

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 173	Date: September 4, 2014
	Change Request 8506

Transmittal 159, dated February 5, 2014, is being rescinded and replaced by Transmittal 173, dated September 4, 2014 to change the effective and implementation dates for ICD-10. All other information remains the same.

SUBJECT: Pub 100-03, Chapter 1, language-only update

I. SUMMARY OF CHANGES: This Change Request (CR) contains language-only changes for updating all four Parts of Pub. 100-03, Chapter 1, for conversion from ICD-9 to ICD-10, conversion from ASC X12 version 4010 to version 5010, conversion of former contractor types to Medicare Administrative Contractors (MACs), and for other miscellaneous updates.

EFFECTIVE DATE: Upon Implementation of ICD-10

IMPLEMENTATION DATE: Upon Implementation of ICD 10

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/Table of Contents
R	1/ Foreword – Purpose for National Coverage Determinations (NCD) Manual
R	1/10.1/ Use of Visual Tests Prior to and General Anesthesia During Cataract Surgery
R	1/10.2/ Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain
R	1/10.4/ Outpatient Hospital Pain Rehabilitation Programs
R	1/10.6/ Anesthesia in Cardiac Pacemaker Surgery
R	1/20.7/ Percutaneous Transluminal Angioplasty (PTA) (Various Effective Dates Below)
R	1/20.8/ Cardiac Pacemakers (Various Effective Dates)
R	1/20.8.1/ Cardiac Pacemaker Evaluation Services
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R	1/20.16/ Cardiac Output Monitoring By Thoracic Electrical Bioimpedance (TEB) – Various Effective Dates Below
R	1/50.1/ Speech Generating Devices
R	1/50.3/ Cochlear Implantation (Effective April 4, 2005)
R	1/70.3/ Physician’s Office Within an Institution - Coverage of Services and Supplies Incident to a Physician’s Services
R	1/70.5/ Hospital and Skilled Nursing Facility Admission Diagnostic Procedures
R	1/80.1/ Hydrophilic Contact Lens for Corneal Bandage
R	1/80.2/ Photodynamic Therapy
R	1/80.2.1/ Ocular Photodynamic Therapy (OPT) - Effective April 3, 2013)
R	1/80.3/ Photosensitive Drugs
R	1/80.3.1/ Verteporfin - Effective April 3, 2013
R	1/80.4/ Hydrophilic Contact Lenses
R	1/100.13/ Laproscopic Cholecystectomy
R	1/110.2/ Certain Drugs Distributed by the National Cancer Institute
R	1/110.8.1/ Stem Cell Transplantation (Various Effective Dates Below)
R	1/110.17/ Anticancer Chemotherapy for Colorectal Cancer (Effective January 28, 2005)
R	1/110.19/ Abarelix for the Treatment of Prostate Cancer (Effective March 15, 2005)

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/110.21/ Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions
R	1/130.1/ Inpatient Hospital Stays for the Treatment of Alcoholism
R	1/130.3/ Chemical Aversion Therapy for Treatment of Alcoholism
R	1/130.6/ Treatment of Drug Abuse (Chemical Dependency)
R	1/130.7/ Withdrawal Treatments for Narcotic Addictions
R	1/140.5/ Laser Procedures
R	1/150.5/ Diathermy Treatment
R	1/150.10/ Lumbar Artificial Disc Replacement (LADR) (Effective August 14, 2007)
R	1/160.1/ Induced Lesions of Nerve Tracts
R	1/160.7/ Electrical Nerve Stimulators
R	1/160.13/ Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES)
R	1/180.2/ Enteral and Parenteral Nutritional Therapy
R	1/200.1/ Nesiritide for Treatment of Heart Failure Patients (Effective March 2, 2006)
R	1/200.2/ Nebulized Beta Adrenergic Agonist Therapy for Lung Diseases – (Effective September 10, 2007)
R	1/210.2/ Screening PAP Smears and Pelvic Examinations for Early Detection of Cervical or Vaginal Cancer
R	1/220.1/ Computed Tomography (CT)
R	1/220.2/ Magnetic Resonance Imaging (MRI) (Various Effective Dates Below)
R	1/220.5/ Ultrasound Diagnostic Procedures (Effective May 22, 2007)
R	1/220.6.13/ FDG Positron Emission Tomography (PET) for Dementia and Neurodegenerative Diseases (Effective September 15, 2004)
R	1/220.6.17/ Positron Emission Tomography (PET) (FDG) for Oncologic Conditions
R	1/220.9/ Digital Subtraction Angiography (DSA)
R	1/220.12/ Single Photon Emission Computed Tomograph (SPECT)
R	1/220.13/ Percutaneous Image-Guided Breast Biopsy
R	1/230.3/ Sterilization
R	1/230.7/ Water Purification and Softening Systems Used in Conjunction with Home Dialysis
R	1/240.2/ Home Use of Oxygen

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
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R	1/250.1/ Treatment of Psoriasis
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R	1/280.1/ Durable Medical Equipment Reference List (Effective May 5, 2005)
R	1/280.7/ Hospital Beds
R	1/280.14/ Infusion Pumps
R	1/300.1/ Obsolete or Unreliable Diagnostic Tests
R	1/310.1/ Routine Costs in Clinical Trials (Effective July 9, 2007)

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC statement of Work. The contractor is not obliged to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Attachment - Business Requirements

Pub. 100-03	Transmittal: 173	Date: September 4, 2014	Change Request: 8506
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SUBJECT: Pub 100-03, Chapter 1, language-only update

EFFECTIVE DATE: Upon Implementation of ICD-10

IMPLEMENTATION DATE: Upon Implementation of ICD-10

I. GENERAL INFORMATION

A. Background: This change request updates Pub. 100-03 to make language consistent with various instructions that have been issued about the conversion from ICD-9 to ICD-10 diagnosis and procedures, conversion from ASC X12 version 4010 to version 5010, and replacing intermediaries, carriers and DMERCs with Medicare Administrative Contractors (MACs).

B. Policy: Changes are only to make Pub. 100-03 consistent with initiatives that have already been implemented in prior publications.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			D M E M A C	Shared-System Maintainers				Other
		A	B	H H H		F I S S	M C S	V M S	C W F	
8506.1	MACs shall be aware of the changes in Pub. 100-03 described in this CR.	X	X	X	X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E M A C	C E D I
		A	B	H H H		
8506.2	MLN Article : A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their	X	X	X	X	

Number	Requirement	Responsibility				
		A/B MAC			D M E	C E D I
		A	B	H H H	M A C	
	Web sites and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Patricia Brocato-Simons, Patricia.Brocato-Simons@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS do not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Medicare National Coverage Determinations Manual

Chapter 1, Part 1 (Sections 10 – 80.12)

Coverage Determinations

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(Rev.173, Issued: 09-04-14)

Foreword – Purpose for National Coverage Determinations (*NCD*) Manual

20.8 - Cardiac Pacemakers (*Various Effective Dates Below*)

70.3 - Physician's Office *within* an Institution - Coverage of Services and Supplies Incident to a Physician's Services

Foreword - Purpose for National Coverage Determinations (*NCD*) Manual (Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

A. Purpose

The statutory and policy framework within which National Coverage *Determinations (NCDs)* are made may be found in title XVIII of the Social Security Act (the Act), and in Medicare regulations and rulings. The *NCD* Manual describes whether specific medical items, services, treatment procedures, or technologies can be paid for under Medicare. *NCDs* have been made on the items addressed in this manual. *Decisions* that items/*services* are not covered are *generally* based on §1862(a)(1) of the Act (the “not reasonable and necessary” exclusion) unless otherwise specifically noted. Where another statutory authority for denial is indicated, that is *the authority* for denial. Where an item/*service* is stated to be covered, but such coverage is explicitly limited to specified indications or specified circumstances, all limitations on coverage of the items/*services* because they do not meet those specified indications or circumstances are based on §1862(a)(1) of the Act. Where coverage of an item/*service* is provided for specified indications or circumstances but is not explicitly excluded for others, or where the item/*service* is not mentioned at all in the *Centers for Medicare & Medicaid Services (CMS) NCD* Manual the Medicare *Administrative Contractor (MAC)* has the *discretion* to make the coverage decision, in consultation with its medical staff, and with CMS when appropriate, based on the law, regulations, *rulings*, and general program instructions

The coverage *determinations* in the manual will be *revised based* on the most recent medical and other scientific and technical *evidence* available to CMS.

Other manuals in this system in which coverage-related instructions may be found are:

- Pub 100-02 (Benefit Policy);
- Pub 100-04 (Claims Processing);
- Pub 100-05 (Medicare Secondary Payer); and
- Pub 100-08 (Program Integrity)

These manuals usually contain more general coverage descriptions and/or *claims* processing instructions. There should be no inconsistencies among the instructions in any of these manuals and the *NCD* Manual *pertaining to coverage*. If any such inconsistencies are found, bring them to the attention of CMS, *Center for Clinical Standards and Quality, Coverage and Analysis Group, Division of Operations and Information Management*.

B. Organization

The *NCD* Manual is organized by categories, e.g., medical procedures, supplies, diagnostic services. A table of contents is provided at the beginning of the manual designating coverage *determination* categories. Each subject discussed within the category is listed and identified by a number.

The revision transmittal sheet identifies new material and summarizes the principal changes. When a change in policy or procedure is involved, the background and effective date for the change is provided. If, at a later date, the reader wishes to refer to the background explanation given on a transmittal sheet, the reader can identify the transmittal by its number which appears on each manual page.

C. CMS Coverage Web site

The CMS Coverage Web page <http://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center.html?redirect=/center/coverage.asp> contains information about pending *NCDs* and also provides access to a database of *NCDs*, National Coverage Analyses, and Local Medical review Policies.

10.1 - Use of Visual Tests Prior to and General Anesthesia During Cataract Surgery

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

A. *Pre-Surgery* Evaluations

Cataract surgery with an intraocular lens (IOL) implant is a high volume Medicare procedure. Along with the surgery, a substantial number of preoperative tests are available to the surgeon. In most cases, a comprehensive eye examination (ocular history and ocular examination) and a single scan to determine the appropriate pseudophakic power of the IOL are sufficient. In most cases involving a simple cataract, a diagnostic ultrasound A-scan is used. For patients with a dense cataract, an ultrasound B-scan may be used.

Accordingly, where the only diagnosis is cataract(s), Medicare does not routinely cover testing other than one comprehensive eye examination (or a combination of a brief/intermediate examination not to exceed the charge of a comprehensive examination) and an A-scan or, if medically justified, a B-scan. Claims for additional tests are denied as not reasonable and necessary unless there is an additional diagnosis and the medical need for the additional tests is fully documented.

Because cataract surgery is an elective procedure, the patient may decide not to have the surgery until later, or to have the surgery performed by a physician other than the diagnosing physician. In these situations, it may be medically appropriate for the operating physician to conduct another examination. To the extent the additional tests are considered reasonable and necessary by the *A/B Medicare Administrative Contractor's* medical staff, they are covered.

B. General Anesthesia

The use of general anesthesia in cataract surgery may be considered reasonable and necessary if, for particular medical indications, it is the accepted procedure among ophthalmologists in the local community to use general anesthesia.

10.2 - Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

The use of transcutaneous electrical nerve stimulation (TENS) for the relief of acute post-operative pain is covered under Medicare. TENS may be covered whether used as an adjunct to the use of drugs, or as an alternative to drugs, in the treatment of acute pain resulting from surgery.

The TENS devices, whether durable or disposable, may be used in furnishing this service. When used for the purpose of treating acute post-operative pain, TENS devices are considered supplies. As such they may be hospital supplies furnished inpatients covered under Part A, or supplies incident to a physician's service when furnished in connection with surgery done on an outpatient basis, and covered under Part B.

It is expected that TENS, when used for acute post-operative pain, will be necessary for relatively short periods of time, usually 30 days or less. In cases when TENS is used for longer periods, *Medicare Administrative Contractors* should attempt to ascertain whether TENS is no longer being used for acute pain but rather for chronic pain, in which case the TENS device may be covered as durable medical equipment as described in §160.27.

Cross-references:

Medicare Benefit Policy Manual, Chapter 1, "Inpatient Hospital Services," §40;

Medicare Benefit Policy Manual, Chapter 2, "Hospital Services Covered Under Part B," §§20, 20.4, and 80;

Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and other Health Services, §110."

10.4 - Outpatient Hospital Pain Rehabilitation Programs

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

Some hospitals also provide pain rehabilitation programs for outpatients. In such programs, services frequently are provided in group settings even though they are being furnished pursuant to each patient's individualized plan of treatment.

Coverage of services furnished under outpatient hospital pain rehabilitation programs, including services furnished in group settings under individualized plans of treatment, is available if the patient's pain is attributable to a physical cause, the usual methods of treatment have not been successful in alleviating it, and a significant loss of ability by the patient to function independently has resulted from the pain. If a patient meets these conditions and the program provides services of the types discussed in §10.3, the services provided under the program may be covered. *Non-covered* services (e.g., vocational counseling, meals for outpatients, or acupuncture) continue to be excluded from coverage, and *A/B Medicare Administrative Contractors* would not be precluded from finding, in the case of particular patients, that the pain rehabilitation program is not reasonable and necessary under §1862(a)(1) of the *Social Security* Act for the treatment of their conditions.

