifying other service/procedure has not been received/adjudicated. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

    - Remittance Advice Remark Code (RARC) M16 – Alert: Please see our web site, mailings, or bulletins for more details concerning this policy/procedure/decision.

    - Group Code PR (Patient Responsibility) assigning financial liability to the beneficiary, if a claim is received with a modifier indicating a signed ABN is on file.

    - Group Code CO (Contractual Obligation) assigning financial liability to the provider, if a claim is received without a modifier indicating no signed ABN is on file.

180.5 – Additional CWF and Contractor Requirements

(Rev 2544, Issued: 09-13-2012, Effective: 10-01-2012, Implementation: 10-01-2012)

- When applying frequency, CWF shall count 11 full months following the month of the last alcohol misuse screening visit, G0442, before allowing subsequent payment of another G0442 screening.

- CWF shall reject incoming claims when G0443 PROF is billed if four G0443 services have been billed and posted to the BEHV auxiliary file within the 12 month period.

- CWF shall continue to reject incoming claims with consistency error code '32#3' when HCPCS code G0442 PROF and HCPCS code G0443 PROF are billed on same day for TOB 71X, 77X, 85X with 096X, 097X and 098X.

- Contractors and CWF shall use the last date of G0442 PROF for counting the 12-month period for G0443 PROF services.

    - Contractors and CWF shall apply all the same TOBs (13x,71x, 77x and 85x with Rev. Code 96, 97 and 98) POS (11, 22, 49 and 71), no deductible/co-insurance and institutional/professional processing for G0443 that was implemented for G0442 in CR 7633.

- If a claim with G0442 is cancelled, CWF shall do a look back for claims with G0443 and create an IUR (Information Unsolicited Response) along with a Trailer '24' back to the contractor to reject the G0443 claim(s) paid within the 12 month period of the G0442 claims.

- CWF shall display the number of counseling sessions remaining for G0443 PROF on all CWF provider query screens (HUQA, HIQA, HIQH, ELGA, ELGB, ELGH).

- CWF shall display the remaining PROF services counting DOWN from four (4) for the HCPCS code 'G0443' on the MBD/NGD extract file.

    - CWF shall calculate a next eligible date for G0442 PROF and G0443 PROF for a given beneficiary.

    - The calculation shall include all applicable factors including beneficiary Part B entitlement status, beneficiary claims history and utilization rules.

    - When there is no next eligible date, the CWF provider query screens shall display an 8-position alpha code in the date field to indicate why there is not a next eligible date.

    - Any change to beneficiary master data or claims data that would result in a change to any next eligible date shall result in an update to the beneficiary's next eligible date.

      NOTE: If G0442 is not paid, the beneficiary is not eligible for G0443.

        - CWF shall create a utility to remove previously posted G0442 TECH for the AUX file.

        - CWF shall remove G0442/G0443 TECH from editing, MBD, NGD, Provider Inquiry screens and all other applicable areas (i.e., HICR) previously done under CR 7633.

Frequency Requirements

When applying frequency, CWF shall count 11 full months following the month of the last alcohol misuse screening visit, G0442, before allowing subsequent payment of another G0442 screening. Additionally, CWF shall create an edit to allow alcohol misuse brief behavioral counseling, HCPCS G0443, no more than 4 times in a 12-month period. CWF shall also count four alcohol misuse counseling sessions HCPCS G0443 in the same 12-month period used for G0442 counting from the date the G0442 screening session was billed.

When applying frequency limitations to G0442 screening on the same date of service as G0443 counseling, CWF shall allow both a claim for the professional service and a claim for a facility fee. CWF shall identify the following institutional claims as facility fee claims for screening services: TOB 13X, TOB 85X when the revenue code is not 096X, 097X, or 098X. CWF shall identify all other claims as professional service claims for screening services (professional claims, and institutional claims with TOB 71X, 77X, and 85X when the revenue code is 096X, 097X, or 098X). NOTE: This does not apply to RHCs and FQHCs.

190 – Billing Requirements for Extracorporeal Photopheresis

(Rev. 3050, Issued: 08-22-14, Effective: 09-23-14, ICD-10: Upon Implementation of ICD-10, Implementation: 09-23-14, ICD-10: Upon Implementation of ICD-10)

Effective for dates of services on and after December 19, 2006, Medicare has expanded coverage for extracorporeal photopheresis for patients with acute cardiac allograft rejection whose disease is refractory to standard immunosuppresive drug treatment and patients with chronic graft versus host disease whose disease is refractory to standard immunosuppresive drug treatment. (See the National Coverage Determinations (NCD) Manual, Pub. 100-03, Chapter 1, part 2, section 110.4, for complete coverage guidelines.)

Effective for claims with dates of service on or after April 30, 2012**,** the Centers for Medicare & Medicaid Services has expanded coverage for extracorporeal photopheresis for the treatment of bronchiolitis obliterans syndrome (BOS) following lung allograft transplantation only when extracorporeal photopheresis is provided under a clinical research study that meets specific requirements to assess the effect of extracorporeal photopheresis for the treatment of BOS following lung allograft transplantation. Further coverage criteria is outlined in Pub. 100-03, Chapter 1, part 2, section 110.4 of the NCD Manual.

190.1 – Applicable Intermediary Bill Types

(Rev. 1206; Issued: 03-16-07; Effective: December 19, 2006; Implementation: 04-02-07)

11X, 13X, or 85X

190.2 – Healthcare Common Procedural Coding System (HCPCS), Applicable Diagnosis Codes and Procedure Code

(Rev. 12822; Issued:09-05-024; Effective:10-01-23 Implementation:11-07-24)

The following HCPCS procedure code is used for billing extracorporeal photopheresis:

- 36522 - Photopheresis, extracorporeal

Effective for claims with dates of service on or after Oct 1, 2015, the following are the applicable ICD-10-CM procedure codes for the new expanded coverage:

- 6A650ZZ Phototherapy, Circulatory, Single
- 6A651ZZ Phototherapy, Circulatory, Multiple

NOTE: Contractors shall edit for an appropriate oncological and autoimmune disorder diagnosis for payment of extracorporeal photopheresis according to the NCD.

Effective for claims with dates of service on or after Oct 1, 2015, in addition to HCPCS 36522, the following ICD-10-CM codes are applicable for extracorporeal photopheresis for the treatment of BOS following lung allograft transplantation only when extracorporeal photopheresis is provided under a clinical research study as outlined in above sections 190 and 190.2 Healthcare Common Procedural Coding System (HCPCS) codes, and applicable diagnosis codes as below::

A reference listing of ICD-10-CM coding and descriptions is listed below:

CUTANEOUS T-CELL LYMPHOMA

C84.01	Mycosis fungoides, lymph nodes of head, face, and neck
C84.02	Mycosis fungoides, intrathoracic lymph nodes
C84.03	Mycosis fungoides, intra-abdominal lymph nodes
C84.04	Mycosis fungoides, lymph nodes of axilla and upper limb
C84.05	Mycosis fungoides, lymph nodes of inguinal region and lower limb
C84.06	Mycosis fungoides, intrapelvic lymph nodes
C84.07	Mycosis fungoides, spleen
C84.08	Mycosis fungoides, lymph nodes of multiple sites
C84.09	Mycosis fungoides, extranodal and solid organ sites
C84.11	Sézary disease, lymph nodes of head, face, and neck
C84.12	Sézary disease, intrathoracic lymph nodes
C84.13	Sézary disease, intra-abdominal lymph nodes
C84.14	Sézary disease, lymph nodes of axilla and upper limb
C84.15	Sézary disease, lymph nodes of inguinal region and lower limb
C84.16	Sézary disease, intrapelvic lymph nodes
C84.17	Sézary disease, spleen
C84.18	Sézary disease, lymph nodes of multiple sites
C84.19	Sezary disease, extranodal/solid organ sites
C84.A0	Cutaneous T-cell lymphoma, unspecified, unspecified site
C84.A1	Cutaneous T-cell lymphoma, unspecified lymph nodes of head, face, and neck
C84.A2	Cutaneous T-cell lymphoma, unspecified, intrathoracic lymph nodes
C84.A3	Cutaneous T-cell lymphoma, unspecified, intra-abdominal lymph nodes
C84.A4	Cutaneous T-cell lymphoma, unspecified, lymph nodes of axilla and upper limb
C84.A5	Cutaneous T-cell lymphoma, unspecified, lymph nodes of inguinal region and lower limb
C84.A6	Cutaneous T-cell lymphoma, unspecified, intrapelvic lymph nodes
C84.A7	Cutaneous T-cell lymphoma, unspecified, spleen
C84.A8	Cutaneous T-cell lymphoma, unspecified, lymph nodes of multiple sites
C84.A9	Cutaneous T-cell lymphoma, unspecified, extranodal and solid organ sites

ACUTE CARDIAC ALLOGRAFT REJECTION/GRAFT-VERSUS-HOST-DISEASE

D89.811	Chronic graft-versus-host disease
D89.812	Acute on chronic graft-versus-host disease
D89.813	Graft-versus-host disease, unspecified
T86.01	Bone marrow transplant rejection
T86.02	Bone marrow transplant failure
T86.03	Bone marrow transplant infection
T86.21	Heart transplant rejection
T86.22	Heart transplant failure
T86.23	Heart transplant infection
T86.290	Cardiac allograft vasculopathy
T86.31	Heart-lung transplant rejection
T86.32	Heart-lung transplant failure
T86.33	Heart-lung transplant infection
T86.5	Complications of stem cell transplant
Z94.3	Heart and lungs transplant status
Z94.81	Bone marrow transplant status

BOS (CED/TRIAL ONLY)

J42	Unspecified chronic bronchitis
J44.0	Chronic obstructive pulmonary disease with (acute) lower respiratory infection
J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation
J44.81	Bronchiolitis obliterans and bronchiolitis obliterans syndrome - Effective 10/1/23
J44.9	Chronic obstructive pulmonary disease, unspecified
T86.810	Lung transplant rejection
T86.811	Lung transplant failure
T86.812	Lung transplant infection
T86.818	Other complications of lung transplant
T86.819	Unspecified complication of lung transplant
Z94.2	Lung transplant status
Z00.6	Encounter for examination for normal comparison and control in clinical research program

190.3 – Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RAs) and Claim Adjustment Reason Code

(Rev.10881; Issued: 08-06-2021; Effective: 09-07-2021; Implementation: 09-07- 2021)

Contractors shall continue to use the appropriate existing messages that they have in place when denying claims submitted that do not meet the Medicare coverage criteria for extracorporeal photopheresis.

Medicare coverage for extracorporeal photopheresis is restricted to the inpatient or outpatient hospital settings specifically for BOS, and not for the other covered diagnosis (including chronic graft versus host disease) which remain covered in the hospital inpatient, hospital outpatient, and non-facility (physician-directed clinic or office settings) settings.

Contractors shall deny claims for extracorporeal photopheresis for BOS when the service is not rendered to an inpatient or outpatient of a hospital, including critical access hospitals using the following codes:

- Claim Adjustment Reason Code (CARC) 96 – Non-covered charge(s). At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason [sic] Code, or Remittance

Advice Remark Code that is not an ALERT.) **NOTE**: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

- CARC 171 – Payment is denied when performed/billed by this type of provider in this type of facility. **NOTE**: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

- Medicare Summary Notice 16.2 - This service cannot be paid when provided in this location/facility." Spanish translation: "Este servicio no se puede pagar cuando es suministrado en esta sitio/facilidad. (Include either MSN 36.1 or 36.2 dependent on liability.)

- Remittance Advice Remark Code (RARC) N428 – Not covered when performed in this place of service. (A/MACs only)

B. Group Code CO (Contractual Obligations) or PR (Patient Responsibility) dependent on liability.

Contractors shall return to provider/ return as unprocessable claims for BOS containing HCPCS procedure code 36522 along with one of the allowable ICD-10 codes if the claim is missing diagnosis code Z00.6 (as primary/secondary diagnosis, institutional only), condition code 30 (institutional claims only), clinical trial modifier Q0/Q1, and value code D4 with an 8-digit clinical trial identifier number (A/MACs only). Use the following messages:

When diagnosis code Z00.6 is missing, use:
- CARC 16 “Claim/service lacks information or has submission/billing error(s).” and
- RARC M76, “Missing/incomplete/invalid diagnosis or condition.”

When Condition Code 30 is missing, use CARC 16 and
- RARC M44 “Missing/incomplete/invalid condition code.”

When Clinical Trial modifier Q0/Q1 is missing, use CARC 16 and
- RARC N822, “Missing procedure modifier(s).”

When Clinical Trial Number is missing, use CARC 16 and
- RARC MA50, “Missing/incomplete/invalid Investigational Device Exemption number or Clinical Trial number.”

When Value Code D4 is missing, use CARC 16 and
- RARC M49, “Missing/incomplete/invalid value code(s) or amount(s).”

190.4 – Advance Beneficiary Notice and Hospital Issued Notice of Noncoverage Information

(Rev. 1206; Issued: 03-16-07; Effective: December 19, 2006; Implementation: 04-02-07)

If this service is not reasonable and necessary under 1862(a)(1)(A) of the Act (falls outside the scope of the revised NCD found in Pub. 100-03, chapter 1, section 110.4), contractors shall advise physicians and/or hospital outpatient departments, including critical access hospitals (CAHs), that they will be held liable for charges unless the physician and/or hospital has the beneficiary sign an Advance Beneficiary Notice in advance of providing the service.

If this service is provided to a hospital inpatient, including CAHs, for a reason unrelated to the admission (outside of the bundled payment) contractors shall advise hospitals billing for inpatient services that they will be held liable for charges unless the hospital has the beneficiary sign a Hospital Issued Notice of Noncoverage letter 11 in advance of providing the service.

200 - Billing Requirements for Vagus Nerve Stimulation (VNS)

(Rev. 1271, Issued: 06-22-07; Effective: 05-04-07; Implementation: 07-23-07)

200.1 - General

(Rev. 1271, Issued: 06-22-07; Effective: 05-04-07; Implementation: 07-23-07)

VNS is a pulse generator, similar to a pacemaker, that is surgically implanted under the skin of the left chest and an electrical lead (wire) is connected from the generator to the left vagus nerve. Electrical signals are sent from the battery-powered generator to the vagus nerve via the lead. These signals are in turn sent to the brain. FDA approved VNS for treatment of refractory epilepsy in 1999. Further coverage guidelines can be found in the National Coverage Determination Manual (Publication 100-03), Chapter 1, Section 160.18. Since the HCPCS codes for VNS can also be used for other indications, contractors must determine if the service being billed are for VNS and make a determination to pay or deny. CMS guidance on payment is listed below.

200.2 - ICD-10 Diagnosis Codes for Vagus Nerve Stimulation(Covered since DOS on and after July 1, 1999)

(Rev. 12435, Issued:12-28-23, Effective:01-29-24, Implementation:01-29-24)

One of the following diagnosis codes must be reported as appropriate, when billing for Vagus Nerve Stimulation:

If ICD-10-CM is applicable:

- G40.011 Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, with status epileptic
- G40.019 Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, without status epilepticus
- G40.111 Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, with status epilepticus
- G40.119 Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, without status epilepticus
- G40.211 Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, with status epilepticus

- G40.219 Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, without status epilepticus

- G40.833 Dravet syndrome, intractable, with status epilepticus

- G40.834 Dravet syndrome, intractable, without status epilepticus

- G40.C11 Lafora progressive myoclonus epilepsy, intractable, with status epilepticus

- G40.C19 Lafora progressive myoclonus epilepsy, intractable, without status epilepticus

200.3 - Carrier/MAC Billing Requirements
(Rev. 1271, Issued: 06-22-07; Effective: 05-04-07; Implementation: 07-23-07)

Effective for services performed on or after July 1, 1999, contractors are accepting claims submitted for vagus nerve stimulation for epilepsy and recurrent seizures.

Effective for services performed on or after July 1, 1999, CMS determined that vagus nerve stimulation is not reasonable and necessary for all other types of seizures which are refractory and for whom surgery is not recommended or for whom surgery has failed.

Effective for services performed on or after May 4, 2007, contractors will deny claims submitted for vagus nerve stimulation for resistant depression. Contractors need to update their local coverage determination policy to include this new NCD determination. There is no coverage for vagus nerve stimulation for patient with resistant depression.

200.4 - Fiscal Intermediary Billing Requirements
(Rev. 1271, Issued: 06-22-07; Effective: 05-04-07; Implementation: 07-23-07)

Effective for services performed on or after July 1, 1999, contractors are accepting claims submitted for vagus nerve stimulation for epilepsy and recurrent seizures.

Effective for services performed on or after July 1, 1999, CMS determined that vagus nerve stimulation is not reasonable and necessary for all other types of seizures which are refractory and for whom surgery is not recommended or for whom surgery has failed.

Effective for services performed on or after May 4, 2007, contractors will reject claims submitted for vagus nerve stimulation for resistant depression.

200.5 - Medicare Summary Notice (MSN), Remittance Advice Remark Code (RARC) and Claim Adjustment Reason Code (CARC) Messages
(Rev.11035, Issued:10-13-21, Effective: 11-17-21; Implementation: 11-17-21)

The following messages are used by Medicare contractors when denying non-covered VNS services:

MSN: 16.10 “Medicare does not pay for this item or service."

CARC: 50 “These are non-covered services because this is not deemed a“medical necessity” by the payer."

The following RARC messages can be used depending on liability:

M27 Alert: The patient has been relieved of liability of payment of these items and services under the limitation of liability provision of the law. You, the provider, are ultimately liable for the patient's waived charges, including any charges for coinsurance, since the items or services were notreasonable and necessary or constituted custodial care, and you knew or could reasonably have been expected to know, that they were not covered.You may appeal this determination. You may ask for an appeal regarding both the coverage determination and the issue of whether you exercised due care. The appeal request must be filed within 120 days of the date youreceive this notice. You must make the request through this office.

Or

M38 Alert: The patient is liable for the charges for this service as you informed the patient in writing before the service was furnished that wewould not pay for it, and the patient agreed to pay.
Contractors will also include group code CO (contractual obligation) or PR(patient responsibility) depending on liability.

200.6 - Advance Beneficiary Notice and HINN Information

(Rev. 1271, Issued: 06-22-07; Effective: 05-04-07; Implementation: 07-23-07)

Physicians are liable for non-covered VNS procedures unless they issue an appropriate advance beneficiary notice (ABN). The following language should be included in the ABN:

Items or Service Section:
"Vagas Nerve Stimulation".

Because Section:
"As specified in section 160.18 of Pub.100-03, Medicare National Coverage Determination Manual, Medicare will not pay for this procedure as it is not a reasonable and necessary treatment for (select either "your type of seizure disorder" or "resistant depression.")

Note that the ABN is the appropriate notice for Part B services and is valid whether the language above is inserted or not.

210 - Billing Requirements for Continuous Positive Airway Pressure (CPAP) for Obstructive Sleep Apnea (OSA)
(Rev.)

220 - Billing Requirements for Thermal Intradiscal Procedures (TIPs)
(Rev. 1646, Issued: 12-09-08, Effective: 09-29-08, Implementation: 01-05-09)

220.1 - General
(Rev. 1646, Issued: 12-09-08, Effective: 09-29-08, Implementation: 01-05-09)

Effective for services on or after September 29, 2008, the Center for Medicare & Medicaid Services (CMS) made the decision that Thermal Intradiscal Procedures (TIPS) are not reasonable and necessary for the treatment of low back pain. Therefore, TIPs are non-covered. Refer to Pub.100-03, Medicare National Coverage Determination (NCD) Manual Chapter 1, Part 2, Section 150.11, for further information on the NCD.

220.2 - Contractors, A/B Medicare Administrative Contractors (MACs)

(Rev. 1646, Issued: 12-09-08, Effective: 09-29-08, Implementation: 01-05-09)

The following Healthcare Common Procedure Coding System (HCPCS) codes will be nationally non-covered by Medicare effective for dates of service on and after September 29, 2008:

22526: Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level

22527: Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; one or more additional levels

0062T: Percutaneous intradiscal annuloplasty, any method except electrothermal, unilateral or bilateral including fluoroscopic guidance; single level

0063T: Percutaneous intradiscal annuloplasty, any method except electrothermal, unilateral or bilateral including fluoroscopic guidance; one or more additional levels

NOTE: The change to add the non-covered indicator for the above HCPCS codes will be part of the January 2009 Medicare Physician Fee Schedule Update. The change to the status indicator to non-cover the above HCPCS will be part of the January Integrated Outpatient Code Editor (IOCE) update.

Claims submitted with the non-covered HCPCS codes on or after September 29, 2008, will be denied by Medicare contractors.

220.3 - Medicare Summary Notice (MSN), Claim Adjustment Reason Code (CARC), and Remittance Advice Remark Code (RARC)

(Rev. 1646, Issued: 12-09-08, Effective: 09-29-08, Implementation: 01-05-09)

The following messages are used by Medicare contractors when denying non-covered TIP services:

- MSN: 21.11 "This service was not covered by Medicare at the time you received it."
- CARC: 96 "Non-covered charge(s)"

N386 "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at http://www.cms.hhs.gov/med/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD."

220.4 - Advance Beneficiary Notice (ABN)

(Rev. 1646, Issued: 12-09-08, Effective: 09-29-08, Implementation: 01-05-09)

Providers are liable for charges if TIPS is used in surgery, unless the beneficiary was informed that he/she would be financially responsible prior to performance of the procedure. To avoid this liability the provider should have the beneficiary sign an ABN.

230 – Billing Wrong Surgical or Other Invasive Procedures Performed on a Patient, Surgical or Other Invasive Procedures Performed on the Wrong Body Part, and Surgical or Other Invasive Procedures Performed on the Wrong Patient

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

The Centers for Medicare & Medicaid Services (CMS) internally generated a request for a national coverage analysis (NCA) to establish national coverage determinations (NCDs) addressing Medicare coverage of Wrong Surgical or Other Invasive Procedures Performed on a Patient, Surgical or Other Invasive Procedures Performed on the Wrong Body Part, and Surgical or Other Invasive Procedures Performed on the Wrong Patient. Information regarding these NCDs can be found in Publication (Pub.) 100-03, Chapter 1, sections 140.6, 140.7, and 140.8, respectively.

Inpatient Claims

Hospitals are required to bill two claims when a surgical error is reported and a covered service is also being reported:

- One claim with covered service(s)/procedure(s) unrelated to the erroneous surgery(s) on a Type of Bill (TOB) 11X (with the exception of 110), and
- The other claim with the non-covered service(s)/procedure(s) related to the erroneous surgery(s) on a TOB 110 (no-pay claim)

NOTE: Both the covered and non-covered claim shall have a matching Statement Covers Period.

For discharges prior to October 1, 2009, the non-covered TOB 110 must indicate on the 837 institutional claim format, or in the Remarks field of the Form CMS1450 one of the applicable erroneous surgery(s) two-digit codes (entered exactly as specified below):

- For a wrong surgery on patient, enter the following: **MX**
- For a surgery on a wrong body part, enter the following: **MY**
- For a surgery on wrong patient, enter the following: **MZ**

For discharges on or after October 1, 2009, the non-covered TOB 110 must have one of the following diagnosis codes reported in diagnosis position 2-9, instead of billing the aforementioned two-digit codes in Remarks:

If ICD-9-CM Is Applicable

- **E876.5** - Performance of wrong operation (procedure) on correct patient (existing code)
- **E876.6** - Performance of operation (procedure) on patient not scheduled for surgery
- **E876.7**- Performance of correct operation (procedure) on wrong side/body part

NOTE: The above codes shall not be reported in the External Cause of Injury (E-code) field.

If ICD-10-CM Is Applicable

- Y65.51 Performance of wrong procedure (operation) on correct patient
- Y65.52 Performance of procedure (operation) on patient not scheduled for surgery
- Y65.53 Performance of correct procedure (operation) on wrong side of body parts

Outpatient, Ambulatory Surgical Centers, and Practitioner Claims

Providers are required to append one of the following applicable HCPCS modifiers to all lines related to the erroneous surgery(s):

- PA: Surgery Wrong Body Part
- PB: Surgery Wrong Patient
- PC: Wrong Surgery on Patient

All claims

Claim/Lines submitted with a surgical error will be denied/line-item denied using the following:

Medicare Summary Notice
23.17 – Medicare won't cover these services because they are not considered medically necessary."

23.17 – Medicare no cubrirá estos servicios porque no son considerados necesarios por razones médicas.

Claim Adjustment Reason Code
CARC 50 – These are non-covered services because this is not deemed a 'medical necessity" by the payer.

Group Code
CO – Contractual Obligation

Beneficiary Liability

Generally, beneficiary liability notices such an Advance Beneficiary Notice of Non-coverage (ABN) or a Hospital Issued Notice of Non-coverage (HINN) is appropriate when a provider is furnishing an item or service that the provider reasonably believes Medicare will not cover on the basis of §1862(a)(1). An ABN must include all of the elements described in Pub. 100-04, Claims Processing Manual (CPM), Ch. 30, §50.6.3, in order to be considered valid. For example, the ABN must specifically describe the item or service expected to be denied (e.g. a left leg amputation) and must include a cost estimate for the non-covered item or service. Similarly, HINNs must specifically describe the item or service expected to be denied (e.g. a left leg amputation) and must include all of the elements described in the instructions found in the CPM Ch. 3,0 §200. Thus, a provider cannot shift financial liability for the non-covered services to the beneficiary, unless the ABN or the HINN satisfies all of the applicable requirements in the CPM Ch. 30, §50.6.3 and §200, respectively. Given these requirements, CMS cannot envision a scenario in which HINNs or ABNs could be validly delivered in these NCD cases. However, an ABN or a HINN could be validly delivered prior to furnishing services related to the follow-up care for the non-covered surgical error that would not be considered a related service to the non-covered surgical error.

240 – Special Instructions for Services with a Gender/Procedure Conflict
(Rev. 1877, Issued: 12-18-09, Effective: 04-01-10, Implementation: 04-05-10)

Claims for some services for beneficiaries with transgender, ambiguous genitalia, and hermaphrodite issues, may inadvertently be denied due to sex related edits unless these services are billed properly.

The National Uniform Billing Committee (NUBC) has approved condition code 45 (Ambiguous Gender Category) as a result of the increasing number of claims received that are denied due to sex/diagnosis and sex/procedure edits. This claim level condition code should be used by institutional providers to identify these unique claims and alerts the fiscal intermediary that the gender/procedure or gender/diagnosis conflict is not an error allowing the sex related edits to be by-passed.

The KX modifier (Requirements specified in the medical policy have been met) is now a multipurpose informational modifier and will also be used identify services for transgender, ambiguous genitalia, and hermaphrodite beneficiaries in addition to its other existing uses. Physicians and non-physician practitioners should use modifier KX with procedure codes that are gender specific in the particular cases of transgender, ambiguous genitalia, and hermaphrodite beneficiaries. Therefore, if a gender/procedure or gender/diagnosis conflict edit occurs, the KX modifier alerts the MAC that it is not an error and will allow the claim to continue with normal processing.

240.1 - Billing Instructions for Institutional Providers
(Rev. 1877, Issued: 12-18-09, Effective: 04-01-10, Implementation: 04-05-10)

Institutional providers are to report condition code 45 on any inpatient or outpatient claim related to transgender, ambiguous genitalia, or hermaphrodite issues.

240.2 – Billing Instructions for Physicians and Non-Physician Practitioners

(Rev. 1877, Issued: 12-18-09, Effective: 04-01-10, Implementation: 04-05-10)

The KX modifier is to be billed on the detail line only with the procedure code(s) that is gender specific for transgender, ambiguous genitalia, and hermaphrodite beneficiaries. (NOTE: The KX modifier is a multipurpose informational modifier, and may also be used in conjunction with other medical policies.)

250 – Pharmacogenomic Testing for Warfarin Response

(Rev. 1889, Issued: 01-08-10; Effective Date: 08-03-09; Implementation Date: 04-05-10)

250.1 – Coverage Requirements

(Rev. 1889, Issued: 01-08-10; Effective Date: 08-03-09; Implementation Date: 04-05-10)

Effective August 3, 2009, pharmacogenomic testing to predict warfarin responsiveness is covered only when provided to Medicare beneficiaries who are candidates for anticoagulation therapy with warfarin; i.e., have not been previously tested for CYP2C9 or VKORC1 alleles; and have received fewer than five days of warfarin in the anticoagulation regimen for which the testing is ordered; and only then in the context of a prospective, randomized, controlled clinical study when that study meets certain criteria as outlined in Pub 100-03, section 90.1, of the NCD Manual.

NOTE: A new temporary HCPCS Level II code effective August 3, 2009, G9143, warfarin responsiveness testing by genetic technique using any method, any number of specimen(s), was developed to enable implementation of CED for this purpose.

250.2 – Billing Requirements

(Rev. 11021; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

Institutional clinical trial claims for pharmacogenomic testing for warfarin response are identified through the presence of all of the following elements:

- Value Code D4 and 8-digit clinical trial number (when present on the claim) - Refer to Transmittal 310, Change Request 5790, dated January 18, 2008;
- ICD-10 diagnosis code Z00.6 (secondary) - Refer to Transmittal 310, Change Request 5790, dated January 18, 2008; and Z79.01 (primary);
- Condition Code 30 - Refer to Transmittal 310, Change Request 5790, dated January 18, 2008;
- HCPCS modifier Q0: outpatient claims only - Refer to Transmittal 1418, Change Request 5805, dated January 18, 2008; and,
- HCPCS code G9143 (mandatory with the April 2010 Integrated Outpatient Code Editor (IOCE) and the January 2011 Clinical Laboratory Fee Schedule (CLFS) updates. Prior to these times, any trials should bill FIs for this test as they currently do absent these instructions, and the FIs should process and pay those claims accordingly.)

Practitioner clinical trial claims for pharmacogenomic testing for warfarin response are identified through the presence of all of the following elements:

- ICD-10-diagnosis code Z00.6 (secondary), and ICD-10 diagnosis code Z79.01 (primary) MCS edit 031L70.7;

- 8-digit clinical trial number(when present on the claim);
- HCPCS modifier Q0; and, MCS edit 031L
- HCPCS code G9143 (to be carrier priced for claims with dates of service on and after August 3, 2009, that are processed prior to the January 2011 CLFS update.)

NOTE: This NCD does not determine coverage to identify CYP2C9 or VKORC1 alleles for other purposes beside warfarin responsiveness, nor does it determine national coverage to identify other alleles to predict warfarin responsiveness. These decisions are made at the local MAC level.

250.3 – Payment Requirements

(Rev. 11021; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

Beginning April 5, 2010, for claims with dates of service on and after August 3, 2009, the Medicare Shared System will track the number of times a beneficiary receives pharmacogenomic testing for warfarin response. When a claim is received for pharmacogenomic testing for warfarin response, and the shared system has determined that the beneficiary has already received the test in his/her lifetime, it will generate a Medicare line-item denial and the Medicare contractor will provide the following messages to enforce the one-time limitation for the test:

Claim Adjustment Reason Code (CARC) 50 – These are non-covered services because this is not deemed a 'medical necessity' by the payer. This change to be effective April 1, 2010: These are non-covered services because this is not deemed a 'medical necessity' by the payer.

NOTE: Refer to the 835 Healthcare Policy Identification Segment, if present.

Remittance Advice Remark Code (RARC) N362 – The number of Days or Units of Service exceeds our acceptable maximum.

Group Code CO – Contractual Obligation

Medicare Summary Notice (MSN) 16.76 – This service/item was not covered because you have exceeded the lifetime limit for getting this service/item. (Este servicio/artículo no fue cubierto porque usted ya se ha pasado del límite permitido de por vida, para recibirlo.).

The Medicare shared system and the A/B MACs (B) will also ensure that pharmacogenomic testing for warfarin response is billed in accordance with clinical trial reporting requirements. In other words, the shared system and the A/B MACs (B) will return to provider/return as unprocessable lines for pharmacogenomic testing for warfarin response when said line is not billed with HCPCS modifier Q0 and ICD-10- CM diagnosis code if applicable, ICD-10-CM Z00.6 is not present as a secondary diagnosis. When the system or the A/B MAC (B) initiates the line- item return to provider or returns the claim as unprocessable, the Medicare contractor will respond with the following messages:

For a missing Q0 modifier:
CARC 4 - The procedure code is inconsistent with the modifier used or a required modifier is missing.

For a missing Z00.6 diagnosis code when a HCPCS Q0 modifier is reported with HCPCS G9143:

CARC 16 - Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.)

Remark Code M64 - Missing/incomplete/invalid other diagnosis.

For either a missing Q0 modifier and/or a missing ICD-10-CM Z00.6 diagnosis code:

Group Code CO- Contractual Obligation

MSN 16.77 – This service/item was not covered because it was not provided as part of a qualifying trial/study. (Este servicio/artículo no fue cubierto porque no estaba incluido
como parte de un ensayo clínico/estudio calificado.)

260 - Dermal Injections for Treatment of Facial Lipodystrophy Syndrome (LDS)

(Rev. 2105, Issued: 11-24-10, Effective: 03-23-10, Implementation: 07-06-10)

260.1 – Policy

(Rev. 2105, Issued: 11-24-10, Effective: 03-23-10, Implementation: 07-06-10)

The Centers for Medicare & Medicaid Services (CMS) received a request for national coverage of treatments for facial lipodystrophy syndrome (LDS) for human immunodeficiency virus (HIV)-infected Medicare beneficiaries. Facial LDS is often characterized by a loss of fat that results in a facial abnormality such as severely sunken cheeks. This fat loss can arise as a complication of HIV and/or highly active antiretroviral therapy. Due to their appearance and stigma of the condition, patients with facial LDS may become depressed, socially isolated, and in some cases may stop their HIV treatments in an attempt to halt or reverse this complication.

Effective for claims with dates of service on and after March 23, 2010, dermal injections for facial LDS are only reasonable and necessary using dermal fillers approved by the Food and Drug Administration for this purpose, and then only in HIV-infected beneficiaries who manifest depression secondary to the physical stigmata of HIV treatment.

See Pub. 100-03, National Coverage Decision manual, section 250.5, for detailed policy information concerning treatment of LDS.

260.1.1– Hospital Billing Instructions

(Rev. 11021; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

A - Hospital Outpatient Claims

For hospital outpatient claims, hospitals must bill covered dermal injections for treatment of facial LDS by having all of the required elements on the claim:

1. A line with HCPCS codes Q2026 or Q2027 with a Line Item Date of service (LIDOS) on or after March 23, 2010,

   NOTE: Q2027 is replaced with Q2028 effective 1/1/14 as per the 2014 HCPCS update.

2. A line with HCPCS code G0429 with a LIDOS on or after March 23, 2010,

3. If ICD-10-CM is applicable, ICD-10-CM diagnosis codes B20 Human Immunodeficiency Virus (HIV) disease and E88.1 Lipodystrophy, not elsewhere classified

The applicable NCD is 250.5 Facial Lipodystrophy.

B - Outpatient Prospective Payment System (OPPS) Hospitals or Ambulatory Surgical Centers (ASCs):

For line item dates of service on or after March 23, 2010, and until HCPCS codes Q2026 and Q2027 are billable, facial LDS claims shall contain a temporary HCPCS code C9800, instead of HCPCS G0429 and HCPCS Q2026/Q2027, as shown above.

NOTE: Q2027 is replaced with Q2028 effective 1/1/14 as per the 2014, HCPCS update.

C - Hospital Inpatient Claims

Hospitals must bill covered dermal injections for treatment of facial LDS by having all of the required elements on the claim:

C. Discharge date on or after March 23, 2010,

D. If ICD-10-PCS is applicable,

- ICD-10-PCS procedure code 3E00XGC Introduction of Other Therapeutic Substance into Skin and Mucous Membrances, External Approach, or

E. If ICD-10-CM is applicable on or after 10/01/2015,

- ICD-10-CM diagnosis codes B20 Human Immunodeficiency Virus [HIV] disease and E88.1 Lipodystrophy not elsewhere classified.

A diagnosis code for a comorbidity of depression may also be required for coverage on an outpatient and/or inpatient basis as determined by the individual Medicare contractor's policy.

260.2 –Billing Instructions

(Rev. 2105, Issued: 11-24-10, Effective: 03-23-10, Implementation: 07-06-10)

260.2.1 – Hospital Billing Instructions

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

A - Hospital Outpatient Claims

For hospital outpatient claims, hospitals must bill covered dermal injections for treatment of facial LDS by having all of the required elements on the claim:

- A line with HCPCS codes Q2026 or Q2027 with a Line Item Date of service (LIDOS) on or after March 23, 2010,

- A line with HCPCS code G0429 with a LIDOS on or after March 23, 2010,
- If ICD-9-CM is applicable, ICD-9-CM diagnosis codes 042 (HIV) and 272.6 (Lipodystrophy) or,
- If ICD-10-CM is applicable, ICD-10-CM diagnosis codes B20 Human Immunodeficiency Virus (HIV) disease and E88.1 Lipodystrophy, not elsewhere classified

The applicable NCD is 250.5 Facial Lipodystrophy.

B - Outpatient Prospective Payment System (OPPS) Hospitals or Ambulatory Surgical Centers (ASCs):

For line item dates of service on or after March 23, 2010, and until HCPCS codes Q2026 and Q2027 are billable, facial LDS claims shall contain a temporary HCPCS code C9800, instead of HCPCS G0429 and HCPCS Q2026/Q2027, as shown above.

C - Hospital Inpatient Claims

Hospitals must bill covered dermal injections for treatment of facial LDS by having all of the required elements on the claim:

- Discharge date on or after March 23, 2010,
- **If ICD-9-CM is applicable,**
    - ICD-9-CM procedure code 86.99 (other operations on skin and subcutaneous tissue, i.e., injection of filler material), or
    - ICD-9-CM diagnosis codes 042 (HIV) and 272.6 (Lipodystrophy)
- **If ICD-10-PCS is applicable,**
    - ICD-10-PCS procedure code 3E00XGC Introduction of Other Therapeutic Substance into Skin and Mucous Membrances, External Approach, or
    - ICD-10-CM diagnosis codes B20 Human Immundodeficiency Virus [HIV] disease and E88.1 Lipodystrophy not elsewhere classified.

A diagnosis code for a comorbidity of depression may also be required for coverage on an outpatient and/or inpatient basis as determined by the individual Medicare contractor's policy.

260.2.2 – Practitioner Billing Instructions

(Rev. 11021; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

Practitioners must bill covered claims for dermal injections for treatment of facial LDS by having all of the required elements on the claim:

<u>Performed in a non-facility setting</u>:

- A line with HCPCS codes Q2026 or Q2027 with a LIDOS on or after March 23, 2010,

NOTE: Q2027 is replaced with Q2028 effective 1/1/14 per the 2014 HCPCS update.

- A line with HCPCS code G0429 with a LIDOS on or after March 23, 2010,

51 If ICD-10-CM applies, diagnosis codes B20 Human Immunodeficiency Virus (HIV) disease and E88.1 (Lipodystrophy not elsewhere classified). Both diagnoses are required on the claim.

NOTE: A diagnosis code for a comorbidity of depression may also be required for coverage based on the individual Medicare contractor's policy.

52 A line with HCPCS code G0429 with a LIDOS on or after March 23, 2010,

53 If ICD-10 CM- applies, ICD-10-CM diagnosis codes B20 Human immunodeficiency Virus (HIV) disease and E88.1 (Lipodystrophy not elsewhere classified). Both diagnoses are required on the claim.

NOTE: A diagnosis code for a comorbidity of depression may also be required for coverage based on the individual Medicare contractor's policy.

260.3 – Claims Processing System Editing

(Rev. 11021; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

Billing for Services Prior to Medicare Coverage

Hospitals and practitioners billing for dermal injections for treatment of facial LDS prior to the coverage date of March 23, 2010, will receive the following messages upon their Medicare denial:

- Claim Adjustment Reason Code (CARC) 26: Expenses incurred prior to coverage.

NOTE: Outpatient hospitals and beneficiaries that received services in a hospital outpatient setting may receive different message as established by their particular Medicare contractor processing the claim.)

Medicare beneficiaries whose provider bills Medicare for dermal injections for treatment of facial LDS prior to the coverage date of March 23, 2010, will receive the following Medicare Summary Notice (MSN) message upon the Medicare denial:

- - This service was not covered by Medicare at the time you received it. (Spanish Version: Este servicio no estaba cubierto por Medicare cuando usted lo recibió.)

Billing for Services Not Meeting Comorbidity Coverage Requirements

Hospitals and practitioners billing for dermal injections for treatment of facial LDS on patients that do not have a comorbidity of HIV and lipodystrophy (or even depression if deemed required by the Medicare contractor) will receive the following messages upon their Medicare denial:

- CARC 50: These are non-covered services because this is not deemed a 'medical necessity' by the payer. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

- RARC N386: This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

- RARC M64: Missing/incomplete/invalid other diagnosis.

- Group Code: CO

Medicare beneficiaries who do not meet Medicare comorbidity requirements of HIV and lipodystrophy (or even depression if deemed required by the Medicare contractor) and whose provider bills Medicare for dermal injections for treatment of facial LDS will receive the following MSN message upon the Medicare denial:

15.4 - The information provided does not support the need for this service or item. (Spanish Version: La información proporcionada no confirma la necesidad para este servicio oículo.)

270 – Claims Processing for Implantable Automatic Defibrillators
(Rev. 2005, Issued: 7-23-10, Effective: 8-31-10, Implementation: 8-31-10)

Coverage Requirements- The implantable automatic defibrillator is an electronic device designed to detect and treat life threatening tachyarrhythmias. The device consists of a pulse generator and electrodes for sensing and defibrillating.
See §20.4 -Medicare National Coverage Determinations (NCD) Manual for the complete list of covered indications.

270.1– Coding Requirements for Implantable Cardiac Defibrillators (ICDs)
(Rev. 13641; Issued:02-13-26; Effective:10-20-23 Implementation:04-06-26)

A. For outpatient institutional and professional claims with dates of service on or after February 15, 2018, contractors shall accept and pay outpatient and professional ICD services that meet the coverage criteria outlined in the NCD Manual, Section 20.4, using the following procedure/HCPCS codes:

Group 1 Device Codes (DEFIBRILLATOR SPECIFIC CODES):

33223, 33230, 33231, 33240, 33241, 33243, 33244, 33249, 33262, 33263, 33264, 33270, 33271, 33272, 33273, and G0448

Effective for claims with dates of service on or after October 1, 2023, ICD-10 PCS 0WHC0GZ, 0WHC3GZ, 0WHC4GZ, 0WPC0GZ, 0WPC3GZ, 0WPC4GZ, 0WPCXGZ, 0WWC0GZ, 0WWC3GZ, 0WWC4GZ, 0WWCXGZ

Effective for claims with dates of service on or after October 20, 2023, Medicare also covers the following procedure codes for the Aurora™ extravascular ICD (EV-ICD) system:

0571T – insertion or replacement of an implantable cardioverter-defibrillator (ICD) system with substernal electrode(s), including all imaging guidance and electrophysiological evaluation (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming of sensing or therapeutic parameters), when performed

0572T – Insertion of substernal implantable defibrillator electrode

0573T – Removal of substernal implantable defibrillation electrode

0574T – Repositioning of a previously implanted substernal implantable defibrillator-pacing electrode.