10.6 - Anesthesia in Cardiac Pacemaker Surgery

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

The use of general or monitored anesthesia during transvenous cardiac pacemaker surgery may be reasonable and necessary and therefore covered under Medicare only if adequate documentation of medical necessity is provided on a case-by-case basis. The *Medicare Administrative Contractor* obtains advice from its medical consultants or from appropriate specialty physicians or groups in its locality regarding the adequacy of documentation before deciding whether a particular claim should be covered.

A second type of pacemaker surgery that is sometimes performed involves the use of the thoracic method of implantation which requires open surgery. Where the thoracic method is employed, general anesthesia is always used and should not require special medical documentation.

20.7 - Percutaneous Transluminal Angioplasty (PTA) (Various Effective Dates Below)

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

A. General

This procedure involves inserting a balloon catheter into a narrow or occluded blood vessel to recanalize and dilate the vessel by inflating the balloon. The objective of *percutaneous transluminal angioplasty (PTA)* is to improve the blood flow through the diseased segment of a vessel so that vessel patency is increased and embolization is decreased. With the development and use of balloon angioplasty for treatment of atherosclerotic and other vascular stenoses, PTA (with and without the placement of a stent) is a widely used technique for dilating lesions of peripheral, renal, and coronary arteries.

Indications and Limitations of Coverage

B. Nationally Covered Indications

The PTA is covered when used under the following conditions:

1. Treatment of Atherosclerotic Obstructive Lesions

-In the lower extremities, i.e., the iliac, femoral, and popliteal arteries, or in the upper extremities, i.e., the innominate, subclavian, axillary, and brachial arteries. The upper extremities do not include head or neck vessels.

-Of a single coronary artery for patients for whom the likely alternative treatment is coronary bypass surgery and who exhibit the following characteristics:

- Angina refractory to optimal medical management;
- Objective evidence of myocardial ischemia; and
- Lesions amenable to angioplasty.

-Of the renal arteries for patients in whom there is an inadequate response to a thorough medical management of symptoms and for whom surgery is the likely alternative. PTA for this group of patients is an alternative to surgery, not simply an addition to medical management.

-Of arteriovenous dialysis fistulas and grafts when performed through either a venous or arterial approach.

2. Concurrent with Carotid Stent Placement in Food and Drug Administration (FDA)-Approved Category B Investigational Device Exemption (IDE) Clinical Trials

Effective July 1, 2001, Medicare covers PTA of the carotid artery concurrent with carotid stent placement when furnished in accordance with the FDA-approved protocols governing Category B IDE clinical trials. PTA of the carotid artery, when provided solely for the purpose of carotid artery dilation concurrent with carotid stent placement, is considered to be a reasonable and necessary service when provided in the context of such a clinical trial.

3. Concurrent with Carotid Stent Placement in FDA-Approved Post-Approval *Studies*

Effective October 12, 2004, 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. *The Centers for Medicare & Medicaid Services (CMS)* determines that coverage of PTA of the carotid artery is reasonable and necessary in these circumstances.

4. Concurrent with Carotid Stent Placement in Patients at High Risk for Carotid Endarterectomy (CEA)

Effective March 17, 2005, Medicare covers PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent with embolic protection for the following:

- Patients who are at high risk for CEA and who also have symptomatic carotid artery stenosis $\geq 70\%$. Coverage is limited to procedures performed using FDA-approved carotid artery stenting (*CAS*) systems and FDA-approved or -cleared (effective December 9, 2009) embolic protection devices. If deployment of the embolic protection device is not technically possible, and not performed, then the procedure is not covered by Medicare (effective December 9, 2009);
- Patients who are at high risk for CEA and have symptomatic carotid artery stenosis between 50% and 70%, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (Medicare *National Coverage Determination (NCD)* Manual 310.1), or in accordance with the NCD on *CAS* post-approval studies (Medicare NCD Manual 20.7);
- Patients who are at high risk for CEA and have asymptomatic carotid artery stenosis $\geq 80\%$, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost

under the clinical trials policy (Medicare NCD Manual 310.1), or in accordance with the NCD on CAS post-approval studies (Medicare NCD Manual 20.7).

Coverage is limited to procedures performed using *an* FDA-approved *CAS*, stents and FDA-approved or -cleared embolic protection devices.

The use of an FDA-approved or cleared embolic protection device is required. If deployment of the embolic protection device is not technically possible, and not performed, then the procedure is not covered by Medicare.

Patients at high risk for CEA are defined as having significant comorbidities and/or anatomic risk factors (i.e., recurrent stenosis and/or previous radical neck dissection), and would be poor candidates for CEA. Significant comorbid conditions include but are not limited to:

- Congestive heart failure (CHF) class III/IV;
- Left ventricular ejection fraction (LVEF) <30%;
- Unstable angina;
- Contralateral carotid occlusion;
- Recent myocardial infarction (MI);
- Previous CEA with recurrent stenosis;
- Prior radiation treatment to the neck; *and*,
- Other conditions that were used to determine patients at high risk for CEA in the prior carotid artery stenting trials and studies, such as ARCHER, CABERNET, SAPPHIRE, BEACH, and MAVERIC II.

Symptoms of carotid artery stenosis include carotid transient ischemic attack (distinct focal neurological dysfunction persisting less than 24 hours), focal cerebral ischemia producing a non-disabling stroke (modified Rankin scale <3 with symptoms for 24 hours or more), and transient monocular blindness (amaurosis fugax). Patients who have had a disabling stroke (modified Rankin scale ≥ 3) shall be excluded from coverage.

The determination that a patient is at high risk for CEA and the patient's symptoms of carotid artery stenosis shall be available in the patient medical records prior to performing any procedure.

The degree of carotid artery stenosis shall be measured by duplex Doppler ultrasound or carotid artery angiography and recorded in the patient's medical records. If the stenosis is measured by ultrasound prior to the procedure, then the degree of stenosis must be confirmed by angiography at the start of the procedure. If the stenosis is determined to be <70% by angiography, then CAS should not proceed.

In addition, CMS has determined that CAS with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure and follow-up necessary to ensure optimal patient outcomes. Standards to determine competency include specific physician training standards, facility support requirements and data collection to evaluate outcomes during a required reevaluation.

The CMS has created a list of minimum standards modeled in part on professional society statements on competency. All facilities must at least meet CMS's standards in order to receive coverage for *CAS* for high-risk patients.

- Facilities must have necessary imaging equipment, device inventory, staffing, and infrastructure to support a dedicated carotid stent program. Specifically, high-quality x-ray imaging equipment is a critical component of any carotid interventional suite, such as high-resolution digital imaging systems with the capability of subtraction, magnification, road mapping, and orthogonal angulation.

- Advanced physiologic monitoring must be available in the interventional suite. This includes real time and archived physiologic, hemodynamic, and cardiac rhythm monitoring equipment, as well as support staff who are capable of interpreting the findings and responding appropriately.
- Emergency management equipment and systems must be readily available in the interventional suite such as resuscitation equipment, a defibrillator, vasoactive and antiarrhythmic drugs, endotracheal intubation capability, and anesthesia support.
- Each institution shall have a clearly delineated program for granting carotid stent privileges and for monitoring the quality of the individual interventionalists and the program as a whole. The oversight committee for this program shall be empowered to identify the minimum case volume for an operator to maintain privileges, as well as the (risk-adjusted) threshold for complications that the institution will allow before suspending privileges or instituting measures for remediation. Committees are encouraged to apply published standards from national specialty societies recognized by the American Board of Medical Specialties to determine appropriate physician qualifications. Examples of standards and clinical competence guidelines include those published in the December 2004 edition of the American Journal of Neuroradiology, and those published in the August 18, 2004, Journal of the American College of Cardiology.
- To continue to receive Medicare payment for CAS under this decision, the facility or a contractor to the facility must collect data on all CAS procedures done at that particular facility. This data must be analyzed routinely to ensure patient safety. This data must be made available to CMS upon request. The interval for data analysis will be determined by the facility but shall not be less frequent than every 6 months.

Since there currently is no recognized entity that evaluates CAS facilities, CMS has established a mechanism for evaluating facilities. Facilities must provide written documentation to CMS that the facility meets one of the following:

1. The facility was an FDA-approved site that enrolled patients in prior CAS IDE trials, such as SAPPHIRE, and ARCHER;
2. The facility is an FDA-approved site that is participating and enrolling patients in ongoing CAS IDE trials, such as CREST;
3. The facility is an FDA-approved site for one or more FDA post approval studies; *or*,
4. The facility has provided a written affidavit to CMS attesting that the facility has met the minimum facility standards. This should be sent to:

Director, Coverage and Analysis Group
7500 Security Boulevard, Mailstop S3-02-01
Baltimore, MD 21244

The letter must include the following information:

- Facility's name and complete address;
- Facility's national provider identifier (formerly referred to as the Medicare provider number);
- Point-of-contact for questions with telephone number;
- Discussion of how each standard has been met by the hospital;
- Mechanism of data collection of CAS procedures; *and*,
- Signature of a senior facility administrative official.

A list of certified facilities will be made available and viewable at:
<http://www.cms.hhs.gov/coverage/carotid-stent-facilities.asp>.

In addition, CMS will publish a list of approved facilities in the *Federal Register*.

Facilities must recertify every two (2) years in order to maintain Medicare coverage of CAS procedures. Recertification will occur when the facility documents that and describes how it continues to meet the CMS standards.

The process for recertification is as follows:

1. At 23 months after initial certification:
 - Submission of a letter to CMS stating how the facility continues to meet the minimum facility standards as listed above.
2. At 27 months after initial certification:
 - Submission of required data elements for all CAS procedures performed on patients during the previous two (2) years of certification.

Data elements:

- a. Patients' Medicare identification number if a Medicare beneficiary;
- b. Patients' date of birth;
- c. Date of procedure;
- d. Does the patient meet high surgical risk criteria (defined below)?
 - Age ≥ 80 ;
 - Recent (<30 days) *MI*;
 - *LVEF* <30%;
 - Contralateral carotid occlusion;
 - New York Heart Association (NYHA) Class III or IV congestive heart failure;
 - Unstable angina: Canadian Cardiovascular Society (CCS) Class III/IV;
 - Renal failure: *end*-stage renal disease on dialysis;
 - Common Carotid Artery (CCA) lesion(s) below clavicle;
 - Severe chronic lung disease;
 - Previous neck radiation;
 - High cervical Internal Carotid Artery (ICA) lesion(s);
 - Restenosis of prior *CEA*;
 - Tracheostomy;
 - Contralateral laryngeal nerve palsy.
- e. Is the patient symptomatic (defined below)?
 - Carotid Transient Ischemic Attack (TIA) persisting less than 24 hours;
 - Non-disabling stroke: Modified Rankin Scale
 - Transient monocular blindness: amaurosis fugax.
- f. Modified Rankin Scale score if the patient experienced a stroke.
- g. Percent of stenosis of stented lesion(s) by angiography.
- h. Was embolic protection used?
- i. Were there any complications during hospitalization (defined below)?
 - All stroke: an ischemic neurologic deficit that persisted more than 24 hours;
 - *MI*;
 - All death.

Recertification is effective for two (2) additional years during which facilities will be required to submit the requested data every April 1 and October 1.

The CMS will consider the approval of national CAS registries that provide CMS with a comprehensive overview of the registry and its capabilities, and the manner in which the registry meets CMS data collection and evaluation requirements. Specific standards for CMS approval are listed below. Facilities enrolled in a CMS-approved national CAS registry will automatically meet the data collection standards required for initial and continued facility certification. Hospitals' contracts with an approved registry may include authority for the registry to submit required data to CMS for the hospital. A list of approved registries will be available on the CMS Coverage Web site.

National Registries

As noted above, CMS will approve national registries developed by professional societies and other organizations and allow these entities to collect and submit data to CMS on behalf of participating facilities to meet facility certification and recertification requirements. To be eligible to perform these functions and become a CMS-approved registry, the national registry, at a minimum, must be able to:

1. Enroll facilities in every U.S. state and territory;
2. Assure data confidentiality and compliance with HIPPA;
3. Collect the required CMS data elements as listed in the above section;
4. Assure data quality and data completeness;
5. Address deficiencies in the facility data collection, quality, and submission;
6. Validate the data submitted by facilities as needed;
7. Track long term outcomes such as stroke and death;
8. Conduct data analyses and produce facility specific data reports and summaries;
9. Submit data to CMS on behalf of the individual facilities; and
10. Provide quarterly reports to CMS on facilities that do not meet or no longer meet the CMS facility certification and recertification requirements pertaining to data collection and analysis.

Registries wishing to receive this designation from CMS must submit evidence that they meet or exceed our standards. Though the registry requirements pertain to CAS, CMS strongly encourages all national registries to establish a similar mechanism to collect comparable data on CEA. Having both CAS and CEA data will help answer questions about carotid revascularization, in general, in the Medicare population.

The CAS for patients who are not at high risk for CEA remains covered only in FDA-approved Category B IDE clinical trials under 42 CFR 405.201.

The CMS has determined that PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent and an FDA-approved or –cleared embolic protection device is not reasonable and necessary for all other patients.

5. Concurrent with Intracranial Stent Placement in FDA-Approved Category B IDE Clinical Trials

Effective November 6, 2006, Medicare covers PTA and stenting of intracranial arteries for the treatment of cerebral artery stenosis $\geq 50\%$ in patients with intracranial atherosclerotic disease when furnished in accordance with the FDA-approved protocols governing Category B IDE clinical trials. CMS determines that coverage of intracranial PTA and stenting is reasonable and necessary under these circumstances.

C. Nationally Non-Covered Indications

All other indications for PTA with or without stenting to treat obstructive lesions of the vertebral and cerebral arteries remain non-covered.

All other indications for PTA without stenting for which CMS has not specifically indicated coverage remain non-covered.

D. Other

Coverage of PTA with stenting not specifically addressed or discussed in this NCD is at local Medicare *Administrative Contractor* discretion.

20.8 - Cardiac Pacemakers (Various Effective Dates Below)

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

Cardiac pacemakers are self-contained, battery-operated units that send electrical stimulation to the heart. They are generally implanted to alleviate symptoms of decreased cardiac output related to abnormal heart rate and/or rhythm. Pacemakers are generally used for persistent, symptomatic second- or third-degree atrioventricular (AV) block and symptomatic sinus bradycardia.

Cardiac pacemakers are covered as prosthetic devices under the Medicare program, subject to the following conditions and limitations. While cardiac pacemakers have been covered under Medicare for many years, there were no specific guidelines for their use other than the general Medicare requirement that covered services be reasonable and necessary for the treatment of the condition. Services rendered for cardiac pacing on or after the effective dates of this instruction are subject to these guidelines, which are based on certain assumptions regarding the clinical goals of cardiac pacing. While some uses of pacemakers are relatively certain or unambiguous, many other uses require considerable expertise and judgment.

Consequently, the medical necessity for permanent cardiac pacing must be viewed in the context of overall patient management. The appropriateness of such pacing may be conditional on other diagnostic or therapeutic modalities having been undertaken. Although significant complications and adverse side effects of pacemaker use are relatively rare, they cannot be ignored when considering the use of pacemakers for dubious medical conditions, or marginal clinical benefit.

These guidelines represent current concepts regarding medical circumstances in which permanent cardiac pacing may be appropriate or necessary. As with other areas of medicine, advances in knowledge and techniques in cardiology are expected. Consequently, judgments about the medical necessity and acceptability of new uses for cardiac pacing in new classes of patients may change as more conclusive evidence becomes available. This instruction applies only to permanent cardiac pacemakers, and does not address the use of temporary, non-implanted pacemakers.

The two groups of conditions outlined below deal with the necessity for cardiac pacing for patients in general. These are intended as guidelines in assessing the medical necessity for pacing therapies, taking into account the particular circumstances in each case. However, as a general rule, the two groups of current medical concepts may be viewed as representing:

Group I: Single-Chamber Cardiac Pacemakers – a) conditions under which single chamber pacemaker claims may be considered covered without further claims development; and b) conditions under which single-chamber pacemaker claims would be denied unless further claims development shows that they fall into the covered category, or special medical circumstances exist of the sufficiency to convince the *Medicare Administrative Contractor (MAC)* that the claim should be paid.

Group II: Dual-Chamber Cardiac Pacemakers - a) conditions under which dual-chamber pacemaker claims may be considered covered without further claims development, and b) conditions under which dual-chamber pacemaker claims would be denied unless further claims development shows that they fall into the covered categories for single- and dual-chamber pacemakers, or special medical circumstances exist sufficient to convince the *MAC* that the claim should be paid.

The *Centers for Medicare & Medicaid Services (CMS)* opened the *National Coverage Determination (NCD)* on Cardiac Pacemakers to afford the public an opportunity to comment on the proposal to revise the language contained in the instruction. The revisions transfer the focus of the NCD from the actual pacemaker implantation procedure itself to the reasonable and necessary medical indications that justify cardiac pacing. This is consistent with our findings that pacemaker implantation is no longer considered routinely harmful or an experimental procedure.

Group I: Single-Chamber Cardiac Pacemakers (Effective March 16, 1983)

A. Nationally Covered Indications

Conditions under which cardiac pacing is generally considered acceptable or necessary, provided that the conditions are chronic or recurrent and not due to transient causes such as acute myocardial infarction, drug toxicity, or electrolyte imbalance. (In cases where there is a rhythm disturbance, if the rhythm disturbance is chronic or recurrent, a single episode of a symptom such as syncope or seizure is adequate to establish medical necessity.)

1. Acquired complete (also referred to as third-degree) AV heart block.
2. Congenital complete heart block with severe bradycardia (in relation to age), or significant physiological deficits or significant symptoms due to the bradycardia.
3. Second-degree AV heart block of Type II (i.e., no progressive prolongation of P-R interval prior to each blocked beat. P-R interval indicates the time taken for an impulse to travel from the atria to the ventricles on an electrocardiogram).
4. Second-degree AV heart block of Type I (i.e., progressive prolongation of P-R interval prior to each blocked beat) with significant symptoms due to hemodynamic instability associated with the heart block.
5. Sinus bradycardia associated with major symptoms (e.g., syncope, seizures, congestive heart failure (*CHF*)); or substantial sinus bradycardia (heart rate less than 50) associated with dizziness or confusion. The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.
6. In selected and few patients, sinus bradycardia of lesser severity (heart rate 50-59) with dizziness or confusion. The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.
7. Sinus bradycardia is the consequence of long-term necessary drug treatment for which there is no acceptable alternative when accompanied by significant symptoms (e.g., syncope, seizures, *CHF*, dizziness, or confusion). The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.
8. Sinus node dysfunction with or without tachyarrhythmias or AV conduction block (i.e., the bradycardia-tachycardia syndrome, sino-atrial block, sinus arrest) when accompanied by significant symptoms (e.g., syncope, seizures, *CHF*, dizziness, or confusion).
9. Sinus node dysfunction with or without symptoms when there are potentially life-threatening ventricular arrhythmias or tachycardia secondary to the bradycardia (e.g., numerous premature ventricular contractions, couplets, runs of premature ventricular contractions, or ventricular tachycardia).
10. Bradycardia associated with supraventricular tachycardia (e.g., atrial fibrillation, atrial flutter, or paroxysmal atrial tachycardia) with high-degree AV block which is unresponsive to appropriate pharmacological management and when the bradycardia is associated with significant symptoms (e.g., syncope, seizures, *CHF*, dizziness, or confusion).

11. The occasional patient with hypersensitive carotid sinus syndrome with syncope due to bradycardia and unresponsive to prophylactic medical measures.
12. Bifascicular or trifascicular block accompanied by syncope which is attributed to transient complete heart block after other plausible causes of syncope have been reasonably excluded.
13. Prophylactic pacemaker use following recovery from acute myocardial infarction (*MI*) during which there was temporary complete (third-degree) and/or Mobitz Type II second-degree AV block in association with bundle branch block.
14. In patients with recurrent and refractory ventricular tachycardia, "overdrive pacing" (pacing above the basal rate) to prevent ventricular tachycardia.

(Effective May 9, 1985)

15. Second-degree AV heart block of Type I with the QRS complexes prolonged.

B. Nationally Non-Covered Indications

Conditions which, although used by some physicians as a basis for permanent cardiac pacing, are considered unsupported by adequate evidence of benefit and therefore should not generally be considered appropriate uses for single-chamber pacemakers in the absence of the above indications. *MACs* should review claims for pacemakers with these indications to determine the need for further claims development prior to denying the claim, since additional claims development may be required. The object of such further development is to establish whether the particular claim actually meets the conditions in a) above. In claims where this is not the case or where such an event appears unlikely, the *MAC* may deny the claim:

1. Syncope of undetermined cause.
2. Sinus bradycardia without significant symptoms.
3. Sino-atrial block or sinus arrest without significant symptoms.
4. Prolonged P-R intervals with atrial fibrillation (without third-degree AV block) or with other causes of transient ventricular pause.
5. Bradycardia during sleep.
6. Right bundle branch block with left axis deviation (and other forms of fascicular or bundle branch block) without syncope or other symptoms of intermittent AV block).
7. Asymptomatic second-degree AV block of Type I unless the QRS complexes are prolonged or electrophysiological studies have demonstrated that the block is at or beyond the level of the His bundle (a component of the electrical conduction system of the heart).

Effective October 1, 2001

8. Asymptomatic bradycardia in post-*MI* patients about to initiate long-term beta-blocker drug therapy.

C. Other

All other indications for single-chamber cardiac pacing for which CMS has not specifically indicated coverage remain nationally *non-covered*, except for Category B Investigational Device Exemption (IDE)

clinical trials, or as routine costs of single-chamber cardiac pacing associated with clinical trials, in accordance with section 310.1 of the NCD Manual.

Group II: Dual-Chamber Cardiac Pacemakers – (Effective May 9, 1985)

A. Nationally Covered Indications

Conditions under dual-chamber cardiac pacing are considered acceptable or necessary in the general medical community unless conditions 1 and 2 under Group II. B., are present:

1. Patients in who single-chamber (ventricular pacing) at the time of pacemaker insertion elicits a definite drop in blood pressure, retrograde conduction, or discomfort.
2. Patients in whom the pacemaker syndrome (atrial ventricular asynchrony), with significant symptoms, has already been experienced with a pacemaker that is being replaced.
3. Patients in whom even a relatively small increase in cardiac efficiency will importantly improve the quality of life, e.g., patients with **CHF** despite adequate other medical measures.
4. Patients in whom the pacemaker syndrome can be anticipated, e.g., in young and active people, etc.

Dual-chamber pacemakers may also be covered for the *conditions as* listed in Group I. A., if the medical necessity is sufficiently justified through adequate claims development. Expert physicians differ in their judgments about what constitutes appropriate criteria for dual-chamber pacemaker use. The judgment that such a pacemaker is warranted in the patient meeting accepted criteria must be based upon the individual needs and characteristics of that patient, weighing the magnitude and likelihood of anticipated benefits against the magnitude and likelihood of disadvantages to the patient.

B. Nationally Non-Covered Indications

Whenever the following conditions (which represent overriding contraindications) are present, dual-chamber pacemakers are not covered:

1. Ineffective atrial contractions (e.g., chronic atrial fibrillation or flutter, or giant left atrium).
2. Frequent or persistent supraventricular tachycardias, except where the pacemaker is specifically for the control of the tachycardia.
3. A clinical condition in which pacing takes place only intermittently and briefly, and which is not associated with a reasonable likelihood that pacing needs will become prolonged, e.g., the occasional patient with hypersensitive carotid sinus syndrome with syncope due to bradycardia and unresponsive to prophylactic medical measures.
4. Prophylactic pacemaker use following recovery from acute **MI** during which there was temporary complete (third-degree) and/or Type II second-degree AV block in association with bundle branch block.

C. Other

All other indications for dual-chamber cardiac pacing for which CMS has not specifically indicated coverage remain nationally *non-covered*, except for Category B IDE clinical trials, or as routine costs of dual-chamber cardiac pacing associated with clinical trials, in accordance with section 310.1 of the NCD Manual.

20.8.1 - Cardiac Pacemaker Evaluation Services

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

Medicare covers a variety of services for the post-implant follow-up and evaluation of implanted cardiac pacemakers. The following guidelines are designed to assist *Medicare Administrative Contractors (MACs)* in identifying and processing claims for such services.

NOTE: These new guidelines are limited to lithium battery-powered pacemakers, because mercury-zinc battery-powered pacemakers are no longer being manufactured and virtually all have been replaced by lithium units. *MACs* still receiving claims for monitoring such units should continue to apply the guidelines published in 1980 to those units until they are replaced.

There are two general types of pacemakers in current use - single-chamber pacemakers which sense and pace the ventricles of the heart, and dual-chamber pacemakers which sense and pace both the atria and the ventricles. These differences require different monitoring patterns over the expected life of the units involved. One fact of which *MACs* should be aware is that many dual-chamber units may be programmed to pace only the ventricles; this may be done either at the time the pacemaker is implanted or at some time afterward. In such cases, a dual-chamber unit, when programmed or reprogrammed for ventricular pacing, should be treated as a single-chamber pacemaker in applying screening guidelines.

The decision as to how often any patient's pacemaker should be monitored is the responsibility of the patient's physician who is best able to take into account the condition and circumstances of the individual patient. These may vary over time, requiring modifications of the frequency with which the patient should be monitored. In cases where monitoring is done by some entity other than the patient's physician, such as a commercial monitoring service or hospital outpatient department, the physician's prescription for monitoring is required and should be periodically renewed (at least annually) to assure that the frequency of monitoring is proper for the patient. Where a patient is monitored both during clinic visits and transtelephonically, the *MAC* should be sure to include frequency data on both types of monitoring in evaluating the reasonableness of the frequency of monitoring services received by the patient. Since there are over 200 pacemaker models in service at any given point, and a variety of patient conditions that give rise to the need for pacemakers, the question of the appropriate frequency of monitoring is a complex one. Nevertheless, it is possible to develop guidelines within which the vast majority of pacemaker monitoring will fall and *MACs* should do this, using their own data and experience, as well as the frequency guidelines which follow, in order to limit extensive claims development to those cases requiring special attention.