0575T- Programming device evaluation (in person) of implantable cardioverter-defibrillator system with substernal electrode, with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified healthcare professional

0576T- Interrogation device evaluation (in person) of implantable cardioverter-defibrillator system with substernal electrode, with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter

0577T- Electrophysiological evaluation of implantable cardioverter-defibrillator system with substernal electrode (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)

0578T- Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter-defibrillator system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional

0579T- Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter-defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results

0580T- Removal of substernal implantable defibrillator pulse generator only

0614T- Removal and replacement of substernal implantable defibrillator pulse generator

Group 2 Device Codes (DUAL DEVICE DEFIBRILLATOR/ PACEMAKER CODES):

33202, 33203, 33215, 33216, 33217, 33218, 33220, 33224, and 33225

Effective for Group 2 ASC claims with dates of service on or after January 1, 2023, Medicare covers HCPCS codes: C7537, C7538, C7539, and C7540

B. Effective for Professional claims with dates of service on or after February 15, 2018, contractors shall accept the following International Classification of Disease (ICD) -10 diagnosis codes for ICD services:

Group 1- ICD-10 Diagnosis Codes

I42.1, I42.2, I45.6, I45.81, I45.89, I46.2, I46.9, I47.20, I47.21, I47.29, I49.01, I49.02, I49.3, I49.9, I5A, T82.110A, T82.111A, T82.118A, T82.119A, T82.120A, T82.121A, T82.128A, T82.129A, T82.190A, T82.191A, T82.198A,
T82.199A, T82.7XXA, Z45.02, Z86.74, and (Z00.6 ONLY in the context of a Category B IDE trial denoted by the presence of an IDE number)

Effective for Claims with dates of service on or after October 1, 2021, Medicare covers ICD-10 diagnosis code I5.A

Effective for Claims with dates of service on or after October 1, 2022, Medicare covers ICD-10 diagnosis codes I47.20, I47.21, I47.29

Group 2 - ICD-10 Diagnosis Codes

G90.01, I42.1, I47.20, I47.21, I47.29, **I44.0, I44.1, I44.2, I44.30, I44.7, I45.10, I45.19, I45.2, I45.3,** I45.6, I45.81, I45.89,
I46.2, I46.9**,** I47.2, **I47.9, I48.11, I48.19, I48.3, I48.4, I48.91, I48.92,** I49.01, I49.02, I49.3, **I49.5,** I49.9, I5A, **Q24.6,** T82.110A, T82.111A, T82.118A, T82.119A, T82.120A, T82.121A, T82.128A, T82.129A, T82.190A, T82.191A, T82.198A, T82.199A, T82.7XXA, Z00.6, Z45.02, and Z86.74

Effective for Claims with dates of service on or after October 1, 2021, Medicare covers ICD-10 diagnosis code I5.A

Effective on or after September 30, 2023, Medicare no longer covers ICD-10 diagnosis code I47.1

Effective on or after October 1, 2023. Medicare covers ICD-10 diagnosis codes I47.10, I47.11, I47.19

Note: Codes **BOLDED** indicate pacemaker diagnosis codes.

C. Effective for outpatient institutional claims with dates of service on or after February 15, 2018, that contain a procedure/HCPCS code from Group 1; contractors shall accept one (1) of the following three (3) conditions for diagnosis codes for ICD services:

Group 1- ICD-10 Diagnosis Codes

One of the following ICD-10 diagnosis codes: I42.1, I42.2, I45.6, I45.81, I45.89, I46.2, I46.9, I47.20, I47.21, I47.29, I49.01, I49.02, I49.3, I49.9, I5A, T82.110A, T82.111A, T82.118A, T82.119A, T82.120A, T82.121A, T82.128A, T82.129A, T82.190A, T82.191A, T82.198A, T82.199A, T82.7XXA, Z45.02, Z86.74, (Z00.6), Effective October 1, 2021: I5.A

1) ONLY in the context of a Category B IDE trial denoted by the presence of an IDE number)

OR

2) One of the following ICD-10 diagnosis codes: I25.2, I25.5, I42.0, I42.6, I42.7, I42.8; paired with one of the following ICD-10 diagnosis codes: I50.21, I50.22, I50.23, I50.41, I50.42, I50.43

OR

3) The following ICD-10 diagnosis codes: Z76.82; paired with the following ICD-10 diagnosis codes: I50.84

Effective for outpatient institutional claims with dates of service on or after February 15, 2018, that contain a procedure/HCPCS code from Group 2; contractors shall accept one (1) of the following three (3) conditions for diagnosis codes for ICD services:

Group 2 - ICD-10 Diagnosis Codes

One of the following ICD-10 diagnosis codes: **G90.01,** I42.1, I42.2**, I44.0, I44.1, I44.2, I44.30, I44.7, I45.10, I45.19, I45.2, I45.3,** I45.6, I45.81, I45.89, I46.2, I46.9, I47.20, I47.21, I47.29, **I47.9, I48.11, I48.19, I48.3, I48.4, I48.91, I48.92,** I49.01, I49.02, I49.3, **I49.5,** I49.9, **Q24.6,** T82.110A, T82.111A, T82.118A, T82.119A, T82.120A, T82.121A, T82.128A, T82.129A, T82.190A, T82.191A, T82.198A, T82.199A, T82.7XXA, Z45.02,

Z86.74, (Z00.6 ONLY in the context of a Category B IDE trial denoted by the presence of an IDE number) Effective October 1, 2021: I5.A Effective on or after October 1, 2023, Medicare covers ICD-10 diagnosis codes I47.10, I47.11, I47.19

OR

1) One of the following ICD-10 diagnosis codes: I25.2, I25.5, I42.0, I42.6, I42.7, I42.8; paired with one of the following ICD-10 diagnosis codes: I50.21, I50.22, I50.23, I50.41, I50.42, I50.43

OR

2) The following ICD-10 diagnosis Code: Z76.82; paired with the following ICD-10 diagnosis code: I50.84

Note: Codes **BOLDED** indicate pacemaker diagnosis codes

D. Contractors shall process EV-ICD professional claims when submitted with CPT code 0571T, 0572T, 0573T, 0574T, 0575T, 0576T, 0577T, 0578T, 0579T, 0580T, or 0614T and submitted with the following criteria: Group 1- ICD-10 DIAGNOSIS CODES
I42.1, I42.2, I45.6, I45.81, I45.89, I46.2, I46.9, I47.20, I47.21, I47.29, I49.01, I49.02, I49.3, I49.9, I5A, T82.110A, T82.111A, T82.118A, T82.119A, T82.120A, T82.121A, T82.128A, T82.129A, T82.190A, T82.191A, T82.198A, T82.199A, T82.7XXA, Z45.02, Z86.74

OR, 1 of the following:

I25.2, I25.5, I42.0, I42.6, I42.7, I42.8

AND, paired with 1 of the following:

I50.21, I50.22, I50.23, I50.41, I50.42, I50.43

OR

Z76.82

AND, paired with:

I50.84

AND Z00.6 (as other diagnosis)

AND
Place of Service (POS) 19, 21, 22, 24 or 26

270.2 – Billing Requirements for Patients Enrolled in a Data Collection System

(Rev.11759, Issued:12-21-2022, Effective:01-23-2023, Implementation:01-23-2023)

Effective for dates of service on or after April 1, 2005, Medicare required that patients receiving a defibrillator for the primary prevention of sudden cardiac arrest be enrolled in a qualifying data collection system. Providers shall use modifier Q0 to identify patients whose data is being submitted to a data collection system.

The following diagnosis codes identify non-primary prevention (secondary prevention) patient or replacement implantations (e.g. due to recalled devices):

If ICD-9-CM is applicable, select from the following diagnosis codes:

427.1 Ventricular tachycardia

427.41 Ventricular fibrillation

427.42 Ventricular flutter

427.5 Cardiac arrest

427.9 Cardiac dysrhythmia, unspecified

V12.53 Personal history of sudden cardiac arrest

996.04 Mechanical complication of cardiac device, implant, and graft, due to automatic implantable cardiac defibrillator

V53.32 Fitting and adjustment of other device, automatic implantable cardiac defibrillator

If ICD-10-CM is applicable, select from the following list:

I47.0 Re-entry Ventricular Arrhythmia

I47.2 Ventricular Tachycardiaselect - end date September 30, 2022

I47.20 Ventricular Tachycardia, unspecified - effective October 1, 2022

I47.21 Torsades De Pointes - effective October 1, 2022

I47.29 Other Ventricular Tachycardia - effective October 1, 2022

I49.3 Ventricular Premature depolarization

I49.01 Ventricular Fibrillation

I49.02 Ventricular Flutter

I46.2 Cardiac arrest due to underlying cardiac condition

I46.8 Cardiac arrest due to other underlying condition

I46.9 Cardiac arrest, cause unspecified

I49.9 Cardiac arrhythmia, unspecified

T82.110A Breakdown (mechanical) of cardiac electrode, initial encounter

T82.111A Breakdown (mechanical) of cardiac pulse generator (battery), initial encounter

T82.118A Breakdown (mechanical) of other cardiac electronic device, initial encounter

T82.119A Breakdown (mechanical) of unspecified cardiac electronic device, initial encounter

T82.120A Displacement of cardiac electrode, initial encounter

T82.121A Displacement of cardiac pulse generator (battery), initial encounter

T82.128A Displacement of other cardiac electronic device, initial encounter

T82.129A Displacement of unspecified cardiac electronic device, initial encounter

T82.190A Other mechanical complication of cardiac electrode, initial encounter

T82.191A Other mechanical complication of cardiac pulse generator (battery), initial encounter

T82.198A Other mechanical complication of other cardiac electronic device, initial encounter

T82.199A Other mechanical complication of unspecified cardiac device, initial encounter

Z86.74 Personal history of sudden cardiac arrest

Z45.02 Encounter for adjustment and management of automatic implantable cardiac defibrillator

When any of the above codes appear on a claim, the Q0 modifier is not required. The Q0 modifier may be appended to claims for secondary prevention indications when data is being entered into a qualifying data collection system.

270.3- Messaging

(Rev. 13641; Issued:02-13-26; Effective:10-20-23 Implementation:04-06-26)

Type of Bill (TOB) and Place of Service (POS)

Contractors shall return as unprocessable claims for ICD services when the service is not rendered to an inpatient or outpatient of a hospital, including critical access hospitals, hospital-based outpatient clinics, Ambulatory Surgery Center (ASC), or Military facilities as indicated by institutional claims Type of Bills (TOB's) 011x, 012x, 013x, and 85x and professional claim Place of Service (POS) codes 19, 21, 22, 24 and 26 using the following messaging:

Claim Adjustment Reason Code (CARC) 58: Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service.

Group Code CO (Contractual Obligation)

Diagnosis Coding

Contractors shall deny claims for ICD services that do not contain an appropriate diagnosis code using the following messages:

Contractors shall deny a line-item on EV-ICD claims submitted with CPT code 0571T, 0572T, 0573T, 0574T, 0575T, 0576T, 0577T, 0578T, 0579T, 0580T, or 0614T and submitted without the required Group 1 ICD-10-CM diagnosis code.

CARC 167: This (these) diagnosis(es) is (are) not covered.

RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Group Code CO (Contractual Obligation) or PR (Patient Responsibility) dependent on liability:

Use PR on professional claims, when the GA modifier is appended to a claim line-item CPT procedure codes 0571T, 0572T, 0573T, 0574T, 0575T, 0576T, 0577T, 0578T, 0579T, 0580T, or 0614T.
Use PR on institutional claims, when Occurrence Code 32 is present, and the GA modifier is appended to a line item with CPT procedure codes 0571T, 0572T, 0573T, 0574T, 0575T, 0576T, 0577T, 0578T, 0579T, 0580T, or 0614T

Medicare Summary Notice (MSN) 15.19: “We used a Local Coverage Determination (LCD) to decide coverage for your claim. To appeal, get a copy of the LCD at www.cms.gov/medicare-coverage-database (use the MSN Billing Code for the CPT/HCPCS Code) and send with information from your doctor."

Spanish Version - Usamos una Determinación de Cobertura Local (LCD) para decidir la cobertura de su reclamo. Para apelar, obtenga una copia del LCD en www.cms.gov/medicare-coverage-database (use el código de facturación de MSN para el código "CPT/HCPCS") y envíela con la información de su médico.

Use PR on professional claims, when the GA modifier is appended to a line item with CPT codes 0571T, 0572T, 0573T, 0574T, 0575T, 0576T, 0577T, 0578T, 0579T, 0580T, or 0614T.

MSN 15.20: The following policies were used when we made this decision: NCD 20.4

Spanish Version – Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD
20.4.

280 - Autologous Cellular Immunotherapy Treatment of Prostate Cancer
(Rev. 2380, Issued: 01-06-12, Effective: 06-30-11, Implementation: 08-08-11)

280.1 - Policy
(Rev. 2380, Issued: 01-06-12, Effective: 06-30-11, Implementation: 08-08-11)

Effective for services furnished on or after June 30, 2011, a National Coverage Determination (NCD) provides coverage of sipuleucel-T (PROVENGE®) for patients with asymptomatic or minimally symptomatic metastatic, castrate-resistant (hormone refractory) prostate cancer. Conditions of Medicare Part A and Medicare Part B coverage for sipuleucel-T are located in the Medicare NCD Manual, Publication 100-03, section 110.22.

280.2 - Healthcare Common Procedure Coding System (HCPCS) Codes and Diagnosis Coding
(Rev. 2380, Issued: 01-06-12, Effective: 06-30-11, Implementation: 08-08-11)

HCPCS Codes

Effective for claims with dates of service on June 30, 2011, Medicare providers shall report one of the following HCPCS codes for PROVENGE®:

- C9273 - Sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF, including leukapheresis and all other preparatory procedures, per infusion, or
- J3490 – Unclassified Drugs, or
- J3590 – Unclassified Biologics.

NOTE: Contractors shall continue to process claims for HCPCS code C9273, J3490, and J3590, with dates of service June 30, 2011, as they do currently.

Effective for claims with dates of service on and after July 1, 2011, Medicare providers shall report the following HCPCS code:

- Q2043 – Sipuleucel-T, minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF, including leukapheresis and all other preparatory procedures, per infusion; short descriptor, Sipuleucel-T auto CD54+.

ICD-9 Diagnosis Coding

For claims with dates of service on and after July 1, 2011, for PROVENGE®, the on-label indication of asymptomatic or minimally symptomatic metastatic, castrate-resistant (hormone refractory) prostate cancer, must be billed using ICD-9 code 185 (malignant neoplasm of prostate) and at least one of the following ICD-9 codes:

ICD-9 code	Description
196.1	Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes

196.2	Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes
196.5	Secondary and unspecified malignant neoplasm of lymph nodes of inguinal region and lower limb
196.6	Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes
196.8	Secondary and unspecified malignant neoplasm of lymph nodes of multiple sites
196.9	Secondary and unspecified malignant neoplasm of lymph node site unspecified - The spread of cancer to and establishment in the lymph nodes.
197.0	Secondary malignant neoplasm of lung – Cancer that has spread from the original (primary) tumor to the lung. The spread of cancer to the lung. This may be from a primary lung cancer, or from a cancer at a distant site.
197.7	Malignant neoplasm of liver secondary - Cancer that has spread from the original (primary) tumor to the liver. A malignant neoplasm that has spread to the liver from another (primary) anatomic site. Such malignant neoplasms may be carcinomas (e.g., breast, colon), lymphomas, melanomas, or sarcomas.
198.0	Secondary malignant neoplasm of kidney - The spread of the cancer to the kidney. This may be from a primary kidney cancer involving the opposite kidney, or from a cancer at a distant site.
198.1	Secondary malignant neoplasm of other urinary organs
198.5	Secondary malignant neoplasm of bone and bone marrow – Cancer that has spread from the original (primary) tumor to the bone. The spread of a malignant neoplasm from a primary site to the skeletal system. The majority of metastatic neoplasms to the bone are carcinomas.
198.7	Secondary malignant neoplasm of adrenal gland
198.82	Secondary malignant neoplasm of genital organs

Coding for Off-Label PROVENGE® Services

The use of PROVENGE® off-label for the treatment of prostate cancer is left to the discretion of the Medicare Administrative Contractors. Claims with dates of service on and after July 1,

2011, for PROVENGE® paid off-label for the treatment of prostate cancer must be billed using either ICD-9 code 233.4 (carcinoma in situ of prostate), or ICD-9 code 185 (malignant neoplasm of prostate) in addition to HCPCS Q2043. Effective with the implementation date for ICD-10 codes, off-label PROVENGE® services must be billed with either ICD-10 code D075(carcinoma in situ of prostate), or C61 (malignant neoplasm of prostate) in addition to HCPCS Q2043.

ICD-10 Diagnosis Coding

Contractors shall note the appropriate ICD-10 code(s) that are listed below for future implementation. Contractors shall track the ICD-10 codes and ensure that the updated edit is turned on as part of the ICD-10 implementation effective October 1, 2013.

ICD-10	Description
C61	Malignant neoplasm of prostate (for on-label or off-label indications)
D075	Carcinoma in situ of prostate (for off-label indications only)
C77.1	Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes
C77.2	Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes
C77.4	Secondary and unspecified malignant neoplasm of inguinal and lower limb lymph nodes
C77.5	Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes
C77.8	Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions
C77.9	Secondary and unspecified malignant neoplasm of lymph node, unspecified
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.7	Secondary malignant neoplasm of liver
C79.00	Secondary malignant neoplasm of unspecified kidney and renal pelvis
C79.01	Secondary malignant neoplasm of right kidney and renal pelvis
C79.02	Secondary malignant neoplasm of left kidney and renal pelvis
C79.10	Secondary malignant neoplasm of unspecified urinary organs
C79.11	Secondary malignant neoplasm of bladder

C79.19	Secondary malignant neoplasm of other urinary organs
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
C79.70	Secondary malignant neoplasm of unspecified adrenal gland
C79.71	Secondary malignant neoplasm of right adrenal gland
C79.72	Secondary malignant neoplasm of left adrenal gland
C79.82	Secondary malignant neoplasm of genital organs

280.3 - Types of Bill (TOB) and Revenue Codes

(Rev. 2380, Issued: 01-06-12, Effective: 06-30-11, Implementation: 08-08-11)

The applicable TOBs for PROVENGE® are: 12X, 13X, 22X, 23X, 71X, 77X, and 85X.

On institutional claims, TOBs 12X, 13X, 22X, 23X, and 85X, use revenue code 0636 - drugs requiring detailed coding.

280.4 - Payment Method

(Rev. 2380, Issued: 01-06-12, Effective: 06-30-11, Implementation: 08-08-11)

Payment for PROVENGE® is as follows:

- TOBs 12X, 13X, 22X and 23X - based on the Average Sales Price (ASP) + 6%,
- TOB 85X – based on reasonable cost,
- TOBs 71X and 77X – based on all-inclusive rate.

For Medicare Part B practitioner claims, payment for PROVENGE® is based on ASP + 6%.

Contractors shall not pay separately for routine costs associated with PROVENGE®, HCPCS Q2043, except for the cost of administration. (Q2043 is all-inclusive and represents all routine costs except for its cost of administration).

280.5 - Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RARCs), Claim Adjustment Reason Codes (CARCs), and Group Codes

(Rev. 2394, Issued: 01-25-12, Effective: 06-30-11 for-(claims with dates of service on or after 07-01- 11 processed on or after July 02-12, Implementation: 07-02-12)

Contractors shall use the following messages when denying claims for the on-label indication for PROVENGE®, HCPCS Q2043, submitted without ICD-9-CM diagnosis code 185 and at least one diagnosis code from the ICD-9 table in Section 280.2 above:

MSN 14.9 - Medicare cannot pay for this service for the diagnosis shown on the claim.

Spanish Version - Medicare no puede pagar por este servicio debido al diagnóstico indicado en la reclamación.

RARC 167 - This (these) diagnosis (es) are not covered. Note: Refer to the 835 Healthcare Policy Identification segment (loop 2110 Service Payment Information REF), if present.

Group Code – CO (Contractual Obligation)

Contractors shall use the following messages when denying claims for the off-label indication for PROVENGE®, HCPCS Q2043, submitted without ICD-9-CM diagnosis code 233.4:

MSN 14.9 - Medicare cannot pay for this service for the diagnosis shown on the claim.

Spanish Version - Medicare no puede pagar por este servicio debido al diagnóstico indicado en la reclamación.

RARC 167 - This (these) diagnosis (es) are not covered. Note: Refer to the 835 Healthcare Policy Identification segment (loop 2110 Service Payment Information REF), if present.

Group Code – CO (Contractual Obligation)

For claims with dates of service on or after July 1, 2012, processed on or after July 2, 2012, when denying claims for PROVENGE®, HCPCS Q2043® that exceed three (3) services in a patient's lifetime, contractors shall use the following messages:

MSN 20.5 - These services cannot be paid because your benefits are exhausted at this time.

Spanish Version - Estos servicios no pueden ser pagados porque sus beneficios se han agotado.

RARC N362 - The number of Days or Units of Service exceeds our acceptable maximum.

CARC 149 - Lifetime benefit maximum has been reached for this service/benefit category.
Group Code – CO (Contractual Obligation)

290 – Transcatheter Aortic Valve Replacement (TAVR)

(Rev. 10179, Issued: 06-10-20, Effective: 06-21-19, Implementation: 06-12-20)

Transcatheter aortic valve replacement (TAVR - also known as TAVI or transcatheter aortic valve implantation) is used in the treatment of aortic stenosis. A bioprosthetic valve is inserted percutaneously using a catheter and implanted in the orifice of the aortic valve.

The most recent reconsideration of the TAVR policy is effective for claims with dates of service on and after June 21, 2019. It makes changes to the criteria for the heart team and the hospital, and to the trial outcomes and the registry questions/criteria. Please see Publication 100-03, National Coverage Determination Manual Part 1, section 20.32, for complete national policy criteria.

HISTORICAL NOTE: CR 7897, Transmittal (TR) 2552, issued September 24, 2012, implemented the initial NCD for TAVR, effective May 1, 2012. CR 8168, TR 2628, issued January 7, 2013, implemented replacement coding to TAVR effective January 1, 2013. CR 8255, TR 2737, issued July 11, 2013, implemented clinical trial number reporting effective July 1, 2013. CR 8537, TR 2827, issued November 29, 2013, implemented replacement CPT coding effective January 1, 2013.

290.1 – Coding Requirements for TAVR Furnished on or After May 1, 2012, through December 31, 2012

(Rev. 10179, Issued: 06-10-20, Effective: 06-21-19, Implementation: 06-12-20)

The following are the applicable Current Procedural Terminology (CPT) codes for TAVR:

0256T: Implantation of catheter-delivered prosthetic aortic heart valve; endovascular approach

0257T: Implantation of catheter-delivered prosthetic aortic heart valve; open thoracic approach (eg, transapical, transventricular)

0258T: Transthoracic cardiac exposure (i.e. sternotomy, thoracotomy, subxiphoid) for catheter-delivered aortic valve replacement; without cardiopulmonary bypass

0259T: Transthoracic cardiac exposure (i.e. sternotomy, thoracotomy, subxiphoid) for catheter-delivered aortic valve replacement; with cardiopulmonary bypass

The following are the International Classification of Diseases (ICD)-9 procedure codes applicable for TAVR:

35.05: Endovascular replacement of aortic valve
35.06: Transapical replacement of aortic valve

The following are the ICD-10 procedure codes applicable for TAVR:

35.05: 02RF37Z, 02RF38Z. 02RF3JZ, 02RF3KZ
35.06: 02RF37H, 02RF38H, 02RF3JH, 02RF3KH

290.1.1 - Coding Requirements for TAVR Services Furnished on or After January 1, 2013

(Rev. 10179, Issued: 06-10-20, Effective: 06-21-19, Implementation: 06-12-20)

Beginning January 1, 2013, the following are the applicable CPT codes for TAVR:

33361 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach

33362 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral approach

33363 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach

33364 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach

33365 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (e.g., median sternotomy, mediastinotomy)

0381T Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical approach (e.g., left thoracotomy)

Beginning January 1, 2014, temporary CPT code 0318T above is retired. TAVR claims with dates of service on and after January 1, 2014, shall instead use permanent CPT code 33366.

290.2 - Claims Processing Requirements for TAVR Services on Professional Claims

(Rev. 10179, Issued: 06-10-20, Effective: 06-21-19, Implementation: 06-12-20)

Place of Service (POS) Professional Claims

Effective for claims with dates of service on and after May 1, 2012, place of service (POS) code 21 shall be used for TAVR services. All other POS codes shall be denied.

The following messages shall be used when Medicare contractors deny TAVR claims for POS:

Claim Adjustment Reason Code (CARC) 58: “Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. NOTE: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”

Remittance advice remark code (RARC) N428: “Not covered when performed in this place of service.” Beginning January 2, 2020, contractors shall no longer report RARC N428 for claims denied for invalid POS.

Medicare Summary Notice (MSN) 21.25: “This service was denied because Medicare only covers this service in certain settings.”

Spanish Version: “El servicio fue denegado porque Medicare solamente lo cubre en ciertas situaciones."

Professional Claims Modifier -62

For TAVR claims with dates of service on or after July 1, 2013, contractors shall pay claim lines with 33361, 33362, 33363, 33364, 33365 & 0318T only when billed with modifier -62. Claim lines billed without modifier -62 shall be returned as unprocessable.

Beginning January 1, 2014, temporary CPT code 0318T above is retired. TAVR claims with dates of service on and after January 1, 2014 shall instead use permanent CPT code 33366.

The following messages shall be used when Medicare contractors return TAVR claims billed without modifier -62 as unprocessable:

CARC 4: “The procedure code is inconsistent with the modifier used or a required modifier is missing. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”

RARC N29: “Missing documentation/orders/notes/summary/report/chart.” Beginning January 2, 2020, contractors shall no longer report RARC N29 on remittance for claims billed without modifier -62 and returned as unprocessable.

RARC MA130: “Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.”

Professional Claims Modifier -Q0

For claims with dates of service on or after January 1 , 2013, contractors shall pay TAVR claim lines for 33361, 33362, 33363, 33364, 33365 & 0318T when billed with modifier-Q0. Claim lines billed without modifier -Q0 shall be returned as unprocessable.

Beginning January 1, 2014, temporary CPT code 0318T above is retired. TAVR claims with dates of service on and after January 1, 2014, shall instead use permanent CPT code 33366.

The following messages shall be used when Medicare contractors return TAVR claims billed without modifier -Q0 as unprocessable:

CARC 4: "The procedure code is inconsistent with the modifier used or a required modifier is missing. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present."

RARC N29: "Missing documentation/orders/notes/summary/report/chart." Beginning January 2, 2020, contractors shall no longer report RARC N29 on remittance for claims billed without modifier –Q0 and returned as unprocessable.

RARC MA130: "Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information."

Diagnosis Coding

For claims with dates of service on or after July 1, 2013, contractors shall pay TAVR claim lines for 33361, 33362, 33363, 33364, 33365 & 0318T when billed with diagnosis code V70.7 (ICD-10 Z00.6). Claim lines billed without diagnosis code V70.7 (ICD-10 Z00.6) shall be returned as unprocessable.

Beginning January 1, 2014, temporary CPT code 0318T above is retired. TAVR claims with dates of service on and after January 1, 2014 shall instead use permanent CPT code 33366.

The following messages shall be used when Medicare contractors return TAVR claims billed without diagnosis code V70.7 (ICD-10 Z00.6) as unprocessable:

CARC 16: "Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT)."

RARC M76: "Missing/incomplete/invalid diagnosis or condition"

RARC MA130: "Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information."

Group Code – Contractual Obligation (CO): Beginning January 2, 2020, contractors shall no longer report Group Code CO on remittances for claims billed without ICD-10 dx Z00.6 and returned as unprocessable.

MSN 16.77: This service/item was not covered because it was not provided as part of a qualifying trial/study. Spanish version: Este servicio/articulo no fue cubierto porque no estaba incluido como parte de un ensavo clinic/studio calificado. Beginning January 2, 2020, contractors shall no longer report MSN 16.77 on remittances for claims billed without ICD-10 diagnosis Z00.6 and returned as unprocessable.

<u>Professional Claims 8-digit ClinicalTrials.gov Identifier Number</u>

For claims with dates of service on or after July 1, 2013, contractors shall pay TAVR claim lines for 33361, 33362, 33363, 33364, 33365 & 0318T when billed with the numeric, 8-digit

clinicaltrials.gov identifier number preceded by the two alpha characters “CT” when placed in Field 19 of paper Form CMS-1500, or when entered without the “CT” prefix in the electronic 837P in Loop 2300REF02(REF01=P4). Claim lines billed without an 8-digit clinicaltrials.gov identifier number shall be returned as unprocessable.

Beginning January 1, 2014, temporary CPT code 0318T above is retired. TAVR claims with dates of service on and after January 1, 2014 shall instead use permanent CPT code 33366.

The following messages shall be used when Medicare contractors return TAVR claims billed without an 8-digit clinicaltrials.gov identifier number as unprocessable:

CARC 16: “Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT).”

RARC MA50: “Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services.”

RARC MA130: “Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.”

NOTE: Clinicaltrials.gov identifier numbers for TAVR are listed on our website: (http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Transcatheter-Aortic-Valve-Replacement-TAVR-.html)

290.3 - Claims Processing Requirements for TAVR Services on Inpatient Hospital Claims

(Rev. 10179, Issued: 06-10-20, Effective: 06-21-19, Implementation: 06-12-20)

Inpatient hospitals shall bill for TAVR on an 11X TOB effective for discharges on or after May 1, 2012. Refer to Section 69 of this chapter for further guidance on billing under CED. Inpatient hospital discharges for TAVR shall be covered when billed with:

• ICD-9 V70.7 through September 30, 2015, ICD-10 Z00.6 for dates of service on or after October 1, 2015. and Condition Code 30.

• An 8-digit clinicaltrials.gov identifier number listed on the CMS website (effective July 1, 2013)

Inpatient hospital discharges for TAVR shall be rejected when billed without:

• ICD-9 V70.7 through September 30, 2015, ICD-10 Z00.6 for dates of service on or after October 1, 2015, and Condition Code 30.

• An 8-digit clinicaltrials.gov identifier number listed on the CMS website (effective July 1, 2013)

Claims billed by hospitals not participating in the trial/registry shall be rejected with the following messages:

CARC 50: These are non-covered services because this is not deemed a “medical necessity” by the payer.

RARC N386: This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered.

A copy of this policy is available at http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Group Code:Contractual Obligation (CO)

MSN 16.77: This service/item was not covered because it was not provided as part of a qualifying trial/study. Spanish version: Este servicio/artículo no fue cubierto porque no estaba incluido como parte de un ensayo clínico/estudio calificado.

290.4 - Claims Processing Requirements for TAVR Services for Medicare Advantage (MA) Plan Participants

(Rev. 3898, Issued: 10-27-17; Effective: 04-01- 15, Implementation: 04-02-18)

MA plans are responsible for payment of TAVR services for MA plan participants. Medicare coverage for TAVR is not included under section 310.1 of the NCD Manual (Routine Costs in Clinical Trials).

300 – Billing Requirements for Ocular Photodynamic Therapy (OPT) with Verteporfin

(Rev. 2728, Issued: 06-14-13-Effective: 04-03-13, Implementation: 07-16-13)

Ocular Photodynamic Therapy (OPT) is used in the treatment of ophthalmologic diseases; specifically, for age-related macular degeneration (AMD), a common eye disease among the elderly. OPT involves the infusion of an intravenous photosensitizing drug called Verteporfin, followed by exposure to a laser. For complete Medical coverage guidelines, see National Coverage Determinations (NCD) Manual (Pub 100-03) § 80.2 through 80.3.1.

300.1 - Coding Requirements for OPT with Verteporfin

(Rev. 2728, Issued: 06-14-13, Effective: 04-03-13, Implementation: 07-16-13)

The following are applicable Current Procedural Terminology (CPT) codes for OPT with Verteporfin:

67221- Destruction of localized lesion of choroid (e.g. choroidal neovascularization); photodynamic therapy (includes intravenous infusion)

67225- Destruction of localized lesion of choroid (e.g. choroidal neovascularization); photodynamic therapy, second eye, at single session (List separately in addition to code for primary eye treatment)

The following are applicable Healthcare Common Procedure Coding System (HCPCS) code for OPT with Verteporfin:

J3396- Injection, Verteporfin, 0.1 mg

300.2 - Claims Processing Requirements for OPT with Verteporfin Services on Professional Claims and Outpatient Facility Claims

(Rev. 13608; Issued: 01-29-26; Effective: 08-25-25; Implementation: 08-25-25)

OPT with Verteporfin is a covered service when billed with the below ICD-10-CM codes
Nationally Covered ICD-10-CM codes

H35.3210	Exudative age-related macular degeneration, right eye, stage unspecified

H35.3211	Exudative age-related macular degeneration, right eye, with active choroidal neovascularization
H35.3212	Exudative age-related macular degeneration, right eye, with inactive choroidal neovascularization
H35.3213	Exudative age-related macular degeneration, right eye, with inactive scar
H35.3220	Exudative age-related macular degeneration, left eye, stage unspecified
H35.3221	Exudative age-related macular degeneration, left eye, with active choroidal neovascularization
H35.3222	Exudative age-related macular degeneration, left eye, with inactive choroidal neovascularization
H35.3223	Exudative age-related macular degeneration, left eye, with inactive scar
H35.3230	Exudative age-related macular degeneration, bilateral, stage unspecified
H35.3231	Exudative age-related macular degeneration, bilateral, with active choroidal neovascularization
H35.3232	Exudative age-related macular degeneration, bilateral, with inactive choroidal neovascularization
H35.3233	Exudative age-related macular degeneration, bilateral, with inactive scar

ICD-10- Codes for OPT with Verteporfin for other ocular indications are eligible for local coverage determinations through individual contractor discretion.

B39.4	Histocapsulati, unspecified
	(Translates to combination of both B39.4 & H32)
B39.5	Histoplasmosis duboisii
	(Requires H32 coverage)
B39.9	Histoplasmosis, unspecified
	(Requires H32 coverage)
H32	Chorioretinal disorders in diseases classified elsewhere
	(Requires B39.4 coverage)
H44.2A1	Degenerative myopia with choroidal neovascularization, right eye
H44.2A2	Degenerative myopia with choroidal neovascularization, left eye
H44.2A3	Degenerative myopia with choroidal neovascularization, bilateral eye
H44.2B1	Degenerative myopia with macular hole, right eye
H44.2B2	Degenerative myopia with macular hole, left eye
H44.2B3	Degenerative myopia with macular hole, bilateral eye
H44.2C1	Degenerative myopia with retinal detachment, right eye
H44.2C2	Degenerative myopia with retinal detachment, left eye
H44.2C3	Degenerative myopia with retinal detachment, bilateral eye
H44.2D1	Degenerative myopia with foveoschisis, right eye
H44.2D2	Degenerative myopia with foveoschisis, left eye
H44.2D3	Degenerative myopia with foveoschisis, bilateral eye
H44.2E1	Degenerative myopia with other maculopathy, right eye
H44.2E2	Degenerative myopia with other maculopathy, left eye

H44.2E3	Degenerative myopia with other maculopathy, bilateral eye
H44.21	Degenerative Myopia, right eye
H44.22	Degenerative Myopia, left eye
H44.23	Degenerative Myopia, bilateral
H35.711	Central serous chorioretinopathy, right eye
H35.712	Central serous chorioretinopathy, left eye
H35.713	Central serous chorioretinopathy, bilateral

Coverage is denied when billed with the below Nationally Non-Covered ICD-10-CM codes Nationally Non-Covered ICD-10-CM codes:

H35.30	Unspecified macular degeneration
H35.3110	Nonexudative age-related macular degeneration, right eye, stage unspecified
H35.3111	Nonexudative age-related macular degeneration, right eye, early dry stage
H35.3112	Nonexudative age-related macular degeneration, right eye, intermediate dry stage
H35.3113	Nonexudative age-related macular degeneration, right eye, advanced atrophic without subfoveal involvement
H35.3114	Nonexudative age-related macular degeneration, right eye, advanced atrophic with subfoveal involvement
H35.3120	Nonexudative age-related macular degeneration, left eye, stage unspecified
H35.3121	Nonexudative age-related macular degeneration, left eye, early dry stage
H35.3122	Nonexudative age-related macular degeneration, left eye, intermediate dry stage
H35.3123	Nonexudative age-related macular degeneration, left eye, advanced atrophic without subfoveal involvement
H35.3124	Nonexudative age-related macular degeneration, left eye, advanced atrophic with subfoveal involvement
H35.3130	Nonexudative age-related macular degeneration, bilateral, stage unspecified
H35.3131	Nonexudative age-related macular degeneration, bilateral, early dry stage
H35.3132	Nonexudative age-related macular degeneration, bilateral, intermediate dry stage
H35.3133	Nonexudative age-related macular degeneration, bilateral, advanced atrophic without subfoveal involvement
H35.3134	Nonexudative age-related macular degeneration, bilateral, advanced atrophic with subfoveal involvement

Payment for OPT service (CPT code 67221/67225) must be billed on the same claim as the drug (J3396) for the same date of service.

Claims for OPT with Verteporfin for dates of service prior to April 3, 2013, are covered at the initial visit as determined by a fluorescein angiogram (FA) CPT code 92235. Subsequent follow-up visits also require a FA prior to treatment.

For claims with dates of service on or after April 3, 2013, contractors shall accept and process claims for subsequent follow-up visits with either a FA, CPT code 92235, or

optical coherence tomography (OCT), CPT codes 92133, 92134 or 92137 (effective 01/01/2025) prior to treatment.
Regardless of the date of service of the claim, the FA or OCT is not required to be submitted on the claim for OPT and can be maintained in the patient's file for audit purposes.

300.3 - Claims Processing Requirements for OPT with Verteporfin Services on Inpatient Facility Claims

(Rev. 11021; Issued: 10-01-21; Effective: 10-29-21; Implementation: 10-29-21)

Inpatient facilities shall report ICD-10-CM codes H35.3210-H35.3233 (Exudative Age-related Macular Degeneration) and ICD-10-PCS codes 085E3ZZ (Destruction of Right Retina, Percutaneous Approach) and 085F3ZZ (Destruction of Left Retina, Percutaneous Approach)

300.4 - Medicare Summary Notice (MSN) and Remittance Advice (RA) Messages

(Rev. 2728, Issued: 06-14-13, Effective: 04-03-13, Implementation: 07-16-13)

The following message shall be used to notify beneficiaries and providers of denial situations that may occur:

MSN 14.9: "Medicare cannot pay for this service for the diagnosis shown on the claim." (English version) or "Medicare no puede pagar por este servicio debido al diagnostic indicado en la reclamacion." (Spanish Version)

Claims Adjustment Reason Code B22: "This payment is adjusted based on the diagnosis."

310 - Transesophageal Doppler Used for Cardiac Monitoring

(Rev. 2743, Issued: 07-25-13, Effective: 07-01-01-13, Implementation, 08-26-13)

Effective May 17, 2007, Transesophageal Doppler used for cardiac monitoring is covered for ventilated patients in the ICU and operative patients with a need for intra-operative fluid optimization was deemed reasonable and necessary. See National Coverage Determinations Manual (Pub. 100-03) §220.5, for complete coverage guidelines.

A new Healthcare Common Procedure Coding System (HCPCS) code, G9157, Transesophageal Doppler used for cardiac monitoring, will be made effective for use for dates of service on or after January 1, 2013.

310.1 - Coding Requirements for Transesophageal Doppler Cardiac Monitoring Furnished Before January 1, 2013

(Rev. 2743, Issued: 07-25-13, Effective: 07-01-01-13, Implementation, 08-26-13)

Prior to January 1, 2013, the applicable HCPCS code for Transesophageal Doppler cardiac monitoring is:

HCPCS 76999 (billed with modifier -26) when performed in a hospital setting for ventilated patients in the ICU or for operative patients with a need for intra-operative fluid optimization.

If globally billed using code 76999, it shall be returned as unprocessable to the provider using a claim adjustment reason code (CARC) such as:

CARC 58: “Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”

HCPCS 76999 (billed with modifier -TC) shall be denied when performed in a hospital setting for ventilated patients in the ICU or for operative patients with a need for intra-operative fluid optimization with a message such as:

CARC 58: “Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”

RARC M77: “Missing/incomplete/invalid place of service.”

MSN 17.9: “Medicare (Part A/Part B) pays for this service. The provider must bill the correct Medicare contractor.” (English version) or “Este servicio es pagado por Medicare (Parte A/Parte B). El proveedor debe enviar la facture al contratista de Medicare correcto.”(Spanish version).

HCPCS 76999 (billed globally or with -26 or -TC) when performed in an ASC setting for operative patients with a need for intra-operative fluid optimization, ultrasound diagnostic procedures are covered when performed by an entity other than the ASC.

310.2 - Coding Requirements for Transesophageal Doppler Cardiac Monitoring Furnished On or After January 1, 2013

(Rev. 2743, Issued: 07-25-13, Effective: 07-01-01-13, Implementation, 08-26-13)

After January 1, 2013, the applicable HCPCS code for Transesophageal Doppler cardiac monitoring is:

HCPCS G9157: Transesophageal Doppler used for cardiac monitoring

Contractors shall allow HCPCS G9157 to be billed when services are provided in POS 21 for ventilated patients in the ICU or for operative patients with a need for intra-operative fluid optimization.

Contractors shall deny HCPCS 76999 when billed for Esophageal Doppler for ventilated patients in the ICU or for operative patients with a need for intra-operative fluid optimization using the following messages:

CARC 189: “’Not otherwise classified’ or ‘unlisted’ procedure code (CPT/HCPCS) was billed when there is a specific procedure code for this procedure/service.”

RARC M20: “Missing/incomplete/invalid HCPCS.”

MSN 16.13: “The code(s) your provider used is/are not valid for the date of service billed.” (English version) or “El/los código(s) que usó su proveedor no es/son válido(s) en la fecha de servicio facturada.” (Spanish version).

Group Code: Contractual Obligation (CO)

310.3 - Correct Place of Service (POS) Code for Transesophageal Doppler Cardiac Monitoring Services on Professional Claims

(Rev. 2743, Issued: 07-25-13, Effective: 07-01-01-13, Implementation, 08-26-13)

Contractors shall pay for Transesophageal Doppler cardiac monitoring, G9157, only when services are provided at POS 21.

Contractors shall deny HCPCS G9157 when billed globally in any POS other than 21 for ventilated patients in the ICU or for operative patients with a need for intra-operative fluid optimization using the following messages:

CARC 58: "Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

MSN 16.2: This service cannot be paid when provided in this location/facility.
Group Code: CO

320 - Artificial Hearts and Related Devices

(Rev.10837; Issued: 06-11-21; Effective: 12-01-20; Implementation: 07-27-21)

Effective for claims with dates of service on or after December 1, 2020, as a result of a reconsideration of National Coverage Determination (NCD) 20.9 of the Medicare NCD Manual, coverage determinations for artificial hearts and related devices shall be made by the Medicare Administrative Contractors.

320.1 – Coding Requirements for Artificial Hearts Furnished Before May 1, 2008

(Rev. 3054, Issued: 08-29-14, Effective: 10-30- 13, Implementation: 09-30-14)

Effective for discharges before May 1, 2008, Medicare does not cover the use of artificial hearts, either as a permanent replacement for a human heart or as a temporary life-support system until a human heart becomes available for transplant (often referred to a "bridge to transplant").

320.2 – Coding Requirements for Artificial Hearts Furnished On or After May 1, 2008

(Rev. 3054, Issued: 08-29-14, Effective: 10-30- 13, Implementation: 09-30-14)

Effective for discharges on or after May 1, 2008, the use of artificial hearts will be covered by Medicare under Coverage with Evidence Development (CED) when beneficiaries are enrolled in a clinical study that meets all of the criteria listed in IOM Pub. 100-03, Medicare NCD Manual, section 20.9.