20.8.1.1 - Transtelephonic Monitoring of Cardiac Pacemakers

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

A. General

Transtelephonic monitoring of pacemakers is furnished by commercial suppliers, hospital outpatient departments, and physicians' offices.

Telephone monitoring of cardiac pacemakers as described below is medically efficacious in identifying early signs of possible pacemaker failure, thus reducing the number of sudden pacemaker failures requiring emergency replacement. All systems that monitor the pacemaker rate (bpm) in both the free-running and/or magnetic mode are effective in detecting subclinical pacemaker failure due to battery depletion. More sophisticated systems are also capable of detecting internal electronic problems within the pulse generator itself and other potential problems. In the case of *dual*-chamber pacemakers in particular, such monitoring may detect failure of synchronization of the atria and ventricles, and the need for adjustment and reprogramming of the device.

NOTE: The transmitting device furnished to the patient is simply one component of the diagnostic system, and is not covered as durable medical equipment. Those engaged in transtelephonic pacemaker monitoring should reflect the costs of the transmitters in setting their charges for monitoring.

B. Definition of Transtelephonic Monitoring

In order for transtelephonic monitoring services to be covered, the services must consist of the following elements:

- *A minimum 30-second readable strip of the pacemaker in the free-running mode;*
- *Unless contraindicated, a minimum 30-second readable strip of the pacemaker in the magnetic mode; and,*
- *A minimum 30 seconds of readable ECG strip.*

C. Frequency Guidelines for Transtelephonic Monitoring

The guidelines below constitute a system which *Medicare Administrative Contractors (MACs)* should use, in conjunction with their knowledge of local medical practices, to screen claims for transtelephonic monitoring prior to payment. It is important to note that they are not recommendations with respect to a minimum frequency for such monitorings, but rather a maximum frequency (within which payment may be made without further claims development). As with previous guidelines, more frequent monitorings may be covered in cases where *MACs* are satisfied that such monitorings are medically necessary; e.g., based on the condition of the patient, or with respect to pacemakers exhibiting unexpected defects or premature failure. *MACs* should seek written justification for more frequent monitorings from the patient's physician and/or any monitoring service involved.

These guidelines are divided into two broad categories - Guideline I which will apply to the majority of pacemakers now in use, and Guideline II which will apply only to pacemaker systems (pacemaker and leads) for which sufficient long-term clinical information exists to assure that they meet the standards of the Inter-Society Commission for Heart Disease Resources (ICHHD) for longevity and end-of-life decay. (The ICHHD standards are: (1) 90% cumulative survival at 5 years following implant; and (2) an end-of-life decay of less than a 50% drop of output voltage and less than 20% deviation of magnet rate, or a drop of 5 beats per minute or less, over a period of 3 months or more.) *MACs* should consult with their medical advisers and other appropriate individuals and organizations (such as the North American Society of Pacing and Electrophysiology which publishes product reliability information) should questions arise over whether a pacemaker system meets the ICHHD standards.

The two groups of guidelines are then further broken down into two general categories – *single-chamber* and *dual-chamber* pacemakers. *MACs* should be aware that the frequency with which a patient is monitored may be changed from *time-to-time* for a number of reasons, such as a change in the patient's overall condition, a reprogramming of the patient's pacemaker, the development of better information on the pacemaker's longevity or failure mode, etc. Consequently, changes in the proper set of guidelines may be required. *MACs* should inform physicians and monitoring services to alert *MACs* to any changes in the patient's monitoring prescription that might necessitate changes in the screening guidelines applied to that patient. (Of particular importance is the reprogramming of a dual-chamber pacemaker to a single-chamber mode of operation. Such reprogramming would shift the patient from the appropriate dual-chamber guideline to the appropriate single-chamber guideline.)

Guideline I

- 1 - Single-chamber pacemakers
 - 1st month - every 2 weeks.
 - 2nd through 36th month - every 8 weeks.
 - 37th month to failure - every 4 weeks.
- 2 - Dual-chamber pacemaker

- 1st month - every 2 weeks.
- 2nd through 6th month - every 4 weeks.
- 7th through 36th month - every 8 weeks.
- 37th month to failure - every 4 weeks.

Guideline II

1 - Single-chamber pacemakers

- 1st month - every 2 weeks.
- 2nd through 48th month - every 12 weeks.
- 49th through 72nd month - every 8 weeks.
- Thereafter - every 4 weeks.

2 - Dual-chamber pacemaker

- 1st month - every 2 weeks.
- 2nd through 30th month - every 12 weeks.
- 31st through 48th month - every 8 weeks.
- Thereafter - every 4 weeks.

D. Pacemaker Clinic Services

1. General

Pacemaker monitoring is also covered when done by pacemaker clinics. Clinic visits may be done in conjunction with transtelephonic monitoring or as a separate service; however, the services rendered by a pacemaker clinic are more extensive than those currently possible by telephone. They include, for example, physical examination of patients and reprogramming of pacemakers. Thus, the use of one of these types of monitoring does not preclude concurrent use of the other.

2. Frequency Guidelines

As with transtelephonic pacemaker monitoring, the frequency of clinic visits is the decision of the patient's physician, taking into account, among other things, the medical condition of the patient. However, **MACs** can develop monitoring guidelines that will prove useful in screening claims. The following are recommendations for monitoring guidelines on lithium-battery pacemakers:

- For single-chamber pacemakers - twice in the first 6 months following implant, then once every 12 months.
- For dual-chamber pacemakers - twice in the first 6 months, then once every 6 months.

20.15 - Electrocardiographic Services

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

A. General

1. An electrocardiogram (EKG) is a graphic representation of electrical activity within the heart. Electrodes placed on the body in predetermined locations sense this electrical activity, which is then recorded by various means for review and interpretation. EKG recordings are used to diagnose a wide range of heart disease and other conditions that manifest themselves by abnormal cardiac electrical activity.

EKG services are covered diagnostic tests when there are documented signs and symptoms or other clinical indications for providing the service. Coverage includes the review and interpretation of EKGs only by a physician. There is no coverage for EKG services when rendered as a screening test or as part of a routine examination unless performed as part of the one-time, "Welcome to Medicare" preventive physical

examination under section 611 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

2. Ambulatory electrocardiography (AECG) refers to services rendered in an outpatient setting over a specified period of time, generally while a patient is engaged in daily activities, including sleep. AECG devices are intended to provide the physician with documented episodes of arrhythmia, which may not be detected using a standard 12-lead EKG. AECG is most typically used to evaluate symptoms that may correlate with intermittent cardiac arrhythmias and/or myocardial ischemia. Such symptoms include syncope, dizziness, chest pain, palpitations, or shortness of breath. Additionally, AECG is used to evaluate patient response to initiation, revision, or discontinuation of arrhythmic drug therapy.

3. The Centers for Medicare & Medicaid Services (CMS), through the national coverage determination (NCD) process, may create new ambulatory EKG monitoring device categories if published, peer-reviewed clinical studies demonstrate evidence of improved clinical utility, or equal utility with additional advantage to the patient, as indicated by improved patient management and/or improved health outcomes in the Medicare population (such as superior ability to detect serious or life-threatening arrhythmias) as compared to devices or services in the currently described categories below.

Descriptions of Ambulatory EKG Monitoring Technologies

1. Dynamic electrocardiography devices that continuously record a real-time EKG, commonly known as Holter™ monitors, typically record over a 24-hour period. The recording is captured either on a magnetic tape or other digital medium. The data is then computer-analyzed at a later time, and a physician interprets the computer-generated report. A 24-hour recording is generally adequate to detect most transient arrhythmias. Documentation of medical necessity is required for monitoring longer than 24 hours. The recording device itself is not covered as durable medical equipment (DME) separate from the total diagnostic service.

2. An event monitor, or event recorder, is a patient-activated or event-activated EKG device that intermittently records cardiac arrhythmic events as they occur. The EKG is recorded on magnetic tape or other digital medium.

Cardiac event monitor technology varies among different devices. For patient-activated event monitors, the patient initiates recording when symptoms appear or when instructed to do so by a physician (e.g., following exercise). For self-sensing, automatically triggered monitors, an EKG is automatically recorded when the device detects an arrhythmia, without patient intervention. Some devices permit a patient to transmit EKG data *transtelephonically* (i.e., via telephone) to a receiving center where the data is reviewed. A technician may be available at these centers to review transmitted data 24 hours per day. In some instances, when the EKG is determined to be outside certain pre-set criteria by a technician or other non-physician, a physician is available 24 hours per day to review the transmitted data and to make clinical decisions regarding the patient. These services are known as “24-hour attended monitoring”. In other instances, transmitted EKG data is reviewed at a later time and are, therefore, considered “non-attended.”

Cardiac event monitors without *transtelephonic* capability must be removed from the patient and taken to a location for review of the stored EKG data. Some devices also permit a "time sampling" mode of operation. The "time sampling" mode is not covered under ambulatory EKG monitoring technology. Some cardiac event monitoring devices with trans-telephonic capabilities require the patient to dial the phone number of a central EKG data reception center and initiate transmission of EKG data. Other devices use Internet-based in-home computers to capture and store EKG data. When such devices detect pre-programmed arrhythmias, data is automatically sent via modem and standard telephone lines to a central receiving center, or independent diagnostic testing facility (IDTF), where the data is reviewed. Internet-based in-home computer systems may also provide the receiving center with a daily computer-generated report that summarizes 24 hours of EKG data.

Certain cardiac event monitors capture electrical activity with a single electrode attached to the skin. Other devices may employ multiple electrodes in order to record more complex EKG tracings. Additionally, devices may be individually programmed to detect patient-specific factors, electrode malfunction, or other factors. Cardiac event monitors can be further categorized as either “pre-event” or “post-event” recorders, based on their memory capabilities:

a. Pre-symptom Memory Loop Recorder (MLR)

Upon detecting symptoms, the wearer presses a button, which activates the recorder to save (i.e., memorize) an interval of pre-symptom EKG data along with data during and subsequent to the symptomatic event. Self-sensing recorders (also known as event-activated or automatic trigger) do not require patient input to capture these data. Single or multiple events may be recorded. The device is worn at all times, usually for up to 30 days.

o Implantable (or Insertable Loop) Recorder (ILR)

Another type of pre-symptom MLR, it is implanted subcutaneously in a patient’s upper left chest and may remain implanted for many months. An ILR is used when syncope is thought to be cardiac-related, but is too infrequent to be detected by either a Holter™ monitor or a traditional pre-symptom MLR.

b. Post-symptom Recorder

The patient temporarily places this device against the chest when symptoms occur and activates it by pressing a button. These recorders represent old technology, as they do not include a memory loop. The device transmits EKG data telephonically in real-time and is usually used for up to 30 days.

B. Nationally Covered Indications

The following indications are covered nationally unless otherwise indicated:

1. Computer analysis of EKGs when furnished in a setting and under the circumstances required for coverage of other EKG services.
2. EKG services rendered by an *IDTF*, including physician review and interpretation. Separate physician services are not covered unless he/she is the patient’s attending or consulting physician.
3. Emergency EKGs (i.e., when the patient is or may be experiencing a life-threatening event) performed as a laboratory or diagnostic service by a portable x-ray supplier only when a physician is in attendance at the time the service is performed or immediately thereafter.
4. Home EKG services with documentation of medical necessity.
5. *Transtelephonic* EKG transmissions (effective March 1, 1980) as a diagnostic service for the indications described below, when performed with equipment meeting the standards described below, subject to the limitations and conditions specified below. Coverage is further limited to the amounts payable with respect to the physician’s service in interpreting the results of such transmissions, including charges for rental of the equipment. The device used by the beneficiary is part of a total diagnostic system and is not considered DME separately. Covered uses are to:

a. Detect, characterize, and document symptomatic transient arrhythmias;

b. Initiate, revise, or discontinue arrhythmic drug therapy; or,

c. Carry-out early post-hospital monitoring of patients discharged after myocardial infarction (MI); (only if 24-hour coverage is provided, see C.5. below).

Certain uses other than those specified above may be covered if, in the judgment of the local *Medicare Administrative Contractor (MAC)*, such use is medically necessary.

Additionally, the transmitting devices must meet at least the following criteria:

- a. *They must be capable of transmitting EKG Leads, I, II, or III; and,*
- b. *The tracing must be sufficiently comparable to a conventional EKG.*

24-hour attended coverage used as early post-hospital monitoring of patients discharged after MI is only covered if provision is made for such 24-hour attended coverage in the manner described below:

24-hour attended coverage means there must be, at a monitoring site or central data center, an EKG technician or other non-physician, receiving calls and/or EKG data; tape recording devices do not meet this requirement. Further, such technicians should have immediate, 24-hour access to a physician to review transmitted data and make clinical decisions regarding the patient. The technician should also be instructed as to when and how to contact available facilities to assist the patient in case of emergencies.