Claims Coding

For claims with dates of service on or after May 1, 2008, artificial hearts in the context of an approved clinical study for a Category A IDE, refer to section 69 in this manual for more detail on CED billing. Appropriate ICD-10 diagnosis and procedure codes are included below:

ICD-10 Diagnosis Code	Definition	Discharges Effective
I09.81	Rheumatic heart failure	On or After ICD-10 Implementation
I11.0	Hypertensive heart disease with heart failure	
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease	

I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease	
I20.0	Unstable angina	
I21.01	ST elevation (STEMI) myocardial infarction involving left main coronary artery	
I21.02	ST elevation (STEMI) myocardial infarction involving left anterior descending coronary artery	
I21.09	ST elevation (STEMI) myocardial infarction involving other coronary artery of anterior wall	
I21.11	ST elevation (STEMI) myocardial infarction involving right coronary artery	
I21.19	ST elevation (STEMI) myocardial infarction involving other coronary artery of inferior wall	
I21.21	ST elevation (STEMI) myocardial infarction involving left circumflex coronary artery	
I21.29	ST elevation (STEMI) myocardial infarction involving other sites	
I21.3	ST elevation (STEMI) myocardial infarction of unspecified site	
I21.4	Non-ST elevation (NSTEMI) myocardial infarction	
I22.0	Subsequent ST elevation (STEMI) myocardial infarction of anterior wall	
I22.1	Subsequent ST elevation (STEMI) myocardial infarction of inferior wall	
I22.2	Subsequent non-ST elevation (NSTEMI) myocardial infarction	
I22.8	Subsequent ST elevation (STEMI) myocardial infarction of other sites	
I22.9	Subsequent ST elevation (STEMI) myocardial infarction of unspecified site	
I24.0	Acute coronary thrombosis not resulting in myocardial infarction	
I24.1	Dressler's syndrome	
I24.8	Other forms of acute ischemic heart disease	
I24.9	Acute ischemic heart disease, unspecified	
I25.10	Atherosclerotic heart disease of native coronary artery without angina pectoris	
I25.110	Atherosclerotic heart disease of native coronary artery with unstable angina pectoris	
I25.111	Atherosclerotic heart disease of native coronary artery with angina pectoris with documented spasm	
I25.118	Atherosclerotic heart disease of native coronary artery with other forms of angina pectoris	
I25.119	Atherosclerotic heart disease of native coronary artery with unspecified angina pectoris	
I25.5	Ischemic cardiomyopathy	
I25.6	Silent myocardial ischemia	
I25.700	Atherosclerosis of coronary artery bypass graft(s), unspecified, with unstable angina pectoris	
I25.701	Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris with documented spasm	
I25.708	Atherosclerosis of coronary artery bypass graft(s), unspecified, with other forms of angina pectoris	
I25.709	Atherosclerosis of coronary artery bypass graft(s), unspecified, with unspecified angina pectoris	

I25.710	Atherosclerosis of autologous vein coronary artery bypass graft(s) with unstable angina pectoris	
I25.711	Atherosclerosis of autologous vein coronary artery bypass graft(s) with angina pectoris with documented spasm	
I25.718	Atherosclerosis of autologous vein coronary artery bypass graft(s) with other forms of angina pectoris	
I25.719	Atherosclerosis of autologous vein coronary artery bypass graft(s) with unspecified angina pectoris	
I25.720	Atherosclerosis of autologous artery coronary artery bypass graft(s) with unstable angina pectoris	
I25.721	Atherosclerosis of autologous artery coronary artery bypass graft(s) with angina pectoris with documented spasm	
I25.728	Atherosclerosis of autologous artery coronary artery bypass graft(s) with other forms of angina pectoris	
I25.729	Atherosclerosis of autologous artery coronary artery bypass graft(s) with unspecified angina pectoris	
I25.730	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unstable angina pectoris	
I25.731	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with angina pectoris with documented spasm	
I25.738	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with other forms of angina pectoris	
I25.739	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unspecified angina pectoris	
I25.750	Atherosclerosis of native coronary artery of transplanted heart with unstable angina	
I25.751	Atherosclerosis of native coronary artery of transplanted heart with angina pectoris with documented spasm	
I25.758	Atherosclerosis of native coronary artery of transplanted heart with other forms of angina pectoris	
I25.759	Atherosclerosis of native coronary artery of transplanted heart with unspecified angina pectoris	
I25.760	Atherosclerosis of bypass graft of coronary artery of transplanted heart with unstable angina	
I25.761	Atherosclerosis of bypass graft of coronary artery of transplanted heart with angina pectoris with documented spasm	
I25.768	Atherosclerosis of bypass graft of coronary artery of transplanted heart with other forms of angina pectoris	
I25.769	Atherosclerosis of bypass graft of coronary artery of transplanted heart with unspecified angina pectoris	
I25.790	Atherosclerosis of other coronary artery bypass graft(s) with unstable angina pectoris	
I25.791	Atherosclerosis of other coronary artery bypass graft(s) with angina pectoris with documented spasm	
I25.798	Atherosclerosis of other coronary artery bypass graft(s) with other forms of angina pectoris	
I25.799	Atherosclerosis of other coronary artery bypass graft(s) with unspecified angina pectoris	
I25.810	Atherosclerosis of coronary artery bypass graft(s) without angina pectoris	
I25.811	Atherosclerosis of native coronary artery of transplanted heart without angina pectoris	
I25.812	Atherosclerosis of bypass graft of coronary artery of transplanted heart without angina pectoris	
I25.89	Other forms of chronic ischemic heart disease	

I25.9	Chronic ischemic heart disease, unspecified	
I34.0	Nonrheumatic mitral (valve) insufficiency	
I34.1	Nonrheumatic mitral (valve) prolapse	
I34.2	Nonrheumatic mitral (valve) stenosis	
I34.8	Other nonrheumatic mitral valve disorders	
I34.9	Nonrheumatic mitral valve disorder, unspecified	
I35.0	Nonrheumatic aortic (valve) stenosis	
I35.1	Nonrheumatic aortic (valve) insufficiency	
I35.2	Nonrheumatic aortic (valve) stenosis with insufficiency	
I35.8	Other nonrheumatic aortic valve disorders	
I35.9	Nonrheumatic aortic valve disorder, unspecified	
I36.0	Nonrheumatic tricuspid (valve) stenosis	
I36.1	Nonrheumatic tricuspid (valve) insufficiency	
I36.2	Nonrheumatic tricuspid (valve) stenosis with insufficiency	
I36.8	Other nonrheumatic tricuspid valve disorders	
I36.9	Nonrheumatic tricuspid valve disorder, unspecified	
I37.0	Nonrheumatic pulmonary valve stenosis	
I37.1	Nonrheumatic pulmonary valve insufficiency	
I37.2	Nonrheumatic pulmonary valve stenosis with insufficiency	
I37.8	Other nonrheumatic pulmonary valve disorders	
I37.9	Nonrheumatic pulmonary valve disorder, unspecified	
I38	Endocarditis, valve unspecified	
I39	Endocarditis and heart valve disorders in diseases classified elsewhere	
I42.0	Dilated cardiomyopathy	
I42.2	Other hypertrophic cardiomyopathy	
I42.3	Endomyocardial (eosinophilic) disease	
I42.4	Endocardial fibroelastosis	
I42.5	Other restrictive cardiomyopathy	
I42.6	Alcoholic cardiomyopathy	
I42.7	Cardiomyopathy due to drug and external agent	
I42.8	Other cardiomyopathies	
I42.9	Cardiomyopathy, unspecified	
I43	Cardiomyopathy in diseases classified elsewhere	
I46.2	Cardiac arrest due to underlying cardiac condition	
I46.8	Cardiac arrest due to other underlying condition	
I46.9	Cardiac arrest, cause unspecified	
I47.0	Re-entry ventricular arrhythmia	
I47.1	Supraventricular tachycardia	
I47.2	Ventricular tachycardia	
I47.9	Paroxysmal tachycardia, unspecified	
I48.0	Atrial fibrillation	
I48.1	Atrial flutter	
I49.01	Ventricular fibrillation	
I49.02	Ventricular flutter	
I49.1	Atrial premature depolarization	
I49.2	Junctional premature depolarization	
I49.3	Ventricular premature depolarization	
I49.40	Unspecified premature depolarization	
I49.49	Other premature depolarization	
I49.5	Sick sinus syndrome	
I49.8	Other specified cardiac arrhythmias	
I49.9	Cardiac arrhythmia, unspecified	
I50.1	Left ventricular failure	
I50.20	Unspecified systolic (congestive) heart failure	

I50.21	Acute systolic (congestive) heart failure	
I50.22	Chronic systolic (congestive) heart failure	
I50.23	Acute on chronic systolic (congestive) heart failure	
I50.30	Unspecified diastolic (congestive) heart failure	
I50.31	Acute diastolic (congestive) heart failure	
I50.32	Chronic diastolic (congestive) heart failure	
I50.33	Acute on chronic diastolic (congestive) heart failure	
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure	
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure	
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure	
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure	
I50.9	Heart failure, unspecified	
I51.4	Myocarditis, unspecified	
I51.9	Heart disease, unspecified	
I52	Other heart disorders in diseases classified elsewhere	
I97.0	Postcardiotomy syndrome	
I97.110	Postprocedural cardiac insufficiency following cardiac surgery	
I97.111	Postprocedural cardiac insufficiency following other surgery	
I97.120	Postprocedural cardiac arrest following cardiac surgery	
I97.121	Postprocedural cardiac arrest following other surgery	
I97.130	Postprocedural heart failure following cardiac surgery	
I97.131	Postprocedural heart failure following other surgery	
I97.190	Other postprocedural cardiac functional disturbances following cardiac surgery	
I97.191	Other postprocedural cardiac functional disturbances following other surgery	
I97.710	Intraoperative cardiac arrest during cardiac surgery	
I97.711	Intraoperative cardiac arrest during other surgery	
I97.790	Other intraoperative cardiac functional disturbances during cardiac surgery	
I97.791	Other intraoperative cardiac functional disturbances during other surgery	
I97.88	Other intraoperative complications of the circulatory system, not elsewhere classified	
I97.89	Other postprocedural complications and disorders of the circulatory system, not elsewhere classified	
M32.11	Endocarditis in systemic lupus erythematosus	
O90.89	Other complications of the puerperium, not elsewhere classified	
Q20.0	Common arterial trunk	
Q20.1	Double outlet right ventricle	
Q20.2	Double outlet left ventricle	
Q20.3	Discordant ventriculoarterial connection	
Q20.4	Double inlet ventricle	
Q20.5	Discordant atrioventricular connection	
Q20.6	Isomerism of atrial appendages	
Q20.8	Other congenital malformations of cardiac chambers and connections	
Q20.9	Congenital malformation of cardiac chambers and connections, unspecified	

Q21.0	Ventricular septal defect	
Q21.1	Atrial septal defect	
Q21.2	Atrioventricular septal defect	
Q21.3	Tetralogy of Fallot	
Q21.4	Aortopulmonary septal defect	
Q21.8	Other congenital malformations of cardiac septa	
Q21.9	Congenital malformation of cardiac septum, unspecified	
Q22.0	Pulmonary valve atresia	
Q22.1	Congenital pulmonary valve stenosis	
Q22.2	Congenital pulmonary valve insufficiency	
Q22.3	Other congenital malformations of pulmonary valve	
Q22.4	Congenital tricuspid stenosis	
Q22.5	Ebstein's anomaly	
Q22.6	Hypoplastic right heart syndrome	
Q22.8	Other congenital malformations of tricuspid valve	
Q22.9	Congenital malformation of tricuspid valve, unspecified	
Q23.0	Congenital stenosis of aortic valve	
Q23.1	Congenital insufficiency of aortic valve	
Q23.2	Congenital mitral stenosis	
Q23.3	Congenital mitral insufficiency	
Q23.4	Hypoplastic left heart syndrome	
Q23.8	Other congenital malformations of aortic and mitral valves	
Q23.9	Congenital malformation of aortic and mitral valves, unspecified	
Q24.0	Dextrocardia	
Q24.1	Levocardia	
Q24.2	Cor triatriatum	
Q24.3	Pulmonary infundibular stenosis	
Q24.4	Congenital subaortic stenosis	
Q24.5	Malformation of coronary vessels	
Q24.6	Congenital heart block	
Q24.8	Other specified congenital malformations of heart	
Q24.9	Congenital malformation of heart, unspecified	
R00.1	Bradycardia, unspecified	
R57.0	Cardiogenic shock	
T82.221A	Breakdown (mechanical) of biological heart valve graft, initial encounter	
T82.222A	Displacement of biological heart valve graft, initial encounter	
T82.223A	Leakage of biological heart valve graft, initial encounter	
T82.228A	Other mechanical complication of biological heart valve graft, initial encounter	
T82.512A	Breakdown (mechanical) of artificial heart, initial encounter	
T82.514A	Breakdown (mechanical) of infusion catheter, initial encounter	
T82.518A	Breakdown (mechanical) of other cardiac and vascular devices and implants, initial encounter	
T82.519A	Breakdown (mechanical) of unspecified cardiac and vascular devices and implants, initial encounter	
T82.522A	Displacement of artificial heart, initial encounter	
T82.524A	Displacement of infusion catheter, initial encounter	
T82.528A	Displacement of other cardiac and vascular devices and implants, initial encounter	
T82.529A	Displacement of unspecified cardiac and vascular devices and implants, initial encounter	

T82.532A	Leakage of artificial heart, initial encounter	
T82.534A	Leakage of infusion catheter, initial encounter	
T82.538A	Leakage of other cardiac and vascular devices and implants, initial encounter	
T82.539A	Leakage of unspecified cardiac and vascular devices and implants, initial encounter	
T82.592A	Other mechanical complication of artificial heart, initial encounter	
T82.594A	Other mechanical complication of infusion catheter, initial encounter	
T82.598A	Other mechanical complication of other cardiac and vascular devices and implants, initial encounter	
T82.599A	Other mechanical complication of unspecified cardiac and vascular devices and implants, initial encounter	
T86.20	Unspecified complication of heart transplant	
T86.21	Heart transplant rejection	
T86.22	Heart transplant failure	
T86.23	Heart transplant infection	
T86.290	Cardiac allograft vasculopathy	
T86.298	Other complications of heart transplant	
T86.30	Unspecified complication of heart-lung transplant	
T86.31	Heart-lung transplant rejection	
T86.32	Heart-lung transplant failure	
T86.33	Heart-lung transplant infection	
T86.39	Other complications of heart-lung transplant	
Z48.21	Encounter for aftercare following heart transplant	
Z48.280	Encounter for aftercare following heart-lung transplant	
Z94.1	Heart transplant status	
Z94.3	Heart and lungs transplant status	
Z95.9	Presence of cardiac and vascular implant and graft, unspecified	
Q24.0	Dextrocardia	
Q24.1	Levocardia	
Q24.2	Cor triatriatum	
Q24.3	Pulmonary infundibular stenosis	
Q24.4	Congenital subaortic stenosis	
Q24.5	Malformation of coronary vessels	
Q24.6	Congenital heart block	
Q24.8	Other specified congenital malformations of heart	
Q24.9	Congenital malformation of heart, unspecified	
R00.1	Bradycardia, unspecified	
R57.0	Cardiogenic shock	
T82.221A	Breakdown (mechanical) of biological heart valve graft, initial encounter	
T82.222A	Displacement of biological heart valve graft, initial encounter	
T82.223A	Leakage of biological heart valve graft, initial encounter	
T82.228A	Other mechanical complication of biological heart valve graft, initial encounter	
T82.512A	Breakdown (mechanical) of artificial heart, initial encounter	
T82.514A	Breakdown (mechanical) of infusion catheter, initial encounter	
T82.518A	Breakdown (mechanical) of other cardiac and vascular devices and implants, initial encounter	

T82.519A	Breakdown (mechanical) of unspecified cardiac and vascular devices and implants, initial encounter	
T82.522A	Displacement of artificial heart, initial encounter	
T82.524A	Displacement of infusion catheter, initial encounter	
T82.528A	Displacement of other cardiac and vascular devices and implants, initial encounter	
T82.529A	Displacement of unspecified cardiac and vascular devices and implants, initial encounter	
T82.532A	Leakage of artificial heart, initial encounter	
T82.534A	Leakage of infusion catheter, initial encounter	
T82.538A	Leakage of other cardiac and vascular devices and implants, initial encounter	
T82.539A	Leakage of unspecified cardiac and vascular devices and implants, initial encounter	
T82.592A	Other mechanical complication of artificial heart, initial encounter	
T82.594A	Other mechanical complication of infusion catheter, initial encounter	
T82.598A	Other mechanical complication of other cardiac and vascular devices and implants, initial encounter	
T82.599A	Other mechanical complication of unspecified cardiac and vascular devices and implants, initial encounter	
T86.20	Unspecified complication of heart transplant	
T86.21	Heart transplant rejection	
T86.22	Heart transplant failure	
T86.23	Heart transplant infection	
T86.290	Cardiac allograft vasculopathy	
T86.298	Other complications of heart transplant	
T86.30	Unspecified complication of heart-lung transplant	
T86.31	Heart-lung transplant rejection	
T86.32	Heart-lung transplant failure	
T86.33	Heart-lung transplant infection	
T86.39	Other complications of heart-lung transplant	
Z48.21	Encounter for aftercare following heart transplant	
Z48.280	Encounter for aftercare following heart-lung transplant	
Z94.1	Heart transplant status	
Z94.3	Heart and lungs transplant status	
Z95.9	Presence of cardiac and vascular implant and graft, unspecified	

ICD-10 Procedure Code	Definition	Discharges Effective
02RK0JZ	Replacement of Right Ventricle with Synthetic Substitute, Open Approach	On or After ICD-10 Implementation
02RL0JZ	Replacement of Left Ventricle with Synthetic Substitute, Open Approach	
02WA0JZ	Revision of Synthetic Substitute in Heart, Open Approach	

NOTE: Total artificial heart is reported with a "cluster" of 2 codes for open replacement with synthetic substitute of the right and left ventricles- 02RK0JZ + 02RL0JZ

320.3 – Ventricular Assist Devices (VADs)

(Rev.10837; Issued: 06-11-21; Effective: 12-01-20; Implementation: 07-27-21)

Medicare may cover a Ventricular Assist Device (VAD). A VAD is surgically attached to one or both intact ventricles and is used to assist or augment the ability of a damaged or weakened native heart to pump blood. Improvement in the performance of the native heart may allow the device to be removed. Refer to the Internet Only Manual Publication 100-03, National Coverage Determination (NCD) Manual, section 20.9.1, for coverage criteria.

320.3.1 – Post-cardiotomy
(Rev.10837; Issued: 06-11-21; Effective: 12-01-20; Implementation: 07-27-21)

Post-cardiotomy is the period following open-heart surgery. VADs used for support of blood circulation post-cardiotomy are covered only if they have received approval from the Food and Drug Administration (FDA) for that purpose, and the VADs are used according to the FDA-approved labeling instructions.

320.3.2 – VADs for Short-term or Long-term Mechanical Circulatory Support
(Rev.10837; Issued: 06-11-21; Effective: 12-01-20; Implementation: 07-27-21)

Effective for claims with dates of service on or after December 1, 2020**,** Left ventricular assist devices (LVADs) are covered if they are FDA-approved for short-term (e.g., bridge-to-recovery and bridge-to-transplant) or long-term (e.g., destination therapy) mechanical circulatory support for heart failure patients who meet specific clinical criteria outlined in NCD 20.9.1.

320.3.3 – Other
(Rev. 13549; Issued: 12-18-25; Effective: 01-20-26; Implementation: 01-20-26)

All other indications for the use of VADs not otherwise listed remain non-covered, except in the context of Category B investigational device exemption clinical trials (42 CFR 405) or as a routine cost in clinical trials defined under section 310.1 of the NCD Manual.

Claims Coding

Appropriate ICD-10 diagnosis and procedure codes are included below:

ICD-10 Diagnosis Code	Definition
I09.81	Rheumatic heart failure
I11.0	Hypertensive heart disease with heart failure
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
I20.0	Unstable angina
I20.2	Refractory angina pectoris
I21.01	ST elevation (STEMI) myocardial infarction involving left main coronary artery
I21.02	ST elevation (STEMI) myocardial infarction involving left anterior descending coronary artery
I21.09	ST elevation (STEMI) myocardial infarction involving other coronary artery of anterior wall
I21.11	ST elevation (STEMI) myocardial infarction involving right coronary artery

I21.19	ST elevation (STEMI) myocardial infarction involving other coronary artery of inferior wall
I21.21	ST elevation (STEMI) myocardial infarction involving left circumflex coronary artery

I21.29	ST elevation (STEMI) myocardial infarction involving other sites
I21.3	ST elevation (STEMI) myocardial infarction of unspecified site
I21.4	Non-ST elevation (NSTEMI) myocardial infarction
I22.0	Subsequent ST elevation (STEMI) myocardial infarction of anterior wall
I22.1	Subsequent ST elevation (STEMI) myocardial infarction of inferior wall
I22.2	Subsequent non-ST elevation (NSTEMI) myocardial infarction
I22.8	Subsequent ST elevation (STEMI) myocardial infarction of other sites
I22.9	Subsequent ST elevation (STEMI) myocardial infarction of unspecified site
I24.0	Acute coronary thrombosis not resulting in myocardial infarction
I24.1	Dressler's syndrome
I24.81	Acute coronary microvascular dysfunction Effective 10/1/23

ICD-10 Diagnosis Code	**Definition**
I24.89	Other forms of acute ischemic heart disease Effective 10/1/23
I24.9	Acute ischemic heart disease, unspecified
I25.10	Atherosclerotic heart disease of native coronary artery without angina pectoris
I25.110	Atherosclerotic heart disease of native coronary artery with unstable angina pectoris
I25.111	Atherosclerotic heart disease of native coronary artery with angina pectoris with documented spasm
I25.112	Atherosclerotic heart disease of native coronary artery with refractory angina pectoris
I25.118	Atherosclerotic heart disease of native coronary artery with other forms of angina pectoris
I25.119	Atherosclerotic heart disease of native coronary artery with unspecified angina pectoris
I25.5	Ischemic cardiomyopathy
I25.6	Silent myocardial ischemia
I25.700	Atherosclerosis of coronary artery bypass graft(s), unspecified, with unstable angina pectoris
I25.701	Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris with documented spasm
I25.702	Atherosclerosis of coronary artery bypass graft(s), unspecified, with refractory angina pectoris
I25.708	Atherosclerosis of coronary artery bypass graft(s), unspecified, with other forms of angina pectoris
I25.709	Atherosclerosis of coronary artery bypass graft(s), unspecified, with unspecified angina pectoris
I25.710	Atherosclerosis of autologous vein coronary artery bypass graft(s) with unstable angina pectoris
I25.711	Atherosclerosis of autologous vein coronary artery bypass graft(s) with angina pectoris with documented spasm

I25.712	Atherosclerosis of autologous vein coronary artery bypass graft(s) with refractory angina pectoris
I25.718	Atherosclerosis of autologous vein coronary artery bypass graft(s) with other forms of angina pectoris

I25.719	Atherosclerosis of autologous vein coronary artery bypass graft(s) with unspecified angina pectoris
I25.720	Atherosclerosis of autologous artery coronary artery bypass graft(s) with unstable angina pectoris
I25.721	Atherosclerosis of autologous artery coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.722	Atherosclerosis of autologous artery coronary artery bypass graft(s) with refractory angina pectoris
I25.728	Atherosclerosis of autologous artery coronary artery bypass graft(s) with other forms of angina pectoris
I25.729	Atherosclerosis of autologous artery coronary artery bypass graft(s) with unspecified angina pectoris
I25.730	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unstable angina pectoris
I25.731	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with angina pectoris with documented spasm

ICD-10 Diagnosis Code	**Definition**
I25.732	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with refractory angina pectoris
I25.738	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with other forms of angina pectoris
I25.739	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unspecified angina pectoris
I25.750	Atherosclerosis of native coronary artery of transplanted heart with unstable angina
I25.751	Atherosclerosis of native coronary artery of transplanted heart with angina pectoris with documented spasm
I25.752	Atherosclerosis of native coronary artery of transplanted heart with refractory angina pectoris
I25.758	Atherosclerosis of native coronary artery of transplanted heart with other forms of angina pectoris
I25.759	Atherosclerosis of native coronary artery of transplanted heart with unspecified angina pectoris
I25.760	Atherosclerosis of bypass graft of coronary artery of transplanted heart with unstable angina
I25.761	Atherosclerosis of bypass graft of coronary artery of transplanted heart with angina pectoris with documented spasm
I25.762	Atherosclerosis of bypass graft of coronary artery of transplanted heart with refractory angina pectoris

I25.768	Atherosclerosis of bypass graft of coronary artery of transplanted heart with other forms of angina pectoris
I25.769	Atherosclerosis of bypass graft of coronary artery of transplanted heart with unspecified angina pectoris
I25.790	Atherosclerosis of other coronary artery bypass graft(s) with unstable angina pectoris

I25.791	Atherosclerosis of other coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.792	Atherosclerosis of other coronary artery bypass graft(s) with refractory angina pectoris
I25.798	Atherosclerosis of other coronary artery bypass graft(s) with other forms of angina pectoris
I25.799	Atherosclerosis of other coronary artery bypass graft(s) with unspecified angina pectoris
I25.810	Atherosclerosis of coronary artery bypass graft(s) without angina pectoris
I25.811	Atherosclerosis of native coronary artery of transplanted heart without angina pectoris
I25.812	Atherosclerosis of bypass graft of coronary artery of transplanted heart without angina pectoris
I25.89	Other forms of chronic ischemic heart disease
I25.9	Chronic ischemic heart disease, unspecified
I34.0	Nonrheumatic mitral (valve) insufficiency
I34.1	Nonrheumatic mitral (valve) prolapse
I34.2	Nonrheumatic mitral (valve) stenosis
I34.81	Nonrheumatic mitral (valve)
I34.89	Other nonrheumatic mitral valve disorders
I34.9	Nonrheumatic mitral valve disorder, unspecified
I35.0	Nonrheumatic aortic (valve) stenosis
I35.1	Nonrheumatic aortic (valve) insufficiency
I35.2	Nonrheumatic aortic (valve) stenosis with insufficiency
I35.8	Other nonrheumatic aortic valve disorders
I35.9	Nonrheumatic aortic valve disorder, unspecified

ICD-10 Diagnosis Code	**Definition**
I36.0	Nonrheumatic tricuspid (valve) stenosis
I36.1	Nonrheumatic tricuspid (valve) insufficiency
I36.2	Nonrheumatic tricuspid (valve) stenosis with insufficiency
I36.8	Other nonrheumatic tricuspid valve disorders
I36.9	Nonrheumatic tricuspid valve disorder, unspecified
I37.0	Nonrheumatic pulmonary valve stenosis
I37.1	Nonrheumatic pulmonary valve insufficiency
I37.2	Nonrheumatic pulmonary valve stenosis with insufficiency
I37.8	Other nonrheumatic pulmonary valve disorders
I37.9	Nonrheumatic pulmonary valve disorder, unspecified
I38	Endocarditis, valve unspecified

I39	Endocarditis and heart valve disorders in diseases classified elsewhere
I42.0	Dilated cardiomyopathy
I42.2	Other hypertrophic cardiomyopathy
I42.3	Endomyocardial (eosinophilic) disease

I42.4	Endocardial fibroelastosis
I42.5	Other restrictive cardiomyopathy
I42.6	Alcoholic cardiomyopathy
I42.7	Cardiomyopathy due to drug and external agent
I42.8	Other cardiomyopathies
I42.9	Cardiomyopathy, unspecified
I43	Cardiomyopathy in diseases classified elsewhere
I46.2	Cardiac arrest due to underlying cardiac condition
I46.8	Cardiac arrest due to other underlying condition
I46.9	Cardiac arrest, cause unspecified
I47.0	Re-entry ventricular arrhythmia
I47.10	Supraventricular tachycardia, unspecified Effective 10/1/23
I47.11	Inappropriate sinus tachycardia, so stated Effective 10/1/23
I47.19	Other supraventricular tachycardia Effective 10/1/23
I47.20	Ventricular tachycardia, unspecified
I47.21	Torsades de pointes
I47.29	Other ventricular tachycardia
I47.9	Paroxysmal tachycardia, unspecified
I48.0	Atrial fibrillation
I48.11	Longstanding persistent atrial fibrillation
I48.19	Other persistent atrial fibrillation
I49.01	Ventricular fibrillation
I49.02	Ventricular flutter
I49.1	Atrial premature depolarization
I49.2	Junctional premature depolarization

ICD-10 Diagnosis Code	**Definition**
I49.3	Ventricular premature depolarization
I49.40	Unspecified premature depolarization
I49.49	Other premature depolarization
I49.5	Sick sinus syndrome
I49.8	Other specified cardiac arrhythmias
I49.9	Cardiac arrhythmia, unspecified
I50.1	Left ventricular failure
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure

I50.23	Acute on chronic systolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure

I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.84	End-stage heart failure
I50.9	Heart failure, unspecified
I51.4	Myocarditis, unspecified
I51.9	Heart disease, unspecified
I52	Other heart disorders in diseases classified elsewhere
I5A	Non-ischemic myocardial injury (non-traumatic)
I97.0	Postcardiotomy syndrome
I97.110	Postprocedural cardiac insufficiency following cardiac surgery
I97.111	Postprocedural cardiac insufficiency following other surgery
I97.120	Postprocedural cardiac arrest following cardiac surgery
I97.121	Postprocedural cardiac arrest following other surgery
I97.130	Postprocedural heart failure following cardiac surgery
I97.131	Postprocedural heart failure following other surgery
I97.190	Other postprocedural cardiac functional disturbances following cardiac surgery
I97.191	Other postprocedural cardiac functional disturbances following other surgery
I97.710	Intraoperative cardiac arrest during cardiac surgery
I97.711	Intraoperative cardiac arrest during other surgery
I97.790	Other intraoperative cardiac functional disturbances during cardiac surgery
I97.791	Other intraoperative cardiac functional disturbances during other surgery
I97.88	Other intraoperative complications of the circulatory system, not elsewhere classified
I97.89	Other postprocedural complications and disorders of the circulatory system, not elsewhere classified

ICD-10 Diagnosis Code	**Definition**
M32.11	Endocarditis in systemic lupus erythematosus
R00.1	Bradycardia, unspecified
R57.0	Cardiogenic shock
T82.221A	Breakdown (mechanical) of biological heart valve graft, initial encounter
T82.222A	Displacement of biological heart valve graft, initial encounter
T82.223A	Leakage of biological heart valve graft, initial encounter
T82.228A	Other mechanical complication of biological heart valve graft, initial encounter
T82.512A	Breakdown (mechanical) of artificial heart, initial encounter
T82.514A	Breakdown (mechanical) of infusion catheter, initial encounter

T82.518A	Breakdown (mechanical) of other cardiac and vascular devices and implants, initial encounter
T82.522A	Displacement of artificial heart, initial encounter
T82.528A	Displacement of other cardiac and vascular devices and implants, initial encounter
T82.529A	Displacement of unspecified cardiac and vascular devices and implants, initial encounter
T82.532A	Leakage of artificial heart, initial encounter
T82.538A	Leakage of other cardiac and vascular devices and implants, initial encounter
T82.592A	Other mechanical complication of artificial heart, initial encounter
T82.598A	Other mechanical complication of other cardiac and vascular devices and implants, initial encounter
T86.20	Unspecified complication of heart transplant
T86.21	Heart transplant rejection
T86.22	Heart transplant failure
T86.23	Heart transplant infection
T86.290	Cardiac allograft vasculopathy
T86.298	Other complications of heart transplant
T86.30	Unspecified complication of heart-lung transplant
T86.31	Heart-lung transplant rejection
T86.32	Heart-lung transplant failure
T86.33	Heart-lung transplant infection
T86.39	Other complications of heart-lung transplant
Z48.21	Encounter for aftercare following heart transplant
Z48.280	Encounter for aftercare following heart-lung transplant
Z94.1	Heart transplant status
Z94.3	Heart and lungs transplant status
Z95.811	Presence of heart assist device effective 12/01/20

This policy does not address coverage of VADs for right ventricular support, biventricular support, use in beneficiaries under the age of 18, use in beneficiaries with complex congenital heart disease, or use in beneficiaries with acute heart failure without a history of chronic heart failure. Coverage under section 1862(a) (1) (A) of the Social Security Act for VADs in these situations will be made by local Medicare Administrative Contractors (MACs) within their respective jurisdictions.

320.3.4– Replacement Accessories and Supplies for External VADs or Any VAD

(Rev.10837; Issued: 06-11-21; Effective: 12-01-20; Implementation: 07-27-21)

Effective April 1, 2013, claims for replacement of accessories and supplies for VADs implanted in patients who were not eligible for coverage under Medicare Part A or had other insurance that paid for the device and hospital stay at the time that the device was implanted, but are now eligible for coverage of the replacement supplies and accessories under Part B, should be submitted using HCPCS code Q0509. Those claims will be manually reviewed.

In rare instances it may be appropriate to pay for replacement of supplies and accessories for external VADs used by patient who are discharged from the hospital. In addition, in some rare instances, it may be necessary for a patient to have an emergency back-up controller for an external VAD. Coverage of these items is at the discretion of the contractor. Claims for replacement of supplies and accessories used with an external VAD that are furnished by suppliers should be billed to the Part B MACs. Claims for replacement of supplies and accessories used with an external VAD that are furnished by hospitals and other providers should be billed to the Part AMACs. Effective April 1, 2013, these items should be billed using code Q0507 so that the claims can be manually reviewed.

Claims for replacement supplies or accessories used with VADs that do not have specific HCPCS codes and do not meet the criteria of codes Q0507 and Q0509 should be billed using code Q0508.

Claims Coding

HCPCS	Definition	Effective Date
Q0507	Miscellaneous Supply Or Accessory For Use With An External Ventricular Assist Device	**April 1, 2013**
Q0508	Miscellaneous Supply or Accessory For Use With An Implanted Ventricular Assist Device	**April 1, 2013**
Q0509	Miscellaneous Supply Or Accessory For Use With Any Implanted Ventricular Assist Device For Which Payment Was Not Made Under Medicare Part A	**April 1, 2013**

Q0480:Driver for use with pneumatic ventricular assist device, replacement only

Q0481:Microprocessor control unit for use with electric ventricular assist device, replacement only

Q0482:Microprocessor control unit for use with electric/pneumatic combination ventricular assist device, replacement only

Q0483:Monitor/display module for use with electric ventricular assist device, replacement only

Q0484:Monitor/display module for use with electric or electric/pneumatic ventricular assist device, replacement only

Q0485:Monitor control cable for use with electric ventricular assist device, replacement only

Q0486:Monitor control cable for use with electric/pneumatic ventricular assist device, replacement only

Q0487:Leads (pneumatic/electrical) for use with any type electric/pneumatic ventricular assist device, replacement only

Q0488:Power pack base for use with electric ventricular assist device, replacement only

Q0489:Power pack base for use with electric/pneumatic ventricular assist device, replacement only

Q0490:Emergency power source for use with electric ventricular assist device, replacement only

Q0491:Emergency power source for use with electric/pneumatic ventricular assist device, replacement only

Q0492:Emergency power supply cable for use with electric ventricular assist device, replacement only

Q0493:Emergency power supply cable for use with electric/pneumatic ventricular assist device, replacement only

Q0494:Emergency hand pump for use with electric or electric/pneumatic ventricular assist device, replacement only

Q0495:Battery/power pack charger for use with electric or electric/pneumatic ventricular assist device, replacement only

Q0496:Battery, other than lithium-ion, for use with electric or electric/pneumatic ventricular assist device, replacement only

Q0497:Battery clips for use with electric or electric/pneumatic ventricular assist device, replacement only

Q0498:Holster for use with electric or electric/pneumatic ventricular assist device, replacement only

Q0499:Belt/vest/bag for use to carry external peripheral components of any type ventricular assist device, replacement only

Q0500:Filters for use with electric or electric/pneumatic ventricular assist device, replacement only

Q0501:Shower cover for use with electric or electric/pneumatic ventricular assist device, replacement only

Q0502:Mobility cart for pneumatic ventricular assist device, replacement only

Q0503:Battery for pneumatic ventricular assist device, replacement only, each

Q0504:Power adapter for pneumatic ventricular assist device, replacement only, vehicle type

Q0506:Battery, lithium-ion, for use with electric or electric/pneumatic ventricular assist device, replacement only

NOTE: When determined to be medically necessary, dressings used with VADs are covered under the prosthetic device benefit as a supply necessary for the effective use of the VAD/prosthetic device. Claims for dressings necessary for the

effective use of a VAD should be billed using the appropriate miscellaneous VAD supply code, depending upon whether the patient was eligible for coverage under Medicare Part A at the time that the VAD was implanted. The claims processing jurisdiction for dressings used with VADs is identical to that of other VAD replacement supplies and accessories and does not fall under Durable Medical Equipment MAC jurisdiction.

330 – Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS)

(Rev. 2959, Issued: 05-16-14, Effective: 01-09-14, Implementation: 10-06-14)

PILD is a posterior decompression of the lumbar spine performed under indirect image guidance without any direct visualization of the surgical area. This is a procedure proposed as a treatment for symptomatic LSS unresponsive to conservative therapy. This procedure is generally described as a non-invasive procedure using specially designed instruments to percutaneously remove a portion of the lamina and debulk the ligamentum flavum. The procedure is performed under x-ray guidance (e.g., fluoroscopic, CT) with the assistance of contrast media to identify and monitor the compressed area via epiduragram. For complete Medical coverage guidelines, see National Coverage Determinations (NCD) Manual (Pub 100-03) §150.13.

330.1 – Claims Processing Requirements for Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) on Professional Claims

(Rev. 13709; Issued:04-02-26, Effective: 06-02-26; Implementation: 06-02-26)

For claims with dates of service on or after January 9, 2014, PILD (procedure code 0275T - *end date 12/31/25*) is a covered service when billed as part of a clinical trial approved by CMS.

The description for CPT 0275T *end date 12/31/25* is : "Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy", any method, under indirect image guidance (e.g., fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar" .

CPT 62330 describes percutaneous image-guided lumbar decompression (PILD) for spinal stenosis, involving the removal of the ligamentum flavum and laminotomy, with imaging (CT or fluoroscopy) and epidurography.

Effective January 1, 2026, 62330 is replacing the former CPT code (0275T – end date effective 12/31/25).

For claims with dates of service on or after January 1, 2015, PILD (procedure code G0276) is a covered service when billed as part of a clinical trial approved by CMS. HCPCS G0276 is "Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD), or placebo control, performed in an approved coverage with evidence development (CED) clinical trial".

Effective for dates of service on or after December 7, 2016, Medicare will cover PILD under CED for beneficiaries with LSS who are enrolled in a CMS-approved prospective longitudinal study for PILD procedures using a FDA-approved/cleared device that completed a CMS-approved randomized, controlled clinical trial (RCT) that met the criteria listed in the January 2014 NCD (see CR 8757, transmittal # 2959, dated May 16, 2014).

The claim may only contain one of these procedure codes, not both. To *report* G0276, the procedure must be performed within a *CMS approved* CED clinical trial that is randomized, blinded, and *includes* a placebo control arm of the trial. CMS will cover procedure code 0275T (*end date effective 12/31/25)* for PILD only when the procedure is performed

within any other CED approved clinical trial. Regardless of the type of CED approved clinical trial (e.g. G0276 vs 0275T (*end date effective 12/31/25*), PILD is only covered when billed for the ICD-9 diagnosis of 724.01-724.03 or the ICD-10 diagnosis of M48.05-M48.07, when billed in places of service *19 (Off Campus-Outpatient Hospital (effective 01/01/16)*, 22 (Outpatient) or 24 (Ambulatory Surgical Center), when billed along with V70.7 (ICD-9) or Z00.6 (ICD-10) in either the primary/secondary positions, and when billed with modifier Q0.

Additionally, per Transmittal 2805 (Change Request 8401), issued October 30, 2013, all claims for clinical trials must contain the 8-digit clinical trial identifier number.

The following message(s) shall be used to notify providers of return situations that may occur:

Professional Claims 8-digit Clinical Trial Number

For PILD claims with procedure code 0275T (*end date 12/31/25)* with dates of service on or after January 9, 2014, or claims with procedure code G0276 with dates of service on or after January 1, 2015, contractors shall pay for PILD only when billed with the numeric, 8-digit clinical trial identifier number preceded by the two alpha characters "CT" when placed in Field 19 of paper Form CMS-1500, or when entered without the "CT" prefix in the electronic 837P in Loop 2300 REF02 (REF01=P4). Claims for PILD which are billed without an 8-digit clinical trial identifier number shall be returned as un-processable.

Note: Effective January 1, 2026, CPT 62330 is replacing the former CPT code (0275T – end date effective 12/31/25).

The following messages shall be used when Medicare contractors return PILD claims billed without an 8-digit clinical trial identifier number as un-processable:

Claims Adjustment Reason Code 16: "Claim/service lacks information or has submission/billing error(s) which is needed for adjudication".

Remittance Advice Remark Code N721: "This service is only covered when performed as part of a clinical trial."

Remittance Advice Remark Code MA50: "Missing/incomplete/invalid Investigational Device Exemption number or Clinical Trial number."

Remittance Advice Remark Code N704: "Alert: You may not appeal this decision but can resubmit this claim/service with corrected information if warranted."

Professional Claims Place of Service – *19 (effective 01/01/16)*, 22 or 24 CMS

For PILD claims with procedure code *62330 effective 01/01/26* or for claims with procedure code G0276 with dates of service on or after January 1, 2015, contractors shall pay for PILD for LSS claims only when billed in place of service *19, 22* or 24. Claims for PILD which are billed in any other place of service shall be returned as un-processable.

The following messages shall be used when Medicare contractors return PILD claims not billed in place of service *19,* 22 or 24:

Claims Adjustment Reason Code 58: "Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service."

Remittance Advice Remark Code N704: "Alert: You may not appeal this decision but can resubmit this claim/service with corrected information if warranted."

Professional Claims Modifier – Q0

For PILD claims with procedure code 0275T *has an end date 12/31/25,* with dates of service on or after January 9, 2014, (*note: 0275T is being replaced with 62330* effective 01/01/26) or for claims with procedure code G0276 with dates of service on or after January 1, 2015, contractors shall pay for PILD for LSS claims only when billed with modifier Q0. Claims for PILD which are billed without modifier Q0 shall be returned as un-processable.

The following messages shall be used when Medicare contractors return PILD claims billed without modifier Q0 as un-processable:

Claims Adjustment Reason Code 4: "The procedure code is inconsistent with the modifier used or a required modifier is missing."

Remittance Advice Remark Code N657: "This should be billed with the appropriate code for these services."

Remittance Advice Remark Code N704: "Alert: You may not appeal this decision but can resubmit this claim/service with corrected information if warranted."

Non-covered Diagnosis

For PILD claims with procedure code 0275T *end date 12/31/25,* with dates of service on or after January 9, 2014 (*note: 0275T is being replaced with 62330* effective 01/01/26), or for claims with procedure code G0276 with dates of service on or after January 1, 2015, contractors shall pay for PILD for LSS claims only when billed with the ICD-9 diagnosis of 724.01-724.03 or the ICD-10 diagnosis of M48.05-M48.07.

The following messages shall be used when Medicare contractors return PILD claims, billed without the covered diagnosis, as un-processable:

Claims Adjustment Reason Code B22: "This payment is adjusted based on the diagnosis."

Remittance Advice Remark Code N704: "Alert: You may not appeal this decision but can resubmit this claim/service with corrected information if warranted."

Clinical Trial Diagnosis

For PILD claims with procedure code 0275T and *end date 12/31/25* with dates of service on or after January 9, 2014, (*note 0275T is being replaced with 62330* effective 01/01/26), or for claims with procedure code G0276 with dates of service on or after January 1, 2015, contractors shall pay for PILD only when billed with the ICD-9 diagnosis of V70.7 (ICD-9) or Z00.6 (ICD-10) in either the primary or secondary positions. The following messages shall be used when Medicare contractors return PILD claims, billed without the clinical trial diagnosis, as un-processable:

Claims Adjustment Reason Code B22: "This payment is adjusted based on the diagnosis."

Remittance Advice Remark Code N704: "Alert: You may not appeal this decision but can resubmit this claim/service with corrected information if warranted."

330.2 - Claims Processing Requirements for PILD for Outpatient Facilities

(Rev. 13709; Issued:04-02-26, Effective: 06-02-26; Implementation: 06-02-26)

Hospital Outpatient facilities shall bill for percutaneous image-guided lumbar decompression (PILD) procedure code 0275T *end date 12/31/25* effective on or after January 9, 2014 (*note 0275T is being replaced with 62330* effective 01/01/26), or procedure code G0276 effective on or after January 1, 2015, for lumbar spinal stenosis (LSS) on a 13X or 85X TOB. Refer to Section 69 of this chapter for further guidance on billing under CED.

Effective for dates of service on or after December 7, 2016, Medicare will cover PILD under CED for beneficiaries with LSS who are enrolled in a CMS-approved prospective longitudinal study for PILD procedures using a FDA-approved/cleared device that completed a CMS-approved randomized, controlled clinical trial (RCT) that met the criteria listed in the January 2014 NCD (see CR 8757, transmittal # 2959, dated May 16, 2014).

Hospital outpatient procedures for PILD shall be covered when billed with:

- ICD-9 V70.7 (ICD-10 Z00.6) and Condition Code 30.
- Modifier Q0
- An 8-digit clinical trial identifier number listed on the CMS Coverage with Evidence Development website

Hospital outpatient procedures for PILD shall be rejected when billed without:

- ICD-9 V70.7 (ICD-10 Z00.6) and Condition Code 30.
- Modifier Q0
- An 8-digit clinical trial identifier number listed on the CMS Coverage with Evidence Development website

Claims billed by hospitals not participating in the trial /registry, shall be rejected with the following message:

CARC: 50 -These are non-covered services because this is not deemed a “medical necessity” by the payer.

RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Group Code –Contractual Obligation (CO)

MSN 16.77 – This service/item was not covered because it was not provided as part of a qualifying trial/study. (Este servicio/artículo no fue cubierto porque no estaba incluido como parte de un ensayo clínico/estudio calificado.)

340 – Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation

(Rev. 10985; Issued:09-08-21, Effective:01-19-21; Implementation:10-08-21)

Transcatheter Edge-to-Edge Repair (TEER) of the mitral valve (previously named Transcatheter Mitral Valve Repair (TMVR)) is used in the treatment of mitral regurgitation (MR). TEER approximates the anterior and posterior mitral valve leaflets by grasping them with a clipping device in an approach similar to a treatment developed in cardiac surgery called the Alfieri stitch.

The most recent reconsideration of NCD 20.33 (TEER for Mitral Valve Regurgitation (previously named TMVR)) is effective for claims with dates of service on and after January 19, 2021. It expands coverage of mitral valve TEER procedures for the treatment of functional MR and maintains coverage of TEER for the treatment of degenerative MR, through coverage with evidence development (CED) and with mandatory registry participation. It also makes changes to the criteria for the heart team and hospital, and to the registry questions/criteria and the trial requirements and outcomes. For more detailed information see Pub. 100-03, Medicare National Coverage Determinations (NCD) Manual, Chapter 1, Section 20.33.

For services furnished between August 7, 2014 and January 19, 2021, the CMS covered TMVR for MR when furnished under CED when the treatment was furnished for an FDA-approved indication with an FDA-approved device as follows: (1) Treatment of significant, symptomatic, degenerative MR when furnished according to an FDA-approved indication and all CMS coverage criteria are met, and, (2) TMVR for MR uses not expressly listed as FDA-approved indications but only within the context of an FDA-approved, randomized clinical trial that meets all CMS coverage criteria. TMVR was non-covered outside CED or for non-MR indications.

Historical Note: For claims processing instructions from August 7, 2014, through January 19, 2021, please see the following links:

Change request (CR) 9002, Transmittal (TN) 178, issued December 5, 2014, informed Medicare Administrative Contractors to pay for TMVR under CED and revised the NCD manual to add NCD 20.33: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R178NCD.pdf.

CR 9002, TR 3142, issued December 5, 2014, implemented the initial NCD for TMVR, effective August 7, 2014. TR 3241 rescinded and replaced TN 3142 on April 25, 2014: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3241CP.pdf.

ICD-10 Coding Updates: https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/ICD10

340.1 – Coding Requirements for Mitral Valve TEER Claims Furnished on or After August 7, 2014

(Rev. 10985; Issued:09-08-21, Effective:01-19-21; Implementation:10-08-21)

Current Procedural Terminology (CPT) Codes for Mitral Valve TEER Claims

CPT code 33418, Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis, effective January 1, 2015.

CPT code 33419, Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; additional prosthesis (es) during same session, effective January 1, 2015. (List separately in addition to code for primary procedure).

0345T - Transcatheter mitral valve repair percutaneous approach via the coronary sinus

ICD-10 Procedure Code for Mitral Valve TEER Claims

02UG3JZ – Supplement mitral valve with synthetic substitute, percutaneous approach
02UG3JH – Supplemental mitral valve with synthetic substitute, transapical, percutaneous approach

ICD-10 Diagnosis Codes for Mitral Valve TEER

I34.0 – Nonrheumatic mitral (valve) insufficiency, or,

I34.1 – Nonrheumatic mitral (valve) prolapse, and,
Z00.6 – Encounter for examination for normal comparison and control in clinical research program

340.2 – Claims Processing Requirements for Mitral Valve TEER Services on Professional Claims
(Rev. 12883; Issued: 10-11-25; Effective: 01-01-25; Implementation: 01-16-25)

Professional Claims Place of Service (POS) Codes for Mitral Valve TEER Claims
Effective for claims with dates of service on and after August 7, 2014, place of service (POS) code 21 shall be used for mitral valve TEER services. All other POS codes shall be denied.

The following messages shall be used when Medicare contractors deny mitral valve TEER claims for POS:

Claim Adjustment Reason Code (CARC) 58: "Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present."

Group Code: CO (Contractual Obligation) assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file.)
Medicare Summary Notice (MSN) 21.25: "This service was denied because Medicare only covers this service in certain settings."

Spanish Version: El servicio fue denegado porque Medicare solamente lo cubre en ciertas situaciones."

Professional Claims Modifiers for Mitral Valve TEER Claims

Effective for claims with dates of service on or after August 7, 2014, contractors shall pay claim lines for mitral valve TEERs billed with the most recent CPT codes 33418, 33419, and 0345T in a clinical trial when billed with modifier -Q0. Mitral valve TEER claim lines in a clinical trial billed without modifier -Q0 shall be returned as unprocessable.

The following messages shall be used when Medicare contractors return mitral valve TEER claim lines in a clinical trial billed without modifier -Q0 as unprocessable:

CARC 4: "The procedure code is inconsistent with the modifier used or a required modifier is missing. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present."

N386: This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Group Code: CO "(Contractual Obligation) assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file.)"

Professional Clinical Trial Diagnostic Coding for Mitral Valve TEER Claims

Effective for claims with dates of service on or after August 7, 2014 contractors shall pay claim lines for mitral valve TEERs billed with the most recent CPT codes 33418, 33419 and 0345T in a clinical trial when billed with the most recent ICD-10 diagnosis codes ICD-10 I34.0 or I34.1 and Z00.6. Mitral valve TEER claim lines in a clinical trial billed without ICD-10 diagnosis code I34.0 or I34.1 and Z00.6 shall be denied.

*Note: Effective 01/01/25, ICD-10 I34.0 or I34.1 codes are no longer required to be listed as primary, along with clinical trial ICD-10 Z00.6 as secondary. These codes can be reported in any position. See IOM 100-03-chapter 1, section NCD 20.33 for additional information.
The following messages shall be used when Medicare contractors deny mitral valve TEER claim lines in a clinical trial billed without ICD-10 diagnosis code Z00.6:

CARC 50: These are non-covered services because this is not deemed a "medical necessity" by the payer.

RARC N386: This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD Group Code: CO (Contractual Obligation) assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file.)

MSN 15.20: The following policies [NCD 20.33]] were used when we made this decision

Spanish Version: MSN 15.20: Las siguientes políticas [NCD 20.33] fueron utilizadas cuando se tomó esta decisión.

Mandatory National Clinical Trial (NCT) Number for Mitral Valve TEER Claims

Effective for claims with dates of service on or after August 7, 2014, contractors shall pay mitral valve TEER claim lines billed with the most recent CPT codes 33418, 33419, and 0345T in a clinical trial only when billed with an 8-digit national clinical trial (NCT) number. Contractors shall accept the numeric, 8-digit NCT number preceded by the two alpha characters of "CT" when placed in Field 19 of paper Form CMS-1500, or when entered WITHOUT the "CT" prefix in the electronic 837P in Loop 2300 REF02 (REF01=P4). **NOTE**: The "CT" prefix is required on a paper claim, but it is not required on an electronic claim. Mitral valve TEER claim lines in a clinical trial billed without an 8- digit NCT number shall be returned as unprocessable.

The following messages shall be used when Medicare contractors return mitral valve TEER claim lines as unprocessable when billed without an 8-digit NCT number:

CARC 16: "Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.)"

RARC MA50: "Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services."

Group Code: CO (Contractual Obligation) assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file.)

340.3 - Claims Processing Requirements for Mitral Valve TEER Services on Inpatient Hospital Claims

(Rev. 10985; Issued:09-08-21, Effective:01-19-21; Implementation:10-08-21)

Inpatient hospitals shall bill for mitral valve TEER on an 11X type of bill (TOB) effective for discharges on or after August 7, 2014. Refer to Section 69 of this chapter for further guidance on billing under CED.

In addition to the ICD-10 procedure and diagnosis codes mentioned above, inpatient hospital discharges for mitral valve TEER shall be covered when billed with the following clinical trial coding:

- Secondary ICD-10 diagnosis code Z00.6

- Condition Code 30
- Value code D4 - Clinical Trial Number Assigned by NLM/NIH with an 8-digit clinicaltrials.gov identifier number listed on the CMS website

Inpatient hospital discharges for mitral valve TEERs shall be denied when billed without the ICD-10 diagnosis, procedure codes and clinical trial coding mentioned above. Claims that do not include these required codes shall be rejected with the following messages:

CARC 50: These are non-covered services because this is not deemed a "medical necessity" by the payer.

RARC N386: This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Group Code: CO (Contractual Obligation) assigning financial liability to the provider

MSN 15.20: The following policies [NCD 20.33] were used when we made this decision

Spanish Version: MSN 15.20 - Las siguientes políticas [NCD 20.33] fueron utilizadas cuando se tomó esta decisión.

340.4 - Claims Processing Requirements for Mitral Valve TEER Services for Medicare Advantage (MA) Plan Participants

(Rev. 10985; Issued:09-08-21, Effective:01-19-21; Implementation:10-08-21)

MA plans are responsible for payment of mitral valve TEER services for MA plan participants. Medicare coverage for mitral valve TEERs is not included under section 310.1 of the NCD Manual (Routine Costs in Clinical Trials).

350 - Emergency and Foreign Hospital Services

(Rev. 3287, Issued: 06-30-15, Effective: 04-21-15, Implementation: 04-21-15)

The conditions for payment for services furnished in a foreign country can be found in 42 CFR 424.120-127, Subpart H - Special Conditions: Emergency Services Furnished In a Foreign Country. The payment exclusion for services furnished outside the U.S. is located at 42 CFR 411.9 and 42 CFR 411.9(a)(2) describes the applicability of the payment exclusion when services are furnished on board a ship.

350.1 - Services Rendered By Nonparticipating Providers

(Rev. 3287, Issued: 06-30-15, Effective: 04-21-15, Implementation: 04-21-15)

A. Services in Nonparticipating Domestic Hospital

Payment may be made for certain Part A inpatient and Part B outpatient hospital services provided in a nonparticipating U.S. hospital where they are necessary to prevent the death or serious impairment of the health of the individual. Because of the threat to the life or health of the individual, the use of the most accessible hospital equipped to furnish such services is necessary. Items and services furnished in a domestic nonparticipating hospital may be reimbursed if the following apply:

The hospital meets the definition of an emergency hospital. (See §350.3.)

The services meet the definition of emergency services. (See §350.2.)

The hospital is substantially more accessible from the site of the emergency than is the nearest participating hospital. (See §350.4.)

B. Services Received by Medicare Beneficiaries outside the United States

Items and services furnished outside the United States and certain services rendered on board a ship are excluded from coverage except for the following services:

Emergency inpatient hospital services where the emergency occurred:
- o While the beneficiary was physically present in the United States; or
- o In Canada while the beneficiary was traveling without reasonable delay and by the most direct route between Alaska and another State.

Emergency or nonemergency inpatient hospital services furnished by a hospital located outside the United States, if the hospital was closer to, or substantially more accessible from, the beneficiary's United States residence than the nearest participating United States hospital that was adequately equipped to deal with, and available to provide treatment for the illness or injury.

Physician and ambulance services furnished in connection with a covered foreign hospitalization. Program payment may not be made for any other Part B medical and other health services, including outpatient services furnished outside the United States.

Services rendered on board a ship in a United States port, or within 6 hours of when the ship arrived at, or departed from, a United States port, are considered to have been furnished in United States territorial waters. Services not furnished in a United States port, or within 6 hours of when the ship arrived at, or departed from, a United States port, are considered to have been furnished outside United States territorial waters, even if the ship is of United States registry.

The term "United States" means the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, the Northern Mariana Islands, American Samoa and, for purposes of services rendered on a ship, includes the territorial waters adjoining the land areas of the United States.

A hospital that is not physically situated in one of the above jurisdictions is considered to be outside the United States, even if it is owned or operated by the United States Government.

C. Ship Physician's Office is in the United States.

When the physician's office is inside of the United States, the contractor designated to process the shipboard claim is determined by the beneficiary's residence.

D. Ship Physician's Office is Outside of the United States.

When the physician's office is outside of the United States, the contractor designated to process the shipboard claim is determined by the beneficiary's residence.

MSN message 16.240 (English)

Services provided aboard a ship are covered only when the ship is in United States waters. In addition, the service must be provided by a doctor licensed to practice in the United States.

MSN message 16.240 (Spanish)

Servicios proporcionados abordo de un barco son cubiertos solamente cuando el barco está en aguas territoriales de los Estados Unidos. Además, el servicio debe ser proporcionado por un médico con licencia para practicar en los Estados Unidos.

Payment may not be made for any item provided or delivered to the beneficiary outside the United States, even though the beneficiary may have contracted to purchase the item while he or she was within the United States or purchased the item from an American firm.

Under the Railroad Retirement Act, payment is made to qualified Railroad Retirement beneficiaries (QRRBs) by the RRB for covered hospital services furnished in Canadian hospitals as well as in the U.S. Physician and ambulance services are not covered by the Railroad Retirement Act; however, under an agreement between CMS and RRB, if the QRRB claims payment for Part B services in connection with Canadian hospitalization, RRB processes the Part B claim. In such cases the RRB determines:

Whether the requirements are met for the inpatient services; and

Whether the physician and/or ambulance services were furnished in connection with the services.

Services for an individual who has elected religious nonmedical health care status may be covered if the above requirements are met but this revokes the religious nonmedical health care institution election.

350.2 - Establishing an Emergency

(Rev. 3287, Issued: 06-30-15, Effective: 04-21-15, Implementation: 04-21-15)

Claims for emergency services must be accompanied by a physician's statement describing the nature of the emergency and stating that the services were necessary to prevent the death, or the serious impairment of, the beneficiary. A statement that an emergency existed is not sufficient. In addition, when inpatient services are involved, the statement must include the date when, in the physicians' judgment, the emergency ceased.

The finding of whether the patient's condition required emergency diagnosis or treatment is ordinarily based upon the physician's evaluation of the patient's condition immediately upon the beneficiary's arrival at the hospital.

However, the emergency nature of the situation may have been assessed by a physician who attended the patient where the incident resulting in hospitalization occurred (for example, a heart attack or an automobile accident). In these cases, the attending physician who ordered the hospitalization may substantiate the claim that emergency hospitalization was necessary.

Most emergencies are of relatively short duration so that only one bill is submitted. Generally, only one physician's statement is necessary. However, in the rare situation where an emergency continued over an extended period, subsequent requests for payment must be accompanied by a physician's statement containing sufficient information to indicate clearly that the emergency situation still existed. A statement that the emergency continued to exist is not acceptable.

Additional information to support a finding that the services were emergency services from the physician, the hospital, and others (e.g., the police department at the scene of an accident) may be requested.

Medical necessity can be documented by the physician on a CMS-l77l, Attending Physician's Statement and Documentation of Medicare Emergency or by the beneficiary's medical records. The CMS-1771 can be obtained from:

Centers for Medicare & Medicaid Services

Forms Management Section
7500 Security Blvd.
Baltimore, MD 21244-1850

Or, the form can be downloaded from http://cms.hhs.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-List.html

350.3 - Qualifications of an Emergency Services Hospital

(Rev. 3287, Issued: 06-30-15, Effective: 04-21-15, Implementation: 04-21-15)

An emergency services hospital is a nonparticipating hospital that meets the requirements of the law's definition of a "hospital" relating to full-time nursing services and licensure under State or applicable local law. (A federal hospital need not be licensed under state or local licensing laws to meet this definition.) In addition, the hospital must be primarily engaged in providing, under the supervision of doctors of medicine or osteopathy, services of the type described in defining the term hospital.

The hospital must not be primarily engaged in providing skilled nursing care and related services for patients who require medical or nursing care. Psychiatric hospitals can qualify as emergency hospitals.

350.4 - Coverage Requirements for Emergency Hospital Services Furnished Outside of the United States

(Rev. 3287, Issued: 06-30-15, Effective: 04-21-15, Implementation: 04-21-15)

The following requirements must be met for payment to be made for emergency services received by Medicare beneficiaries in foreign hospitals:

- The hospital must meet the definition of an emergency hospital and be licensed or approved by the appropriate agency of the country in which it is located.

- The services meet the criteria of emergency services.

The foreign hospital must be closer to or substantially more accessible from the site of the emergency than the nearest U.S. hospital that was adequately equipped and available to treat the illness or injury.

1. Emergency Occurred in the U.S. (See §350.1.B for definition of the U.S.)

If the individual was physically present in the U.S. at the time the emergency occurred, the individual's reason for departure from the U.S. must have been specifically to obtain treatment at the foreign hospital. Services are not covered where the person's departure from the U.S. is part of a trip abroad and the foreign hospital is more accessible simply because the individual was in the process of travel. For example, the airplane on which the individual was traveling could not readily return to permit the person's removal.

2. Emergency Occurred in Canada

If the emergency occurred in Canada, the beneficiary must have been traveling, without unreasonable delay, by the most direct route between Alaska and another state. Benefits are not payable if the emergency occurred while a beneficiary was vacationing. The requirement of travel without unreasonable delay by the most direct route will be considered met if the emergency occurred while the beneficiary was enroute between Alaska and another state by the shortest practicable route, or while making a necessary stopover in connection with such travel.

NOTE: An emergency occurring within the Canadian inland waterway between the States of Washington and Alaska is considered to have occurred in Canada.

Ordinarily, the "shortest practicable route" is the one that results in the least amount of travel in Canada, consistent with the mode of travel used between the point of entry into Canada and the intended point of departure. The amount of travel in the U.S., prior to entering Canada is not pertinent. A route involving greater travel within Canada may be considered the "shortest practicable route" if the additional travel resulted in a saving of time or was necessary because of such factors as:

- Road or weather conditions;
- The age of the traveler;
- Health, or physical condition of the traveler;
- The need to make suitable travel arrangements; or
- The need to obtain acceptable accommodations.

However, the individual would be considered to have deviated from the "shortest practicable route" if the detour was unrelated to the purpose of reaching their destination (e.g., for the principal purpose of sightseeing or vacationing).

The term "necessary stopover" means a routine stopover for rest, food, or servicing of the vehicle, and a non-routine stopover (even though of significant duration) caused by such factors as unsuitable road or weather conditions, the age, health, or physical condition of the traveler, the need to make suitable travel arrangements, or to obtain acceptable accommodations.

350.5 - Services Furnished in a Foreign Hospital Nearest to Beneficiary's U.S. Residence

(Rev. 3287, Issued: 06-30-15, Effective: 04-21-15, Implementation: 04-21-15)

Coverage is provided for inpatient hospital services furnished in a foreign hospital that is closer to, or substantially more accessible from, the beneficiary's U.S. residence than the nearest available participating U.S. hospital that is adequately equipped to deal with the illness or injury, whether or not an emergency existed and without regard to where the illness or injury occurred.

"Residence" means the beneficiary's fixed and permanent home to which they intend to return whenever they are away or a dwelling where the beneficiary periodically spends some time (e.g., a summer home).

The foreign hospital must meet accreditation requirements equivalent to Joint Commission standards. For example, the Canadian Council on Hospital Accreditation (CCHA) has equivalent requirements. Thus, Canadian hospitals accredited by the CCHA meet the qualifying requirements. In the case of Mexican hospitals, the Dallas or San Francisco RO makes the determination, depending upon the hospital's location. Claims for services provided in countries other than Canada or Mexico should be sent to the MAC that is responsible for the state or territory where the emergency arose. In other words, the foreign claim would be processed similarly to how claims are processed in the state or territory where the emergency arose.

See §350.11.4 below for discussion of accessibility criteria.

Some claims for services furnished in a foreign hospital nearest to the beneficiary's U.S. residence will not be "emergency." In these nonemergency situations, it may be necessary to deny payment in whole or part, (even though it has been approved with regard to accessibility) because the services are not medically reasonable and necessary or involve custodial care (i.e., exclusions under §§1862(a)(1) and (9)). However, in the case of denials under the medical

necessity and custodial care exclusions, the MAC applies the limitation on liability considerations under §1879 of the Act before issuing the denial notice.

The MAC examines claims involving medical necessity or custodial care denials to determine if there is any evidence that the beneficiary (or the person acting on behalf of the beneficiary) was aware that the beneficiary did not require, or no longer required, a covered level of care. The foreign hospital, since it is not participating, is not under any obligation to furnish a written notice of noncoverage to a beneficiary in order to protect itself from being held liable under the §1879 waiver of liability provision. However, there may be instances where the medical records of the denied foreign claim show that the beneficiary was advised that the beneficiary did not require, or no longer required, Medicare covered services, (e.g., written notice of noncoverage from the hospital's staff or a prior CMS denial notice). It will probably be rare where a finding is made that the beneficiary had knowledge of noncoverage, so that, generally, payments are made under the waiver of liability provision. The MAC uses appropriate Medicare Summary Notice (MSN) and Remittance Advice denial messages for determinations involving the limitation on liability provision. For additional information regarding the application of the §1879 liability provisions, see Pub 100-04, chapter 30.

350.6 – Coverage of Physician and Ambulance Services Furnished Outside U.S.

(Rev. 3287, Issued: 06-30-15, Effective: 04-21-15, Implementation: 04-21-15)

Payment is made for necessary physician and ambulance services that meet the other coverage requirements of the Medicare program, and are furnished in connection with a covered foreign hospitalization.

A. Coverage of Physician and Ambulance Services Furnished Outside the U.S.

Where inpatient services in a foreign hospital are covered, payment may also be made for:

Physicians' services furnished to the beneficiary while he/she is an inpatient,

Physicians' services furnished to the beneficiary outside the hospital on the day of his/her admission as an inpatient, provided the services were for the same condition for which the beneficiary was hospitalized (including the services of a physician who furnishes emergency services in Canadian waters on the day the patient is admitted to a Canadian hospital for a covered emergency stay) and,

Ambulance services, where necessary, for the trip to the hospital in conjunction with the beneficiary's admission as an inpatient. Return trips from a foreign hospital are not covered.

In cases involving foreign ambulance services, the general requirements in chapter 15 are also applicable, subject to the following special rules:

If the foreign hospitalization was determined to be covered on the basis of emergency services, the medical necessity requirements outlined in chapter 15 are considered met.

The definition of "physician," for purposes of coverage of services furnished outside the U.S., is expanded to include a foreign practitioner, provided the practitioner is legally licensed to practice in the country in which the services are furnished.

Only the beneficiary may file for Part B benefits. The assignment method may not be used. However, where the beneficiary is deceased, the rule for settling Part B underpayments is applicable, i.e., payment may be made to the foreign physician or ambulance company on the basis of an unpaid bill, provided the physician or ambulance company accepts the MACs reasonable charge determination as the full charge.

The regular deductible and coinsurance requirements apply to physician and ambulance services.

350.7 - Claims for Services Furnished in Canada to Qualified Railroad Retirement Beneficiaries
(Rev. 3287, Issued: 06-30-15, Effective: 04-21-15, Implementation: 04-21-15)

All claims for hospital and/or related physician or ambulance services furnished in Canada to qualified railroad retirement beneficiaries (QRRB's) are forwarded first to the Railroad Retirement Board (RRB). Under the Railroad Retirement Act, payment is made by the RRB to Qualified Railroad Retirement Beneficiaries (QRRB) for covered hospital services furnished in Canadian hospitals as well as in the U.S. The Railroad Retirement Act does not cover physician and ambulance services; however, under an agreement between CMS and RRB, if the QRRB claims payment for Part B services in connection with Canadian hospitalization, RRB processes the Part B claim. In such cases the RRB determines:

- Whether the requirements in §§350.1.B and 350.6 are met in regard to the inpatient services; and
- Whether the requirements in§350.6.A are met in regard to the physician and/or ambulance services were furnished in connection with the services

If either is not met, RRB denies the claim and notifies the beneficiary. If met, RRB refers the claim to the RRB MAC, Palmetto GBA, to determine if the coverage criteria for physician and/or ambulance services are met.

The hospital must forward all claims for services furnished QRRBs in Canada to:

Retirement Medicare Section
U.S. Railroad Retirement Board
844 North Rush Street
Chicago, IL 60611-2092

If a QRRB is a resident of Canada, Medicare payments are reduced by the amount of payment made for the same services by the Canadian Provincial Health Insurance Plan.

B. Claims for services furnished in other foreign countries

The RRB does not pay for health care services furnished in Mexico or any foreign countries other than Canada.

All claims for inpatient hospital services and/or related physician or ambulance services furnished in Mexico to QRRB's should be forwarded directly to the Railroad Retirement Board. If the Railroad Retirement Board determines that the requirements in §350.6.A are not met, the Railroad Retirement Board will deny the claim and send notice to the beneficiary. If the requirements in §350.6.A or B are met, the Railroad Retirement Board will hold any potentially allowable Part B claim until an MAC determination regarding the coverage of Part A services has been made. When the information regarding Part A coverage is available, the Railroad Retirement Board will send the Part B claim, together with pertinent information regarding the Part A determination, to Palmetto Government Benefits for consideration of whether the other requirements for Part B coverage are met, and further processing.

350.8 - Claims from Hospital-Leased Laboratories Not Meeting Conditions of Participation
(Rev. 3287, Issued: 06-30-15, Effective: 04-21-15, Implementation: 04-21-15)

Services furnished by a laboratory that does not meet the hospital laboratory conditions of participation and is operated under a lease arrangement in a domestic emergency hospital are covered only if they are emergency inpatient services reimbursable under Part A.

A MAC may send a claim from such a laboratory and identify it as an "Emergency Lead." The MAC checks its files to see if a claim for emergency services was filed and, if so, determines whether the laboratory services were furnished

during the period of emergency. If the emergency claim was forwarded to the appropriate MAC for processing, it enters the date received on the laboratory claim.

If no emergency claim was filed, or laboratory services were not furnished in the period covered by the emergency claim, the MAC develops the claim as a possible emergency. It includes the laboratory claim with any subsequent claim.

If no emergency is alleged, the MAC records on the claim that no emergency existed and disallows it.

350.9 - Nonemergency Part B Medical and Other Health Services
(Rev. 3287, Issued: 06-30-15, Effective: 04-21-15, Implementation: 04-21-15)

A. Coverage

Nonemergency services to Medicare beneficiaries may be paid for if the coverage requirements for the services are met, and are not covered as Part A emergency inpatient services.

Program payment may be made for the following Part B medical and other health services furnished by a U.S. nonparticipating hospital on a nonemergency basis:

- Diagnostic x-ray tests, diagnostic laboratory tests and other diagnostic tests. (The hospital must meet the applicable conditions of participation for the services.)

- X-ray, radium, and radioactive isotope therapy, including materials and services of technicians. (The hospital must meet the applicable conditions of participation for these services.)

- Services of residents and interns, nurses, therapists, etc., which are directly related to the provision of x-ray or laboratory or other diagnostic tests, or the provisions of x-ray or radium therapy.

- Prosthetic devices (other than dental) which replace all or part of an internal body organ (including contiguous tissue) or replace all or part of the functions of a permanently inoperative or malfunctioning internal body organ, including replacement of such devices.

- Leg, arm, back, and neck braces, trusses and artificial legs, arms, and eyes, including replacement, if required, because of a change in the patient's physical condition.

B. Distinction Between Emergency and Nonemergency Medical and Other Health Services

Emergency coverage, particularly Part B emergency outpatient coverage, is broader than the nonemergency Part B Medical and Other Health Services coverage provisions. When the emergency requirements are met, program payment may be made to the hospital for the full range of outpatient hospital services. In addition to the nonemergency coverage list, emergency coverage includes hospital services (including drugs and biologicals - blood is a biological - which cannot be self-administered), "incident to physicians' services rendered to outpatients," and outpatient physical therapy and speech-language pathology. The latter two services are not covered under the nonemergency provisions. Payment for "incident to" services can be only under the emergency rather than the nonemergency provisions.

Whether Part B payment is made under the emergency or nonemergency provisions, it may be made for diagnostic laboratory tests furnished by an emergency hospital only if the hospital meets the conditions of participation relating to hospital laboratories. It may be made only for radiology services furnished by an emergency hospital if the hospital meets the conditions of participation relating to radiology departments. Part B payment may be made for diagnostic laboratory tests furnished by a nonparticipating hospital which is not an emergency hospital only if the hospital

laboratory meets the conditions of coverage of independent laboratories and for radiology services furnished by it, only if it meets the conditions of participation relating to radiology departments.

C. Claims Processing

The hospital enters the annotation "nonemergency-hospital accepts assignment" in Remarks of the Form CMS-1450. If it is determined that some or all of the services are not covered under the nonemergency provisions, the claim is returned to it (if hospital-filed) or to the beneficiary (if patient-filed) to determine whether the services might be covered as emergency services.

350.10 - Elections to Bill for Services Rendered By Nonparticipating Hospitals

(Rev. 3287, Issued: 06-30-15, Effective: 04-21-15, Implementation: 04-21-15)

A. Nonparticipating U.S. Hospitals

As a nonparticipating U.S. hospital meeting emergency requirements, the hospital has the option to bill the program during a calendar year by filing an election with its MAC. If it files an election, it should submit claims for the following services furnished all Medicare beneficiaries throughout the year:

- Emergency inpatient services; and
- Emergency outpatient services.

In addition, the hospital may not bill any beneficiary beyond deductibles, coinsurance, and noncovered services in that calendar year. It must agree to refund any monies incorrectly collected. It may not file an election for the calendar year if it has already charged any beneficiary for covered services furnished in that year.

If the hospital does not file a billing election, the beneficiary can file a claim. The beneficiary may request information from the hospital or the MAC as appropriate.

During November of each year, the MAC will send the non-participating hospital a letter (see §360.3.1). Also, during November of each year, the MAC will send a letter to each domestic hospital, giving it an opportunity to elect to bill Medicare if it has not been doing so (§360.3.2).

If during the year the hospital requests to bill the program, its MAC will send the model letter in §360.3.3.

B. Billing for Services Furnished Prior to Certification

The following rules apply if a bill is submitted for services rendered before and after a hospital's certification (participation) date:

- PPS hospitals are paid the DRG, if the date of discharge is after the certification date.
- Other hospitals are paid for services rendered after the certification date. However, the hospital must include services before certification date on its cost report.

It should annotate in the upper right hand corner of the claim "Emergency Conversion."

C. Foreign Hospitals

Foreign hospitals may submit a statement to the appropriate MAC stating that they will bill for all claims. If they do not, the beneficiary may claim the payment. When the MAC is aware that a hospital is willing to bill the program for all covered services, it solicits the hospital's agreement to:

- Bill for all covered services for the calendar year (except for deductible and coinsurance amounts);
- Not bill the beneficiary for any amounts other than for deductible and coinsurance and charges for noncovered services; and
- Refund to the beneficiary any monies incorrectly collected.

A hospital may not file an election for a calendar year if it has charged any beneficiary for covered services during that year.

D. Submitting Claims

The beneficiary or the hospital that has elected to bill the program may submit emergency claims for payment to the appropriate MAC for evaluation of accessibility or emergency factors.

The hospital completes the claim (Form CMS-1450 or electronic equivalent) according to billing instructions in chapter 25. It enters "hospital filed emergency admission" in Item 94 "Remarks." It sends the completed bill and the necessary emergency documentation (Form CMS-1771, Attending Physicians Statement and Documentation of Medicare Emergency) or medical records to substantiate the emergency to the appropriate MAC.

NOTE: See §360.2, "Designated Contractors."

If the hospital submits a claim but has not filed an election to bill the program, the MAC will contact the hospital to determine if it is qualified and wish to bill the program. If it declines, the claim will be denied. A claim will be solicited from the beneficiary.

If the hospital has filed a billing election and the beneficiary files a claim, the beneficiary's claim is denied and the MAC contacts the hospital regarding the claim.

350.11 - Processing Claims

(Rev. 3287, Issued: 06-30-15, Effective: 04-21-15, Implementation: 04-21-15)

All claims are subject to development to determine whether the Medicare secondary payer provisions apply. (See Pub. 100-05, Medicare Secondary Payer Manual.)

A. Nonparticipating Hospitals

The processing MAC is responsible for making accessibility and medical emergency determinations for physician and ambulance services.

1. Claims Subject to Technical Denials

The following claims are subject to technical denial:

- Foreign nonemergency services claims if:
    - The residence requirement is not met. (See §350.5.)

- The hospital rendering the service does not meet Joint Commission or equivalent accreditation requirements set by a hospital approval program of the country in which it is located.

- The accessibility requirements are not met. (See §350.11.4.)

- Canadian travel claims when the requirements in §350.4 are not met.

- Emergency services claims for which the hospital does not meet the definition of an emergency hospital.

- Claims for which the query response shows the beneficiary is not entitled to benefits.

- Any foreign claim when Part A benefits are exhausted and Part B physician or ambulance claims are not involved.

2. Either the Accessibility or Medical Emergency Requirements are Not Met

Claim is denied but retained in case of an appeal by the beneficiary.

NOTE: Even though Part A or Part B emergency services furnished by U.S. hospitals are denied, Part B payment may be possible for Medical and Other Health Services specified in Pub. 100-02, Medicare Benefit Policy Manual, chapter 6. Claim is retained in case of an appeal by the beneficiary.

3. Emergency Services Partially Denied

When the medical emergency is approved but not for the entire period, the claim is processed and payment made for the covered period.

B. Foreign Part B Physician and Ambulance Claims

The hospital must attach any Part B claim for foreign physician and ambulance services to the corresponding Part A claim and forward to the MAC.

If the MAC determines that the inpatient services were covered, it sends the physician and/or independent ambulance claim to the designated MAC for processing and payment. (See §350.6.)

If the Part A claim is denied on the basis of accessibility of medical emergency, the MAC denies the Part B claim, and sends a MSN to the beneficiary. It retains copies in case of an appeal by the beneficiary.

NOTE: Even though Part A benefits are totally or partially exhausted, payment may be made by the MAC for physician and independent ambulance services furnished if all coverage requirements are met.

If a Part A claim was partially denied because the emergency terminated, the MAC makes a decision on the claim and any provider-based ambulance claim. It sends copies to the appropriate MAC for processing.

350.11.1 - Contractors Designated to Process Foreign Claims

(Rev. 3287, Issued: 06-30-15, Effective: 04-21-15, Implementation: 04-21-15)

Per contractor Statement of Work (SOW) all contractors are designated to process claims for physicians' and ambulance services furnished in connection with a covered foreign hospital stay for their beneficiaries who reside in the states/areas for which they process claims.

All contractors are designated to determine whether the requirements in §350.6 are met for claims for inpatient services based upon the geographic location of the foreign hospitals furnishing the services.

All contractors are designated to process these claims if there is evidence that the Part B services were furnished in connection with covered foreign inpatient hospital services. If there is no evidence, the Contractor must send a front-end rejection notice in accordance with §350.11.2.

350.11.2 - Contractor Processing Guidelines

(Rev. 3287, Issued: 06-30-15, Effective: 04-21-15, Implementation: 04-21-15)

Per contractor Statement of Work (SOW) all contractors are responsible for processing foreign, emergency and shipboard claims for their beneficiaries who reside in the states/areas for which they process claims.

The A/B MAC determines whether the requirements in §350.6.A are met. If these requirements are not met, the A/B MAC denies the Part A claim and related Part B claim and notifies the beneficiary. Where the A/B MAC determines that the requirements in §350.6.A are met, the A/B MAC determines whether other applicable Part A coverage requirements are met. If the A/B MAC disallows the Part A claim, it denies the related Part B claim and notifies the beneficiary. However, the A/B MAC will not be involved in the processing of foreign claims if, for any reason, the related Part A claim is denied.

If the claim does not show that the beneficiary was hospitalized, the A/B MAC sends the beneficiary a front-end rejection notice. In filling out the Notification of Medicare Determination, the A/B MACs should check "other" and include the following explanation: "Foreign physician or ambulance services are not covered unless they were furnished in connection with a covered inpatient stay."

350.11.3 - Medicare Approved Charges for Services Rendered in Canada or Mexico

(Rev. 3287, Issued: 06-30-15, Effective: 04-21-15, Implementation: 04-21-15)

For Canadian services, the Medicare approved charge will be the lower of:

1. The allowed amount for the same service in the U.S. locality closest to where the service was furnished (as determined by the designated MAC), or

2. The Canadian Provincial fee.

Therefore, the designated MAC must obtain the most recent schedule of fees published by the appropriate Canadian Province. Most of the designated MACs deal with only one Provincial schedule.

For Mexican services, the maximum charge is the Medicare allowed amount for the same service in the locality closest to where the service was furnished (as determined by the designated MAC).

350.11.4 - Accessibility Criteria

(Rev. 4111, Issued: 08-10-18, Effective: 9-11-18, Implementation: 9-11-18)

A. Emergency Claims

The MAC uses the same criteria in domestic and foreign emergency claims. This includes services in a foreign religious non-medical health care institution and Canadian Travel claims. (See §350.4 and §350.9.)

Emergency determinations take into account such matters as relative distances of a participating hospital, and road conditions. The MAC considers whether the nature of the emergency required immediate transportation to the nearest available hospital (i.e., the nonparticipating hospital) or, without hazard to the patient, would have permitted the additional transportation time to take the patient to a more distant participating hospital in the same general area.

The MAC does not consider in its determination such factors involving selection of a hospital which reflect the personal preferences of the individual or physician, (e.g., physician does not have staff privileges at the participating hospital) nearness to beneficiary's residence, presence of previous medical records at the nonparticipating hospital, cost, or type of accommodations available.

The following sections discuss documentation of the accessibility requirement and provide guidelines for making a determination where the participating hospital is:

- Closer to the site of the emergency than is the admitting nonparticipating hospital;
- Fifteen or fewer miles farther from the site of the emergency than is the nonparticipating hospital; or
- Sixteen or more miles farther from the site of the emergency than is the admitting nonparticipating hospital.

In urban and suburban areas, where both participating and nonparticipating hospitals are similarly available, it is presumed, in the absence of clear and convincing evidence to the contrary, that the services could have been provided in the participating hospital.

1. Participating Hospital Closer to Site of Emergency

If there is an adequately equipped participating hospital with available beds closer to the site of the emergency than the nonparticipating hospital, accessibility is not met. Claim is denied unless extenuating circumstances were present that necessitated admission to the nonparticipating hospital, e.g., because of road or traffic conditions additional travel time would have been needed.

2. Participating Hospital 15 or Fewer Miles Farther From the Location of the Emergency Than the Admitting Nonparticipating Hospital

In this situation the accessibility is provisionally not met. The claim is reviewed to determine if the nature of the emergency required the immediate transportation to the nonparticipating hospital. If the review indicates that the nature of the emergency would have allowed the additional transportation time needed to take the patient to the participating hospital without undue hazard, the accessibility requirement is not met. The claim is denied.

3. Participating Hospital More than 15 Miles Farther From the Location of the Emergency Than the Admitting Nonparticipating Hospital

The accessibility requirement is deemed met.

B. Foreign Nonemergency Claims

The following presumptions are applied to the relative accessibility of the nearest participating U.S. and foreign hospitals.

1. Admitting Foreign Hospital is Closer to the Beneficiary's Residence Than the Nearest Participating U.S. Hospital

The accessibility requirement is met.

2. Admitting Foreign Hospital is Farther From the Beneficiary's Residence Than the Nearest Participating U.S. Hospital

The accessibility requirement is not met unless evidence establishes the practical necessity for the beneficiary's admission. This requirement is met if the use of a closer participating U.S. hospital was impractical, e.g., non-availability of beds, needed equipment or personnel, or transportation not available.

In determining whether a foreign hospital is more accessible than a participating hospital, the MAC does not consider the personal preference of the beneficiary, physician, or others in the selection of a hospital, the type of accommodations available, or the nonavailability of staff privileges to the attending physician.

350.11.5 - Medical Necessity

(Rev. 3287, Issued: 06-30-15, Effective: 04-21-15, Implementation: 04-21-15)

A. Emergency Services

Reimbursement for emergency inpatient hospital services is permitted only for those periods during which the patient's state of injury or disease is such that a health or life-endangering emergency existed and continued to exist, requiring immediate care that could be provided only in a hospital. The allegation that an emergency existed must be substantiated by sufficient medical information from the physician or hospital. If the physician's statement does not provide it, or is not supplemented by adequate clinical corroboration of this allegation, it does not constitute sufficient evidence.

Death of the patient does not necessarily establish the existence of a medical emergency, since in some chronic, terminal illnesses, time is available to plan admission to a participating hospital. The lack of adequate care at home or lack of transportation to a participating hospital does not constitute a reason for emergency hospital admission, without an immediate threat to the life and health of the patient. Since the existence of medical necessity for emergency services is based upon the physician's assessment of the patient prior to admission, serious medical conditions developing after a non-emergency admission are not "emergencies" under the emergency services provisions of the Act.

The emergency ceases when it becomes safe, from a medical standpoint, to move the individual to a participating hospital, another institution, or to discharge the individual.

B. Criteria

Since the decision that a medical emergency existed can be a matter of subjective medical judgment involving the entire gamut of disease and accident situations, it is impossible to provide arbitrary guidelines.

1. Diagnosis is Considered "Usually an Emergency"

An emergency condition is an unanticipated deterioration of a beneficiary's health which requires the immediate provision of inpatient hospital services because the patient's chances of survival, or regaining prior health status, depends upon the speed with which medical or surgical procedures are, or can be, applied. While many diagnoses (e.g., myocardial infarction, acute appendicitis) are normally considered emergencies, the hospital must check medical documentation for internal consistencies (e.g., signs and symptoms upon admission, notations concerning changes in a preexisting condition, results of diagnostic tests).