C. **Nationally Non-Covered** Indications

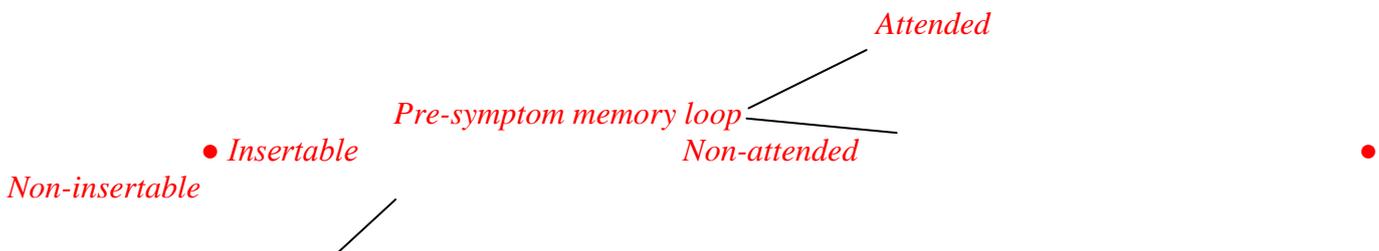
The following indications are non-covered nationally unless otherwise specified below:

1. The time-sampling mode of operation of ambulatory EKG cardiac event monitoring/recording.
2. Separate physician services other than those rendered by an IDTF unless rendered by the patient's attending or consulting physician.
3. Home EKG services without documentation of medical necessity.
4. Emergency EKG services by a portable x-ray supplier without a physician in attendance at the time of service or immediately thereafter.
5. 24-hour attended coverage used as early post-hospital monitoring of patients discharged after MI unless provision is made for such 24-hour attended coverage in the manner described in section B.5. above.
6. Any marketed Food and Drug Administration (FDA)-approved ambulatory cardiac monitoring device or service that cannot be categorized according to the framework below.

D. **Other**

Ambulatory cardiac monitoring performed with a marketed, FDA-approved device, is eligible for coverage if it can be categorized according to the framework below. Unless there is a specific NCD for that device or service, determination as to whether a device or service that fits into the framework is reasonable and necessary is according to local *MAC* discretion.

Electrocardiographic Services Framework



*Patient/Event-Activated
Intermittent Recorders*

Post-symptom (no memory loop) _____ Non-attended

Non-Activated

*Continuous Recorders _____ Dynamic Electrocardiography _____ Non-attended
(e.g., Holter™ Monitor)*

**20.16 - Cardiac Output Monitoring By Thoracic Electrical Bioimpedance (TEB) –
Various Effective Dates Below**

*(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon
Implementation of ICD 10)*

A. General

Thoracic electrical bioimpedance (TEB) devices, a form of plethysmography, monitor cardiac output by non-invasively measuring hemodynamic parameters, including: stroke volume, systemic vascular resistance, and thoracic fluid status. Under a previous coverage determination, effective for services performed on and after July 1, 1999, use of TEB was covered for the “noninvasive diagnosis or monitoring of hemodynamics in patients with suspected or known cardiovascular disease.” In reconsidering this policy, the Centers for Medicare & Medicaid Services (CMS) concluded that this use was neither sufficiently defined nor supported by available clinical literature to offer the guidance necessary for practitioners to determine when TEB would be covered for patient management. Therefore, CMS revised its coverage policy language in response to a request for reconsideration to offer more explicit guidance and clarity for coverage of TEB based on a complete and updated literature review.

B. Nationally Covered Indications

Effective for services performed on and after January 23, 2004, TEB is covered for the following uses:

1. Differentiation of cardiogenic from pulmonary causes of acute dyspnea when medical history, physical examination, and standard assessment tools provide insufficient information, and the treating physician has determined that TEB hemodynamic data are necessary for appropriate management of the patient.
2. Optimization of atrioventricular (A/V) interval for patients with A/V sequential cardiac pacemakers when medical history, physical examination, and standard assessment tools provide insufficient information, and the treating physician has determined that TEB hemodynamic data are necessary for appropriate management of the patient.
3. Monitoring of continuous inotropic therapy for patients with terminal congestive heart failure, when those patients have chosen to die with comfort at home, or for patients waiting at home for a heart transplant.
4. Evaluation for rejection in patients with a heart transplant as a predetermined alternative to a myocardial biopsy. Medical necessity must be documented should a biopsy be performed after TEB.
5. Optimization of fluid management in patients with congestive heart failure when medical history, physical examination, and standard assessment tools provide insufficient information, and the treating physician has determined that TEB hemodynamic data are necessary for appropriate management of the patient.

C. Nationally Non-Covered Indications

1. TEB is non-covered when used for patients:

- a) *With proven or suspected disease involving severe regurgitation of the aorta;*
- b) *With minute ventilation (MV) sensor function pacemakers, since the device may adversely affect the functioning of that type of pacemaker;*
- c) *During cardiac bypass surgery; or,*
- d) *In the management of all forms of hypertension (with the exception of drug-resistant hypertension as outlined below).*

2. All other uses of TEB not otherwise specified remain non-covered.

D. Other

Medicare Administrative Contractors have discretion to determine whether the use of TEB for the management of drug-resistant hypertension is reasonable and necessary. Drug resistant hypertension is defined as failure to achieve goal blood pressure in patients who are adhering to full doses of an appropriate 3-drug regimen that includes a diuretic. Effective November 24, 2006, after reconsideration of Medicare policy, CMS will continue current Medicare policy for TEB.

50 - Ear, Nose and Throat (ENT)

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

50.1 - Speech Generating Devices

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

Effective January 1, 2001, augmentative and alternative communication devices or communicators which are hereafter referred to as “speech generating devices” are now considered to fall within the *durable medical equipment (DME)* benefit category established by §1861(n) of the Social Security Act (*the Act*). They may be covered if the *Medicare Administrative Contractor* medical staff determines that the patient suffers from a severe speech impairment and that the medical condition warrants the use of a device based on the following definitions.

Definition of Speech Generating Devices

Speech generating devices are defined as speech aids that provide an individual who has a severe speech impairment with the ability to meet his functional speaking needs. Speech generating *devices* are characterized by:

- Being a dedicated speech device, used solely by the individual who has a severe speech impairment;
- May have digitized speech output, using prerecorded messages, less than or equal to 8 minutes recording time;
- May have digitized speech output, using prerecorded messages, greater than 8 minutes recording time;
- May have synthesized speech output which requires message formulation by spelling and device access by physical contact with the device-direct selection techniques;
- May have synthesized speech output which permits multiple methods of message formulation and multiple methods of device access; or
- May be software that allows a laptop computer, desktop computer or personal digital assistant (PDA) to function as a speech generating device.

Devices that would not meet the definition of speech generating devices and therefore, do not fall within the scope of §1861(n) of the Act are characterized by:

- Devices that are not dedicated speech devices, but are devices that are capable of running software for purposes other than for speech generation, e.g., devices that can also run a word processing package, an accounting program, or perform other than non-medical function.
- Laptop computers, desktop computers, or PDA's which may be programmed to perform the same function as a speech generating device, are noncovered since they are not primarily medical in nature and do not meet the definition of DME. For this reason, they cannot be considered speech-generating devices for Medicare coverage purposes.
- A device that is useful to someone without severe speech impairment is not considered a speech-generating device for Medicare coverage purposes.

50.3 - Cochlear Implantation (Effective April 4, 2005)

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

A. General

A cochlear implant device is an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze, and code sound. Cochlear implant devices are available in single-channel and multi-channel models. The purpose of implanting the device is to provide awareness and identification of sounds and to facilitate communication for persons who are moderately to profoundly hearing impaired.

B. Nationally Covered Indications

1. Effective for services performed on or after April 4, 2005, cochlear implantation may be covered for treatment of bilateral pre- or-post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification. Limited benefit from amplification is defined by test scores of less than or equal to 40% correct in the best-aided listening condition on tape-recorded tests of open-set sentence cognition. Medicare coverage is provided only for those patients who meet all of the following selection guidelines.

- Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids;
- Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation;
- Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system;
- No contraindications to surgery; and
- The device must be used in accordance with Food and Drug Administration (FDA)-approved labeling.

2. Effective for services performed on or after April 4, 2005, cochlear implantation may be covered for individuals meeting the selection guidelines above and with hearing test scores of greater than 40% and less

than or equal to 60% only when the provider is participating in, and patients are enrolled in, either an FDA-approved category B investigational device exemption clinical trial as defined at 42 CFR 405.201, a trial under the Centers for Medicare & Medicaid (CMS) Clinical Trial Policy as defined at section 310.1 of the National Coverage Determinations Manual, or a prospective, controlled comparative trial approved by CMS as consistent with the evidentiary requirements for National Coverage Analyses and meeting specific quality standards.

C. Nationally *Non-Covered* Indications

Medicare beneficiaries not meeting all of the coverage criteria for cochlear implantation listed are deemed not eligible for Medicare coverage under section 1862(a)(1)(A) of the Social Security Act.

D. Other

All other indications for cochlear implantation not otherwise indicated as nationally covered or non-covered above remain at local *Medicare Administrative Contractor* discretion.

70.3 - Physician's Office *within* an Institution - Coverage of Services and Supplies Incident to a Physician's Services

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

Coverage of Services and Supplies Incident to a Physician's Services

Where a physician establishes an office within a nursing home or other institution, coverage of services and supplies furnished in the office must be determined in accordance with the "incident to a physician's professional service" provision (see the Medicare Benefit Policy Manual, Chapter 6, "Hospital Services Covered Under Part B," §20.4.1 or the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §60.1) as in any physician's office. A physician's office within an institution must be confined to a separately identified part of the facility which is used solely as the physician's office and cannot be construed to extend throughout the entire institution. Thus, services performed outside the "office" area would be subject to the coverage rules applicable to services furnished outside the office setting.

In order to accurately apply the criteria in the Medicare Benefit Policy Manual, Chapters 6, §20.4.1, or Chapter 15, "Covered Medical and Other Health Services," §60.1, the *Medicare Administrative Contractor (MAC)* gives consideration to the physical proximity of the institution and physician's office. When his office is located within a facility, a physician may not be reimbursed for services, supplies, and use of equipment which fall outside the scope of services "commonly furnished" in physician's offices generally, even though such services may be furnished in his institutional office. Additionally, make a distinction between the physician's office practice and the institution, especially when the physician is administrator or owner of the facility. Thus, for their services to be covered under the criteria in the Medicare Benefit Policy Manual, Chapter 6, §20.4.1, or the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §60.1, the auxiliary medical personnel must be members of the office staff rather than of the institution's staff, and the cost of supplies must represent an expense to the physician's office practice. Finally, services performed by the employees of the physician outside the "office" area must be directly supervised by the physician; his presence in the facility as a whole would not suffice to meet this requirement. (In any setting, of course, supervision of auxiliary personnel in and of itself is not considered a "physician's professional service" to which the services of the auxiliary personnel could be an incidental part, i.e., in addition to supervision, the physician must perform or have performed a personal professional service to the patient to which the services of the auxiliary personnel could be considered an incidental *part.*) Denials for failure to meet any of these requirements would be based on §1861(s)(2)(A) of the *Social Security Act*.

Establishment of an office within an institution would not modify rules otherwise applicable for determining coverage of the physician's personal professional services within the institution. However, in view of the

opportunity afforded to a physician who maintains such an office for rendering services to a sizable number of patients in a short period of time or for performing frequent services for the same patient, claims for physicians' services rendered under such circumstances would require careful evaluation by the *MAC* to assure that payment is made only for services that are reasonable and necessary.

Cross-reference:

The Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services."

The Medicare Benefit Policy Manual, Chapter 6, "Hospital Services Covered Under Part B," §20.4.1.

70.5 - Hospital and Skilled Nursing Facility Admission Diagnostic Procedures

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

These instructions *describe* the application of the reasonable and necessary payment exclusion to diagnostic procedures, such as chest x-rays, urinalysis, etc. provided to patients upon admission to a hospital or skilled nursing facility.

The major factors which support a determination that a diagnostic procedure performed as part of the admitting procedure to a hospital or skilled nursing facility is reasonable and necessary, are:

A. The test is specifically ordered by the admitting physician (or a hospital or skilled nursing facility staff physician having responsibility for the patient where there is no admitting physician): i.e., it is not furnished under the standing orders of a physician for his patients;

B. The test is medically necessary for the diagnosis or treatment of the individual patient's condition; and

C. The test does not unnecessarily duplicate the same test performed on an outpatient basis prior to admission or performed in connection with a recent hospital or skilled nursing facility admission.

Where the *Medicare Administrative Contractor* has not already done so, consult with the Quality Improvement Organizations (QIOs) to obtain information gathered by the QIOs on a sample basis as to whether x-rays and diagnostic tests are being specifically ordered as described under subsection (A).