EXAMPLE: If the diagnosis is given as "coronary," the physician's statement is "coronary," without further explanatory remarks, and the statement of services rendered gives no indication that an electrocardiogram was taken, or that the patient required intensive care, etc., further information is required. On the other hand, if the diagnosis is one that ordinarily indicates a medical and/or surgical emergency, and the treatment, diagnostic procedures, and period of hospitalization are consistent with the diagnosis, further documentation may be unnecessary. An example is: admitting

diagnosis - appendicitis; discharge diagnosis - appendicitis; surgical procedures - appendectomy; period of inpatient stay - 7 days.

2. Patient Dies During Hospitalization

If an emergency existed at the time of admission and the patient subsequently expires, the claim is allowed for emergency services if the period of coverage is reasonable. However, death of the patient is not prima facie evidence that an emergency existed; e.g., death can occur as a result of elective surgery or in the case of a chronically ill patient who has a long terminal hospitalization. Such claims are denied.

3. Patient's Physician Does Not Have Staff Privileges at a Participating Hospital

The fact that the beneficiary's attending physician does not have staff privileges at a participating hospital has no bearing on the emergency services determination. If the lack of staff privileges in an accessible participating hospital is the governing factor in the decision to admit the beneficiary to an "emergency hospital," the claim is denied irrespective of the seriousness of the medical situation.

4. Beneficiary Chooses to be Admitted to a Nonparticipating Hospital

The claim is denied if the beneficiary chooses to be admitted to a non-participating hospital as a personal preference (e.g., participating hospital is on the other side of town) when a bed for the required service is available in an accessible, participating hospital.

5. Beneficiary Cannot be Cared for Adequately at Home

The patient who cannot be cared for adequately at home does not necessarily require emergency services. The claim is denied in the absence of an injury, the appearance of a disease or disorder, or an acute change in a pre-existing disease state which poses an immediate threat to the life or health of the individual and which necessitates the use of the most accessible hospital equipped to furnish emergency services.

6. Lack of Suitable Transportation to a Participating Hospital

Lack of transportation to a participating hospital does not, in and of itself, constitute a reason for emergency services. The availability of suitable transportation can be considered only when the beneficiary's medical condition contraindicates taking the time to arrange transportation to a participating hospital. The claim is denied if there is no immediate threat to the life or health of the individual, and time could have been taken to arrange transportation to a participating hospital.

7. "Emergency Condition" Develops Subsequent to a Non-emergency Admission to a Nonparticipating Hospital

Program payment cannot be made for emergency services furnished by a nonparticipating hospital when the emergency condition arises after a non-emergency admission. An example: treatment of postoperative complications following an elective surgical procedure or treatment of a myocardial infarction that occurred during a hospitalization for an elective surgical procedure. The existence of medical necessity for emergency services is based upon the physician's initial assessment of the apparent condition of the patient at the time of the patient's arrival at the hospital, i.e., prior to admission.

8. Additional "Emergency Condition" Develops Subsequent to an Emergency Admission to a Nonparticipating Hospital

If the patient enters a nonparticipating hospital under an emergency situation and subsequently has other injuries, diseases or disorders, or acute changes in preexisting disease conditions, related or unrelated to the condition for which the patient entered, which pose an immediate threat to life or health, emergency services coverage continues.

Emergency services coverage ends when it becomes safe from a medical standpoint to move the patient to an available bed in a participating institution or to discharge the patient, whichever occurs first.

C. Documenting Medical Necessity

1. Physician's Supporting Statement

Claims for emergency services by a non-participating hospital should be accompanied by an Attending Physician's Statement and Documentation of Medicare Emergency, Form CMS-1771 or its equivalent. This form describes the nature of the emergency, furnishing relevant clinical information about the patient, and certifying that the services rendered were required as emergency services. However, a copy of the patient's hospital records may be submitted instead. It should include history, physical, and admission notes, the medical record admission sheet, nurses' notes, doctors' orders, discharge summary, and all progress notes. A statement that an emergency existed, or the listing of diagnoses, without supporting information, is not sufficient. In addition, the statement must include the date, in the physician's judgment, the emergency ceased. The physician who attended the patient at the hospital makes the statement concerning emergency services. Only in exceptional situations, with appropriate justification, may another physician having full knowledge of the case, make the certification.

2. Beneficiary's Statement in Canadian Travel Claims

In Canadian travel claims, the beneficiary's statement is considered in making a determination regarding medical necessity for emergency services; i.e., whether an emergency occurred while a beneficiary was traveling between Alaska and another State by the most direct route without unreasonable delay. (See §350.4.)

350.11.6 - Time Limitation on Emergency and Foreign Claims

(Rev. 3287, Issued: 06-30-15, Effective: 04-21-15, Implementation: 04-21-15)

The regular time limits apply to requests and claims for payment for emergency hospital services and hospital services outside the U.S., for physician and ambulance services furnished in connection with foreign hospitalization, and for nonemergency services furnished by a domestic nonparticipating hospital. See chapter 1 for a description of these requirements.

A. Beneficiary Denial Notices

MACs shall send denial letters for non-covered foreign related claims.

Part B MACs will send an MSN for covered foreign emergency and shipboard claims related to a covered Part A foreign claim. An MSN is also sent for shipboard services provided within US territories.

B. Termination of Emergency Services

No payment will be made for inpatient or outpatient emergency services rendered after a reasonable period of medical care in relation to the emergency condition in question. Some services may be covered in a domestic nonparticipating hospital as Part B Medical and Other Health Services. (See the Medicare Benefit Policy Manual, chapter 6.) If, based upon all information, the total period claimed for emergency services coverage does not exceed the time required for a reasonable period of emergency medical care, the entire inpatient stay is covered. The fact that a medical record or other information states that the patient showed definite improvement several days prior to discharge is not necessarily an indication that the need for emergency services ceased as of that date. The concept of a reasonable period of emergency medical care is most easily applied when relatively short-term medical care is followed by the patient’s progressive improvement. There are situations or conditions in which the determination of the end of covered emergency services may be more difficult because the patient’s impairment is prolonged, there is no progressive improvement, or the

patient's course may be progressively downhill, even though the condition is not critical. The stroke patient may be in this category. In such cases the need for emergency medical care usually ceases before the need for medical care in an institutional setting (i.e., hospital or SNF) ceases. Thus, the reasonable period of emergency care does not include the entire hospital stay if the stay was prolonged beyond the point when major diagnostic evaluation and treatment were carried out.

The MAC will make the determination based upon all information available. As a general rule, if the period claimed for emergency services exceeds by more than 3 to 5 days the date on which the record definitely indicates that there was substantial improvement in the patient's condition so that the patient could possibly have been moved to a participating facility or discharged without damage to health, the period beyond the 3 to 5 days is denied. If the total period claimed for emergency services exceeds by no more than 3 to 5 days the date on which the record indicates substantial improvement in the patient's condition, the entire period is allowed.

This rule is intended to screen out short stay emergency hospitalization cases in which the patient was either discharged or transferred to a participating provider within a reasonable time after the medical record definitely indicated substantial improvement in the patient's condition.

The reasonable period of emergency care is that period required to provide relief of acute symptoms or for initial management of the condition while arrangements are made for definitive treatment. Two examples:

- Prostatic hypertrophy which results in acute urinary retention; and
- Mental illness with suicidal and/or homicidal tendencies.

In acute urinary retention, the reasonable period of emergency medical care includes the period required for catheterization and stabilization of the patient. The patient could then be transferred to a participating hospital for surgery or other required treatment. For the suicidal or homicidal patient, a reasonable period of emergency medical care includes the time required for initial management of the case while arrangements are made for transfer (by commitment or otherwise) to a participating hospital. A period of 24 to 48 hours of emergency care is usually sufficient in both cases.

350.11.7 – Payment Denial for Medicare Services furnished to Alien Beneficiaries Who are Not Lawfully Present in the United States

(Rev. 3287, Issued: 06-30-15, Effective: 04-21-15, Implementation: 04-21-15)

Medicare payment may not be made for items and services furnished to an alien beneficiary who was not lawfully present in the United States on the date of service.

The CWF must establish an auxiliary file based on enrollment data contained in the Enrollment Data Base maintained by the Centers for Medicare & Medicaid Services in order to appropriately edit the claims specifically associated with alien beneficiaries. The auxiliary file will be the basis for an edit that rejects claims for a beneficiary that was not lawfully present in the U.S. on the date of service. MACs and DMACs must deny claims for items and services, rejected by CWF on the basis that the beneficiary was not lawfully present in the U.S. on the date of service. MACs and DMACs must refer to the CWF documentation on this subject for the error code MSN Message 5.7, assigned to this editing.

Upon receipt of an error code MSN Message 5.7, A/B MACs, DME MACs, and A/B MACs (HHH) must deny the claim and use reason code (CARC) 177 – "Patient has not met the required eligibility requirements." When CWF rejects a claim, MACs and DMACs must use MSN message 5.7, "Medicare payment may not be made for the item or service because, on the date of service, you were not lawfully present in the United States." 5.7, Medicare no puede pagar por este artículo o servicio porque, en la fecha en que lo recibió, usted no estaba legalmente en los Estados Unidos.

A party to a claim denied in whole or in part under this policy may appeal the initial determination on the basis that the beneficiary was lawfully present in the United States on the date of service. In addition, this same information must be published in your next regularly scheduled bulletin. If you have a listserv that targets the affected provider communities, you must use it to notify subscribers that information "Medicare Services for Alien Beneficiaries Lawfully present the United States" is available on your Web site.

NOTE: Section 401 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA), codified at 8 U.S.C. §1611, prohibits aliens who are not "qualified aliens" from receiving Federal public benefits including Medicare.

However, Section 5561 of the Balanced Budget Act of 1997 (BBA) amended Section 401 of the PRWORA to create a Medicare exemption to the prohibition on eligibility for non-qualified alien beneficiaries, who are lawfully present in the United States and who meet certain other conditions. Specifically, payment may be made for services furnished to an alien who is lawfully present in the United States (and provided that with respect to benefits payable under Part A of Title XVIII of the Social Security Act [42 U.S.C. 1395c et seq.], who was authorized to be employed with respect to any wages attributable to employment which are counted for purposes of eligibility for Medicare benefits). The definition for "lawfully present in the United States" is found at 8 CFR 1.3.

350.12 - Appeals on Claims for Emergency and Foreign Services

(Rev. 3287, Issued: 06-30-15, Effective: 04-21-15, Implementation: 04-21-15)

When a MAC receives a beneficiary appeal of a claim submitted by the beneficiary for services provided by a non-participating provider, the MAC will process the appeal in accordance with the guidelines in Pub. 100-04 chapter 29.

When a MAC receives an appeal from a non-participating provider of a claim that was submitted by, or on behalf of, a beneficiary, the MAC shall dismiss the appeal request as the non-participating provider is not a proper party. The MAC shall send a copy of the dismissal to the beneficiary. A non-participating provider does not have standing to file an appeal for the individual claims for payment it submits on behalf of a beneficiary, or for claims the beneficiary submits for services it has furnished. See, 42 CFR 405.906(a)(3) and 405.902 (for the definition of provider); Pub. 100-04, chapter 29, §210 and the glossary in Pub. 100-04, chapter 29, §110 (for the definition of provider). Only a beneficiary (or the beneficiary's authorized representative, or an appointed representative on behalf of the beneficiary) can appeal claim determinations for services furnished by a non-participating provider.

NOTE: Non-participating providers have appeal rights under the provider and supplier enrollment appeals process in 42 CFR Part 498 for MAC determinations related to the non-participating provider's election to file claims (see §350.10).

NOTE: The RRB conducts Part B redeterminations under the Railroad Retirement Act for services rendered in Canada.

360 - Payment for Services Received By Nonparticipating Providers

(Rev. 3287, Issued: 06-30-15, Effective: 04-21-15, Implementation: 04-21-15)

The condition of payment regulations for emergency services received in Nonparticipating Providers can be found in the 42 CFR 424.100-109, Subpart G—Special Conditions: Emergency Services Furnished by a Nonparticipating Hospital.

The Form CMS-1450 or its electronic equivalent must be used.

A. Hospital Filed Claims

1. Inpatient Services

The payment rate for inpatient claims is 100 percent of the nonparticipating provider's customary charges (see 42 C.F.R. 413.74(b) and 42 C.F.R. 424.104(a)(3)).

The cost of the services is adjusted by any applicable deductible and coinsurance amounts for which the beneficiary is responsible.

Payment will be made to Federal hospitals that furnish emergency services, on an inpatient basis, to individuals entitled to hospital benefits. Payment will be based on the lower of the actual charges from the hospital or rates published for Federal hospitals in the "Federal Register" under Office of Management and Budget - Cost of Hospital and Medical Care and Treatment Furnished by the United States; Certain Rates Regarding Recovery from Tortiously Liable Third Persons.

Medicare will not pay federal hospitals for emergency items or services furnished to veterans, retired military personnel or eligible dependents. However, Medicare can pay for the inpatient deductible charged by VA hospitals, or credit that amount to the Medicare Part A deductible, for emergency services furnished to veterans. If a Part A claim is denied, a denial notice will be forwarded to the beneficiary from the MAC. The beneficiary can use this notice to forward to their private insurer, if applicable.

The VA or Department Of Defense hospital must file a statement of election for each calendar year to receive direct payment from Medicare for all claims filed that year.

2. Outpatient Services

The amount paid by Medicare for emergency outpatient claims is obtained as follows:

- Eighty-five percent of the total covered charges is the estimated cost figure. The applicable Part B deductible is subtracted. Coinsurance is subtracted from the remainder.

- Subtracting the deductible from 85 percent of the total covered charges and applying the 20 percent coinsurance rate to the remainder obtains the patient's coinsurance amount. The hospital will be paid cost (85 percent of covered charges) minus deductible and coinsurance.

3. Part B Medical and Other Health Services

Part B medical and other health services, including hospital-based ambulance services whether hospital or beneficiary filed, may be covered and paid on a non-emergency basis. To calculate the amount paid by Medicare, the hospital subtracts the Part B deductible from the total covered charges and applies the 80 percent payment rate.

4. Special Letters for Partially or Totally Denied (Hospital-Filed) Claims for Emergency Inpatient Services

The patient receives a notice from CMS covering the emergency payment of a partially denied claim. A denial letter and a Part B explanation of benefits is sent to the patient. The MAC includes its address on this letter.

B. Beneficiary Filed Claim

1. Emergency Inpatient Claims

The payment computation follows:

- Any noncovered accommodation charge is subtracted from the total accommodation charges. The amount of the inpatient deductible or coinsurance met on this bill is subtracted. Any remainder is multiplied by 60 percent.

- The total noncovered ancillary charge is subtracted from the total ancillary charge. Any inpatient deductible or coinsurance that remains is subtracted. The remainder is multiplied by 80 percent.

- The benefit amounts obtained are added.

2. Emergency Outpatient Services

To calculate the amount paid by Medicare, the hospital must subtract any applicable Part B deductible from the total covered charges and apply the 80 percent payment rate.

3. Part B Medical and Other Health Services

Part B medical and other health services furnished by nonparticipating hospitals, including hospital-based ambulance services, may be covered and paid on a non-emergency basis.

To calculate the amount paid by Medicare, the hospital must subtract any applicable Part B deductible from the total covered charges and apply an 80 percent payment rate.

4. Special Letters for Patient-Filed Claims for Emergency Inpatient Services

For emergency admissions to nonparticipating hospitals where direct payment is made to the patient, the MAC sends the beneficiary one of the letters described below, as appropriate.

The letter explains the Part A payments made. Part B payments are made for ancillary services not covered by Part A and are also explained in a letter. This letter also explains the beneficiary's right of appeal.

The MAC retains a duplicate of all notices sent for documentation in any appeals process. It enters the date the notice is released on both copies of all notices.

Sample paragraphs:

- "Enclosed is a check for $_____, which is the amount Medicare can pay for inpatient hospital services you received from (date of admission) to (date of discharge) in (hospital)."

- "Medicare is able to pay 60 percent of the charges for your room and board plus 80 percent of the charges for all other covered services during the period (date emergency began) to (date payment ended)."

  "Medicare is able to pay 60 percent of the charges for your room and board, 80 percent of the charges for other separately identified charges, and 66 2/3 percent of the other charges which were not separately identified on the hospital bill."

- "Medicare does not pay (the first $ ____ of charges) (the first three pints of blood) ($ ____ a day after the 60th day) in a benefit period. (Select one or more, if applicable.)"

- "If lifetime reserve days are used, add $ ___ a day from _____ to _____."

- "If you believe your Medicare hospital insurance should have covered all or more of your expenses, you may get in touch with us at the address shown on this letter."

- "If you believe that the determination is not correct, you may request a reconsideration for hospital insurance (or a review for medical insurance). You may make the request by mail to the address shown on this letter. If you come in person, please bring this notice with you."

- "This check includes a medical insurance payment for 80 percent of the charges for certain nonroutine hospital services which you received from _____ through _____. These services are listed on the enclosed form."

- "If a hospital bill is not itemized, Medicare can pay 66 2/3 percent of the total covered charges. Payment is being made at this rate for charges from (date emergency began) to (date payment ended)."

- "We are enclosing a check for $ _____. This is your payment under Part B for 80 percent of the charges for the services which you received from (admission date) through (discharge date) while in (name of hospital). These services are listed on the enclosed form."

When payment cannot be made under hospital insurance, medical insurance covers some, but not all, of the hospital services. Room and board and certain other services are not covered by medical insurance.

360.1 - Payment for Services from Foreign Hospitals

(Rev. 3287, Issued: 06-30-15, Effective: 04-21-15, Implementation: 04-21-15)

The condition of payment regulations for emergency services received in Nonparticipating Providers can be found in the 42 CFR 424.100-109, Subpart G—Special Conditions: Emergency Services Furnished by a Nonparticipating Hospital

A. Hospital Filed Claim

A foreign hospital that elects to bill the Medicare program receives 100 percent of its customary charges, subject to applicable deductible and coinsurance amounts. The hospital establishes its customary charges for the services by submitting an itemized bill with each claim. This eliminates the need to file a cost report.

Regardless of the billing form used, the MAC must:

- Recode the bill using revenue codes for the Form CMS-1450;

- Prepare an HUIP or HUOP input record for CWF; and

- Send a Medicare Summary Notice (MSN) to the beneficiary.

The nonparticipating hospital must file a statement of election for each calendar year to receive direct payment from Medicare for all claims filed that year.

Payment is subject to the official exchange rate on the date the patient is discharged.

B. Beneficiary Filed Claim

To calculate the amount paid by Medicare for Part B Hospital-Based Ambulance Claims, the hospital must subtract any unmet Part B deductible from the total covered charges and apply the 80 percent payment rate.

Payment to the beneficiary is subject to the official exchange rate on the date of discharge.

360.1.1 - Attending Physician's Statement and Documentation of Medicare Emergency

(Rev. 4111, Issued: 08-10-18, Effective: 9-11-18, Implementation: 9-11-18)

Form CMS-1771 - go to https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-List.html

360.2 - Designated Contractors
(Rev. 3287, Issued: 06-30-15, Effective: 04-21-15, Implementation: 04-21-15)

Per Contractor Statement of Work (SOW) all contractors are designated to process claims for physicians' and ambulance services furnished in connection with a covered hospital stay in Canada and Mexico for their beneficiaries who reside in the states/areas for which they process claims.

360.3 - Model Letters, Nonparticipating Hospital and Emergency Claims
(Rev. 3287, Issued: 06-30-15, Effective: 04-21-15, Implementation: 04-21-15)

360.3.1 - Model Letter to Nonparticipating Hospital That Elected to Bill For Current Year
(Rev.3287, Issued: 6-30-15, Effective:04-21-15, Implementation: 04-21-15)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTERS FOR MEDICARE & MEDICAID SERVICES

REFER TO:

Identification Number:_____

Dear _____:

Your election to bill the Medicare program for emergency services furnished to Medicare beneficiaries will expire on December 31. Payment for emergency services can be made to a nonparticipating hospital only if the hospital elects to receive reimbursement from Medicare for all emergency services furnished to Medicare beneficiaries in a calendar year.

If you elect to bill the program, please return to us in the enclosed self-addressed envelope a statement signed by an authorized official of your hospital stating that you elect to claim payment under the Medicare program. An election to bill cannot be withdrawn during the year. If a statement is not received by December 31, we will assume that you do not wish to continue to bill the program at this time. However, you still retain the right to elect to bill the program at any time during the coming year if, when you make your election, you have not yet charged any Medicare beneficiary in that year for emergency hospital services rendered to him.

Hospitals electing to bill the program for emergency services may obtain information on reimbursement by contacting the MAC serving nonparticipating hospitals in your State. If you do not elect to bill, the beneficiary may apply for reimbursement by submitting an itemized bill.

Please contact us if you need any further information. In addition, if at any time you decide to request full participation as a provider of hospital services under the Medicare program, please contact your Medicare MAC for complete particulars.

Sincerely,

360.3.2 - Model Letter to Nonparticipating Hospital That Did Not Elect to Bill for Current Year
(Rev. 3287, Issued: 06-30-15, Effective: 04-21-15, Implementation: 04-21-15)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

REFER TO:

Identification Number:_____

Dear _____:

Under the Medicare program, hospital benefits ordinarily can be paid only for care furnished to patients of hospitals that are participating in the program. However, the program can also pay for hospital services furnished to a beneficiary who is admitted to a nonparticipating hospital in an emergency. To receive payments for emergency services, a nonparticipating hospital must meet certain conditions specified in the law. We have determined that your hospital meets these conditions.

Payment for emergency services can be made to a nonparticipating hospital only if the hospital elects to receive reimbursement from Medicare for all emergency services furnished to Medicare beneficiaries in a calendar year. Although your hospital did not elect to bill the program for the current calendar year, you may wish to bill for the coming year. If you so choose, please have an authorized official of your hospital sign a statement to this effect and return in the enclosed self-addressed envelope. Retain a copy for your records. An election to bill cannot be withdrawn during the year.

If we have not received a statement from you by December 31, we will assume that you do not wish to bill the program at this time. However, you still retain the right to elect to bill the program at any time during the coming year if, when you make your election, you have not yet charged any Medicare beneficiary in that year for emergency hospital services rendered to him.

Hospitals electing to bill the program for emergency services may obtain information on reimbursement by contacting us. If a hospital does not elect to bill, the beneficiary may apply for reimbursement by submitting an itemized bill.

If at any time you decide to request full participation as a provider of hospital services under the Medicare program, please contact your Medicare intermediary for complete particulars.

Sincerely,

360.3.3 - Model Letter to Nonparticipating Hospital That Requests to Bill the Program

(Rev. 3287, Issued: 06-30-15, Effective: 04-21-15, Implementation: 04-21-15)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTERS FOR MEDICARE & MEDICAID SERVICES

REFER TO:

Identification Number:_____

Dear _____:

This refers to your inquiry concerning payment for emergency hospital services rendered to a Medicare beneficiary in a hospital which is not participating in the Medicare program. Under the Medicare program, hospital benefits ordinarily can be paid only for care furnished to patients of hospitals that are participating in the program. However, the program can also pay for hospital services furnished to a beneficiary who is admitted to a nonparticipating hospital in an emergency. To receive payments for emergency services, a nonparticipating hospital must meet certain conditions specified in the law. We have determined that your hospital meets these conditions.

Payment for emergency services can be made to a nonparticipating hospital only if you elect to receive reimbursement from Medicare for all emergency services furnished to Medicare beneficiaries in a calendar year. Your hospital may now choose to bill the program for all emergency services furnished to Medicare beneficiaries during the current calendar year, if you have not yet charged any Medicare beneficiary this year for emergency hospital services rendered to him.

If you so choose, please have an authorized official of your hospital sign a statement to this effect and return in the enclosed self-addressed envelope. Retain a copy for your records. An election to bill cannot be withdrawn during the year.

Hospitals electing to bill the program for emergency services may obtain information on reimbursement by contacting us. If you do not elect to bill, the beneficiary may apply for reimbursement by submitting an itemized bill.

If at any time you decide to request full participation as a provider of hospital services under the Medicare program, please contact your Medicare intermediary for complete particulars.

Sincerely,

360.3.4 - Full Denial - Hospital-Filed or Beneficiary-Filed Emergency Claim
(Rev. 4203, Issued: 01-18-19, Effective: 02-19-19, Implementation: 02-19-19)

The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.

Contractors shall include beneficiary appeal rights language and include in the mailing a redetermination request form where applicable.

MODEL DENIAL NOTICE A
(MAC'S NAME AND ADDRESS)

Date: _____

Beneficiary: _____

Claim Number _____

DETERMINATION ON EMERGENCY HOSPITAL SERVICES

We are sorry, but payment cannot be made for your stay from _____ through _____ at (hospital). This is because the (hospital) does not participate in the Medicare program and it has been determined that your treatment there does not qualify as emergency care.

Under the law, payment for services received in a nonparticipating hospital can be made only if you go, or are brought to, the hospital to receive emergency care. Emergency care under Medicare is defined as:

a. Care which is necessary to prevent the death or serious impairment to the health of the individual; and

b. Which, because of threat to the life or health of the individual, requires the use of the nearest hospital (in miles or travel time) that has a bed available and is equipped to handle the emergency.

The medical facts of your hospital admission and stay have been carefully reviewed. Based upon this review, we have found that, although it was necessary for you to be hospitalized, a medical emergency did not exist. There would have been time for you to have been admitted to a hospital participating in Medicare.

If you have questions about this notice, you may call 1-800-MEDICARE (1-800-633-4227) for additional information. If you believe the determination is not correct, you may request a redetermination. You must file your request within 120 days from the date you receive this notice. A request for a redetermination must be filed either on Form CMS-20027 or on a written request that includes all of the elements listed below.

- Beneficiary name
- Medicare beneficiary identifier
- Specific service and/or item(s) for which a redetermination is being requested
- Specific date(s) of service
- Signature of the beneficiary or the beneficiary's authorized or appointed representative.

You may send the request to our address above. Please keep a copy of any written correspondence for your files.

Sincerely,

360.3.5 - Partial Denial - Hospital-Filed or Beneficiary-Filed Emergency Claim

(Rev. 4203, Issued: 01-18-19, Effective: 02-19-19, Implementation: 02-19-19)

The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.

MODEL DENIAL NOTICE A
(MAC'S NAME AND ADDRESS)

Date: _____

Beneficiary: _____

Claim Number _____

DETERMINATION ON EMERGENCY HOSPITAL SERVICES

This refers to your request for payment under Medicare for the services received while a patient at (hospital), from _____ through _____.

Payment can be made under the hospital insurance part of Medicare only for the costs of your hospitalization from _____ to _____.

The (hospital) does not participate in the Medicare program. Under the law, payment for services received in a nonparticipating hospital can be made only if you go, or are brought to, the hospital to receive emergency care. Emergency care under Medicare is defined as:

a. Care which is necessary to prevent the death or serious impairment to the health of the individual; and

b. Which, because of threat to the life or health of the individual, requires the use of the nearest hospital (in miles or travel time) which has a bed available and is equipped to handle the emergency.

Payment for emergency services stops when the emergency ends and it is permissible, from a medical standpoint, either to transfer the patient to a participating hospital or to discharge him.

The medical facts of your hospital admission and stay have been carefully reviewed. Based upon this review, we have found that an emergency condition existed when you were admitted. However, the medical information indicates that this emergency condition ended on _____. At that time, your condition had improved to the extent that you could have been transferred to a hospital participating in the Medicare program.

If you have questions about this notice, you may call 1-800-MEDICARE (1-800-633-4227) for additional information. If you believe the determination is not correct, you may request a redetermination. You must file your request within 120 days of the date you receive this notice. A request for a redetermination must be filed either on Form CMS-20027 or on a written request that includes all of the elements listed below.

- Beneficiary name
- Medicare beneficiary identifier
- Specific service and/or item(s) for which a redetermination is being requested
- Specific date(s) of service
- Signature of the beneficiary or the beneficiary's authorized or appointed representative.

You may send the request to our address listed above. Please keep a copy of any written correspondence for your files.

Sincerely,

360.3.6 - Denial - Military Personnel/Eligible Dependents

(Rev. 4203, Issued: 01-18-19, Effective: 02-19-19, Implementation: 02-19-19)

The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.

MODEL DENIAL NOTICE A
(MAC'S NAME AND ADDRESS)

Date: _____

Beneficiary: _____

Claim Number _____

DETERMINATION ON EMERGENCY HOSPITAL SERVICES

We are sorry, but payment cannot be made for your stay from_____ through_____ at (hospital).

Under the law, medical services that have been furnished by a federal hospital to retired members of the armed services, or their eligible dependents, are not covered under the Medicare program.

If you have questions about this notice, you may call 1-800-MEDICARE (1-800-633-4227) for additional information. If you believe the determination is not correct, you may request a redetermination. You must file your request within 120 days from the date you receive this notice. A request for a redetermination must be filed either on Form CMS-20027 or on a written request that includes all of the elements listed below.

- Beneficiary name
- Medicare beneficiary identifier
- Specific service and/or item(s) for which a redetermination is being requested
- Specific date(s) of service
- Signature of the beneficiary or the beneficiary's authorized or appointed representative.

You may send the request to our address listed above. Please keep a copy of any written correspondence for your files.

Sincerely,

360.3.7 - Full Denial - Shipboard Claim - Beneficiary Filed

(Rev. 4203, Issued: 01-18-19, Effective: 02-19-19, Implementation: 02-19-19)

The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.

MODEL DENIAL NOTICE
(MAC'S NAME AND ADDRESS)

Date: _____

Beneficiary: _____

Claim Number: _____

DETERMINATION ON SHIPBOARD SERVICES

We are sorry, but medical services provided on the (vessel/ship's name) cruise ship are not covered. The Medicare program can make payment for medically necessary shipboard services only if all of the following requirements are met:

1. The services are furnished while the ship is within the territorial waters of the United States (in a U.S. port, or within 6 hours of departure or arrival at a U.S. port).
2. The services are furnished to an individual who is entitled to Part B benefits;
3. The services are furnished in connection with covered inpatient hospital services;
4. The services furnished on the ship are for the same condition that required inpatient admission;
5. The physician is legally authorized to practice in the country where he or she furnishes the services.

If you have a supplemental insurance policy, you should check with the company carrying that policy to see if they cover these services and what procedures you should follow in submitting your claim.

If you have questions about this notice, you may call 1-800-MEDICARE (1-800-633-4227) for additional information. If you believe the determination is not correct, you may request a redetermination. You must file your request within 120 days from the date you receive this notice. A request for a redetermination must be filed either on Form CMS-20027 or on a written request that includes all of the elements listed below.

- Beneficiary name
- Medicare beneficiary identifier
- Specific service and/or item(s) for which a redetermination is being requested
- Specific date(s) of service
- Signature of the beneficiary or the beneficiary's authorized or appointed representative.

You may send the request to our address listed above. Please keep a copy of any written correspondence for your files.
Sincerely,

360.3.8 - Full Denial - Foreign Claim - Beneficiary Filed

(Rev. 4203, Issued: 01-18-19, Effective: 02-19-19, Implementation: 02-19-19)

The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.

MODEL DENIAL
NOTICE (MAC'S NAME AND ADDRESS)

Date:_____

Beneficiary:_____

Claim Number: _____

DETERMINATION ON FOREIGN HOSPITAL SERVICES

We are sorry, but payment cannot be made for your stay
from_____through
_____at (hospital) in (country).

Medicare law prohibits payment for items and services furnished outside the United States except in certain limited circumstances. The term "outside the U.S." means anywhere other than the 50 states of the U.S., the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

There are three situations when Medicare may pay for certain types of health care services rendered in a foreign hospital (a hospital outside the U.S.):

1. You're in the U.S. when you have a medical emergency and the foreign hospital is closer than the nearest U.S. hospital that can treat your illness or injury.
2. You're traveling through Canada without unreasonable delay by the most direct route between Alaska and another state when a medical emergency occurs, and the Canadian hospital is closer than the nearest U.S. hospital that can treat your illness or injury. Medicare determines what qualifies as "without unreasonable delay" on a case-by-case basis.
3. You live in the U.S. and the foreign hospital is closer to your home than the nearest U.S. hospital that can treat your medical condition, regardless of whether it's an emergency.

In these situations, Medicare will pay only for the Medicare-covered services you get in a foreign hospital.

If you have a supplemental insurance policy, you should check with the company carrying that policy to see if they cover these services and what procedures you should follow in submitting your claim.

If you have questions about this notice, you may call 1-800-MEDICARE (1-800-633-4227) for additional information. If you believe the determination is not correct, you may request a redetermination. You must file your request within 120 days from the date you receive this notice. A request for a redetermination must be filed either on Form CMS-20027 or on a written request that includes all of the elements listed below.

- Beneficiary name
- Medicare beneficiary identifier
- Specific service and/or item(s) for which a redetermination is being requested
- Specific date(s) of service
- Signature of the beneficiary or the beneficiary's authorized or appointed representative.

You may send the request to our address listed above. Please keep a copy of any written correspondence for your files.

Sincerely,

370 – Microvolt T-wave Alternans (MTWA)

(Rev. 3265, Issued: 05-22-15, Effective: 01-13-15, Implementation: 06-23-15)

On March 21, 2006, the Centers for Medicare & Medicaid Services (CMS) began national coverage of microvolt T-wave Alternans (MTWA) diagnostic testing when it was performed using only the spectral analysis (SA) method for the evaluation of patients at risk for sudden cardiac death (SCD) from ventricular arrhythmias and patients who may be candidates for Medicare coverage of the placement of an implantable cardiac defibrillator (ICD).

Effective for claims with dates of service on and after January 13, 2015, Medicare Administrative Contractors (MACs) may determine coverage of MTWA diagnostic testing when it is performed using methods of analysis other than SA for the evaluation of patients at risk for SCD from ventricular arrhythmias. Further information can be found at Publication 100-03, section 20.30, of the National Coverage Determinations Manual.

370.1 - Coding and Claims Processing for MTWA

(Rev. 12396; Issued: 12-07-23; Effective: 01-09-24; Implementation: 01-09-24)

Effective for claims with dates of service on and after March 21, 2006, MACs shall accept CPT 93025 (MTWA for assessment of ventricular arrhythmias) for MTWA diagnostic testing for the evaluation of patients at risk for SCD with the SA method of analysis only. All other methods of analysis for MTWA are non-covered.

Effective for claims with dates of service on and after January 13, 2015, MACs shall at their discretion determine coverage for CPT 93025 for MTWA diagnostic testing for the evaluation of patients at risk for SCD with methods of analysis other than SA. The –KX modifier shall be used as an attestation by the practitioner and/or provider of the service that documentation is on file verifying the MTWA was performed using a method of analysis other than SA for the evaluation of patients at risk for SCD from ventricular arrhythmias and that all other NCD criteria was met.

NOTE: The –KX modifier is NOT required on MTWA claims for the evaluation of patients at risk for SCD if the SA analysis method is used.

NOTE: This diagnosis code list/translation was approved by CMS/Coverage. It may or may not be a complete list of covered indications/diagnosis codes that are covered but should serve as a finite starting point.

As this policy indicates, individual A/B MACs within their respective jurisdictions have the discretion to make coverage determinations they deem reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act. Therefore, A/B MACs may have additional covered diagnosis codes in their individual policies where contractor discretion is appropriate.

ICD-10-Codes:

ICD-10 CM	**ICD-10 DX Description**
I21.01	ST elevation (STEMI) myocardial infarction involving left main coronary artery
I21.02	ST elevation (STEMI) myocardial infarction involving left anterior descending coronary artery
I21.09	ST elevation (STEMI) myocardial infarction involving other coronary artery of anterior wall
I21.11	ST elevation (STEMI) myocardial infarction involving right coronary artery
I21.19	ST elevation (STEMI) myocardial infarction involving other coronary artery of inferior wall
I21.21	ST elevation (STEMI) myocardial infarction involving left circumflex coronary artery
I21.29	ST elevation (STEMI) myocardial infarction involving other sites
I21.3	ST elevation (STEMI) myocardial infarction of unspecified site
I21.4	Non-ST elevation (NSTEMI) myocardial infarction
I21.A1	Myocardial infarction type 2
I21.B	Myocardial infarction with coronary microvascular dysfunction
I22.0	Subsequent ST elevation (STEMI) myocardial infarction of anterior wall
I22.1	Subsequent ST elevation (STEMI) myocardial infarction of inferior wall
I22.2	Subsequent non-ST elevation (NSTEMI) myocardial infarction
I22.8	Subsequent ST elevation (STEMI) myocardial infarction of other sites
I22.9	Subsequent ST elevation (STEMI) myocardial infarction of unspecified site
I24.81	Acute coronary microvascular dysfunction
I24.89	Other forms of acute ischemic heart disease
I24.9	Acute ischemic heart disease, unspecified
I47.0	Re-entry ventricular arrhythmia
I47.2	Ventricular tachycardia
I49.01	Ventricular fibrillation

I49.02	Ventricular flutter
R55	Syncope and collapse

370.2 - Messaging for MTWA

(Rev. 3265, Issued: 05-22-15, Effective: 01-13-15, Implementation: 06-23-15)

Effective for claims with dates of service on and after January 13, 2015, MACs shall deny claims for MTWA CPT 93025 with methods of analysis other than SA without modifier -KX using the following messages:

CARC 4: "The procedure code is inconsistent with the modifier used or a required modifier is missing. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present."

RARC N657 – This should be billed with the appropriate code for these services.

Group Code: CO (Contractual Obligation) assigning financial liability to the provider

MSN 15.20 - The following policies [NCD 20.30] were used when we made this decision

Spanish Equivalent - 15.20 - Las siguientes políticas [NCD 20.30] fueron utilizadas cuando se tomó esta decisión.

380 - Leadless Pacemakers

(Rev. 3815, Issued: 07-28-17, Effective: 01-18-18, Implementation: 08-29-17 - for MAC local edits; January 2, 2018 - for MCS shared edits)

Effective for dates of service on or after January 18, 2017, contractors shall cover leadless pacemakers through Coverage with Evidence Development (CED) when procedures are performed in CMS-approved CED studies. Please refer to the National Coverage Determinations Manual (Publication 100-03, Section 20.8.4) for more information.

380.1 - Leadless Pacemaker Coding and Billing Requirements for Professional Claims

(Rev. 3815, Issued: 07-28-17, Effective: 01-18-18, Implementation: 08-29-17 - for MAC local edits; January 2, 2018 - for MCS shared edits)

Effective for dates of service on or after January 18, 2017, contractors shall allow the following procedure codes on claims for leadless pacemakers:

0387T Transcatheter insertion or replacement of permanent leadless pacemaker, ventricular

0389T Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report, leadless pacemaker system.

0390T Peri-procedural device evaluation (in person) and programming of device system parameters before or after surgery, procedure or test with analysis, review and report, leadless pacemaker system.

0391T Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, leadless pacemaker system.

Effective for dates of service on or after January 18, 2017, contractors shall allow the following ICD-10 diagnosis codes on claims for leadless pacemakers:

Z00.6 – Encounter for examination for normal comparison and control in clinical research program.

380.1.1 - Leadless Pacemaker Place of Service Restrictions

(Rev. 3815, Issued: 07-28-17, Effective: 01-18-18, Implementation: 08-29-17 - for MAC local edits; January 2, 2018 - for MCS shared edits)

Effective for dates of service on or after January 18, 2017, contractors shall only pay claims for leadless pacemakers when services are provided in one of the following places of service (POS):

POS 06 – Indian Health Service Provider Based Facility

POS 21 – Inpatient Hospital

POS 22 - On Campus-Outpatient Hospital

POS 26 – Military Treatment Facility

380.1.2 - Leadless Pacemaker Modifier

(Rev. 3815, Issued: 07-28-17, Effective: 01-18-18, Implementation: 08-29-17 - for MAC local edits; January 2, 2018 - for MCS shared edits)

Effective for claims with dates of service on or after January 18, 2017, modifier **Q0** – Investigational clinical service provided in a clinical research study that is an approved clinical research study, must also be included.

380.1.3 - Leadless Pacemaker Additional Claim Billing Information

(Rev. 3815, Issued: 07-28-17, Effective: 01-18-18, Implementation: 08-29-17 - for MAC local edits; January 2, 2018 - for MCS shared edits)

The professional claim must also contain the 8-digit clinical trial identifier in item 23 of the CMS-1500 form or the electronic equivalent.

380.2 - Leadless Pacemaker Claim Adjustment Reason Codes (CARC), Remittance Advice Remark Codes (RARC) and Medicare Summary Notice (MSN) Messages Applicable for Professional Claims Only

(Rev. 3815, Issued: 07-28-17, Effective: 01-18-18, Implementation: 08-29-17 - for MAC local edits; January 2, 2018 - for MCS shared edits)

Effective for claims with dates of service on or after January 18, 2017, contractors shall deny professional claim lines for leadless pacemakers that do not contain an appropriate POS code and use the following messages:

CARC 58: “Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”

RARC N386: “This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at

http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD."

MSN 21.25: "This service was denied because Medicare only covers this service in certain settings."

Spanish Version: El servicio fue denegado porque Medicare solamente lo cubre en ciertas situaciones."

Group Code –Contractual Obligation (CO).

- Effective for dates of service on or after January 18, 2017, contractors shall return claims with the procedure codes listed in 380.2 billed without modifier Q0 and use the following messages:

  CARC 4: "The procedure code is inconsistent with the modifier used or a required modifier is missing. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present."

  RARC N572: This procedure not payable unless appropriate non-payable reporting.

  Group Code – Contractual Obligation (CO).

- Effective for dates of service on or after January 18, 2017, contractors shall return claims as unprocessable with the procedure codes listed in 10117-04.2 billed without ICD-10 Z00.6 and use the following messages:

  CARC 16 - Claim/service lacks information or has submission/billing error(s) which is needed for adjudication. Do not use this code for claims attachment(s)/other documentation. At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.) Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

  RARC M76 - Missing/incomplete/invalid diagnosis or condition.

- Effective for claims with dates of service on or after January 18, 2017, contractors shall return claims as unprocessable that are billed with the Q0 modifier and do not contain the 8-digit clinical trial identifier in item 23 of the CMS-1500 form or the electronic equivalent. Use the following messages:

  CARC 16: "Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.)"

  RARC MA50: Missing/incomplete/invalid Investigational Device Exemption number or Clinical Trial number.

  Group Code – Contractual Obligation (CO).

390 - Supervised exercise therapy (SET) Symptomatic Peripheral Artery Disease

(Rev. 4049, Issued: 05- 11-18, Effective: 05-25-17, Implementation: 07-02-18)

Effective for claims with dates of service on or after May 25, 2017, the Centers for Medicare and Medicaid Services (CMS) will cover supervised exercise therapy (SET) for beneficiaries with intermittent claudication (IC) for the treatment of symptomatic peripheral artery disease (PAD). Up to 36 sessions over a 12 week period are covered if all of the following components of a SET program are met:

The SET program must:

- consist of sessions lasting 30-60 minutes comprising a therapeutic exercise-training program for PAD in patients with claudication;
- be conducted in a physician's office;
- be delivered by qualified auxiliary personnel necessary to ensure benefits exceed harms, and who are trained in exercise therapy for PAD; and
- be under the direct supervision of a physician (as defined in 1861(r)(1)) of the Social Security Act (the Act)), physician assistant, or nurse practitioner/clinical nurse specialist (as identified in 1861(aa)(5)) of (the Act) who must be trained in both basic and advanced life support techniques.

Beneficiaries must have a face-to-face visit with the physician responsible for PAD treatment to obtain the referral for SET. At this visit, the beneficiary must receive information regarding cardiovascular disease and PAD risk factor reduction, which could include education, counseling, behavioral interventions, and outcome assessments.