80.1 - Hydrophilic Contact Lens for Corneal Bandage

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

Some hydrophilic contact lenses are used as moist corneal bandages for the treatment of acute or chronic corneal pathology, such as bulbous keratopathy, dry eyes, corneal ulcers and erosion, keratitis, corneal edema, descemetocele, corneal ectasis, Mooren's ulcer, anterior corneal dystrophy, neurotrophic keratoconjunctivitis, and for other therapeutic reasons.

Payment may be made under §1861(s)(2) of the *Social Security* Act for a hydrophilic contact lens approved by the Food and Drug Administration (FDA) and used as a supply incident to a physician's service.

Payment for the lens is included in the payment for the physician's service to which the lens is incident.

Medicare Administrative Contractors are authorized to accept an FDA letter of approval or other FDA published material as evidence of FDA approval. (See §80.4 for coverage of a hydrophilic contact lens as a prosthetic device.) See the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," and the Medicare Benefit Policy Manual, Chapter 6, "Hospital Services Covered Under Part B," §20.4

80.2 - Photodynamic Therapy

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

Photodynamic therapy is a medical procedure which involves the infusion of a photosensitive (light-activated) drug with a very specific absorption peak. This drug is chemically designed to have a unique affinity for the diseased tissue intended for treatment. Once introduced to the body, the drug accumulates and is retained in diseased tissue to a greater degree than in normal tissue. Infusion is followed by the targeted irradiation of this tissue with a non-thermal laser, calibrated to emit light at a wavelength that corresponds to the drug's absorption peak. The drug then becomes active and locally treats the diseased tissue.

Ocular Photodynamic Therapy (OPT)

Ocular Photodynamic Therapy (OPT) is used in the treatment of ophthalmologic diseases. OPT is only covered when used in conjunction with verteporfin (see section 80.3, "Photosensitive Drugs").

- Classic Subfoveal Choroidal Neovascular (CNV) Lesions - OPT is covered with a diagnosis of neovascular age-related macular degeneration (AMD) with predominately classic subfoveal choroidal neovascular (CNV) lesions (where the area of classic CNV occupies $\geq 50\%$ of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram (*FA*). Subsequent follow-up visits will require either an optical coherence *tomography or an FA* to assess treatment response. There are no requirements regarding visual acuity, lesion size, and number of re-treatments.
- Occult Subfoveal CNV Lesions - OPT is non-covered for patients with a diagnosis of AMD with occult and no classic CNV lesions.

Other Conditions - Use of OPT with verteporfin for other types of AMD (e.g., patients with minimally classic CNV lesions, atrophic, or dry AMD) is *non*-covered. OPT with verteporfin for other ocular indications such as pathologic myopia or presumed ocular histoplasmosis syndrome, is eligible for coverage through individual *Medicare Administrative Contractor* discretion.

80.2.1 - Ocular Photodynamic Therapy (OPT) - Effective April 3, 2013)

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

A. General

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. OPT is only covered when used in conjunction with verteporfin.

Effective July 1, 2001, OPT with verteporfin was approved for a diagnosis of neovascular AMD with predominately classic subfoveal choroidal neovascularization (CNV) lesions (where the area of classic CNV occupies $\geq 50\%$ of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram (*FA*).

On October 17, 2001, *the Centers for Medicare & Medicaid Services* (CMS) announced its "intent to cover" OPT with verteporfin for AMD patients with occult and no classic subfoveal CNV as determined by *an FA*. The October 17, 2001, decision was never implemented.

On March 28, 2002, after thorough review and reconsideration of the October 17, 2001, intent to cover policy, CMS determined that the current non-coverage policy for OPT for verteporfin for AMD patients with occult and no classic subfoveal CNV as determined by *an FA* should remain in effect.

Effective August 20, 2002, CMS issued a non-coverage instruction for OPT with verteporfin for AMD patients with occult and no classic subfoveal CNV as determined by *an FA*.

B. *Nationally Covered Indications*

Effective April 1, 2004, OPT with verteporfin continues to be approved for a diagnosis of neovascular AMD with predominately classic subfoveal CNV lesions (where the area of classic CNV occupies $\geq 50\%$ of the area of the entire lesion) at the initial visit as determined by *an FA*. (CNV lesions are comprised of classic and/or occult components.) Subsequent follow-up visits require either an optical coherence tomography (OCT) (effective April 3, 2013) or an FA (effective April 1, 2004) to assess treatment response. There are no requirements regarding visual acuity, lesion size, and number of re-treatments when treating predominantly classic lesions.

In addition, after thorough review and reconsideration of the August 20, 2002, non-coverage policy, CMS determines that the evidence is adequate to conclude that OPT with verteporfin is reasonable and necessary for treating:

1. Subfoveal occult with no classic CNV associated with AMD; and,
2. Subfoveal minimally classic CNV (where the area of classic CNV occupies $< 50\%$ of the area of the entire lesion) associated with AMD.

The above 2 indications are considered reasonable and necessary only when:

1. The lesions are small (4 disk areas or less in size) at the time of initial treatment or within the 3 months prior to initial treatment; and,
2. The lesions have shown evidence of progression within the 3 months prior to initial treatment. Evidence of progression must be documented by deterioration of visual acuity (at least 5 letters on a standard eye examination chart), lesion growth (an increase in at least 1 disk area), or the appearance of blood associated with the lesion.

C. *Nationally Non-Covered Indications*

Other uses of OPT with verteporfin to treat AMD not already addressed by CMS will continue to be non-covered. These include, but are not limited to, the following AMD indications:

- *Juxtafoveal or extrafoveal CNV lesions (lesions outside the fovea),*
- *Inability to obtain a fluorescein angiogram,*
- *Atrophic or “dry” AMD.*

D. *Other*

The OPT with verteporfin for other ocular indications, such as pathologic myopia or presumed ocular histoplasmosis syndrome, continue to be eligible for local coverage determinations through individual *Medicare Administrative Contractor* discretion.

80.3 - Photosensitive Drugs

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

Photosensitive drugs are the light-sensitive agents used in photodynamic therapy. Once introduced into the body, these drugs selectively identify and adhere to diseased tissue. The drugs remain inactive until they are exposed to a specific wavelength of light, by means of a laser, that corresponds to their absorption peak. The

activation of a photosensitive drug results in a photochemical reaction which treats the diseased tissue without affecting surrounding normal tissue.

Verteporfin

Verteporfin, a benzoporphyrin derivative, is an intravenous lipophilic photosensitive drug with an absorption peak of 690 nm. This drug was first approved by the Food and Drug Administration on April 12, 2000, and subsequently, approved for inclusion in the United States Pharmacopoeia on July 18, 2000, meeting Medicare's definition of a drug when used in conjunction with ocular photodynamic therapy (*OPT*) (see *section 80.2*, "Photodynamic Therapy") when furnished intravenously incident to a physician's service. For patients with age-related macular degeneration (*AMD*), *verteporfin* is only covered with a diagnosis of neovascular *AMD* with predominately classic subfoveal choroidal neovascular (CNV) lesions (where the area of classic CNV occupies $\geq 50\%$ of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram (*FA*). Subsequent follow-up visits will require either an optical coherence tomography or an FA to assess treatment response. OPT with verteporfin is covered for the above indication and will remain non-covered for all other indications related to AMD (see *section 80.2*). OPT with *verteporfin* for use in non-AMD conditions is eligible for coverage through individual Medicare Administrative Contractor discretion.

80.3.1- Verteporfin - Effective April 3, 2013

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

A. General

Verteporfin, a benzoporphyrin derivative, is an intravenous lipophilic photosensitive drug with an absorption peak of 690 nm. Verteporfin was first approved by the Food and Drug Administration on April 12, 2000, and subsequently approved for inclusion in the United States Pharmacopoeia on July 18, 2000, meeting Medicare's definition of a drug as defined under §1861(t)(1) of the Social Security Act. Verteporfin is only covered when used in conjunction with ocular photodynamic therapy (*OPT*) when furnished intravenously incident to a physician's service.

B. Nationally Covered Indications

Effective April 1, 2004, OPT with verteporfin is covered for patients with a diagnosis of neovascular age-related macular degeneration (AMD) with:

- Predominately classic subfoveal choroidal neovascularization (CNV) lesions (where the area of classic CNV occupies $\geq 50\%$ of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram (*FA*). (CNV lesions are comprised of classic and/or occult components.) Subsequent follow-up visits require either an optical coherence tomography (effective April 3, 2013) or an *FA* (effective April 1, 2004) to assess treatment response.

There are no requirements regarding visual acuity, lesion size, and number of retreatments when treating predominantly classic lesions.

- Subfoveal occult with no classic *CNV* associated with AMD.
- Subfoveal minimally classic CNV (where the area of classic CNV occupies $< 50\%$ of the area of the entire lesion) associated with AMD.

The above 2 indications are considered reasonable and necessary only when:

1. The lesions are small (4 disk areas or less in size) at the time of initial treatment or within the 3 months prior to initial treatment; and,

2. The lesions have shown evidence of progression within the 3 months prior to initial treatment. Evidence of progression must be documented by deterioration of visual acuity (at least 5 letters on a standard eye examination chart), lesion growth (an increase in at least 1 disk area), or the appearance of blood associated with the lesion.

C. *Nationally Non-Covered Indications*

Other uses of OPT with verteporfin to treat AMD not already addressed by *the Centers for Medicare & Medicaid Services* will continue to be non-covered. These include, but are not limited to, the following AMD indications: juxtafoveal or extrafoveal CNV lesions (lesions outside the fovea), inability to obtain an FA, or atrophic or “dry” AMD.

D. *Other*

The OPT with verteporfin for other ocular indications, such as pathologic myopia or presumed ocular histoplasmosis syndrome, continue to be eligible for local coverage determinations through individual *Medicare Administrative Contractor* discretion.

80.4 - Hydrophilic Contact Lenses

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

Hydrophilic contact lenses are eyeglasses within the meaning of the exclusion in §1862(a)(7) of the *Social Security* Act and are not covered when used in the treatment of non-diseased eyes with spherical ametropia, refractive astigmatism, and/or corneal astigmatism. Payment may be made under the prosthetic device benefit, however, for hydrophilic contact lenses when prescribed for an aphakic patient.

Medicare Administrative Contractors are authorized to accept a *Food and Drug Administration* (FDA) letter of approval or other FDA-published material as evidence of FDA approval. (See §80.1 for coverage of a hydrophilic lens as a corneal bandage.)

Cross-references:

The Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,” §100 and §120.

The Medicare Benefit Policy Manual, Chapter 16, “General Exclusions from Coverage,” §20 and §90.

Medicare National Coverage Determinations Manual

Chapter 1, Part 2 (Sections 90 – 160.26)

Coverage Determinations

100.13 - Laproscopic Cholecystectomy

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

Laparoscopic cholecystectomy is a covered surgical procedure in which a diseased gall bladder is removed through the use of instruments introduced via cannulae, with vision of the operative field maintained by use of a high-resolution television camera-monitor system (video laparoscope). For inpatient claims, *report the diagnosis* code for *laparoscopic* cholecystectomy. For all other claims, report the *appropriate CPT code* for laparoscopy, surgical; cholecystectomy (any method), and the *appropriate CPT code* for laparoscopy, surgical: cholecystectomy with cholangiography.

110.2 - Certain Drugs Distributed by the National Cancer Institute

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

Under its Cancer Therapy Evaluation, the Division of Cancer Treatment of the National Cancer Institute (NCI), in cooperation with the Food and Drug Administration, approves and distributes certain drugs for use in treating terminally ill cancer patients. One group of these drugs, designated as Group C drugs, unlike other drugs distributed by the NCI, *is* not limited to use in clinical trials for the purpose of testing their efficacy. Drugs are classified as Group C drugs only if there is sufficient evidence demonstrating their efficacy within a tumor type and that they can be safely administered.

A physician is eligible to receive Group C drugs from the Division of Cancer Treatment only if the following requirements are met:

- A physician must be registered with the NCI as an investigator by having completed an FD-Form 1573;
- A written request for the drug, indicating the disease to be treated, must be submitted to the NCI;
- The use of the drug must be limited to indications outlined in the NCI's guidelines; and
- All adverse reactions must be reported to the Investigational Drug Branch of the Division of Cancer Treatment.

In view of these NCI controls on distribution and use of Group C drugs, *A/B Medicare Administrative Contractors (MACs)* may assume, in the absence of evidence to the contrary, that a Group C drug and the related hospital stay are covered if all other applicable coverage requirements are satisfied.

If there is reason to question coverage in a particular case, the matter should be resolved with the assistance of the Quality Improvement Organization (QIO), or if there is none, the assistance of the *MAC's* medical consultants.