SET is non-covered for beneficiaries with absolute contraindications to exercise as determined by their primary attending physician. .

Please refer to the National Coverage Determinations Manual (Publication 100-03, Section 20.35) for more information.

390.1 General Billing Requirements

(Rev. 4049, Issued: 05- 11-18, Effective: 05-25-17, Implementation: 07-02-18)

Effective for claims with date of services on or after May 25, 2017, contractors shall pay claims for SET for beneficiaries with IC for the treatment of symptomatic PAD, with a referral from the physician responsible for PAD treatment.

Medicare Administrative Contractors (MACs) have the discretion to cover SET beyond 36 sessions over 12 weeks and may cover an additional 36 sessions over an extended period of time. Contractors shall accept the inclusion of the **KX** modifier on the claim line(s) as an attestation by the provider of the services that documentation is on file verifying that further treatment beyond the 36 sessions of SET over a 12 week period meets the requirements of the medical policy.

390.2 Coding Requirements for SET

(Rev. 4049, Issued: 05- 11-18, Effective: 05-25-17, Implementation: 07-02-18)

- **CPT 93668 –** Under Peripheral Arterial Disease Rehabilitation

- **ICD-10 Codes**

I70.211 –right leg

I70.212 – left leg

I70.213 – bilateral legs

I70.218 – other extremity

I70.311 – right leg

I70.312 – left leg

I70.313 – bilateral legs

I70.318 – other extremity

I70.611 – right leg

I70.612 – left leg

I70.613 – bilateral legs

I70.618 – other extremity

I70.711 – right leg

I70.712 – left leg

I70.713 – bilateral legs

I70.718 – other extremity

390.3 Special Billing Requirements for Institutional Claims
(Rev.4049, Issued: 05- 11-18, Effective: 05-25-17, Implementation: 07-02-18)

Contractors shall pay claims for SET services containing CPT code 93668 on Types of Bill (TOBs) 13X under OPPS and 85X based on reasonable cost.

Contractors shall pay claims for SET services containing CPT 93668 with revenue codes 096X, 097X, or 098X when billed on TOB 85X Method II based on 115% of the lesser of the fee schedule amount or the submitted charge.

390.4 Common Working File (CWF) Requirements
(Rev.4049, Issued: 05- 11-18, Effective: 05-25-17, Implementation: 07-02-18)

CWF shall create a new edit for CPT 93668 to reject claims when a beneficiary has reached 36 SET sessions within 84 days after the date of the first SET session and the KX modifier is not included on the claim or to reject any SET session provided after 84 days from the date of the first session and the KX modifier is not included on the claim.

CWF shall determine the remaining SET sessions.

The CWF determination, to parallel claims processing, shall include all applicable factors including:

- Beneficiary entitlement status
- Beneficiary claims history
- Utilization rules

CWF shall update the determination when any changes occur to the beneficiary master data or claims data that would result in a change to the calculation.

CWF shall display the remaining SET sessions on all CWF provider query screens.

The Multi-Carrier System Desktop Tool (MCSDT) shall display the remaining SET sessions in a format equivalent to the CWF HIMR screen(s).

390.5 Applicable Medicare Summary Notice (MSN), Remittance Advice Remark Codes and Claim Adjustment Reason Code Messaging

(Rev.4049, Issued: 05- 11-18, Effective: 05-25-17, Implementation: 07-02-18)

- Contractors shall deny claims for SET when services are provided on other than TOBs 13X and 85X using the following messages:
  MSN 15.20: "The following policies NCD 20.35 were used when we made this decision."

  Spanish Version – "Las siguientes políticas NCD 20.35 fueron utilizadas cuando se tomó esta decisión."
  (Part A only) MSN 15.19: "Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD".

  Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800-MEDICARE (1800-633-4227).

  Claim Adjustment Reason Code (CARC) 58:
  "Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. NOTE: Refer to the 832 Healthcare Policy Identification Segment (loop 2110 Service payment Information REF), if present.

  Remittance advice remark code (RARC) N386: This decision was based on a National Coverage Determination (NCD) 20.35. An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Contractors shall use Group Code CO (Contractual Obligation) assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.

- Contractors deny/reject claim lines for CPT 93668 without one of the diagnosis codes listed in 390.2 and use the following messages:

  MSN 15.20: "The following policies NCD 20.35 were used when we made this decision."

  Spanish Version – "Las siguientes políticas NCD 20.35 fueron utilizadas cuando se tomó esta decisión."

  (Part A only) MSN 15.19: "Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD".

Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800-MEDICARE (1800-633-4227).

CARC 167 – This (these) diagnosis(es) is (are) not covered. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC N386 – "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD."

Contractors shall use Group Code PR (Patient Responsibility) assigning financial liability to the beneficiary if a claim is received with a GA modifier indicating a signed ABN is on file.

Contractors shall use Group CO (Contractual Obligation) assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.

- Contractors shall reject claims with CPT 93668 which exceed 36 sessions within 84 days from the date of the first session when the KX modifier is not included on the claim line OR any SET session provided after 84 days from the date of the first session and the KX modifier is not included on the claim and use the following messages:

96- Non-covered charge(s). At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason [sic] Code, or Remittance Advice Remark Code that is not an ALERT.)

Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

N640 Exceeds number/frequency approved/allowed within time period.

Group Code CO (Contractual Obligation) assigning financial liability to the provider (if a claim line-item is received with a GZ modifier indicating no signed ABN is on file and occurrence code 32 is not present).

- Contractors shall deny/reject claim lines with CPT 93668 when sessions have reached 73 sessions using the following messages:

MSN 15.20: "The following policies NCD 20.35 were used when we made this decision."

Spanish Version – "Las siguientes políticas NCD 20.35 fueron utilizadas cuando se tomó esta decisión."

(Part A only) MSN 15.19: "Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD".

Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y

enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800-MEDICARE (1800-633-4227).

CARC 119: “Benefit maximum for this time period or occurrence has been reached.”

RARC N386: “This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.”

Group Code PR (Patient Responsibility) assigning financial responsibility to the beneficiary (if a claim is received with occurrence code 32 with or without a GA modifier or a claim-line is received with a GA modifier indicating a signed ABN is on file)

Group Code CO (Contractual Obligation) assigning financial liability to the provider (if a claim line-item is received with a GZ modifier indicating no signed ABN is on file and occurrence code 32 is not present

- Contractors shall deny claim line-items for SET, CPT 93668, when sessions have reached 73 sessions with or without the KX Modifier present using the following messages:

  MSN 15.20: “The following policies NCD 20.35 were used when we made this decision.”

  Spanish Version – “Las siguientes políticas NCD 20.35 fueron utilizadas cuando se tomó esta decisión.”

  (Part A only) MSN 15.19: “Local Coverage Determinations (LCDs) help Medicare decide what is covered. An LCD was used for your claim. You can compare your case to the LCD, and send information from your doctor if you think it could change our decision. Call 1-800-MEDICARE (1-800-633-4227) for a copy of the LCD”.

  Spanish Version - Las Determinaciones Locales de Cobertura (LCDs en inglés) le ayudan a decidir a Medicare lo que está cubierto. Un LCD se usó para su reclamación. Usted puede comparar su caso con la determinación y enviar información de su médico si piensa que puede cambiar nuestra decisión. Para obtener una copia del LCD, llame al 1-800- MEDICARE (1800-633-4227).

  CARC 119: “Benefit maximum for this time period or occurrence has been reached.”

  RARC N386: “This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.”

  Group Code PR (Patient Responsibility) assigning financial responsibility to the beneficiary (if a claim is received with occurrence code 32 with or without a GA modifier or a claim-line is received with a GA modifier indicating a signed ABN is on file)

  Group Code CO (Contractual Obligation) assigning financial liability to the provider (if a claim line-item is received with a GZ modifier indicating no signed ABN is on file and occurrence code 32 is not present).

400 - Chimeric Antigen Receptor (CAR) T-cell Therapy

(Rev. 11721; Issued: 11-28-22; Effective: 01-01-23; Implementation: 01-03-23)

T-cells employ a number of mechanisms to fight abnormal cells such as cancer. One type of therapy that leverages the immune system, immunotherapy, is Chimeric Antigen Receptor (CAR) T-cell therapy. CAR T-cells have been genetically altered in order to improve the ability of the T-cells to fight cancer.

400.1 - Coverage Requirements

(Rev. 11721; Issued: 11-28-22; Effective: 01-01-23; Implementation: 01-03-23)

Effective for services performed on or after August 7, 2019, the Centers for Medicare & Medicaid Services (CMS) covers autologous treatment for cancer with T-cells expressing at least one CAR when administered at healthcare facilities enrolled in the Food and Drug Administration (FDA) risk evaluation and mitigation strategies (REMS) and used for a medically accepted indication as defined at Social Security Act (the Act) section 1861(t)(2), i.e., is used for either an FDA-approved indication (according to the FDA-approved label for that product), or for other uses when the product has been FDA-approved and the use is supported in one or more CMS-approved compendia. See Publication 100-03, National Coverage Determination (NCD) Manual 110.24 for complete coverage criteria. See the following websites for specific REMS facility information:

Kymriah® https://www.us.kymriah.com/treatment-center-locator
Yescarta® https://www.yescarta.com/find-a-treatment-center
Tecartus™ https://www.tecartus.com/hcp/treatment-center-locator
Breyanzi® https://www.celltherapy360.com/locations
ABECMA® https://www.celltherapy360.com/locations
CARVYKTI™ https://www.carvyktihcp.com/treatment-centers

NOTE: The use of allogenic T-cells from healthy donors are not autologous CAR T-cell treatments and shall not be billed as autologous CAR T-cell treatments.

400.2 - Billing Requirements

(Rev. 13608; Issued: 01-29-26; Effective: 08-25-25; Implementation: 08-25-25)

Effective for dates of service on or after August 7, 2019, contractors shall pay for line-item professional claims from approved providers for the administration of autologous treatment for cancer with T-cells expressing at least one CAR with Current Procedural Terminology (CPT) code 0540T end date 12/31/24 replaced with 38228 effective 01/01/25.

Contractors shall not require the NCD 110.24 -KX modifier and diagnosis codes for clinical trials under NCD 310.1. These claims shall bill with the NCT number for the specific trial, the -Q0 clinical trial modifier, and the Z00.6 clinical trial diagnosis code on the *0540T claim line effective for dates of service on or after August 7, 2019. (*0540T end date 12/31/24 and replaced with 38228 effective 01/01/25.)
For Part A Outpatient (OPPS) contractors shall not require NCD 110.24 REMS facility and diagnosis codes for CAR T-cell therapy CPT code *0540T in clinical trials under NCD 310.1 billed with the NCT number for the specific trial, the -Q0 clinical trial modifier, condition code 30, value code D4, and the Z00.6 clinical trial diagnosis code effective for dates of service on or after August 7, 2019. (*0540T end date 12/31/24 and replaced with 38228 effective 01/01/25.)

400.2.1 - A/B Medicare Administrative Contractor (MAC) (A) Bill Types

(Rev. 10891, Issued: 07-20-21, Effective: 08-07-19, Implementation: 09-20-21)

Valid type of bills (TOBs) for billing inpatient CAR T-cell therapy services may include (but are not necessarily limited to):

011x – Inpatient Hospital
012x – Inpatient Ancillary Hospital

Valid TOBs for billing outpatient CAR T-cell therapy services may include (but are not necessarily limited to):

013x – Outpatient Hospital
085x – Critical Access Hospital

400.2.2 - A/B MAC (A) Revenue Code

(Rev. 13608; Issued: 01-29-26; Effective: 08-25-25; Implementation: 08-25-25)

The following Revenue Codes are used for billing inpatient and outpatient CAR T-cell therapy services:

0871 – Cell Collection w/CPT code 0537T end date 12/31/24 and replaced with 38225 effective 01/01/25.

0872 – Specialized Biologic Processing and Storage – Prior to Transport w/CPT code 0538T end date 12/31/24 and replaced with 38226 effective 01/01/25.

0873 – Storage and Processing after Receipt of Cells from Manufacturer w/CPT code 0539T end date 12/31/24 and replaced with 38227 effective 01/01/25.

0874 – Infusion of Modified Cells w/CPT code 0540T end date 12/31/24 and replaced with 38228 effective 01/01/25.

0891 – Special Processed Drugs – FDA Approved Cell Therapy w/ Healthcare Common Procedure Coding System (HCPCS) codes Q2041, Q2042, C9073 (replaced with Q2053 April 1, 2021), C9076 (replaced with Q2054 October 1, 2021), C9081 (replaced with Q2055 January 1, 2022), C9098 (replaced with Q2056 October 1, 2022), or C9399

400.2.3 - A/B MAC Billing HCPCS Codes

(Rev. 13608; Issued: 01-29-26; Effective: 08-25-25; Implementation: 08-25-25)

The following HCPCS/CPT procedure codes are used for billing outpatient CAR T-cell therapy services:

HCPCS Code Q2041 for Axicabtagene Ciloleucel

HCPCS Code Q2042 for Tisagenlecleucel

HCPCS Code Q2053 for Brexucabtagene Autoleucel (effective April 1, 2021)

HCPCS Code Q2054 for Lisocabtagene Maraleucel (effective October 1, 2021)

HCPCS Code Q2055 for Idecabtagene Vicleucel (effective January 1, 2022)

HCPCS Code Q2056 for Ciltacabtagene Autoleucel (effective October 1, 2022)

HCPCS Code C9073 for Brexucabtagene Autoleucel (prior to April 1, 2021)

HCPCS Code C9076 for Lisocabtagene maraleucel (prior to October 1, 2021)

HCPCS Code C9081 for Idecabtagene Vicleucel (prior to January 1, 2022)

HCPCS Code C9098 for Ciltacabtagene Autoleucel (prior to October 1, 2022)

HCPCS Code C9399, J3490, J3590, or J9999 for unclassified drugs or biologicals when dose of CAR T-cell therapy exceeds code descriptor or when other CAR T-cell therapy obtains FDA approval but has not yet received a specific HCPCS code

CPT Code 0537T collection/handling* end date 12/31/24 and replaced with 38225 effective 01/01/25.

CPT Code 0538T preparation for transport* end date 12/31/24 and replaced with 38226 effective 01/01/25.

CPT Code 0539T receipt and preparation* end date 12/31/24 and replaced with 38227 effective 01/01/25.

CPT Code 0540T the provider (physician/NPP) procedure to administer CAR T-cells end date 12/31/24 and replaced with 38228 effective 01/01/25.

* Procedure represents the various steps required to collect and prepare the genetically modified T-cells, and these steps are not paid separately under the Outpatient Prospective Payment System (OPPS)/Medicare Physician Fee Schedule (MPFS).

400.2.3.1 – A/B MAC (B) Places of Service (POS)

(Rev. 13608; Issued: 01-29-26; Effective: 08-25-25; Implementation: 08-25-25)

The following places of service (POS) are covered for CAR T-cells product HCPCS codes (Q2041, Q2042, Q2053-Q2056, J3490, J3590, and J9999):

11 (Office)

49 (Independent clinic)

Professional claims for the procedure to administer CAR T-cells (0540T) end date 12/31/24 and replaced with 38228 effective 01/01/25 may include (but are not necessarily limited to):

11 (Office)

19 (Off Campus-Outpatient Hospital)

21 (Inpatient Hospital)

22 (On Campus-Outpatient Hospital)

49 (Independent Clinic)

400.2.4 - A/B MAC Diagnosis and Procedure Code Requirements

(Rev. 13608; Issued: 01-29-26; Effective: 08-25-25; Implementation: 08-25-25)

Please see NCD spreadsheet for the applicable International Classification of Disease (ICD)-10-CM diagnosis codes for CAR T-cell therapy coverage.

The following are the applicable ICD-10-PCS procedure codes for CAR T-cell therapy coverage for inpatient claims:

For dates of service on or after October 1, 2021:

CARVYKTI™ - XW033A7: Introduction of Ciltacabtagene Autoleucel into Peripheral Vein, Percutaneous Approach, New Technology Group 7

CARVYKTI™ - XW043A7: Introduction of Ciltacabtagene Autoleucel into Central Vein, Percutaneous Approach, New Technology Group 7

When other CAR T-cell therapy obtains FDA approval but has not yet received a specific PCS code, and for use in clinical trials FDA-approved under NCD 310.1 – XW033C7: Introduction of Autologous Engineered Chimeric Antigen Receptor T-cell Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7

When other CAR T-cell therapy obtains FDA approval but has not yet received a specific PCS code, and for use in clinical trials FDA-approved under NCD 310.1 – XW043C7: Introduction of Autologous Engineered Chimeric Antigen Receptor T-cell Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7

Yescarta® - XW033H7: Introduction of Axicabtagene Ciloleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7

Yescarta® - XW043H7: Introduction of Axicabtagene Ciloleucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7

Kymriah® - XW033J7: Introduction of Tisagenlecleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7

Kymriah® - XW043J7: Introduction of Tisagenlecleucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7

ABECMA® - XW033K7: Introduction of Idecabtagene Vicleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7

ABECMA® - XW043K7: Introduction of Idecabtagene Vicleucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7

Tecartus™ - XW033M7: Introduction of Brexucabtagene Autoleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7

Tecartus™ - XW043M7: Introduction of Brexucabtagene Autoleucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7

Breyanzi® - XW033N7: Introduction of Lisocabtagene Maraleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7

Breyanzi® - XW043N7: Introduction of Lisocabtagene Maraleucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7
Aucatzyl® - XW0338A: Introduction of Obecabtagene Autoleucel into Peripheral Vein, Percutaneous Approach, New Technology Group 10 (FDA Approval date of November 8, 2024). This code is covered in a clinical trial, see below.

Aucatzyl® - XW0438A: Introduction of Obecabtagene Autoleucel into Central Vein, Percutaneous Approach, New Technology Group 10 (FDA Approval date of November 8, 2024). This code is covered in a clinical trial, see below.

For dates of service prior to October 1, 2021:

Yescarta®, ABECMA®, Kymriah® - XW033C3: Introduction of Engineered Autologous Chimeric Antigen

Receptor T-cell Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 3

Yescarta®, ABECMA®, Kymriah® - XW043C3: Introduction of Engineered Autologous Chimeric Antigen Receptor T-cell Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 3

Tecartus™ - XW23346 - Transfusion of Brexucabtagene Autoleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 6

Tecartus™ - XW24346 - Transfusion of Brexucabtagene Autoleucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 6

Breyanzi® - XW23376 – Transfusion of lisocabtagene maraleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 6

Breyanzi®- XW24376 – Transfusion of lisocabtagene maraleucel immunotherapy into central vein, percutaneous approach, new technology 6

NOTE: Since allogenic T-cells are by definition not autologous CAR T-cells, it is inappropriate to use any of the above autologous CAR T-cell ICD-10 PCS procedure codes for allogenic T-cell treatments.
For Part A Inpatient contractors shall not require NCD 110.24 REMS facility and diagnosis codes for autologous CAR T-cell therapy ICD-10-PCS codes XW033A7/XW043A7, XW033H7/XW043H7, XW033J7/XW043J7, XW033K7/XW043K7, XW033M7/XW043M7, XW033N7/XW043N7, and XW0338A/XW0438A in clinical trials under NCD 310.1 billed with the NCT number for the specific trial, condition code 30, value code D4, and the Z00.6 clinical trial diagnosis code effective for dates of service on or after August 7, 2019.

400.2.5 – Billing Information for Professional Claims

(Rev. 11721; Issued: 11-28-22; Effective: 01-01-23; Implementation: 01-03-23)

Professional claims for CAR T-cell therapy and related services are billed using the Form CMS-1500 or 837P following instructions in chapter 12 of this manual (www.cms.hhs.gov/manuals/104_claims/clm104index.asp).

Contractors shall pay professional claims for CAR T-cell therapy when the service is administered at a healthcare facility that is enrolled in the REMS program as a REMS participating site. Contractors shall use the CMS HCPCS Website for current HCPCS codes, https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update, and the individual REMS facility websites noted at section 400.1.

Contractors shall create an edit that only allows CAR T-cell therapy services to be submitted by, or performed in, an FDA REMS approved facility when the line item has a -KX modifier appended. **Note:** When a provider submits a -KX modifier on CAR T-cell therapy services, they are acknowledging that the service is being submitted by or performed in an FDA REMS approved facility.

Contractors shall create an edit that only allows CAR T-cell therapy services when the line item has a -LU modifier appended in addition to a -KX modifier. **Note:** When a provider submits an -LU modifier on a CAR T-cell claim, it informs the MAC that the service is fractionated. The total units shall not exceed 1 unit.

Contractors shall set up their systems to allow fractionated units on multiple claims for CAR T-cell products on the same DOS. These claims should suspend for proper adjudication of payment.

The total payment will be divided by 10 and the provider will need to bill in 0.1 unit fractions. The provider will need to bill a total of 10 fractional units to reach the total Medicare allowed payment amount.

Example: CAR T-cell product allowed payment $445,000:

0.2 units = $89,000.06
0.2 units = $89,000.00
0.2 units = $88,999.99
0.2 units = $88,999.98
0.2 units = $88,999.97

Note: Contractors shall only pay up to 1 unit, anything exceeding 1 unit must be denied.

For CAR T-cell products when the dose exceeds the code descriptor, use HCPCS code J3490, J3590, or J9999 for the exceeded dosage. Include the CAR T-cell product name and the exceeded dosage in Block 19 of the 1500 claim form or its electronic equivalent.

Example: CAR T-cell product with dose exceeded allowed payment $150,000:

0.5 units = $74,999.00
0.5 units = $75,001.00

For CAR T-cell products when the dose exceeds the code descriptor, the provider would bill a total of 1 unit of the Q code plus a total of 1 unit of the J code.
For example, Q2041 Axicabtagene ciloleucel, up to 200 million autologous anti-CD19 CAR positive T- cells. If the provider gives 300 million cells, they will bill:

Q2041 for 0.1 fraction $42,294.00 x10 for 200 million cells (total $422,940.00)
J9999 for 0.2 fractions $42,294.00 x5 for 100 million cells (total $211,470.00)

NOTE: The FDA labels for CAR T-cell products state the maximum number of cells that are to be infused. The HCPCS code descriptors for Q2041, Q2042, Q2053, Q2054, Q2055, and Q2056 all align with the FDA label maximum number of cells that are to be infused. If a provider exceeds the HCPCS code descriptor number of cells, this is off label use. This should be extremely rare.

Contractors shall allow a -76 modifier (repeat procedure or service by same physician or other qualified healthcare professional) on subsequent claims billed on the same date of service to assist with preventing duplicate denials.

400.3 - Payment Requirements

(Rev. 13608; Issued: 01-29-26; Effective: 08-25-25; Implementation: 08-25-25)

Inpatient

The A/ B MAC billing requirements will allow for CAR T-cell therapy when the services are submitted on the following TOB: 11X. Type of facility and setting determines the basis of payment:

For services performed in inpatient hospitals, TOB 11X, under the Inpatient PPS is based on the Medicare Severity-Diagnosis Related Group (MS-DRG).

For services performed in Critical Access Hospital (CAH) inpatient TOB 11X, payment is based on 101% of reasonable cost.

Outpatient

The A/B MAC billing requirements will pay for CAR T-cell therapy when the services are submitted on the TOBs: 13X and 85x. Type of facility and setting determines the basis of payment:

For services performed in hospital outpatient departments (HOPDs), TOBs 13X, or inpatient ancillary TOB 12X, payment is based on OPPS.

For services performed in CAH OPDs, TOB 85X, payment is based on reasonable cost.

For services performed in CAH Method II with revenue code 096X, 097X, and 098X, TOB 85X, payment is based on the lesser of the actual charge or the Medicare Physician Fee Schedule (115% of the lesser of the fee schedule amount and submitted charge).

HOPDs may report CPT codes 0537T, 0538T, and 0539T (end date 12/31/24 replaced with 38225, 38226, and 38227 effective 01/01/25) to allow tracking of these services when furnished in the outpatient setting. Medicare will reject these lines as Medicare does not separately pay for these services under the OPPS.

These following scenarios present further clarification on how to report items and services related to CAR-T in various clinical scenarios.

Scenario 1: CAR-T Dosing and Preparation Services and Viable T-cells Administered in HOPDs:

In instances when you administer the CAR-T drug in the HOPD setting, report CPT code 0540T (end date 12/31/24 and replaced with 38228 effective 01/01/25) for the administration and HCPCS Q2041, Q2042, Q2053 (effective April 1, 2021), C9073 (prior to April 1, 2021), C9076, or, if a more specific code is unavailable, the most appropriate unclassified drug code (e.g., C9399 for unclassified drugs or biologicals). NOTE: the drug codes will be denied as a Part A service even if billed with the administration.) For specific instructions on billing unclassified drug codes, refer to Chapter 26, Section 10.4 of the "Medicare Claims Processing Manual" on the CMS website at: Regulations-and-Guidance.Ch26. As discussed in the Calendar Year (CY) 2019 OPPS/Ambulatory Surgery Center final rule (83 FR 58904), the procedures described by CPT *0537T (collection/handling), 0538T (preparation for transport), and 0539T (receipt and preparation) (*0537T, 0538T, and 0539T end date 12/31/24 and replaced with 38225, 38226, and 38227 effective 01/01/25) represent the various steps required to collect and prepare the genetically modified T-cells, and these steps are not paid separately under the OPPS. However, you may report the charges for these various steps to collect and prepare the CAR T-cells separately and Medicare will reject them on the HOPD claim, or they may be included in the charge reported for the biological.

Note: When including the charges for collection and preparation of the CAR-T cells in the charge for the CAR-T product, outpatient providers should code the CAR-T product service on the date that the CAR-T administration took place and not on the date when the cells were collected.

Scenario 2: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Not Administered:

In instances when the CAR-T drug is not ultimately administered to the beneficiary, but the CAR-T preparation services are initiated or performed in the HOPD facility, the hospital may not report the drug Q code (which only applies when the T-cells are administered in the HOPD setting). HOPDs may report CPT *0537T, 0538T, and 0539T (as appropriate) and (*0537T, 0538T, and 0539T end date 12/31/24 and replaced with 38225, 38226, and 38227 effective 01/01/25) the charges associated with each code under the appropriate revenue code on the HOPD claim. Medicare will reject these codes.

Scenario 3: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Administered in the Hospital Inpatient Setting:

When CAR T-cell preparation services are initiated and furnished in the HOPD setting, but the CAR T-cells are administered in the inpatient setting, the hospital may not report the drug Q code (which only applies when the T-cells are administered in the HOPD setting). Report the charge associated with the various steps to collect and prepare the CAR T-cells on the inpatient claim (TOB 11x) separately using revenue codes 0871, 0872, or 0873. Alternatively, the hospital may include the charges for these various steps in the charge reported for the biological using revenue code 0891 – Special Processed Drugs – FDA (U.S. Food and Drug Administration) Approved Cell Therapy – Charges for Modified cell therapy.

Note: When the cells are collected in the HOPD setting and the CAR-T is administered in the hospital inpatient setting, inpatient providers should report the date that the CAR-T administration took place and not the date the cells were collected.

Physician Office or Non-Hospital Clinic

The A/B MAC billing requirements will pay for CAR T-cell therapy when the services are submitted on the Form CMS-1500 or electronic 837P.

Scenario 1: CAR-T Dosing and Preparation Services and Viable T-cells Administered in Physician Office or Non-Hospital Clinic:

In instances when you administer the CAR-T drug in the physician office setting or other non-hospital clinic setting that is enrolled in the REMS program as a REMS participating site, report CPT code 0540T (end date 12/31/24 and replaced with 38228 effective 01/01/25) for the administration and HCPCS Q2041, Q2042, Q2053 (effective April 1, 2021), C9073 (prior to April 1, 2021), C9076, or, if a more specific code is unavailable, the most appropriate unclassified drug code (e.g., J3590 for unclassified biologics). For specific instructions on billing unclassified drug codes, refer to Chapter 26, Section 10.4 of the "Medicare Claims Processing Manual" on the CMS website at: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf

The procedures described by CPT *0537T (collection/handling), 0538T (preparation for transport), and 0539T (receipt and preparation) represent the various steps required to collect and prepare the genetically modified T-cells, and these steps are not paid separately under the MPFS. However, you may report them separately, and Medicare will reject them on the professional claim. (*0537T, 0538T, and 0539T end date 12/31/24 and replaced with 38225,38226, and 38227 effective 01/01/25.)

Note: Practitioners should code the CAR-T product service on the date that the CAR-T administration took place and not on the date when the cells were collected.

Scenario 2: CAR-T Dosing and Preparation Services Administered in Physician Office or Non-Hospital Clinic, but Viable T-cells Not Administered:

In instances when the CAR-T drug is not ultimately administered to the beneficiary, but the CAR-T preparation services are initiated or performed in the physician office or other non-hospital clinic facility, the practitioner may not report the drug HCPCS code (which only applies when the T-cells are administered in the setting). The practitioner may report CPT 0537T, 0538T, and 0539T. (0537T, 0538T, and 0539T end date 12/31/24 and replaced with 38225, 38226, and 38227 effective 01/01/25.)

Scenario 3: CAR T-cells Dosing and Preparation Services in Physician Office or Non-Hospital Clinic, but Viable T-cells Administered in the Hospital Inpatient Setting:

When CAR T-cell preparation services are initiated and furnished in the physician office or other non-hospital clinic setting, but the CAR T cells are administered in the hospital inpatient setting, the practitioner may not report the drug HCPCS code (which only applies when viable T-cells are administered in the setting). The hospital that administers the T-cells will report the charge associated with the various steps to collect and prepare the CAR T-cells on the inpatient claim (TOB 11x) separately using revenue codes 0871, 0872, or 0873. Alternatively, the hospital may include the charges for these various steps in the charge reported for the biological using revenue code 0891 – Special Processed Drugs – FDA (U.S. Food and Drug Administration) Approved Cell Therapy – Charges for Modified cell therapy.
Note: When the cells are collected in the physician office setting and the CAR T-cell is administered in the hospital inpatient setting, inpatient providers shall report the date that the CAR T-cell administration took place and not the date the cells were collected.

400.4 - Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages

(Rev. 11721; Issued: 11-28-22; Effective: 01-01-23; Implementation: 01-03-23)

Contractors shall continue to use the appropriate existing messages that they have in place when denying claims submitted that do not meet the Medicare coverage criteria for CAR T-cell therapy.

--Contractors shall deny claims for CAR T-cell therapy when the service is not administered through healthcare facilities that are enrolled in the FDA REMS requirements using the following messages:

CARC 58 Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. Usage: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC N386 – This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Group Code CO (Contractual Obligations).

MSN 16.2 – This service cannot be paid when provided in this location/facility.

Spanish Version – Este servicio no se puede pagar cuando es suministrado en esta sitio/facilidad.

In addition to the codes listed above, contractors shall afford appeal rights to all denied parties.

--When denying claims for covered CAR T-cell therapy procedures because the appropriate ICD-10 coding was not used, use the following messages:

CARC 50 - These are **non-covered services** because this is not deemed a "medical necessity" by the payer. Usage: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Group Code CO or PR dependent upon liability.

MSN 15.20 - “The following polices were used when we made this decision: NCD 110.24.”
Spanish Version – “Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 110.24.”

--When denying claims for covered CAR T-cell therapy procedures because they are not performed in POS 11 or 49, use the following messages:

CARC 58 Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. Usage: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Group Code CO or PR (Patient Responsibility) dependent upon liability. (Use PR when the GA modifier is appended to the line item).

MSN 09.040 - This item or service was denied because information required to make payment was incorrect.

MSN 15.20 - “The following polices were used when we made this decision: NCD 110.24.”

Spanish Version – “Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 110.24.”

--When denying claims for covered CAR T-cell therapy procedures because they do not contain new modifier - LU, use the following messages:

CARC 4 - The procedure code is inconsistent with the modifier used. Usage: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Group Code CO

MSN 15.20 - “The following polices were used when we made this decision: NCD 110.24.”

Spanish Version – “Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 110.24.”

--When denying claims for covered CAR T-cell therapy procedures because the fractional units exceed 1 unit, use the following messages:

CARC 151 - Payment adjusted because the payer deems the information submitted does not support this many/frequency of services.

Group Code CO

MSN 15.060 - The information provided does not support the need for this many services or items within this period of time.

Spanish Version - (La información proporcionada no confirma la necesidad de estos servicios o artículos en este periodo de tiempo.)

-- Contractors shall reject claims for allogeneic CAR T-cell therapy ICD-10-PCS codes XW033G7 and XW043G7 and autologous CAR T-cell therapy ICD-10-PCS codes XW033C7 and XW043C7 when not billed for clinical trials under NCD 310.1 with the NCT number for the specific trial, condition code 30, value code D4, and the Z00.6 clinical trial diagnosis code effective for dates of service on or after October 1, 2021, using the following messages:

CARC 55: Procedure/treatment/drug is deemed experimental/investigational by the payor.

Group Code: CO

MSN 16.77 – This service/item was not covered because it was not provided as part of a qualifying trial/study.

Spanish Version – (Este servicio/artículo no fue cubierto porque no estaba incluido como parte de un ensayo clínico/estudio calificado.)

In addition to the codes listed above, contractors shall afford appeal rights to all denied parties.

400.5 - Claims Editing

(Rev. 11721; Issued: 11-28-22; Effective: 01-01-23; Implementation: 01-03-23)

A. Fee-For-Service Medicare

Medicare edits CAR T-cell therapy claims based on requirements found in NCD 110.24.

B. Beneficiaries enrolled in Medicare Advantage (MA) plans

Effective for clams with dates of service on and after August 7, 2019, CMS determined that the NCD requiring coverage of CAR T-cell therapy for cancer is a significant cost under section 422.109(a)(2) of title 42 of the Code of Federal Regulations. As a result, for CYs 2019 (beginning August 7, 2019) and 2020 only, original fee-for-service Medicare will pay for CAR T-cell therapy for cancer obtained by beneficiaries enrolled in Medicare Advantage (MA) plans when the coverage criteria outlined in the NCD are met. Plans should account for CAR T-cell therapy for cancer items and services in their contract year 2021 bids.

Consistent with §1862 (t)(2) of the Act, MACs will pay for CAR T-cell therapy for cancer for Medicare beneficiaries enrolled in MA plans in CYs 2019 (beginning August 7, 2019) and 2020.

410 – Acupuncture for Chronic Low Back Pain (cLBP)

(Rev. 10337, Issued: 08-027-20, Effective: 01-21-20, Implementation: 06-24 - 20 - A/B MACs; 10-05-20-SSM Edits; 01- 04-21 - BR 13 CWF only)

Acupuncture is the selection and manipulation of specific acupuncture points through the insertion of needles or "needling," or other "non-needling" techniques focused on these points.

410.1 - Coverage Requirements

(Rev. 10337, Issued: 08-027-20, Effective: 01-21-20, Implementation: 06-24 - 20 - A/B MACs; 10-05-20-SSM Edits; 01- 04-21 - BR 13 CWF only)

Effective for services on or after January 21, 2020, the Centers for Medicare & Medicaid Services (CMS) will cover acupuncture for chronic low back pain (cLBP) under section 1862(a)(1)(A) of the Social Security Act. Up to 12 visits in 90 days are covered for Medicare beneficiaries under the following circumstances:

- For the purpose of this decision, cLBP is defined as:
    - Lasting 12 weeks or longer;
    - nonspecific, in that it has no identifiable systemic cause (i.e., not associated with metastatic, inflammatory, infectious, etc. disease);
    - not associated with surgery; and
    - not associated with pregnancy.
- An additional 8 sessions will be covered for those patients demonstrating an improvement. No more than 20 acupuncture treatments may be administered annually. Example: If the 1st service is performed on March 21, 2020, the next service beginning a new year cannot be performed until March 1, 2021. This means 11 full months must pass from the date of the 1st service before eligibility begins again.

All types of acupuncture including dry needling for any condition other than cLBP are non-covered by Medicare.

410.2 – Claims Processing General Information

(Rev. 10337, Issued: 08-027-20, Effective: 01-21-20, Implementation: 06-24 - 20 - A/B MACs; 10-05-20-SSM Edits; 01- 04-21 - BR 13 CWF only)

Effective for claims with dates of service (DOS) on or after January 21, 2020, contractors shall recognize acupuncture for cLBP services reported with CPT codes 97810, 97811, 97813, 97814, 20560, and 20561 as covered services under National Coverage Determination (NCD) 30.3.3 no more than 20 times per annum.

NOTE: If the 1st service is performed on March 21, 2020, the next service beginning a new year cannot be performed until March 1, 2021, 11 full months following the 1st service.

The attached includes the International Classification of Diseases (ICD)-10 diagnosis codes are applicable and must be reported for acupuncture for cLBP services:

Contractors shall accept and process acupuncture for cLBP claims with the -KX modifier for the 13th through 20th service per annum.

NOTE: The 1st through 12th service over a 90-day period do not require the –KX modifier. There is a 20 service maximum per annum for this benefit.

NOTE: By applying the -KX modifier to the claim, the therapy provider is confirming that the additional services are medically necessary as justified by appropriate documentation in the medical record.

410.3 – Institutional Claims Bill Type and Revenue Coding Information

(Rev. 10337, Issued: 08-027-20, Effective: 01-21-20, Implementation: 06-24 - 20 - A/B MACs; 10-05-20-SSM Edits; 01- 04-21 - BR 13 CWF only)

Effective for claims with DOS on or after January 21, 2020, contractors shall recognize acupuncture for cLBP services reported on institutional claims on types of bill (TOBs) 12X, 13X, 71X, 77X, and 85X (and revenue codes not equal to 096X, 097X, and 098X for CAH Method I).

Effective for claims with DOS on or after January 21, 2020, contractors shall recognize acupuncture for cLBP services reported with Revenue Code 0940 on institutional claims.

Effective for claims with DOS on or after January 21, 2020, contractors shall recognize acupuncture for cLBP services reported on institutional claims on TOB 12X, 71X, 77X 85X CAH Method II with revenue codes 096X, 097X, and 098X.

410.4 – Messaging

(Rev. 10337, Issued: 08-027-20, Effective: 01-21-20, Implementation: 06-24 - 20 - A/B MACs; 10-05-20-SSM Edits; 01- 04-21 - BR 13 CWF only)

Effective for claims with DOS on or after January 21, 2020, contractors shall reject/deny claims that do not contain the appropriate diagnosis/procedure coding noted in section 410.2 and use these messages:

Claim Adjustment Reason Code (CARC) 50 - These are non-covered services because this is not deemed a 'medical necessity' by the payer.

Remittance Advice Remark Code (RARC) M64 – Missing/incomplete/invalid other diagnosis.

Group Code CO (Contractual Obligations) or PR (Patient Responsibility) dependent on liability.

MSN 15.20 - “The following polices were used when we made this decision: NCD 30.3.3.”

Spanish Version – “Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 30.3.3.”

NOTE: Due to system requirement, the Fiscal Intermediary Shared System (FISS) has combined messages 15.19 and 15.20 so that, when used for the same line item, both messages will appear on the same MSN.

In addition to the codes noted in section 410.2, contractors shall afford appeal rights to all denied parties.

Contractors shall return to provider/return as unprocessable claims for acupuncture for cLBP for services 13 through 20 per annum without the -KX modifier and use these messages:

CARC 4 - The procedure code is inconsistent with the modifier used or a required modifier is missing. Usage: Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC N657 - This should be billed with the appropriate code for these services.

Group Code CO

Contractors shall reject/deny more than 20 claims per annum for acupuncture for cLBP and use the following messages:

CARC 96 - Non-covered charge(s). At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason [sic] Code, or Remittance Advice Remark Code that is not an ALERT.) Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC N640 - Exceeds number/frequency approved/allowed within time period.

Group Code - CO (Contractual Obligation)

MSN 15.20 - “The following polices were used when we made this decision: NCD 30.3.3.”

Spanish Version – “Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 30.3.3.”

MSN 15.19: “We used a Local Coverage Determination (LCD) to decide coverage for your claim. To appeal, get a copy of the LCD at www.cms.gov/medicare-coverage-database (use the MSN Billing Code for the CPT/HCPCS Code) and send with information from your doctor."

Spanish Version - Usamos una Determinación de Cobertura Local (LCD) para decidir la cobertura de su reclamo. Para apelar, obtenga una copia del LCD en www.cms.gov/medicare-coverage-database (use el código de facturación de MSN para el código "CPT/HCPCS") y envíela con la información de su médico.

NOTE: Due to system requirements, the Fiscal Intermediary Shared System has combined messages 15.19 and 15.20 so that, when used for the same line item, both messages will appear on the same MSN.

410.5 – Common Working File (CWF) FISS, and Multi-Carrier System (MCS) Editing

(Rev. 10337, Issued: 08-027-20, Effective: 01-21-20, Implementation: 06-24 - 20 - A/B MACs; 10-05-20-SSM Edits; 01- 04-21 - BR 13 CWF only)

The Common Working File (CWF) shall create a new reject for claims with DOS on and after January 21, 2020, for claims received on or after October 5, 2020, to not allow payment for more than 20 acupuncture for cLBP claims per annum.

For acupuncture for cLBP claims CWF, FISS and the Multi-Carrier System (MCS) shall apply appropriate updates to the Next Eligibility Date file for DOS on or after January 21, 2020.

NOTE: Appropriate updates include modifications to HUQA, and Extract Records on the Next Generation Desktop (NGD) and the Medicare Beneficiary Database (MBD) for next eligible date and services remaining.

CWF shall count 11 full months starting with the month of a beneficiary’s 1st acupuncture for cLBP service. EX: If 1st date of service is October 15, 2020, the next eligible date beginning a new year would be October 1, 2021.

NOTE: A new cLBP auxiliary (AUX) file will be created and HIMR will be updated to post the previous acupuncture for cLBP HCPCS 97810, 97811, 97813, 97814, 20560, or 20561.

For acupuncture for cLPB claims with DOS on and after January 21, 2020, the Multi-Carrier System Desktop Tool shall display the acupuncture for cLBP visits in a format equivalent to the CWF HIMR screen.

Effective for claims with DOS on and after January 21, 2020, received on and after October 5, 2020, CWF shall post acupuncture for cLBP HCPCS codes 97810, 97811, 97813, 97814, 20560, and 20561, reported on institutional claims, TOBs 12X, 13X, 71X, 77X, and 85X (and revenue code not equal to 096X, 097X, 098X), as the technical component on the new cLBP AUX file.

NOTE: 1 TECH and 1 PROF on same DOS represents 1 service.

NOTE: CWF shall post the Part B Professional claim line as TECH/PROF for the HCPCS if the modifier is blank.

CWF shall create a new reject for HCPCS 97810, 97811, 97813, 97814, 20560, and 20561 when a beneficiary has reached 20 acupuncture for cLBP sessions and the -KX modifier is not included on the claim line for sessions 13 through 20 (the reject will apply for both PROF and TECH sessions).

CWF shall update the determination when any changes occur to the beneficiary master data or claims data that would result in a change to the calculation

CWF shall create a new HICR function for the new cLBP AUX file.

411– Home Infusion Therapy Services

(Rev. 10269, Issued: 08-07-2020, Effective: 01-01-2021, Implementation: 01-04-2021)

411.1 – Policy

(Rev. 10269, Issued: 08-07-2020, Effective: 01-01-2021, Implementation: 01-04-2021)

Effective beginning on January 1, 2021, the Medicare home infusion therapy benefit covers the professional services, including nursing services, furnished in accordance with the plan of care, patient training and education (not otherwise covered under the durable medical equipment benefit), remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier. Home infusion therapy means the items and services furnished by a qualified home infusion therapy supplier, which are furnished in the individual's home. Payment is for an "infusion drug administration calendar day," which means the day on which home infusion therapy services are furnished by skilled professionals in the individual's home on the day of infusion drug administration. The skilled services provided on such day must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel.