Information regarding those drugs which are classified as Group C drugs may be obtained from:

*Chief, Investigational Drug Branch
Cancer Therapy Evaluation Program*

110.8.1 - Stem Cell Transplantation (Various Effective Dates Below)

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

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 marrow or peripheral blood for intravenous infusion. Autologous stem cell transplants (AuSCT) must be used to effect hematopoietic reconstitution following severely myelotoxic doses of chemotherapy (HDCT) and/or radiotherapy used to treat various malignancies. Allogeneic stem cell transplants may be used to restore function in recipients having an inherited or acquired deficiency or defect. Hematopoietic stem cells are multi-potent stem cells that give rise to all the blood cell types; these stem cells form blood and immune cells. A hematopoietic stem cell is a cell isolated from blood or bone marrow that can renew itself, differentiate to a variety of specialized cells, can mobilize out of the bone marrow into circulating blood, and can undergo programmed cell death, called apoptosis - a process by which cells that are unneeded or detrimental self-destruct.

The Centers for Medicare & Medicaid Services (CMS) is clarifying that bone marrow and peripheral blood stem cell transplantation is a process which includes mobilization, harvesting, and transplant of bone marrow or peripheral blood stem cells and the administration of high dose chemotherapy or radiotherapy prior to the actual transplant. When bone marrow or peripheral blood stem cell transplantation is covered, all necessary steps are included in coverage. When bone marrow or peripheral blood stem cell transplantation is non-covered, none of the steps are covered.

1. Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

Allogeneic hematopoietic stem cell transplantation (HSCT) is a procedure in which a portion of a healthy donor's stem cell or bone marrow is obtained and prepared for intravenous infusion.

a. Nationally Covered Indications

The following uses of allogeneic HSCT are covered under Medicare:

- i. Effective for services performed on or after August 1, 1978, for the treatment of leukemia, leukemia in remission, or aplastic anemia when it is reasonable and necessary,
- ii. Effective for services performed on or after June 3, 1985, for the treatment of severe combined immunodeficiency disease (SCID) and for the treatment of Wiskott-Aldrich syndrome.
- iii. Effective for services performed on or after August 4, 2010, for the treatment of Myelodysplastic Syndromes (MDS) pursuant to Coverage with Evidence Development (CED) in the context of a Medicare-approved, prospective clinical study.

The MDS refers to a group of diverse blood disorders in which the bone marrow does not produce enough healthy, functioning blood cells. These disorders are varied with regard to clinical characteristics, cytologic and pathologic features, and cytogenetics. The abnormal production of blood cells in the bone marrow leads to low blood cell counts, referred to as cytopenias, which are a hallmark feature of MDS along with a dysplastic and hypercellular-appearing bone marrow.

Medicare payment for these beneficiaries will be restricted to patients enrolled in an approved clinical study. In accordance with the Stem Cell Therapeutic and Research Act of 2005 (US Public Law 109-129) a

standard dataset is collected for all allogeneic transplant patients in the United States by the Center for International Blood and Marrow Transplant Research. The elements in this dataset, comprised of two mandatory forms plus one additional form, encompass the information we require for a study under CED.

A prospective clinical study seeking Medicare payment for treating a beneficiary with allogeneic HSCT for MDS pursuant to CED must meet one or more aspects of the following questions:

- Prospectively, compared to Medicare beneficiaries with MDS who do not receive HSCT, do Medicare beneficiaries with MDS who receive HSCT have improved outcomes as indicated by:
 - Relapse-free mortality,
 - progression free survival,
 - relapse, and
 - overall survival?
- Prospectively, in Medicare beneficiaries with MDS who receive HSCT, how do International Prognostic Scoring System (IPSS) score, patient age, cytopenias and comorbidities predict the following outcomes:
 - Relapse-free mortality,
 - progression free survival,
 - relapse, and
 - overall survival?
- Prospectively, in Medicare beneficiaries with MDS who receive HSCT, what treatment facility characteristics predict meaningful clinical improvement in the following outcomes:
 - Relapse-free mortality,
 - progression free survival,
 - relapse, and
 - overall survival?

In addition, the clinical study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

- a. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
- b. The research study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
- c. The research study does not unjustifiably duplicate existing studies.
- d. The research study design is appropriate to answer the research question being asked in the study.
- e. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
- f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46.
- g. All aspects of the research study are conducted according to appropriate standards of scientific integrity (see <http://www.icmje.org>).

- h. The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for CED coverage.
- i. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.
- j. The clinical research study is registered on the ClinicalTrials.gov Web site by the principal sponsor/investigator prior to the enrollment of the first study subject.
- k. The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (<http://www.icmje.org>). However a full report of the outcomes must be made public no later than 3 years after the end of data collection.
- l. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
- m. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Social Security Act, the Agency for Health Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

The clinical research study should also have the following features:

- It should be a prospective, longitudinal study with clinical information from the period before HSCT and short- and long-term follow-up information.
- Outcomes should be measured and compared among pre-specified subgroups within the cohort.
- The study should be powered to make inferences in subgroup analyses.
- Risk stratification methods should be used to control for selection bias. Data elements to be used in risk stratification models should include:

Patient selection:

- Patient Age at diagnosis of MDS and at transplantation
- Date of onset of MDS

- Disease classification (specific MDS subtype at diagnosis prior to preparative/conditioning regimen using World Health Organization (WHO) classifications). Include presence/absence of refractory cytopenias
- Comorbid conditions
- IPSS score (and WHO-adapted Prognostic Scoring System (WPSS) score, if applicable) at diagnosis and prior to transplantation
- Score immediately prior to transplantation and one year post-transplantation
- Disease assessment at diagnosis at start of preparative regimen and last assessment prior to preparative regimen Subtype of MDS (refractory anemia with or without blasts, degree of blasts, etc.)
- Type of preparative/conditioning regimen administered (*myeloablative*, non-myeloablative, reduced-intensity conditioning)
- Donor type
- Cell Source
- IPSS Score at diagnosis

Facilities must submit the required transplant essential data to the Stem Cell Therapeutics Outcomes Database.

b. Nationally Non-Covered Indications

Effective for services performed on or after May 24, 1996, allogeneic HSCT is not covered as treatment for multiple myeloma.

2. Autologous Stem Cell Transplantation (AuSCT)

Autologous stem cell transplantation (AuSCT) is a technique for restoring stem cells using the patient's own previously stored cells.

a. Nationally Covered Indications

i. Effective for services performed on or after April 28, 1989, AuSCT is considered reasonable and necessary under §1862(a)(1)(A) of the Social Security Act (the Act) for the following conditions and is covered under Medicare for patients with:

- Acute leukemia in remission who have a high probability of relapse and who have no human leucocyte antigens (HLA)-matched;
- Resistant non-Hodgkin's lymphomas or those presenting with poor prognostic features following an initial response;
- Recurrent or refractory neuroblastoma; or
- Advanced Hodgkin's disease who have failed conventional therapy and have no HLA-matched donor.

ii. Effective October 1, 2000, single AuSCT is only covered for Durie-Salmon Stage II or III patients 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.

iii. 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 who meet the following criteria:

- Amyloid deposition in 2 or fewer organs; and,
- Cardiac left ventricular ejection fraction (EF) greater than 45%.

b. Nationally Non-Covered Indications

Insufficient data exist to establish definite conclusions regarding the efficacy of AuSCT for the following conditions:

- Acute leukemia not in remission;
- Chronic granulocytic leukemia;
- Solid tumors (other than neuroblastoma);
- Up to October 1, 2000, multiple myeloma;
- Tandem transplantation (multiple rounds of AuSCT) for patients with multiple myeloma;
- Effective October 1, 2000, non-primary AL amyloidosis; and,
- Effective October 1, 2000, thru March 14, 2005, primary AL amyloidosis for Medicare beneficiaries age 64 or older.

In these cases, AuSCT is not considered reasonable and necessary within the meaning of §1862(a)(1)(A) of the Act and is not covered under Medicare.

B. Other

All other indications for stem cell transplantation not otherwise noted above as covered or non-covered nationally remain at local *Medicare Administrative Contractor* discretion.

110.17 – *Anti-Cancer* Chemotherapy for Colorectal Cancer (Effective January 28, 2005) (Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

A. General

Oxaliplatin (Eloxatin™), irinotecan (Camptosar®), cetuximab (Erbitux™), and bevacizumab (Avastin™) are anti-cancer chemotherapeutic agents approved by the Food and Drug Administration (FDA) for the treatment of colorectal cancer. Anti-cancer chemotherapeutic agents are eligible for coverage when used in accordance with *FDA*-approved labeling (see section 1861(t)(2)(B) of the Social Security Act (the Act)), when the off-label use is supported in one of the authoritative drug compendia listed in section 1861(t)(2)(B)(ii)(I) of the Act, or when the *Medicare Administrative Contractor (MAC)* determines an off-label use is medically accepted based on guidance provided by the Secretary (section 1861(t)(2)(B)(ii)(II).

B. Nationally Covered Indications

Pursuant to this national coverage determination (*NCD*), the off-label use of clinical items and services, including the use of the studied drugs oxaliplatin, irinotecan, cetuximab, or bevacizumab, are covered in specific clinical trials identified by the Centers for Medicare & Medicaid Services (CMS). The clinical trials identified by CMS for coverage of clinical items and services are sponsored by the National Cancer Institute (NCI) and study the use of one or more off-label uses of these four drugs in colorectal cancer and in other cancer types. The list of identified trials is on the CMS Web site at: <http://www.cms.hhs.gov/coverage/download/id90b.pdf>.

C. Other

This policy does not alter Medicare coverage for items and services that may be covered or non-covered according to the existing national coverage policy for Routine Costs in a Clinical Trial (*NCD Manual section 310.1*). Routine costs will continue to be covered as well as other items and services provided as a result of coverage of these specific trials in this policy. The basic requirements for enrollment in a trial remain unchanged.

The existing requirements for coverage of oxaliplatin, irinotecan, cetuximab, bevacizumab, or other anticancer chemotherapeutic agents for FDA-approved indications or for indications listed in an approved compendium are not modified.

MACs shall continue to make reasonable and necessary coverage determinations under section 1861(t)(2)(B)(ii)(II) of the Act based on guidance provided by the Secretary for medically accepted uses of off-label indications of oxaliplatin, irinotecan, cetuximab, bevacizumab, or other anticancer chemotherapeutic agents provided outside of the identified clinical trials appearing on the CMS website noted above.

110.19 – Abarelix for the Treatment of Prostate Cancer (Effective March 15, 2005) *(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)*

A. General

An estimated 230,000 new cases of prostate cancer occurred in the United States during 2004. Treatment options vary once the disease is diagnosed depending on age, stage of the cancer, and other individual medical conditions. Surgery (e.g., radical prostatectomy) or radiation is typically used for early-stage disease. Hormonal therapy, chemotherapy, and radiation (or combinations of these treatments) are used for more advanced disease. Prostate cancer is androgen-dependent. In recent years, hormonal therapy has evolved from orchiectomy and estrogens to the use of synthetic drugs known as gonadotropin-releasing hormone (GnRH) agonists or analogues. GnRH agonists include drugs such as leuprolide (LupronTM) and goserelin (ZoladexTM). In contrast with GnRH agonists, newer compounds such as abarelix (PlenaxisTM) are thought to be devoid of agonist activity and to lack an initial androgen-stimulating effect and are thus considered GnRH receptor antagonists. Abarelix has been proposed as a substitute for GnRH agonists with and without anti-androgens in the treatment of patients with advanced prostate cancer for whom a surge in androgen blood levels may pose a risk of worsening symptoms (“clinical flare.”)

B. Nationally Covered Indications

Effective for services performed on or after March 15, 2005, the Centers for Medicare & Medicaid Services (CMS) make the following determinations regarding the use of abarelix in the treatment of patients with prostate cancer:

The evidence is adequate to conclude that abarelix is reasonable and necessary as a palliative treatment in patients with advanced symptomatic prostate cancer: (1) in whom GnRH agonist therapy is not appropriate; (2) who decline surgical castration; and (3) who present with one of the following:

- risk of neurological compromise due to metastases,
- ureteral or bladder outlet obstruction due to local encroachment or metastatic disease, or,
- severe bone pain from skeletal metastases persisting on narcotic analgesia.

The following additional conditions for coverage must be met in accordance with the Food and Drug Administration (FDA) labeling requirements to ensure that abarelix is used only in patients for whom the drug is indicated:

- The patient has been evaluated by, and the drug has been prescribed by, a physician who has attested to the following qualifications and accepted the following responsibilities, and on that basis, has enrolled in the post-marketing risk management program established by the drug manufacturer.
- Physicians have attested willingness and ability to:
 - Diagnose and manage advanced symptomatic prostate cancer;
 - Diagnose and treat allergic reactions, including anaphylaxis;
 - Have access to medication and equipment necessary to treat allergic reactions, including anaphylaxis;
 - Have patients observed for development of allergic reactions for 30 minutes following each administration of abarelix;
 - Understand the risks and benefits of palliative treatment with abarelix;
 - Educate patients on the risks and benefits of palliative treatment with abarelix; and
 - Report serious adverse events as soon as possible to the manufacturer and/or the FDA.

C. Nationally *Non-Covered* Indications

Effective March 15, 2005, CMS determines that the evidence is not adequate to conclude that abarelix is reasonable and necessary for indications other than that specified above. All other uses of abarelix are not covered. In light of the concern regarding safety risks of abarelix, off-label uses that may appear in listed statutory drug compendia on which Medicare and *Medicare Administrative Contractors* rely to make coverage determinations will remain non-covered unless CMS extends coverage through a reconsideration of this National Coverage Determination (*NCD*).