411.2 – Coverage Requirements

(Rev. 10269, Issued: 08-07-2020, Effective: 01-01-2021 Implementation: 01-04-2021)

Payment for an "infusion drug administration calendar day" is only made if a beneficiary is furnished certain drugs and biologicals administered through an item of covered DME, and payable only to suppliers enrolled in Medicare as a "qualified home infusion therapy supplier." The beneficiary must be under the care of an applicable provider, defined as a physician, nurse practitioner, or physician's assistant, and must be under the care of a physician-established plan of care that prescribes the type, amount, and duration of infusion therapy services. A "qualified home infusion therapy supplier" is a pharmacy, physician, or other provider of services or supplier licensed by the state in which supplies or services are furnished. Qualified home infusion therapy suppliers must furnish infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; ensure the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis; and be accredited by an organization designated by the Secretary. The supplier may subcontract with a pharmacy, physician, other qualified supplier or provider of services in order to meet these requirements.

411.3 - Home Infusion Drugs: Healthcare Common Procedural Coding System (HCPCS) Drug Codes

(Rev. 11430; Issued: 05-24-22; Effective: 07-01-22; Implementation: 07-05-22)

The home infusion therapy services payment is intended to cover the professional services needed for the administration of certain home infusion drugs covered as supplies necessary for the effective use of external infusion pumps. This payment separately and explicitly pays for the services related to the administration of the drugs identified on the DME LCD for External Infusion Pumps, when such services are furnished in the individual's home. Section 1861(iii)(3)(C) of the Act defines "home infusion drug" as a parenteral drug or biological administered intravenously, or subcutaneously for an

administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment (as defined in section 1861(n) of the Act). Such term does not include insulin pump systems or self-administered drugs or biologicals on a self-administered drug exclusion list.

Home infusion drugs are assigned to three payment categories, as determined by the HCPCS J-code. Payment category 1 includes certain intravenous antifungals and antivirals, uninterrupted long-term infusions, pain management, inotropic, chelation drugs. Payment category 2 includes subcutaneous immunotherapy and other certain subcutaneous infusion drugs. Payment category 3 includes certain chemotherapy drugs. CMS will continue to use the G-codes, established for the temporary transitional payments in CYs 2019 and 2020, for the professional services furnished on an infusion drug administration calendar day for each payment category. CMS has established a single payment amount for each of the three categories for professional services furnished for each infusion drug administration calendar day. Each payment category will be paid at amounts in accordance with infusion codes and units for such codes under the physician fee schedule for each infusion drug administration calendar day in the individual's home for drugs assigned to such category. The payment amounts are equal to 5 hours of infusion therapy in a physician's office. Further policy information can be found in Publication 100-02, Chapter 15, Section 320.

Category 1	
J-Code	Description
J0133	Injection, acyclovir, 5 mg
J0285	Injection, amphotericin b, 50 mg
J0287	Injection, amphotericin b lipid complex, 10 mg
J0288	Injection, amphotericin b cholesteryl sulfate complex, 10 mg
J0289	Injection, amphotericin b liposome, 10 mg
J0895	Injection, deferoxamine mesylate, 500 mg
J1170	Injection, hydromorphone, up to 4 mg
J1250	Injection, dobutamine hydrochloride, per 250 mg
J1265	Injection, dopamine hcl, 40 mg

J1325	Injection, epoprostenol, 0.5 mg
J1455	Injection, foscarnet sodium, per 1000 mg
J1457	Injection, gallium nitrate, 1 mg
J1570	Injection, ganciclovir sodium, 500 mg
J2175	Injection, meperidine hydrochloride, per 100 mg
J2260	Injection, milrinone lactate, 5 mg
J2270	Injection, morphine sulfate, up to 10 mg
J3010	Injection, fentanyl citrate, 0.1 mg
J3285	Injection, treprostinil, 1 mg
Category 2	
J-Code	Description
J1551 JB	Injection, immune globulin (cutaquig), 100mg
J1555 JB	Injection, immune globulin (cuvitru), 100 mg
J1558 JB	Injection, immune globulin (xembify), 100mg
J1559 JB	Injection, immune globulin (hizentra), 100mg
J1561 JB	Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (e.g. liquid), 500 mg
J1562 JB	Injection, immune globulin (vivaglobin), 100 mg
J1569 JB	Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg
J1575 JB	Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immune globulin
~~J7799 JB~~	~~This NOC code may be used to identify the subcutaneous immune globulin (cutaquig)~~
Category 3	
J-Code	Description
J9000	Injection, doxorubicin hydrochloride, 10 mg
J9039	Injection, blinatumomab, 1 microgram
J9040	Injection, bleomycin sulfate, 15 units
J9065	Injection, cladribine, per 1 mg
J9100	Injection, cytarabine, 100 mg
J9190	Injection, fluorouracil, 500 mg
J9360	Injection, vinblastine sulfate, 1 mg
J9370	Injection, vincristine sulfate, 1 mg

It is important to note that this list is not static. The payment category may be determined by the contractor for any new home infusion drug additions to the Local Coverage Determination (LCD) for External Infusion Pumps as identified by the following not-otherwise-classified (NOC) codes:

- J7799 - Not otherwise classified drugs, other than inhalation drugs, administered through DME
- J7999 - Compounded drug, not otherwise classified.

Attachment A: Billing for Home Infusion Therapy Services on or After January 1, 2021

Table 1 shows the time increments providers should report visit length in 15-minute increments (15 minutes = 1 unit). See the table below for the rounding of units:

Table 1: Time Increments

Unit	Time
1	<23 minutes
2	= 23 minutes to <38 minutes
3	= 38 minutes to <53 minutes
4	= 53 minutes to <68 minutes
5	= 68 minutes to <83 minutes
6	= 83 minutes to <98 minutes
7	= 98 minutes to <113 minutes
8	= 113 minutes to <128 minutes
9	= 128 minutes to <143 minutes
10	= 143 minutes to <158 minutes

Table 2 shows the use of the three G-codes established for the home infusion therapy benefit, and reflects the therapy type and complexity of the drug administration.

Table 2: Payment Categories for Home Infusion Therapy Professional Services (G-Codes)

	Category 1	**Category 2**	**Category 3**
Description **G-Code**	Intravenous anti-infective, pain management, chelation, pulmonary hypertension, inotropic, and other certain intravenous infusion drugs	Subcutaneous immunotherapy and other certain Subcutaneous infusion drugs	Chemotherapy and other certain highly complex intravenous drugs
Initial Visit	G0088	G0089	G0090
Subsequent Visit	G0068	G0069	G0070

Table 3 provides a list of J-codes associated with the home infusion drugs that fall within each category.

Table 3: Payment Categories for Home Infusion Drugs (J-Codes)

Category 1	
J-Code	Description
J0133	Injection, acyclovir, 5 mg
J0285	Injection, amphotericin b, 50 mg
J0287	Injection, amphotericin b lipid complex, 10 mg
J0288	Injection, amphotericin b cholesteryl sulfate complex, 10 mg
J0289	Injection, amphotericin b liposome, 10 mg
J0895	Injection, deferoxamine mesylate, 500 mg
J1170	Injection, hydromorphone, up to 4 mg
J1250	Injection, dobutamine hydrochloride, per 250 mg
J1265	Injection, dopamine hcl, 40 mg
J1325	Injection, epoprostenol, 0.5 mg

J1455	Injection, foscarnet sodium, per 1000 mg
J1457	Injection, gallium nitrate, 1 mg
J1570	Injection, ganciclovir sodium, 500 mg

J2175	Injection, meperidine hydrochloride, per 100 mg
J2260	Injection, milrinone lactate, 5 mg
J2270	Injection, morphine sulfate, up to 10 mg
J3010	Injection, fentanyl citrate, 0.1 mg
J3285	Injection, treprostinil, 1 mg
Category 2	
J-Code	Description
J1551 JB	Injection, immune globulin (cutaquig), 100mg
J1555 JB	Injection, immune globulin (cuvitru), 100 mg
J1558 JB	Injection, immune globulin (xembify), 100mg
J1559 JB	Injection, immune globulin (hizentra), 100mg
J1561 JB	Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (e.g. liquid), 500 mg
J1562 JB	Injection, immune globulin (vivaglobin), 100 mg
J1569 JB	Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg
J1575 JB	Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immune globulin
~~J7799 JB~~	~~This NOC code may be used to identify the subcutaneous immune globulin (cutaquig)~~
Category 3	
J-Code	Description
J9000	Injection, doxorubicin hydrochloride, 10 mg
J9039	Injection, blinatumomab, 1 microgram
J9040	Injection, bleomycin sulfate, 15 units
J9065	Injection, cladribine, per 1 mg
J9100	Injection, cytarabine, 100 mg
J9190	Injection, fluorouracil, 500 mg
J9360	Injection, vinblastine sulfate, 1 mg
J9370	Injection, vincristine sulfate, 1 mg

The payment category may be determined by the contractor for any new home infusion drug additionsto the Local Coverage Determination (LCD) for External Infusion Pumps as identified by the following not- otherwise-classified (NOC) codes:

- J7799 - Not otherwise classified drugs, other than inhalation drugs, administered through DME
- J7999 - Compoundeddrug, not otherwise classified

411.4 - Billing and Payment Requirements

(Rev. 10269, Issued: 08-07-2020, Effective: 01-01-2021, Implementation: 01-04-2021)

Contractors shall accept and pay for home infusion therapy services to eligible home infusion therapy suppliers (new specialty **D6**) effective for claim lines with dates of service on or after January 1, 2021 using the one of the following ‘G’ codes and applicable ‘J’ codes listed in section 411.3 of this chapter. Claims for the home infusion therapy service G-codes are billed to the A/B MACs and are payable to home infusion therapy suppliers; this service is no longer payable to DME suppliers. The applicable ‘J’ codes are billed to the DME MACs by the DME supplier.

Contractors shall use Type of Service (TOS) Code 1 for all six G-codes. Contractors shall pay only one of the G-codes per line item date of service when one of the drugs from the applicable category is billed with the same line item date of service or a date of service within 30 days prior to the G-code visit.

NOTE:

- The fees associated with the G-codes on the MPFSD fee file will be "a per day rate;" therefore, the units on the line should not be multiplied by the rate.
  The drug remains separately payable from the G-code line item

Home infusion therapy suppliers will report the following HCPCS G-codes associated with the payment categories for the professional services furnished in the individual's home and on an infusion drug administration calendar day.

Because the home infusion therapy services are contingent upon a home infusion drug J-code, home infusion therapy suppliers must ensure that the appropriate drug associated with the visit is billed no more than 30 days prior to the visit. In the event that multiple visits occur on the same date of service, or multiple drugs, which are not all assigned to the same payment category, are administered on the same infusion drug administration calendar day, a single payment would be made that is equal to the highest payment category. Suppliers must only bill for one visit and should report the highest paying visit with the applicable drug.

To differentiate the first visit from all subsequent visits, home infusion therapy suppliers may only bill one of the "initial visit" G-codes to indicate an visit for a new patient who had previously received their last home infusion therapy service visit more than 60 days prior to the new initial home infusion therapy service visit.

Home infusion therapy suppliers should report visit length in 15-minute increments (15 minutes=1 unit). See the Table 1 below for the rounding of units.

Table 1: Time Increments

Unit	Time
1	<23 minutes
2	= 23 minutes to <38 minutes
3	= 38 minutes to <53 minutes
4	= 53 minutes to <68 minutes
5	= 68 minutes to <83 minutes
6	= 83 minutes to <98 minutes
7	= 98 minutes to <113 minutes
8	= 113 minutes to <128 minutes
9	= 128 minutes to <143 minutes
10	= 143 minutes to <158 minutes

Table 2 shows the use of the G-codes established for the home infusion therapy benefit, and reflects the therapy type and complexity of the drug administration.

Table 2: Payment Categories for Home Infusion Therapy Professional Services (G-Codes)

	Category 1	**Category 2**	**Category 3**
Description **G-Code**	Intravenous anti-infective, pain management, chelation, pulmonary hypertension, inotropic, and other certain intravenous infusion drugs	Subcutaneous immunotherapy and other certain Subcutaneous infusion drugs	Chemotherapy and other certain highly complex intravenous drugs
Initial Visit	G0088	G0089	G0090
Subsequent Visit	G0068	G0069	G0070

- **G0068:** Professional services for the administration of anti-infective, pain management, chelation, pulmonary hypertension, inotropic, or other intravenous infusion drug or biological (excluding chemotherapy or other highly complex drug or biological) for each infusion drug administration calendar day in the individual's home, each 15 minutes

  Short Descriptor: Adm IV infusion drug in home

- **G0069:** Professional services for the administration of subcutaneous immunotherapy or other subcutaneous infusion drug or biological for each infusion drug administration calendar day in the individual's home, each 15 minutes

  Short Descriptor: Adm SQ infusion drug in home

- **G0070:** Professional services for the administration of intravenous chemotherapy or other intravenous highly complex drug or biological infusion for each infusion drug administration calendar day in the individual's home, each 15 minutes.

Short Descriptor: Adm of IV chemo drug in home

- **G0088:** Professional services, initial visit, for the administration of anti-infective, pain management, chelation, pulmonary hypertension, inotropic, or other intravenous infusion drug or biological (excluding chemotherapy or other highly complex drug or biological) for each infusion drug administration calendar day in the individual's home, each 15 minutes.

  Short Descriptor: Adm IV drug 1st home visit

- **G0089:** Professional services, initial visit, for the administration of subcutaneous immunotherapy or other subcutaneous infusion drug or biological for each infusion drug administration calendar day in the individual's home, each 15 minutes.

  Short Descriptor: Adm SubQ drug 1st home visit

- **G0090:** Professional services, initial visit, for the administration of intravenous chemotherapy or other highly complex infusion drug or biological for each infusion drug administration calendar day in the individual's home, each 15 minutes.

  Short Descriptor: Adm IV chemo 1st home visit

411.5 – Claim Adjustment Reason Codes, Remittance Advice Remark Codes, Group Codes, and Medicare Summary Notice Messages

(Rev. 10269, Issued: 08-07-2020, Effective: 01-01-2021, Implementation: 01-04-2021)

Contractors shall deny the CWF rejected claim if a new G-code is received for the same date of service as a previous claim was paid for the same line item date of service.

NOTE: The provider should submit an adjustment to the original claim to receive the higher payment.

Contractors shall use the following CARC/RARC codes when denying claims:

CARC 97 - The benefit for this service is included in the payment/allowance for another service/procedure that has already been adjudicated. Usage: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC N111 - No appeal right except duplicate claim/service issue. This service was included in a claim that has been previously billed and adjudicated.

Claim Adjustment Group Code - CO (Contractual Obligation)

MSN message: 41.14: This service/item was billed incorrectly. 41.14- Este servicio o artículo fue facturado incorrectamente.

Contractors shall deny the CWF rejected G-code line when the claim has recycled three times without finding the associated drug J-code claim and use the following messages:

CARC 16 - Claim/service lacks information or has submission/billing error(s). Usage: Do not use this code for claims attachment(s)/other documentation. At least one Remark Code must be provided (may be

comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.) Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC N657 - This should be billed with the appropriate code for these services. Claim Adjustment Group Code - CO (Contractual Obligation)

MSN message: 41.14: This service/item was billed incorrectly. 41.14- Este servicio o artículo fue facturado incorrectamente.

Contractors shall deny CWF rejected claims for more than one claim line service of G0088, G0089, or G0090 within a 60 day period and use the following messages:

CARC 96 - Non-covered charge(s). At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason [sic] Code, or Remittance Advice Remark Code that is not an ALERT.) Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC N640 - Exceeds number/frequency approved/allowed within time period.

Group Code - CO (Contractual Obligation)

411.6 – CWF and MCS Editing Requirements

(Rev. 10269, Issued: 08-07-2020, Effective: 01-01-2021, Implementation: 01-04-2021)

MCS shall create a new edit to identify when there is more than one of the following six HCPCS ‘G0068’, ‘G0069’ ‘G0070’, ‘G0088’, ‘G0089’, or ‘G0090’ with Date of Service on or after 1/1/2021 for the same Date of Service on the same Part B Professional claim.

CWF shall create a new reject for a Part B Professional claim with one of the following six HCPCS codes ‘G0068’, ‘G0069’ ‘G0070’, ‘G0088’, ‘G0089’, or ‘G0090’ with Date of Service on or after 1/1/2021 and there is no DME claim in history with one of the identified J-codes within 30 days prior to the incoming Date of Service.

NOTE: This edit shall have override capability at the claim detail line

CWF and contractors shall recycle ‘G0068’, ‘G0069’ ‘G0070’, ‘G0088’, ‘G0089’, or ‘G0090’ claim up to three times for a total of 15 days until a claim containing an allowable drug J-code from above is received with the same line item date of service or within 30 days prior to the line item date of service of the G-code.

CWF shall create a new reject for a Part B Professional claim with one of the following six ‘G0068’, ‘G0069’ ‘G0070’, ‘G0088’, ‘G0089’, or ‘G0090’ codes with a Date of Service on or after 1/1/2021 when there is a Part B claim in history with one of the identified six ‘G0068’, ‘G0069’ ‘G0070’, ‘G0088’, ‘G0089’, or ‘G0090’ codes for the same Date of Service.

NOTE: This edit shall have override capability at the claim detail line

CWF shall create a new reject for a Part B Professional claim with one of the new ‘G0088’, ‘G0089’, or ‘G0090’ codes and in history is an allowed DME or Part B Professional claim with any of the six ‘G0068’,

‘G0069’ ‘G0070’, ‘G0088’, ‘G0089’, or ‘G0090’ codes and the Dates of Service is within 60 days prior to the incoming claim’s Dates of Service. The incoming claim has Dates of Service on or after 1/1/2021.

CWF should still subject an incoming Part B Professional claim to the edit if it is within 60 days of posted DME claim, and if the claim in history is DME and has one of the three existing ‘G0068’, ‘G0069’ ‘G0070’ codes and has Dates of Service prior to 1/1/2021.

CWF shall create a new Informational Unsolicited Response (IUR) when a Part B Professional claim or a DME claim with one of the six ‘G0068’, ‘G0069’ ‘G0070’, ‘G0088’, ‘G0089’, or ‘G0090’ codes is received and in history is a Part B Professional claim with one of the three new ‘G0088’, ‘G0089’, or ‘G0090’ codes with Dates of Service within 60 days after the incoming claim’s Dates of Service.

CWF shall ensure that all new edits and the IUR appear on the ORPN Report.

412 – Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer’s Disease (AD) Policy and Overview

(Rev. 12649; Issued: 05-23-2024; Effective: 04-07-22) Implementation: 06-24-24)

Effective April 7, 2022, CMS covers Food and Drug Administration (FDA)-approved monoclonal antibodies directed against amyloid for the treatment of Alzheimer’s Disease (AD) when furnished in accordance with the coverage criteria below, under coverage with evidence development (CED) for patients who have a clinical diagnosis of mild cognitive impairment (MCI) due to AD or mild AD dementia, both with confirmed presence of amyloid beta pathology consistent with AD. For further information related to coverage, refer to Publication 100-03, National Coverage Determination (NCD) Section 200.3

412.1 - Coding Information

(Rev. 12649; Issued: 05-23-2024; Effective: 04-07-22) Implementation: 06-24-24)

- ICD-10 diagnosis code Z00.6, along with one of the following additional diagnosis codes: G30.0, G30.1, G30.8, G30.9, G31.84, the Q0 or Q1 modifier, and condition code 30 (for institutional claims only).

- Procedure code HCPCS J0174, Injection, lecanemab-irmb, 1 mg, (Leqembi®), OR,

- Procedure code HCPCS J3490 or J3590 or C9399 (for an FDA-approved therapy that is covered under NCD 200.3 that hasn’t received a dedicated HCPCS code), OR,

- Dedicated HCPCS code for any future FDA-approved therapies covered under NCD 200.3 (a subsequent instruction would follow),

- National Clinical Trial (NCT) number consisting of 8 digits, OR,

- Default NCT number 99999999.

412.2 - Claims Processing Instructions

(Rev. 12649; Issued: 05-23-2024; Effective: 04-07-22) Implementation: 06-24-24)

Effective for claims with dates of service on or after April 7, 2022, contractors shall accept and pay for claims for monoclonal antibodies for the treatment of AD with an appropriate HCPCS, along with one of the diagnosis codes listed in Section 412.1 and condition code 30 (institutional claims only).

The following bill types are applicable for claims for monoclonal antibodies for the treatment of AD:

- 012X, 013X, or 085X.

412.3 - Messaging
(Rev. 12649; Issued: 05-23-2024; Effective: 04-07-22) Implementation: 06-24-24)

--Contractors shall return to provider/return as unprocessable any monoclonal antibody claims that do not include an NCT number as indicated in 412.1 and use the following messages:

CARC 16 - Claim/service lacks information or has submission/billing error(s).

RARC MA50 – Missing/incomplete/invalid Investigational Device Exemption number or Clinical Trial number

Group Code: CO

---Contractors shall deny any monoclonal antibody claims that do not have the specified diagnosis codes listed in 412.1 and use the following messages:

MSN 15.20 - “The following polices were used when we made this decision: NCD 200.3.”

Spanish Version – “Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 200.3.”

NOTE: Due to system requirement, the Fiscal Intermediary Shared System (FISS) has combined messages 15.19 and 15.20 so that, when used for the same line item, both messages will appear on the same MSN.

CARC 96 – Non-covered charge(s). At least one Remark Code must be provided (May be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT).

RARC N386 – This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered.

Group Code - CO or PR

---Contractors shall return to provider/return as unprocessable any monoclonal antibody claims that do not have the specified modifiers listed in Section 412.1 and use the following messages:

CARC 16 - Claim/service lacks information or has submission/billing error(s).

RARC N823 – Incomplete/invalid Procedure Modifier(s).

Group Code: CO

--Contractors shall deny claims from any bill type other than those listed 412.1 and use the following messages:

MSN 9.4 - This item or service was denied because information required to make payment was incorrect.

Spanish Version: Este servicio fue denegado debido a que la información requerida para hacer el pago fue incorrecta.

CARC 16 - Claim/service lacks information or has submission/billing error(s).

RARC MA30 - Missing/incomplete/invalid type of bill.

Group Code: CO

413 –Noninvasive Positive Pressure Ventilation (NIPPV) in the Home for the Treatment of Chronic Respiratory Failure (CRF) Consequent to Chronic Obstructive Pulmonary Disease (COPD)

(Rev. 13611; Issued: 01-30-26; Effective: 06-09-25; Implementation: 10-22-25)

Respiratory Assist Devices (RADs) with bi-level capability, with or without a backup rate feature, are devices that use a non-invasive interface (mask) to deliver a higher level of airway pressure when the patient inhales than when the patient exhales. A backup rate feature enables the device to provide a prespecified respiratory rate if the patient's spontaneous respiratory rate decreases below a set number.

A home mechanical ventilator (HMV) delivers a predetermined amount of air with each breath and typically has more monitoring, safety, alarm and backup power features (batteries) than a RAD.

413.1 – Coverage

(Rev. 13611; Issued: 01-30-26; Effective: 06-09-25; Implementation: 10-22-25)

Effective for services performed on or after June 9, 2025, the Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is sufficient to cover RADs, with or without a backup rate feature and HMVs, in the home, to deliver high intensity noninvasive ventilation (NIV) as treatment for patients with chronic respiratory failure (CRF) consequent to chronic obstructive pulmonary disease (COPD) as long as certain patient criteria is met.

Note: This CR does not contain coding and billing instructions for masks.

Please refer to the National Coverage Determinations Manual (Publication, 100-03, Section 240.9 for coverage criteria, frequency, and more information.

413.2 Claims Processing Instructions

(Rev. 13611; Issued: 01-30-26; Effective: 06-09-25; Implementation: 10-22-25)

Effective for claims with dates of service on and after June 9, 2025, contractors shall pay claims for RADs with or without a backup rate feature and HMVs, in the home, as treatment for patients with CRF consequent to COPD under the conditions and coverage criteria outlined in Pub. 100-03, Medicare NCD Manual, Chapter 1, Section 240.9.

RAD:

Contractors shall allow NIPPV claims submitted with HCPCS code E0470 or E0471 with KX modifier.

NOTE: All national ICD-10 diagnosis codes shall be managed locally by the MACs.

HMV:

Contractors shall allow NIPPV claims submitted with HCPCS code E0466, E0467, or E0468.

For the multifunction ventilators (E0467 and E0468), a beneficiary would need to meet the ventilator criteria plus the criteria for one of the other functions for coverage.

NOTE: All national ICD-10 diagnosis codes shall be managed locally by the MACs.

Patients must be evaluated at least twice within the first year after initially receiving a RAD or HMV. Evaluations must occur by the end of the six-month initial coverage period and again during months 7-12.

414 – Transcatheter Tricuspid Valve Replacement (TTVR)

(Rev. 13800; Issued:05-28-26; Effective: 03-19-25; Implementation: 01-05-26)

The Centers for Medicare & Medicaid Services (CMS) covers transcatheter tricuspid valve replacement (TTVR) for the treatment of symptomatic tricuspid regurgitation (TR) under Coverage with Evidence Development (CED) according to the criteria outlined in IOM, Pub. 100-03, National Coverage Determination Manual, Ch 1, section 20.37.

414.1 - Coding Requirements for TTVR

(Rev. 13800; Issued:05-28-26; Effective: 03-19-25; Implementation: 01-05-26)

The following codes are applicable for TTVR:

ICD-10-PCS codes X2RJ3RA - Replacement of Tricuspid Valve with Multi-plane Flex Technology Bioprosthetic Valve, Percutaneous Approach, New Technology Group 10 and 02RJ38Z – Replace tricuspid valve with zooplastic tissue, percutaneous approach CPT code 0646T - Transcatheter tricuspid valve implantation (TTVI)/replacement with a prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed ICD-10 diagnosis codes:

- I07.1

- I07.2
- I08.1
- I08.2
- I08.3
- I36.1
- I36.2
- Q22.8
- Z00.6

414.2 – Claims Processing Instructions for TTVR Professional Claims
(Rev. 13800; Issued:05-28-26; Effective: 03-19-25; Implementation: 01-05-26)

Professional claims for TTVR in a clinical research study shall be covered when billed with:

- HCPCS code 0646T,
- ICD-10 Z00.6 (as other diagnosis code),
- the 8-digit clinical trial identifier number,
- One of the ICD-10 diagnosis codes listed in section 414.1 as principal diagnosis code
- Modifier Q0,

414.3 – Claims Processing Instructions for TTVR Institutional Claims
(Rev. 13800; Issued:05-28-26; Effective: 03-19-25; Implementation: 01-05-26)

Inpatient hospitals shall bill for TTVR on an 11X Type of Bill (TOB).

Inpatient hospital claims for TTVR shall be covered when billed with:

- ICD-10-PCS code X2RJ3RA or 02RJ38Z,
- ICD-10 Z00.6 (as other diagnosis code),
- Condition Code 30,
- Value Code D4 to indicate the 8-digit clinical trial identifier number, and
- One of the ICD-10 diagnosis codes listed in section 414.1 as principal diagnosis code

NOTE: When submitting claims for TTVR provided to Medicare Advantage enrollees, hospitals also report condition code 04. Medicare Advantage Organizations are responsible for payment of the service, consistent with Pub. 100-16, chapter 4, section 10.7.3.

414.4 – Messages
(Rev. 13800; Issued:05-28-26; Effective: 03-19-25; Implementation: 01-05-26)

- Contractors shall use the following messages when denying claims for TTVR submitted with missing/incorrect ICD-10 diagnosis code (I07.1, I07.2, I08.1, I08.2, I08.3, I36.1, I36.2, Q22.8 and Z00.6):

Claim Adjustment Reason Code (CARC) 167: This (these) diagnosis(es) is (are) not covered.
Remittance Advice Remark Code (RARC) N386: This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Group Code (GC) – CO (Contractual Obligation) or PR (Patient Responsibility) dependent upon liability. Use PR when:

- On institutional claims, Occurrence Code 32 is present, and the GA modifier is not present on any lines on the claim.
- On institutional claims, Occurrence Code 32 is present, and the GA modifier is appended to the line item with HCPCS 0646T.
- On professional claims, the GA modifier is appended to the line item with HCPCS 0646T.

Medicare Summary Notice (MSN) 15.20: The following policies were used when we made this decision: NCD 20.37.

Spanish Version – Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 20.37.

Contractors shall Return to Provider (RTP) claims for TTVR submitted on TOB other than 11X, or when submitted without condition code 30, or submitted without value code D4 and the 8-digit National Clinical Trial (NCT).

Contractors shall return as unprocessable line-items on claims containing HCPCS code 0646T in a clinical research study when billed without modifier Q0 using the following messages:

CARC 4: The procedure code is inconsistent with the modifier used.

RARC N519: Invalid combination of HCPCS modifiers.

Group Code: CO

Contractors shall return as unprocessable line-items of claims containing HCPCS code 0646T in a clinical research study when billed without the clinical trial number using the following messages:

CARC 16: Claim/service lacks information or has submission/billing error(s).

RARC MA50: Missing/incomplete Investigational Device Exemption number or clinical trial number.

Group Code: CO

415 – T-TEER
(Rev. 13801; Issued: 05-28-26; Effective: 07-02-25; Implementation: 01-05-26)

The Centers for Medicare & Medicaid Services (CMS) covers T-TEER for the treatment of symptomatic tricuspid regurgitation (TR) under Coverage with Evidence Development (CED) according to the criteria outlined in IOM, Pub. 100-03, National Coverage Determination Manual, Ch 1, section 20.38.

415.1 - Coding Requirements for T-TEER
(Rev. 13801; Issued: 05-28-26; Effective: 07-02-25; Implementation: 01-05-26)

The following codes are applicable for T-TEER:

ICD-10-PCS codes 02UJ3JZ (Supplement tricuspid valve with Synthetic Substitute, Percutaneous approach)
Healthcare Common Procedure Coding System (HCPCS) code 0569T (Transcatheter tricuspid valve repair, percutaneous approach; initial prosthesis) or 0570T (Each additional prosthesis during same session (List separately in addition to code for primary procedure)) ICD-10 diagnosis codes:

- I07.1
- I07.2
- I08.1
- I08.2
- I08.3
- I36.1
- I36.2
- Q22.8 and,

Z00.6 (reported as other diagnosis)

415.2 – Claims Processing Instructions for T-TEER Professional Claims
(Rev. 13801; Issued: 05-28-26; Effective: 07-02-25; Implementation: 01-05-26)

Professional claims for T-TEER in a clinical research study shall be covered when billed with:

- HCPCS code 0569T or 0570T
- ICD-10 Z00.6 (as other diagnosis code),
- the 8-digit clinical trial identifier number,
- One of the ICD-10 diagnosis codes listed in section 415.1 as principal diagnosis code
- Modifier Q0

415.3 – Claims Processing Instructions for T-TEER Institutional Claims
(Rev. 13801; Issued: 05-28-26; Effective: 07-02-25; Implementation: 01-05-26)

Inpatient hospitals shall bill for T-TEER on an 11X Type of Bill (TOB).

Inpatient hospital claims for T-TEER shall be covered when billed with:

- ICD-10-PCS code 02UJ3JZ,
- ICD-10 Z00.6 (as other diagnosis code),
- Condition Code 30,
- Value Code D4 to indicate the 8-digit clinical trial identifier number, and
- One of the ICD-10 diagnosis codes listed in section 415.1 as principal diagnosis code

NOTE: When submitting claims for T-TEER provided to Medicare Advantage enrollees, hospitals also report condition code 04. Medicare Advantage Organizations are responsible for payment of the service, consistent with Pub. 100-16, chapter 4, section 10.7.3.

415.4 – Messages
(Rev. 13801; Issued: 05-28-26; Effective: 07-02-25; Implementation: 01-05-26)

Contractors shall use the following messages when denying claims for T-TEER submitted with missing/incorrect ICD-10 diagnosis code (I07.1, I07.2, I08.1, I08.2, I08.3, I36.1 I36.2, Q22.8 and Z00.6): CARC 167 – This (these) diagnosis(es) is (are) not covered.

RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at: www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Group Code – CO (Contractual Obligation) or PR (Patient Responsibility) dependent upon liability. Use PR when:

- On institutional claims, Occurrence Code 32 is present
- On professional claims, the GA modifier is appended to a line item with HCPCS 0569T or 0570T.

MSN 15.20: “The following policies were used when we made this decision: NCD 20.38”.

Spanish Version – “Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 20.37”.

Contractors shall Return to Provider (RTP) claims for T-TEER submitted on TOB other than 11X, or when submitted without condition code 30, or submitted without value code D4 and the 8-digit National Clinical Trial (NCT).

Contractors shall return as unprocessable line-items on claims containing HCPCS 0569T or 0570T code in a clinical research study when billed without modifier Q0 using the following messages:

CARC 4: The procedure code is inconsistent with the modifier used.

RARC N519: Invalid combination of HCPCS modifiers.

Group Code: CO (Contractual Obligation)

Contractors shall return as unprocessable line-items of claims containing HCPCS code 0569T or 0570T in a clinical research study when billed without the clinical trial number using the following messages:

CARC 16: Claim/service lacks information or has submission/billing error(s).

RARC MA50: Missing/incomplete/invalid Investigational Device Exemption number or clinical trial number.

Group Code: CO (Contractual Obligation)

416 –Noninvasive Positive Pressure Ventilation (NIPPV) in the Home for the Treatment of Chronic Respiratory Failure (CRF) Consequent to Chronic Obstructive Pulmonary Disease (COPD)

(Rev. 13808; Issued:05-29-26; Effective: 06-09-25; Implementation: 10-22-25)

Respiratory Assist Devices (RADs) with bi-level capability, with or without a backup rate feature, are devices that use a non-invasive interface (mask) to deliver a higher level of airway pressure when the patient inhales than when the patient exhales. A backup rate feature enables the device to provide a prespecified respiratory rate if the patient's spontaneous respiratory rate decreases below a set number.

A home mechanical ventilator (HMV) delivers a predetermined amount of air with each breath and typically has more monitoring, safety, alarm and backup power features (batteries) than a RAD.

416.1 Coverage

(Rev. 13808; Issued:05-29-26; Effective: 06-09-25; Implementation: 10-22-25)

Effective for services performed on or after June 9, 2025, the Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is sufficient to cover RADs, with or without a backup rate feature and HMVs, in the home, to deliver noninvasive ventilation (NIV) as treatment for patients with chronic respiratory failure (CRF) consequent to chronic obstructive pulmonary disease (COPD) as long as certain patient criteria is met.

Note: This CR does not contain coding and billing instructions for masks.

Please refer to the National Coverage Determinations Manual (Publication, 100-03, Section 240.9 for coverage criteria, frequency, and more information.

416.2 – Claims Processing Instructions

(Rev. 13808; Issued:05-29-26; Effective: 06-09-25; Implementation: 10-22-25)

Effective for claims with dates of service on and after June 9, 2025, contractors shall pay claims for RADs with or without a backup rate feature and HMVs, in the home, as treatment for patients with CRF consequent to COPD under the conditions and coverage criteria outlined in Pub. 100-03, Medicare NCD Manual, Chapter 1, Section 240.9.

RAD:

Contractors shall allow NIPPV claims submitted with HCPCS code E0470 or E0471 with KX modifier.

NOTE: All national ICD-10 diagnosis codes shall be managed locally by the MACs.

HMV:

Contractors shall allow NIPPV claims submitted with HCPCS code E0466, E0467, or E0468.

For the multifunction ventilators (E0467 and E0468), a beneficiary would need to meet the ventilator criteria plus the criteria for one of the other functions for coverage.

NOTE: All national ICD-10 diagnosis codes shall be managed locally by the MACs.

Patients must be evaluated at least twice within the first year after initially receiving a RAD or HMV. Evaluations must occur by the end of the six-month initial coverage period and again during months 7-12.

417 Renal Denervation (RDN) for Uncontrolled Hypertension – Coverage
(Rev. 13802; Issued: 05-28-26; Effective: 10-28-25; Implementation: 04-06-26)

Effective for claims with dates of service on or after October 28, 2025, the Centers for Medicare & Medicaid Services (CMS) covers radiofrequency renal denervation (rfRDN) and ultrasound renal denervation (uRDN) (collectively, RDN) for uncontrolled hypertension under Coverage with Evidence Development (CED). Refer to the criteria outlined in Publication 100-03, Chapter 1, section 20.40.

417. 1 Coding Requirements:
(Rev. 13802; Issued: 05-28-26; Effective: 10-28-25; Implementation: 04-06-26)

Type of Bill (TOB) 11X

International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) codes:

- X051329: Destruction of Renal Sympathetic Nerve(s) using Ultrasound Ablation, Percutaneous Approach, New Technology Group 9

Note: Recor Medical's Paradise® Ultrasound Renal Denervation

- X05133A: Destruction of Renal Sympathetic Nerve(s) using Radiofrequency Ablation, Percutaneous Approach, New Technology Group 10

Note: Medtronic's Symplicity Spyral™ Renal Denervation System, and

- ICD-10-CM diagnosis Z00.6 (reported as other diagnosis), and
- Value code D4 with the 8-digit National Clinical Trial (NCT), and
- Condition code 30, and 04 (if appropriate)

ICD-10-CM diagnosis is one of the following:

- I10:Essential (primary) hypertension
- I11.0:Hypertensive heart disease with heart failure
- I11.9:Hypertensive heart disease without heart failure
- I12.0:Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage renal disease
- I12.9:Hypertensive chronic kidney disease with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
- I13.0:Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
- I13.10:Hypertensive heart and chronic kidney disease without heart failure, with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
- I13.11:Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease, or end stage renal disease
- I13.2:Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
- I15.0:Renovascular hypertension
- I15.1:Hypertension secondary to other renal disorders
- I15.2:Hypertension secondary to endocrine disorders
- I15.8:Other secondary hypertension
- I15.9:Secondary hypertension, unspecified
- I16.0:Hypertensive urgency
- I16.1:Hypertensive emergency
- I16.9:Hypertensive crisis, unspecified
- I1A.0:Resistant hypertension

Please note:

ICD-10-CM classifies hypertension by type as essential or primary (categories I10-I13), secondary (category I15), hypertensive crisis (category I16), and resistant (category I1A).
ICD-10-CM does not distinguish between controlled vs. uncontrolled hypertension.

TOB 13X and Professional Claims:

CPT Codes:

0338T :Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; unilateral

0339T :Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; bilateral

Professional Claims only:

0935T :Cystourethroscopy with renal pelvic sympathetic denervation, radiofrequency ablation, retrograde ureteral approach, including insertion of guide wire, selective placement of ureteral sheath(s) and multiple conformable electrodes, contrast injection(s), and fluoroscopy, bilateral

HCPCS Codes:

C1735:Catheter(s), intravascular for renal denervation, radiofrequency, including all single use system components

Note: Device code for Medtronic's Symplicity Spyral™ Renal Denervation System

C1736:Catheter(s), intravascular for renal denervation, ultrasound, including all single use system components

Note: Device code for Recor Medical's Paradise® Ultrasound Renal Denervation

417.2 – Special Intermediary Claims Processing Requirements
(Rev. 13802; Issued: 05-28-26; Effective: 10-28-25; Implementation: 04-06-26)

Contractors shall Return to Provider (RTP) RDN claims when TOB is not equal to 11X or 13X.

417.3 – Special Professional Billing Requirements
(Rev. 13802; Issued: 05-28-26; Effective: 10-28-25; Implementation: 04-06-26)

Contractors shall allow claims with place of service (POS) = 19, 21, 22, or 24. Claims with any other POS shall be returned as unprocessable.

417.4 – Messaging
(Rev. 13802; Issued: 05-28-26; Effective: 10-28-25; Implementation: 04-06-26)

Contractors shall return as unprocessable claims for RDN services when services were billed in other than Place of Service (POS) 19, 21, 22 or 24 and use the following messages:

CARC 58: Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service.

Remittance Advice Remark Code (RARC) N386: "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service

is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Group Code: CO

Contractors shall deny RDN claims not submitted with the following ICD-10-CM DX as a diagnosis listed in Section 415.1 and use the following messages:

Claim Adjustment Reason Code (CARC) 167: “This (these) diagnosis(es) is (are) not covered".

Remittance Advice Remark Code (RARC) N386: “This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Group Code – CO (Contractual Obligation) or PR (Patient Responsibility) dependent upon liability.

Use PR when:

- On institutional claims, Occurrence Code 32 is present.

Medicare Summary Notice (MSN) 15.20: “The following policies were used when we made this decision: NCD 20.40”.

Spanish Version – “Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 20.40

Contractors shall return as unprocessable line-items on claims in a clinical research study when billed without the clinical trial number using the following messages:

CARC 16: Claim/service lacks information or has submission/billing error(s).

RARC MA50: Missing/incomplete/invalid Investigational Device Exemption number or clinical trial number.

Group Code: CO

Contractors shall return as unprocessable line-items on claims containing one of the CPT or HCPCS codes mentioned in Section 415.1 when billed without modifier Q0 using the following messages:
CARC 4: The procedure code is inconsistent with the modifier used.
RARC N519: Invalid combination of HCPCS modifiers.
Group Code:CO

Contractors shall deny RDN claims not submitted with the following ICD-10-CM DX as diagnosis

- I10
- I11.0
- I11.9
- I12.0
- I12.9
- I13.0
- I13.10
- I13.11
- I13.2
- I15.0:
- I15.1
- I15.2

- I15.8
- I15.9
- I16.0
- I16.1
- I16.9
- I1A.0 and

Z00.6 (reported as other diagnosis)

Contractors shall use the following messages when denying claims:

Claim Adjustment Reason Code (CARC) 167: “This (these) diagnosis(es) is (are) not covered".

Remittance Advice Remark Code (RARC) N386: “This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Group Code – CO (Contractual Obligation) or PR (Patient Responsibility) dependent upon liability.

Use PR when:

- On institutional claims, Occurrence Code 32 is present.

Medicare Summary Notice (MSN) 15.20: “The following policies were used when we made this decision: NCD 20.40”.

Spanish Version – “Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 20.40

418 - Cardiac Contractility Modulation (CCM) for Heart Failure (HF)

(Rev. 13806, Issued: 05-28-26, Effective: 10-28- 25, Implementation: 04- 06-26)

Effective October 28, 2025, the Centers for Medicare & Medicaid Services (CMS) covers CCM used for the treatment of HF under Coverage with Evidence Development (CED) according to the criteria outlined in NCD manual, chapter 1, section 20.39. Consistent with section 1142 of the Act, AHRQ supports clinical research studies that CMS determines meet all the criteria and standards identified above.

CCM used for the treatment of HF is not covered for patients outside of a CMS-approved study.

418.1 Coding Requirements for Cardiac Contractility Modulation (CCM) for Heart Failure (HF)

(Rev. 13806, Issued: 05-28-26, Effective: 10-28- 25, Implementation: 04- 06-26)

The following CPT codes are applicable for CCM:

Insertion/Replacement procedures
0408T - Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator with transvenous electrodes

0409T- Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator only

0410T- Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; atrial electrode only

0411T- Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; ventricular electrode only

Removal procedures

0412T-Removal of permanent cardiac contractility modulation system; pulse generator only

0413T- Removal of permanent cardiac contractility modulation system; transvenous electrode (atrial or ventricular)

0414T- Removal and replacement of permanent cardiac contractility modulation system pulse generator only

Repositioning procedures

0415T- Repositioning of previously implanted cardiac contractility modulation transvenous electrode (atrial or ventricular lead)

0416T- Relocation of skin pocket for implanted cardiac contractility modulation pulse generator

Programming procedures

0417T- Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, including review and report, implantable cardiac contractility modulation system

0418T- Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, implantable cardiac contractility modulation system

The following PCS codes are applicable for insertion/replacement for CCM:

0JH60AZ- Insertion of Contractility Modulation Device into Chest Subcutaneous Tissue and Fascia, Open Approach

0JH63AZ- Insertion of Contractility Modulation Device into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach

0JH80AZ- Insertion of Contractility Modulation Device into Abdomen Subcutaneous Tissue and Fascia, Open Approach

0JH83AZ- Insertion of Contractility Modulation Device into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach

02H63MZ- Insertion of cardiac lead into right atrium, percutaneous approach (when specified as a lead for a contractility modulation device)

02HK3MZ- Insertion of cardiac lead into right ventricle, percutaneous approach (when specified as a lead for a contractility modulation device)

The following HCPCS codes are applicable for CCM:

C1824- Generator, cardiac contractility modulation (implantable)

C1898- Lead, pacemaker, other than transvenous VDD single pass

NOTE: HCPCS codes C 1824 and C1898 are not separately paid, as the payment is packaged and considered part of the eligible comprehensive procedure.

K1030- External recharging system for battery (internal) for use with implanted cardiac contractility modulation generator, replacement only. Contractors shall establish local fee schedule amounts to pay claims for HCPCS K1030, when applicable.

The following ICD-10-CM diagnosis codes are applicable for CCM:

I50.1- Left ventricular failure, unspecified
I50.20- Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.21- Acute systolic (congestive) heart failure
I50.22- Chronic systolic (congestive) heart failure
I50.23- Acute on chronic systolic (congestive) heart failure
I50.30- Unspecified diastolic (congestive) heart failure
I50.31- Acute diastolic (congestive) heart failure
I50.32- Chronic diastolic (congestive) heart failure
I50.33- Acute on chronic diastolic (congestive) heart failure
I50.40- Unspecified combined systolic (congestive and diastolic (congestive) heart failure
I50.41- Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42- Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43- Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.810- Right heart failure, unspecified
I50.811- Acute right heart failure
I50.812- Chronic right heart failure
I50.813- Acute on chronic right heart failure
I50.814- Right heart failure due to left heart failure
I50.82- Biventricular heart failure
I50.83- High output heart failure
I50.84- End stage heart failure
I50.89- Other heart failure
I50.9- Heart failure, unspecified

Z00.6- encounter for examination for normal comparison and control in a clinical research program (reported as other diagnosis)

418.2 Claims Processing Instructions for Cardiac Contractility Modulation (CCM) for Heart Failure (HF) Professional Claims

(Rev. 13806, Issued: 05-28-26, Effective: 10-28- 25, Implementation: 04- 06-26)

Professional claims for CCM in a clinical research study shall be covered when billed with:

- one of the HCPCS/CPT codes listed in section 418.1
- one of the ICD-10 diagnosis codes listed in section 418.1
- ICD-10 Z00.6 (as other diagnosis code)
- Place of Service 11, 19, 21, 22, 24, 26, 71, or 72
- the 8-digit clinical trial identifier number
- Modifier Q0

418.3 Claims Processing Instructions for Cardiac Contractility Modulation (CCM) for Heart Failure (HF) Institutional Claims

(Rev. 13806, Issued: 05-28-26, Effective: 10-28- 25, Implementation: 04- 06-26)

Institutional claims for CCM in a clinical research study shall be covered when billed with:

- TOB 11X
- one of the PCS codes listed in section 418.1
- one of the ICD-10 diagnosis codes listed in section 418.1
- ICD-10 Z00.6 (as other diagnosis code)
- Condition code 30
- Value Code D4 to indicate the 8-digit clinical trial identifier number

OR

- 012X, 013X, or 085X; and
- one of the CPT codes listed in section 418.1
- one of the HCPCS codes listed in section 418.1
- Value code D4 with the 8-digit with the NCT number, and
- Condition code 30 (claim level) or modifier Q0 (line level), and
- ICD-10-CM diagnosis Z00.6 (as other diagnosis), and
- One of the ICD-10-CM diagnosis codes listed in section 418.1 (as principal diagnosis)

418.4 Messages

(Rev. 13806, Issued: 05-28-26, Effective: 10-28- 25, Implementation: 04- 06-26)

Contractors shall use the following messages when denying CCM claims submitted with missing/incorrect ICD-10 diagnosis code:

Claim Adjustment Reason Code (CARC) 167: “This (these) diagnosis(es) is (are) not covered".

Remittance Advice Remark Code (RARC) N386: “This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Group Code – CO (Contractual Obligation) or PR (Patient Responsibility) dependent upon liability.

Use PR when:

- On institutional claims, Occurrence Code 32 (claim level) is present. Modifier Q0 (line level).

Medicare Summary Notice (MSN) 15.20: “The following policies were used when we made this decision: NCD 20.39”.

Spanish Version – “Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 20.39.

Contractors shall return as unprocessable line-items on CCM claims in a clinical research study when billed without the clinical trial number using the following messages:

CARC 16: Claim/service lacks information or has submission/billing error(s).

RARC MA50: Missing/incomplete/invalid Investigational Device Exemption number or clinical trial number.

Group Code: CO

Contractors shall return as unprocessable line-items on CCM claims containing one of the CPT or HCPCS codes mentioned in Section 415.1 when billed without modifier Q0 using the following messages:

CARC 4: The procedure code is inconsistent with the modifier used.

RARC N519: Invalid combination of HCPCS modifiers.

Group Code: CO

Contractors shall return as unprocessable claims for CCM services when services were billed in other than Place of Service (POS) 11, 19, 21, 22, 24, 26, 71, or 72 and use the following messages:

CARC 58: Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service.

Remittance Advice Remark Code (RARC) N386: “This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Group Code: CO

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R13808CP	05/29/2026	Noninvasive Positive Pressure Ventilation (NIPPV) in the Home for the Treatment of Chronic Respiratory Failure (CRF) Consequent to Chronic Obstructive Pulmonary Disease (COPD)	10/22/2025	14177
R13806CP	05/28/2026	Cardiac Contractility Modulation (CCM) for Heart Failure (HF)	04/06/2026	14311
R13802CP	05/28/2026	NCD 20.40- Renal Denervation (RDN) for Uncontrolled Hypertension	04/06/2026	14302
R13801CP	05/28/2026	NCD 20.38 - Transcatheter Edge-to-Edge Repair for Tricuspid Valve Regurgitation (T-TEER)	01/05/2026	14200
R13800CP	05/28/2026	NCD 20.37 - Transcatheter Tricuspid Valve Replacement (TTVR)	01/05/2026	14149
R13756CP	05/29/2026	Noninvasive Positive Pressure Ventilation (NIPPV) in the Home for the Treatment of Chronic Respiratory Failure (CRF) Consequent to Chronic Obstructive Pulmonary Disease (COPD)- Rescinded and replaced by transmittal 13808	10/22/2025	14177
R13716CP.	04/03/2026	Cardiac Contractility Modulation (CCM) for Heart Failure (HF)- Rescinded and replaced by transmittal 13806	04/06/2026	14311
R13709CP	04/02/2026	Update to the Internet Only Manual (IOM) Publication 100-04, Chapter 18, Section 170.1 and Chapter 32, sections 330.1 and 330.2 for Updates in Change Request (CR) 14356 - International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs)- July 2026	06/02/2026	14430
R13695CP	03/09/2026	NCD 20.40- Renal Denervation (RDN) for Uncontrolled Hypertension- Rescinded and replaced by transmittal 13802	04/06/2026	14302
R13672CP	03/09/2026	Cardiac Contractility Modulation (CCM) for Heart Failure (HF) Rescinded and replaced by transmittal 13716	04/06/2026	14311

Rev #	Issue Date	Subject	Impl Date	CR#
R13640CP	02/13/2026	NCD 20.40- Renal Denervation (RDN) for Uncontrolled Hypertension- Rescinded and replaced by transmittal 13695	04/06/2026	14302
R13641CP	02/13/2026	Update to Claims Processing Instructions for National Coverage Determination (NCD) 20.4 Implantable Cardiac Defibrillators (ICDs)-	04/06/2026	14253
R13612CP	01/30/2026	NCD 20.40- Renal Denervation (RDN) for Uncontrolled Hypertension- Rescinded and replaced by transmittal 13640	04/06/2026	14302
R13611CP	1/30/2026	Noninvasive Positive Pressure Ventilation (NIPPV) in the Home for the Treatment of Chronic Respiratory Failure (CRF) Consequent to Chronic Obstructive Pulmonary Disease (COPD)	10/22/2025	14177
R13608CP	01/26/2026	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 32, Sections 150.4, 150.6, 200.2, 300.2, 400.2, 400.2.2, 400.2.3, 400.2.3.1, 400.2.4, and 400.3 for Coding Revisions to National Coverage Determinations (NCDs) - July 2025 Change Request (CR) 13939	08/25/2025	14108
R13538CP	12/19/2025	Cardiac Contractility Modulation (CCM) for Heart Failure (HF) Rescinded and replaced by transmittal 13672	04/06/2026	14311
R13551CP	12/19/2025	Updates to the Internet Only Manual (IOM) Publication 100-04, Chapter 32, Sections 69.1, 69.6 and 69.9 to Clarify Requirements for Clinical Trial Services	01/21/2026	14268
R13549CP	12/18/2025	Update to the Internet Only Manual (IOM) Publication 100-04, Chapter 18, Sections 150.1, 150.2.1, 150.3 and Chapter 32, Sections 12.1, 12.3, 320.3.3, 400.2.2, 400.2.3 and 400.2.3.1 for Coding Revisions to National Coverage Determina150.tion (NCDs) - October 2025 Change Request (CR) 14041	01/20/2026	14267
R13483CP	12/05/2025	Update to Claims Processing Instructions for National Coverage Determination (NCD) 20.4 Implantable Cardiac Defibrillators (ICDs)- Rescinded and replaced by Transmittal 13641	04/06/2026	14253

Rev #	Issue Date	Subject	Impl Date	CR#
R13427CP	09/22/2025	NCD 20.37 - Transcatheter Tricuspid Valve Replacement (TTVR)- Rescinded and replaced by transmittal 13800	01/05/2026	14149
R13374CP	08/21/2025	Noninvasive Positive Pressure Ventilation (NIPPV) in the Home for the Treatment of Chronic Respiratory Failure (CRF) Consequent to Chronic Obstructive Pulmonary Disease (COPD)- Rescinded and replaced by transmittal 13611	10/22/2025	14177
R13366CP	08/14/2025	NCD 20.38 - Transcatheter Edge-to-Edge Repair for Tricuspid Valve Regurgitation (T-TEER)- Rescinded and replaced by transmittal 13801	01/05/2026	14200
R13343CP	07/30/2025	NCD 20.37 - Transcatheter Tricuspid Valve Replacement (TTVR)- Rescinded and replaced by transmittal 13427	01/05/2026	14149
R13317CP	07/24/2025	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 32, Sections 150.4, 150.6, 200.2, 300.2, 400.2, 400.2.2, 400.2.3, 400.2.3.1, 400.2.4, and 400.3 for Coding Revisions to National Coverage Determinations (NCDs) - July 2025 Change Request (CR) 13939-- Rescinded and replaced by transmittal 13608	08/25/2025	14108
R13304CP	07/15/2025	Technical Revisions Only to the Claims Processing Manual (CPM), Publication (Pub) 100-04, Chapter 18 and Chapter 32	06/23/2025	14070
R13282CP	06/20/2025	National Coverage Determination (NCD) 20.36 Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management	10/06/2025	14000
R13246CP	05/22/2025	National Coverage Determination (NCD) 20.36 Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management- Rescinded and replaced by transmittal 13282	10/06/2025	14000
R13243CP	05/22/2025	Technical Revisions Only to the Claims Processing Manual (CPM), Publication (Pub) 100-04, Chapter 18 and Chapter 32-	06/23/2025	14070
R12883CP	10/11/2024	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 18	01/16/2025	13804

Rev #	Issue Date	Subject	Impl Date	CR#
		Section 170.1 and Chapter 32 Section 340.2 for Coding Revisions to the National Coverage Determinations (NCDs) - January 2025 Change Request (CR) 13706		
R12822CP	09/05/2024	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 18 Section 170.1 and Chapter 32 Section 190.2 for Coding Revisions to the National Coverage Determinations (NCDs)--April 2024 Change Request (CR) 13390	11/07/2024	13738
R12683CP	06/13/2024	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 32, Section 150.3 for Coding Revisions to the National Coverage Determinations (NCDs)--October 2024 Change Request (CR)13596	07/15/2024	13622
R12649CP	05/23/2024	National Coverage Determination (NCD) 200.3 - Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD)	06/24/2024	13598
R12571CP	04/11/2024	National Coverage Determination (NCD) 20.7 Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting	05/13/2024	13512
R12533CP	03/07/2024	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 32, Section 90 for Coding Revisions to the National Coverage Determinations (NCDs)--July 2024 Change Request (CR) 13507.	04/08/2024	13545
R12497CP	02/08/2024	Pulmonary Rehabilitation, Cardiac Rehabilitation and Intensive Cardiac Rehabilitation (PR/CR/ICR) Expansion of Supervising Practitioners	03/12/2024	13513
R12435CP	12/28/2023	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 18, Sections 20.2, 60.3 and Chapter 32, Sections 50.4.1, 200.2 for Coding Revisions to the National Coverage Determinations (NCDs)--April 2024 Change Request (CR) 13391	01/29/2024	12435
R12396CP	12/07/2023	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 32 Sections 320.3.3 and 370.1 for Coding	01/09/2024	13438

Rev #	Issue Date	Subject	Impl Date	CR#
		Revisions to the National Coverage Determinations (NCDs)--April 2024 Change Request (CR) 13390		
R12109CP	06/29/2023	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 32 Sections 130.1, for International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs)--October 2023 Update Change Request (CR) 13166	10/02/2023	13227
R11902CP	03/16/2023	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 18 Sections 50.3-50.4, and Chapter 32 Sections 130.1, 170.2 for Coding Revisions to National Coverage Determinations (NCDs)--July 2023 Change Request (CR) 13070	04/17/2023	13104
R11875CP	02/23/2023	National Coverage Determination (NCD) 50.3 - Cochlear Implantation Manual Update	03/24/2023	13073
R11789CP	01/19/2023	Update to the Internet Only Manual (IOM) For Alpha-Numerical Order in Publication (Pub.) 100-04, Chapter 32, Index, Sections 40.2.1 and 40.2.4	02/21/2023	13025
R11759CP	12/21/2022	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 18 Section 170.1 and Chapter 32 Section 270.2 due to the National Coverage Determinations (NCDs) April 2023 Change Request (CR) 12960	01/23/2023	12993
R11721CP	11/28/2022	National Coverage Determination (NCD 110.24): Chimeric Antigen Receptor (CAR) T-cell Therapy	01/03/2023	12928
R11430CP	05/24/2022	Update to 'J' Drug Code List for Billing Home Infusion Therapy (HIT) Services	07/05/2022	12667
R11426CP	05/20/2022	An Omnibus CR Covering: (1) Removal of Two National Coverage Determination (NCDs), (2) Updates to the Medical Nutrition Therapy (MNT) Policy, and (3) Updates to the Pulmonary Rehabilitation	07/05/2022	12613

Rev #	Issue Date	Subject	Impl Date	CR#
		(PR), Cardiac Rehabilitation (CR), and Intensive Cardiac Rehabilitation (ICR) Conditions of Coverage- Rescinded and replaced by transmittal 11426		
R11272CP	02/18/2022	An Omnibus CR Covering: (1) Removal of Two National Coverage Determination (NCDs), (2) Updates to the Medical Nutrition Therapy (MNT) Policy, and (3) Updates to the Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR), and Intensive Cardiac Rehabilitation (ICR) Conditions of Coverage	07/05/2022	12613
R11214CP	01/20/2022	National Coverage Determination (NCD) 270.3 Blood-Derived Products for Chronic, Non-Healing Wounds	01/03/2022	12403
R11171CP	01/12/2022	National Coverage Determination (NCD) 270.3 Blood-Derived Products for Chronic, Non-Healing Wounds Rescinded and replaced by transmittal 11214	01/03/2022	12403
R11119CP	11/13/2021	National Coverage Determination (NCD) 270.3 Blood-Derived Products for Chronic, Non-Healing Wounds Rescinded and replaced by transmittal 11171	01/03/2022	12403
R11035CP	10/13/2021	Revisions to Chapters 3, 18, and 32 to Update Coding	10/13/2021	12377
R11021CP	10/01/2021	Revisions To Chapters 13, 18 And 32 To Update Coding	10/29/2021	12376
R10981CP	09/10/2021	National Coverage Determination (NCD) 270.3 Blood-Derived Products for Chronic, Non-Healing Wounds - Rescinded and replaced by transmittal 11119	01/03/2022	12403
R10985CP	09/08/2021	Claims Processing Instructions for National Coverage Determination 20.33 - Transcatheter Edge-to-Edge Repair [TEER] for Mitral Valve Regurgitation	10/08/2021	12361
R10881CP	08/06/2021	REVISIONS TO CHAPTERS 13 AND 32 TO UPDATE CODING	09/07/2021	12069

Rev #	Issue Date	Subject	Impl Date	CR#
R10891CP	07/20/2021	National Coverage Determination (NCD 110.24): Chimeric Antigen Receptor (CAR) T-cell Therapy - This CR Rescinds and Fully Replaces CR 11783. 230.2222	09/20/2021	12177
R10796CP		National Coverage Determination (NCD 110.24): Chimeric Antigen Receptor (CAR) T-cell Therapy - This CR Rescinds and Fully Replaces CR 11783- Rescinded and replaced by transmittal 10891	07/23/2021	12177
R10837CP	06/11/2021	National Coverage Determination (NCD) 20.9.1 Ventricular Assist Devices (VADs)	07/27/2021	12290
R10796CP	05/20/2021	National Coverage Determination (NCD 110.24): Chimeric Antigen Receptor (CAR) T-cell Therapy - This CR Rescinds and Fully Replaces CR 11783. - Rescinded and replaced by transmittal 10891	07/23/2021	12177
R10573CP	03/24/2021	Update to Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Program Manual Sections	04/26/2021	12115
R10547CP	12/31/2020	Billing for Home Infusion Therapy Services On or After January 1, 2021	01/04/2021	11880
R10463CP	11/13/2020	Billing for Home Infusion Therapy Services On or After January 1, 2021	01/04/2021	11880
R10343CP	09/04/2020	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 32, Section 40.2.1 and 40.2.4	10/06/2020	11950
R10337CP	08/27/2020	National Coverage Determination (NCD30.3.3): Acupuncture for Chronic Low Back Pain (cLBP)	01/04/2021	11755
R10269CP	08/07/2020	Billing for Home Infusion Therapy Services On or After January 1, 2021- Rescinded and replaced by transmittal 10463	01/04/2021	11880
R10229CP	07/21/2020	Modify Edits in the Fee for Service (FFS) System When a Beneficiary has a Medicare Advantage (MA) Plan	10/05/2020	11580
R10179CP	06/10/2020	NCD (20.32) Transcatheter Aortic Valve Replacement (TAVR)	06/12/2020	11660
R10128CP	05/08/2020	National Coverage Determination (NCD30.3.3): Acupuncture for Chronic	01/04/2021	11755

Rev #	Issue Date	Subject	Impl Date	CR#
		Low Back Pain (cLBP) Rescinded and replaced by transmittal 10337		
R10071CP	05/01/2020	Modify Edits in the Fee for Service (FFS) System When a Beneficiary has a Medicare Advantage (MA) Plan Rescinded and replaced by transmittal 10229	10/05/2020	11580
R4546CP	03/13/2020	NCD (20.32) Transcatheter Aortic Valve Replacement (TAVR) Rescinded and replaced by transmittal 10179	06/12/2020	11660
R4237CP	02/08/2019	Update to the Internet-Only-Manual (IOM) Publication (Pub.) 100-04, Chapter 32, Section 12.1	03/12/2019	11127
R4222CP	02/01/2019	Update to Intensive Cardiac Rehabilitation (ICR) Programs	03/19/2019	11117
R4203CP	01/18/2019	Update to Pub. 100-04 Chapter 32 to Provide Language-Only Changes for the New Medicare Card Project	02/19/2019	11118
R4111CP	08/10/2018	Revisions to Medicare Claims Processing Manual for Foreign, Emergency and Shipboard Claims	09/11/2018	10856
R4049CP	05/11/2018	Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD)	07/02/2018	10295
R4016CP	04/03/2018	Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD)	07/02/2018	10295
R4013CP	03/30/2018	Institutional Billing for No Cost Items	06/29/2018	10521
R3969CP	02/02/2018	Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD)	04/03/2018	10295
R203NCD	11/17/2017	Hyperbaric Oxygen (HBO) Therapy (Section C, Topical Application of Oxygen)	12/18/2017	10220
R3898CP	10/27/2017	Correction to Prevent Payment on Inpatient Information Only Claims for Beneficiaries Enrolled in Medicare Advantage Plans	04/02/2018	10238
R3871CP	09/29/2017	Revisions to Medicare Claims Processing Manual for Foreign, Emergency and Shipboard Claims	10/30/2017	10287

Rev #	Issue Date	Subject	Impl Date	CR#
R3848CP	08/25/2017	Updates to Pub. 100-04, Chapter 18 Preventive and Screening Services and Chapter 32 Billing Requirements for Special Services and Publication 100-03, Chapter 1 Coverage Determinations Part 4	09/26/2017	10199
R3815CP	07/28/2017	National Coverage Determination (NCD20.8.4): Leadless Pacemakers	08/29/2017	10117
R3811CP	07/25/2017	Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS)	06/27/2017	10089
R3805CP	07/11/2017	Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) – Rescinded and replaced by transmittal 3811	08/11/2017	10089
R3787CP	05/26/2017	Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) – Rescinded and replaced by transmittal 3805	06/27/2017	10089
R3556CP	07/01/2016	Stem Cell Transplantation for Multiple Myeloma, Myelofibrosis, Sickle Cell Disease, and Myelodysplastic Syndromes	10/03/2016	9620
R3509CP	04/29/2016	Stem Cell Transplantation for Multiple Myeloma, Myelofibrosis, Sickle Cell Disease, and Myelodysplastic Syndromes - Rescinded and replaced by Transmittal 3556	10/03/2016	9620
R3384CP	10/26/2015	National Coverage Determination (NCD) for Single Chamber and Dual Chamber Permanent Cardiac Pacemakers - This CR rescinds and fully replaces CR 8525	07/06/2015	9078
R3287CP	06/30/2015	Revisions to Medicare Claims Processing Manual for Foreign, Emergency and Shipboard Claims	04/21/2015	8940
R3265CP	05/22/2015	NCD20.30 Microvolt T-wave Alternans (MTWA)	06/23/2015	9162
R3241CP	04/24/2015	Transcatheter Mitral Valve Repair (TMVR)-National Coverage Determination (NCD)	04/06/2014	9002

Rev #	Issue Date	Subject	Impl Date	CR#
R3199CP	02/20/2015	Revisions to Medicare Claims Processing Manual for Foreign, Emergency and Shipboard Claims – Rescinded and replaced by Transmittal 3287	04/21/2015	8940
R3204CP	02/20/2015	National Coverage Determination (NCD) for Single Chamber and Dual Chamber Permanent Cardiac Pacemakers - This CR rescinds and fully replaces CR 8525 - Rescinded and replaced by Transmittal 3384	07/06/2015	9078
R3181CP	01/30/2015	Implementation of New NUBC Condition Code “53” “Initial placement of a medical device provided as part of a clinical trial or a free sample”	07/06/2015	8961
R3175CP	01/30/2015	Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS)-Blinded Clinical Trial – Follow-Up CR to Implement a Second Claims Processing Procedure Code	03/02/2015	8954
R3142CP	12/05/2014	Transcatheter Mitral Valve Repair (TMVR)-National Coverage Determination (NCD) – Rescinded and replaced by Transmittal 3241	04/06/2014	9002
R3105CP	11/06/2014	Medicare Coverage of Items and Services in Category A and B Investigational Device Exemption (IDE) Studies	01/05/2015	8921
R3084CP	10/03/2014	Intensive Cardiac Rehabilitation Program - Benson-Henry Institute Cardiac Wellness Program	11/04/2014	8894
R3058CP	08/29/2014	Cardiac Rehabilitation Programs for Chronic Heart Failure	08/18/2014	8758
R3054CP	08/29/2014	Ventricular Assist Devices for Bridge-to-Transplant and Destination Therapy	09/30/2014	8803
R3050CP	08/22/2014	Extracorporeal Photopheresis	09/23/2014	8808
R2998CP	07/25/2014	Update to Pub. 100-04, Chapter 32 to Provide Language-Only Changes for Updating ICD-10 and ASC X12	08/25/2014	8693
R2989CP	07/18/2014	Cardiac Rehabilitation Programs for Chronic Heart Failure Failure – Rescinded and replaced by Transmittal 3058	08/18/2014	8758

Rev #	Issue Date	Subject	Impl Date	CR#
R2959CP	05/16/2014	Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS)	10/06/2014	8757
R2955CP	05/14/2014	Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims	01/06/2014	8401
R2872CP	02/06/2014	National Coverage Determination (NCD) for Single Chamber and Dual Chamber Permanent Cardiac Pacemakers – Rescinded and replaced by Transmittal 2986	07/07/2014	8525
R2841CP	12/23/2013	Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity	12/17/2013	8484
R2827CP	11/29/2013	Transcatheter aortic valve replacement (TAVR) - Implementation of Permanent CPT Code	01/06/2013	8537
R2816CP	11/15/2013	Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity – Rescinded and replaced by Transmittal 2841	12/17/2013	8484
R2805CP	10/30/2013	Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims – Rescinded and replaced by Transmittal 2955	01/06/2014	8401
R2783CP	09/10/2013	Corrections to the Medicare Claims Processing Manual	09/17/2013	8343
R2758CP	08/09/2013	Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims – Rescinded and replaced by Transmittal 2805	01/06/2014	8401
R2743CP	07/25/2013	Coding Changes to Ultrasound Diagnostic Procedures for Transesophageal Doppler Monitoring	08/26/2013	8330
R2737CP	07/11/2013	National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR) – Implementation of Mandatory Reporting of Clinical Trial Number	10/07/2013	8255
R2728CP	06/14/2013	Ocular Photodynamic Therapy (OPT) with Verteporfin for Macular Degeneration	07/16/2013	8292
R2725CP	06/14/2013	Corrections to the Medicare Claims Processing Manual – Rescinded and replaced by Transmittal 2783	09/17/2013	8343

Rev #	Issue Date	Subject	Impl Date	CR#
R2720CP	06/10/2013	Autologous Platelet-Rich Plasma (PRP) for Chronic Non-Healing Wounds	07/01/2013	8213
R2710CP	05/21/2013	Autologous Platelet-Rich Plasma (PRP) for Chronic Non-Healing Wounds – Rescinded and replaced by Transmittal 2720	07/01/2013	8213
R2689CP	05/03/2013	National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR) – Implementation of Mandatory Reporting of Clinical Trial Number – Rescinded and replaced by Transmittal 2737	10/07/2013	8255
R2666CP	03/08/2013	Autologous Platelet-Rich Plasma (PRP) for Chronic Non-Healing Wounds – Rescinded and replaced by Transmittal 2710	07/01/2013	8213
R2641CP	01/29/2013	Bariatric Surgery for the Treatment of Morbid Obesity National Coverage Determination, Addition of Laparoscopic Sleeve Gastrectomy (LSG)	02/28/2013	8028
R2628CP	01/07/2013	NCD: Transcatheter Aortic Valve Replacement (TAVR) Coding Update/Policy Clarification	04/01/2013	8168
R2590CP	11/09/2012	Bariatric Surgery for the Treatment of Morbid Obesity National Coverage Determination, Addition of Laparoscopic Sleeve Gastrectomy (LSG) – Rescinded and replaced by Transmittal 2641	12/10/2012	8028
R2252CP	09/24/2012	National Coverage Determination (NCD) FOR Transcatheter Aortic Valve Replacement	01/07/2013	7897
R2551CP	09/24/2012	Extracorporeal Photopheresis (ICD-10) – Rescinded and replaced by Transmittal 2551	10/01/2012	7806
R2544CP	09/13/2012	Contractor and Common Working File (CWF) Additional Instructions Related to Change Request (CR) 7633-Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse	10/01/2012	7791
R2543CP	09/07/2012	Extracorporeal Photopheresis (ICD-10) – Rescinded and replaced by Transmittal 2551	10/01/2012	7806

Rev #	Issue Date	Subject	Impl Date	CR#
R2512CP	08/03/2012	National Coverage Determination (NCD) FOR Transcatheter Aortic Valve Replacement – rescinded and Replaced by Transmittal 2552	01/07/2013	7897
R2506CP	08/03/2012	Extracorporeal Photopheresis (ICD-10) – Rescinded and replaced by Transmittal 2543	10/01/2012	7806
R2494CP	07/10/2012	Extracorporeal Photopheresis (ICD-10) – Rescinded and replaced by Transmittal 2506	10/01/2012	7806
R2488CP	06/21/2012	Contractor and Common Working File (CWF) Additional Instructions Related to Change Request (CR) 7633-Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse – Rescinded and replaced by Transmittal 2544	10/01/2012	7791
R2473CP	05/18/2012	Extracorporeal Photopheresis (ICD-10)	10/01/2012	7806
R2454CP	04/26/2012	Contractor and Common Working File (CWF) Additional Instructions Related to Change Request (CR) 7633-Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse – Rescinded and replaced by Transmittal 2488	10/01/2012	7791
R2394CP	01/25/2012	CWF Editing for Autologuous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (PROVENGE®)	07/02/2012	7659
R2380CP	01/06/2012	Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer	08/08/2011	7431
R2339CP	11/02/2011	Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer - Rescinded and replaced by Transmittal 2380	08/08/2011	7431
R2254CP	07/08/2011	Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer – Rescinded and replaced by Transmittal 2339	08/08/2011	7431
R2113CP	12/10/2010	Payment for 510k Post-Approval Extension Studies Using 501k-Cleared Embolic	01/12/2011	7249

Rev #	Issue Date	Subject	Impl Date	CR#
		Protection Devices During Carotid Artery Stenting (CAS) Procedures		
R2105CP	11/24/2010	Dermal Injections for Treatment of Facial Lipodystrophy Syndrome (LDS)	07/06/2010	6953
R2062CP	10/08/2010	Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndrome (MDS)	11/10/2010	7137
R2052CP	09/17/2010	Billing and Processing for Healthy Control Group Volunteers in a Qualified Clinical Trial	07/06/2010	6776
R2005CP	07/23/2010	Billing and Claims Processing for Automatic Implantable Cardiac Defibrillator (ICD) Services	08/31/2010	7015
R1994CP	07/02/2010	Billing and Claims Processing for Automatic Implantable Cardiac Defibrillator (ICD) Services - Rescinded and replaced by Transmittal 2005	08/31/2010	7015
R1978CP	06/04/2010	Dermal Injections for Treatment of Facial Lipodystrophy Syndrome (LDS) – Rescinded and replaced by Transmittal 2105	07/06/2010	6953
R1974CP	05/21/2010	Cardiac Rehabilitation and Intensive Cardiac Rehabilitation	10/04/2010	6850
R1966CP	05/07/2010	Pulmonary Rehabilitation (PR) Services	10/04/2010	6823
R1925CP	03/05/2010	Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting	04/05/2010	6839
R1924CP	02/26/2010	April 2010 Update of the Hospital Outpatient Prospective Payment System (OPPS)	04/05/2010	6857
R1901CP	01/29/2010	Billing and Processing for Healthy Control Group Volunteers in a Qualified Clinical Trial – Rescinded and replaced by Transmittal 2052	07/06/2010	6776
R1889CP	01/08/2010	Pharmacogenomic Testing for Warfarin Response	04/05/2010	6715
R1882CP	12/21/2009	January 2010 Update of the Hospital Outpatient Prospective Payment System (OPPS)	01/04/2010	6751

Rev #	Issue Date	Subject	Impl Date	CR#
R1871CP	12/11/2009	January 2010 Update of the Hospital Outpatient Prospective Payment System (OPPS) - Rescinded and replaced by Transmittal 1882	01/04/2010	6751
R1877CP	12/18/2009	Instructions Regarding Processing Claims Rejecting for Gender/Procedure Conflict	04/05/2010	6638
R1876CP	12/18/2009	Coverage of Kidney Disease Patient Education Services	04/05/2010	6557
R1839CP	10/28/2009	Instructions Regarding Processing Claims Rejecting for Gender/Procedure Conflict - Rescinded and replaced by Transmittal 1877	04/05/2010	6638
R1816CP	09/17/2009	Fiscal Year (FY) 2010 Inpatient Prospective Payment System (IPPS), Long Term Care Hospital (LTCH) PPS, and Inpatient Psychiatric Facility (IPF) PPS Changes	10/05/2009	6634
R1815CP	09/09/2009	Fiscal Year (FY) 2010 Inpatient Prospective Payment System (IPPS), Long Term Care Hospital (LTCH) PPS, and Inpatient Psychiatric Facility (IPF) PPS Changes - Rescinded and replaced by Transmittal 1816	10/05/2009	6634
R1778CP	07/24/2009	Wrong Surgical or Other Invasive Procedure Performed on a Patient; Surgical or Other Invasive Procedure Performed on the Wrong Body Part; Surgical or Other Invasive Procedure Performed on the Wrong Patient	07/06/2009	6405
R1764CP	07/02/2009	Wrong Surgical or Other Invasive Procedure Performed on a Patient; Surgical or Other Invasive Procedure Performed on the Wrong Body Part; Surgical or Other Invasive Procedure Performed on the Wrong Patient – Rescinded and replaced by Transmittal 1778	07/06/2009	6405
R1761CP	06/26/2009	Billing Routine Cost of Clinical Trials	09/28/2009	6431
R1755CP	06/12/2009	Wrong Surgical or Other Invasive Procedure Performed on a Patient; Surgical or Other Invasive Procedure Performed on the Wrong Body Part; Surgical or Other Invasive Procedure Performed on the	07/06/2009	6405

Rev #	Issue Date	Subject	Impl Date	CR#
		Wrong Patient – Rescinded and replaced by Transmittal 1764		
R1743CP	05/22/2009	Billing Routine Cost of Clinical Trials - Rescinded and replaced by Transmittal 1761	07/10/2009	6431
R1742CP	05/22/2009	Clarification of CMS Publication 100-04, Chapter 32, Section 80.8 Billing of Routine Foot Care When Payment Ceases for Loss of Protective Sensation Evaluation and Management	06/08/2009	6456
R1731CP	05/08/2009	Clarification of CMS Publication 100-04, Chapter 32, Section 80.8 Billing of Routine Foot Care When Payment Ceases for Loss of Protective Sensation Evaluation and Management - Rescinded and replaced by Transmittal 1742	06/08/2009	6456
R1728CP	05/01/2009	Surgery for Diabetes	05/18/2009	6419
R1723CP	05/01/2009	Ensuring Only Clinical Trial Services Receive Fee-For-Service Payment on Claims Billed for Managed Care Beneficiaries	10/05/2009	6455
R1721CP	04/29/2009	Billing Routine Cost of Clinical Trials - Rescinded and replaced by Transmittal 1743	07/10/2009	6431
R1711CP	04/17/2009	Surgery for Diabetes – Rescinded and replaced by Transmittal 1728	05/18/2009	6419
R1710CP	04/10/2009	Billing Routine Cost of Clinical Trials - Rescinded and replaced by Transmittal 1721	07/10/2009	6431
R1663CP	01/08/2009	Correction to Prothrombin Time (PT/INR) Monitoring for Home Anticoagulation Management	02/09/2009	6313
R1657CP	12/31/2008	January 2009 Update of the Hospital Outpatient Prospective Payment System (OPPS)	01/05/2009	6320
R1646CP	12/09/2008	Thermal Intradiscal Procedures (TIPs)	01/05/2009	6291
R1593CP	09/12/2008	Smoking and Tobacco Use Cessation Counseling Billing Update for Comprehensive Outpatient Rehabilitation Facilities (CORFs) and Outpatient Physical Therapy Providers (OPTs)	12/12/2008	6163

Rev #	Issue Date	Subject	Impl Date	CR#
R1592CP	09/10/2008	Artificial Hearts	12/01/2008	6185
R1583CP	08/29/2008	Artificial Hearts - Replaced by Transmittal 1592	10/06/2008	6185
R1562CP	07/25/2008	Prothrombin Time (PT/INR) Monitoring for Home Anticoagulation Management - Rescinded and replaced by CR 6313	08/25/2008	6138
R1509CP	05/16/2008	Adjusting Inpatient Prospective Payment System (IPPS) Reimbursement for Replaced Devices Offered Without Cost or With a Credit	10/06/2008	5860
R1498CP	05/02/2008	Adjusting Inpatient Prospective Payment System (IPPS) Reimbursement for Replaced Devices Offered Without Cost or With a Credit – Replaced by Transmittal 1509	10/06/2008	5860
R1472CP	03/06/2008	Update of Institutional Claims References	04/07/2008	5893
R1433CP	02/01/2008	Smoking and Tobacco Use Cessation Counseling Billing Code Update	07/07/2008	5878
R1430CP	02/01/2008	Use of HCPCS V2787 When Billing Approved Astigmatism-Correcting Intraocular Lens (A-CIOLs) in Ambulatory Surgery Centers (ASCs), Physician Offices, and Hospital Outpatient Departments (HOPDs)	03/03/2008	5853
R1421CP	01/25/2008	Update of Institutional Claims References - Rescinded and Replaced by Transmittal 1472	04/07/2008	5893
R1418CP	01/18/2008	New HCPCS Modifiers When Billing for Patient Care in Clinical Research Studies	04/07/2008	5805
R1340CP	09/21/2007	Lumbar Artificial Disc Replacement (LADR)	10/01/2007	5727
R1315CP	08/10/2007	Clarification of Percutaneous Transluminal Angioplasty (PTA) Billing Requirements Issued in CR 3811	10/01/2007	5667
R1271CP	06/22/2007	Vagus Nerve Stimulation (VNS) for Resistant Depression	07/23/2007	5612
R1233CP	04/27/2007	Clarification of Bariatric Surgery Billing Requirements Issued in CR 5013	05/29/2007	5477

Rev #	Issue Date	Subject	Impl Date	CR#
R1228CP	04/27/2007	Instructions for Implementation of CMS 1536-R; Astigmatism-Correcting Intraocular Lens (A-C IOLs)	05/29/2007	5527
R1206CP	03/16/2007	Extracorporeal Photopheresis	04/02/2007	5464
R1192CP	03/02/2007	Payment and Billing for Islet Isolation Add-On in National Institutes of Health (NIH) Clinical Trial	04/02/2007	5505
R1164CP	01/26/2007	Coding Change for Lumbar Artificial Disc Replacement (LADR)	03/13/2007	5462
R1147CP	01/05/2007	Intracranial Percutaneous Transluminal Angioplasty (PTA) with Stenting	02/05/2007	5432
R1111CP	11/09/2006	Clarification on Billing for Cryosurgery of the Prostate Gland	04/02/2007	5376
R1042CP	08/25/2006	Clarification on Billing Requirements for Percutaneous Transluminal Angioplasty (PTA) Concurrent With the Placement of an Investigational or FDA-Approved Carotid Stent	10/02/2006	5022
R1000CP	07/19/2006	Common Working File (CWF) to the Medicare Beneficiary Database (MDB) Data Exchange Changes	10/02/2006	4300
R992CP	06/23/2006	Lumbar Artificial Disc Replacement (LADR)	07/17/2006	5057
R986CP	06/16/2006	Payment for Islet Cell Transplantation in NIH-Sponsored Clinical Trials	07/31/2006	5140
R951CP	05/12/2006	Payment for Carotid Artery Stenting (CAS) Post-Approval Extension Studies	06/12/2006	5088
R931CP	04/28/2006	Billing Requirements for Bariatric Surgery for Treatment of Morbid Obesity	05/30/2006	5013
R911CP	04/21/2006	Clarification on Billing Requirements for Percutaneous Transluminal Angioplasty (PTA) Concurrent With the Placement of an Investigational or FDA-Approved Carotid Stent	10/02/2006	5022
R909CP	04/21/2006	Cardiac Rehabilitation Programs	06/21/2006	4401
R908CP	04/21/2006	Common Working File (CWF) to the Medicare Beneficiary Database (MBD) Data Exchange Changes	10/02/2006	4300
R898CP	03/31/2006	External Counterpulsation (ECP) Therapy	N/A	4350

Rev #	Issue Date	Subject	Impl Date	CR#
R816CP	01/20/2006	Coverage and Billing for Ultrasound Stimulation for Nonunion Fracture Healing	04/03/2006	4085
R801CP	12/30/2005	Instructions for Reporting New HCPCS Code V2788 for Presbyopia-Correcting Intraocular Lenses (P-C IOLs)	01/03/2006	4184
R795CP	12/30/2005	Redefined Type of Bill (TOB) 14X for Non-Patient Laboratory Specimens-CR 3835 Manualization	04/03/2006	4208
R766CP	12/02/2005	Stem Cell Transportation	01/03/2006	4173
R726CP	10/21/2005	Smoking and Tobacco-Use Cessation Counseling Services: Common Working File (CWF) Inquiry for Providers	01/24/2006	4104
R671CP	09/09/2005	Updated Manual Instructions for the Medicare Claims Processing Manual, Regarding Smoking and Tobacco-Use Cessation Counseling Services	10/03/2005	4045
R605CP	07/15/2005	Frequency Instructions for Smoking and Tobacco-Use Cessation Counseling Services	10/03/2005	3929
R601CP	07/01/2005	Cochlear Implantation	07/25/2005	3796
R597CP	06/24/2005	Coverage and Billing for Ultrasound Stimulation for Nonunion Fracture Healing	08/01/2005	3836
R589CP	06/24/2005	Cochlear Implantation	07/05/2005	3796
R562CP	05/20/2005	Smoking and Tobacco-Use Cessation Counseling Services	07/05/2005	3834
R526CP	04/15/2005	Updated Requirements for Autologous Stem Cell Transplantation (AuSCT)	05/16/2005	3797
R498CP	03/11/2005	Billing of the Diagnosis and Treatment of Peripheral Neuropathy with Loss of Protective Sensation in People with Diabetes	N/A	3580
R487CP	03/04/2005	Manualization of Claims Processing Instructions for Medicare Qualifying Clinical Trials	N/A	3625
R486CP	03/04/2005	Manualization of Carrier Claims Processing Instructions for Stem Cell Transplantation	N/A	3684
R371CP	11/19/2004	Updated Billing Instructions for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)	04/04/2005	3487

Rev #	Issue Date	Subject	Impl Date	CR#
R261CP	07/30/2004	Billing Requirements for Islet Cell Transplantation for Beneficiaries in a National Institutes of Health Sponsored Clinical Trial	10/04/2004	3385
R216CP	06/25/2004	Manualization of Instructions for of INR Monitoring	N/A	2323
R187CP	05/28/2004	Manualization of Instructions for Billing for Hyberbaric Oxygen Therapy for the Treatment of Wounds of the Lower Extremities	06/28/2004	3172
R130aCP	03/26/2004	Manualization of Instructions for INR Monitoring	N/A	2323
R128CP	03/26/2004	Manualization of Instructions for Deep Brain Stimulation	N/A	2553
R125CP	03/26/2004	Manualization of Instructions for Sacral Nerve Stimulation	N/A	2532
R124CP	03/19/2004	Policy and Claims Processing Instructions for Electrical Stimulation And Electromagnetic Therapy	07/06/2004	3149
R109CP	02/27/2004	Updated Policy and Claims Processing Instructions for Ambulatory Blood Pressure Monitoring (AMPM)	04/05/2004	2726

Back to top of chapter