D. Other

N/A

110.21 - Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

A. General

Erythropoiesis stimulating agents (ESAs) stimulate the bone marrow to make more red blood cells and are United States Food and Drug Administration (FDA) approved for use in reducing the need for blood transfusion in patients with specific clinical indications. The FDA has issued alerts and warnings for ESAs administered for a number of clinical conditions, including cancer. Published studies report a higher risk of serious and life-threatening events associated with oncologic uses of ESAs.

B. Nationally Covered Indications

ESA treatment for the anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia is only reasonable and necessary under the following specified conditions:

- The hemoglobin level immediately prior to initiation or maintenance of ESA treatment is <10 g/dL (or the hematocrit is $<30\%$).
- The starting dose for ESA treatment is the recommended FDA label starting dose, no more than 150 U/kg/3 times weekly for epoetin and 2.25 mcg/kg/1 time weekly for darbepoetin alpha. Equivalent doses may be given over other approved time periods.
- Maintenance of ESA therapy is the starting dose if the hemoglobin level remains below 10 g/dL (or hematocrit is $<30\%$) 4 weeks after initiation of therapy and the rise in hemoglobin is ≥ 1 g/dL (hematocrit $\geq 3\%$);
- For patients whose hemoglobin rises <1 g/dl (hematocrit rise $<3\%$) compared to pretreatment baseline over 4 weeks of treatment and whose hemoglobin level remains <10 g/dL after the 4 weeks of treatment (or the hematocrit is $<30\%$), the recommended FDA label starting dose may be increased once by 25%. Continued use of the drug is not reasonable and necessary if the hemoglobin rises <1 g/dl (hematocrit rise $<3\%$) compared to pretreatment baseline by 8 weeks of treatment.
- Continued administration of the drug is not reasonable and necessary if there is a rapid rise in hemoglobin >1 g/dl (hematocrit $>3\%$) over 2 weeks of treatment unless the hemoglobin remains below or subsequently falls to <10 g/dL (or the hematocrit is $<30\%$). Continuation and reinstatement of ESA therapy must include a dose reduction of 25% from the previously administered dose.
- ESA treatment duration for each course of chemotherapy includes the 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regimen.

C. Nationally Non-Covered Indications

ESA treatment is not reasonable and necessary for beneficiaries with certain clinical conditions, either because of a deleterious effect of the ESA on their underlying disease or because the underlying disease increases their risk of adverse effects related to ESA use. These conditions include:

- Any anemia in cancer or cancer treatment patients due to folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding, or bone marrow fibrosis;
- The anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML), or erythroid cancers;
- The anemia of cancer not related to cancer treatment;
- Any anemia associated only with radiotherapy;
- Prophylactic use to prevent chemotherapy-induced anemia;

- Prophylactic use to reduce tumor hypoxia;
- Patients with erythropoietin-type resistance due to neutralizing antibodies; and
- Anemia due to cancer treatment if patients have uncontrolled hypertension.

D. Other

Local Medicare *Administrative Contractors* may continue to make reasonable and necessary determinations on all other uses of ESAs not specified in this *National Coverage Determination*.

See the Medicare Benefit Policy Manual, chapter 11, section 90 and chapter 15, section 50.5.2 for coverage of ESAs for end-stage renal disease-related anemia.

130.1 - Inpatient Hospital Stays for the Treatment of Alcoholism

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

A. Inpatient Hospital Stay for Alcohol Detoxification

Many hospitals provide detoxification services during the more acute stages of alcoholism or alcohol withdrawal. When the high probability or occurrence of medical complications (e.g., delirium, confusion, trauma, or unconsciousness) during detoxification for acute alcoholism or alcohol withdrawal necessitates the constant availability of physicians and/or complex medical equipment found only in the hospital setting, inpatient hospital care during this period is considered reasonable and necessary and is therefore covered under the program. Generally, detoxification can be accomplished within two to three days with an occasional need for up to five days where the patient's condition dictates. This limit (five days) may be extended in an individual case where there is a need for a longer period for detoxification for a particular patient.

In such cases, however, there should be documentation by a physician which substantiates that a longer period of detoxification was reasonable and necessary. When the detoxification needs of an individual no longer require an inpatient hospital setting, coverage should be denied on the basis that inpatient hospital care is not reasonable and necessary as required by [§1862\(a\)\(1\)](#) of the *Social Security Act (the Act)*. Following detoxification a patient may be transferred to an inpatient rehabilitation unit or discharged to a residential treatment program or outpatient treatment setting.

B. Inpatient Hospital Stay for Alcohol Rehabilitation

Hospitals may also provide structured inpatient alcohol rehabilitation programs to the chronic alcoholic. These programs are composed primarily of coordinated educational and psychotherapeutic services provided on a group basis. Depending on the subject matter, a series of lectures, discussions, films, and group therapy sessions are led by either physicians, psychologists, or alcoholism counselors from the hospital or various outside organizations. In addition, individual psychotherapy and family counseling (see [§70.1](#)) may be provided in selected cases. These programs are conducted under the supervision and direction of a physician. Patients may directly enter an inpatient hospital rehabilitation program after having undergone detoxification in the same hospital or in another hospital or may enter an inpatient hospital rehabilitation program without prior hospitalization for detoxification.

Alcohol rehabilitation can be provided in a variety of settings other than the hospital setting. In order for an inpatient hospital stay for alcohol rehabilitation to be covered under Medicare it must be medically necessary for the care to be provided in the inpatient hospital setting rather than in a less costly facility or on an outpatient basis. Inpatient hospital care for receipt of an alcohol rehabilitation program would generally be medically necessary where either (1) there is documentation by the physician that recent alcohol rehabilitation services in a less intensive setting or on an outpatient basis have proven unsuccessful and, as a

consequence, the patient requires the supervision and intensity of services which can only be found in the controlled environment of the hospital, or (2) only the hospital environment can assure the medical management or control of the patient's concomitant conditions during the course of alcohol rehabilitation. (However, a patient's concomitant condition may make the use of certain alcohol treatment modalities *medically inappropriate.*)

In addition, the "active treatment" criteria (see the Medicare Benefit Policy Manual, Chapter 2, "Inpatient Psychiatric Hospital Services," §20) should be applied to psychiatric care in the general hospital as well as to psychiatric care in a psychiatric hospital. Since alcoholism is classifiable as a psychiatric condition the "active treatment" criteria must also be met in order for alcohol rehabilitation services to be covered under Medicare. (Thus, it is the combined need for "active treatment" and for covered care which can only be provided in the inpatient hospital setting, rather than the fact that rehabilitation immediately follows a period of detoxification which provides the basis for coverage of inpatient hospital alcohol rehabilitation programs.)

Generally 16-19 days of rehabilitation services are sufficient to bring a patient to a point where care could be continued in other than an inpatient hospital setting. An inpatient hospital stay for alcohol rehabilitation may be extended beyond this limit in an individual case where a longer period of alcohol rehabilitation is medically necessary. In such cases, however, there should be documentation by a physician which substantiates the need for such care. Where the rehabilitation needs of an individual no longer require an inpatient hospital setting, coverage should be denied on the basis that inpatient hospital care is not reasonable and necessary as required by [§1862 \(a\)\(1\)](#) of the Act.

Subsequent admissions to the inpatient hospital setting for alcohol rehabilitation follow-up, reinforcement, or "recap" treatments are considered to be readmissions (rather than an extension of the original stay) and must meet the requirements of this section for coverage under Medicare. Prior admissions to the inpatient hospital setting - either in the same hospital or in a different hospital - may be an indication that the "active treatment" requirements are not met (i.e., there is no reasonable expectation of improvement) and the stay should not be covered. Accordingly, there should be documentation to establish that "readmission" to the hospital setting for alcohol rehabilitation services can reasonably be expected to result in improvement of the patient's condition. For example, the documentation should indicate what changes in the patient's medical condition, social or emotional status, or treatment plan make improvement likely, or why the patient's initial hospital treatment was not sufficient.

C. Combined Alcohol Detoxification/Rehabilitation Programs

Medicare Administrative Contractors (MACs) should apply the guidelines in A. and B. above to both phases of a combined inpatient hospital alcohol detoxification/rehabilitation program. Not all patients who require the inpatient hospital setting for detoxification also need the inpatient hospital setting for rehabilitation. (See [§130.1](#) for coverage of outpatient hospital alcohol rehabilitation services.) Where the inpatient hospital setting is medically necessary for both alcohol detoxification and rehabilitation, generally a 3-week period is reasonable and necessary to bring the patient to the point where care can be continued in other than an inpatient hospital setting.

Decisions regarding reasonableness and necessity of treatment, the need for an inpatient hospital level of care, and length of treatment should be made by *the A/B MAC (A)* based on accepted medical practice with the advice of their medical consultant. (In hospitals under PSRO review, PSRO determinations of medical necessity of services and appropriateness of the level of care at which services are provided are binding on *the A/B MAC (A)* for purposes of adjudicating claims for payment.)

130.3 - Chemical Aversion Therapy for Treatment of Alcoholism

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

Chemical aversion therapy is a behavior modification technique that is used in the treatment of alcoholism. Chemical aversion therapy facilitates alcohol abstinence through the development of conditioned aversions to the taste, smell, and sight of alcohol beverages. This is accomplished by repeatedly pairing alcohol with unpleasant symptoms (e.g., nausea) which have been induced by one of several chemical agents. While a number of drugs have been employed in chemical aversion therapy, the three most commonly used are emetine, apomorphine, and lithium. None of the drugs being used, however, have yet been approved by the Food and Drug Administration specifically for use in chemical aversion therapy for alcoholism. Accordingly, when these drugs are being employed in conjunction with this therapy, patients undergoing this treatment need to be kept under medical observation.

Available evidence indicates that chemical aversion therapy may be an effective component of certain alcoholism treatment programs, particularly as part of multi-modality treatment programs which include other behavioral techniques and therapies, such as psychotherapy. Based on this evidence, *the Centers for Medicare & Medicaid Services*' medical consultants have recommended that chemical aversion therapy be covered under Medicare. However, since chemical aversion therapy is a demanding therapy which may not be appropriate for all Medicare beneficiaries needing treatment for alcoholism, a physician should certify to the appropriateness of chemical aversion therapy in the individual case. Therefore, if chemical aversion therapy for treatment of alcoholism is determined to be reasonable and necessary for an individual patient, it is covered under Medicare.

When it is medically necessary for a patient to receive chemical aversion therapy as a hospital inpatient, coverage for care in that setting is available. (See [§130.1](#) regarding coverage of multi-modality treatment programs.) Follow-up treatments for chemical aversion therapy can generally be provided on an outpatient basis. Thus, where a patient is admitted as an inpatient for receipt of chemical aversion therapy, there must be documentation by the physician of the need in the individual case for the inpatient hospital admission.

Decisions regarding reasonableness and necessity of treatment and the need for an inpatient hospital level of care should be made by *the A/B MAC (A)* based on accepted medical practice with the advice of their medical consultant. (In hospitals under *Quality Improvement Organization (QIO)* review, QIO determinations of medical necessity of services and appropriateness of the level of care at which services are provided are binding on *the A/B MAC (A)* for purposes of adjudicating claims for payment.)

130.6 - Treatment of Drug Abuse (Chemical Dependency)

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

The *Centers for Medicare & Medicaid Services* recognizes that there are similarities between the approach to treatment of drug abuse and alcohol detoxification and rehabilitation. However, the intensity and duration of treatment for drug abuse may vary (depending on the particular substance(s) of abuse, duration of use, and the patient's medical and emotional condition) from the duration of treatment or intensity needed to treat alcoholism. Accordingly, when it is medically necessary for a patient to receive detoxification and/or rehabilitation for drug substance abuse as a hospital inpatient, coverage for care in that setting is available. Coverage is also available for treatment services that are provided in the outpatient department of a hospital to patients who, for example, have been discharged from an inpatient stay for the treatment of drug substance abuse or who require treatment but do not require the availability and intensity of services found only in the inpatient hospital setting. The coverage available for these services is subject to the same rules generally applicable to the coverage of outpatient hospital services. (See the Medicare Benefit Policy Manual (*BPM*), Chapter 6, "Hospital Services Covered Under Part B," §§20.) The services must also be reasonable and necessary for treatment of the individual's condition. (See the Medicare *BPM*, Chapter 16, "General Exclusions *from* Coverage," §90.) Decisions regarding reasonableness and necessity of treatment, the need for an inpatient hospital level of care and length of treatment, should be made by *A/B Medicare Administrative Contractors (MACs)* based on accepted medical practice with the advice of their medical consultant. (In hospitals under *Quality Improvement Organization (QIO)* review, QIO determinations of medical necessity of services and appropriateness of the level of care at which services are provided are binding on *A/B MACs* for purposes of adjudicating claims for payment.)

130.7 - Withdrawal Treatments for Narcotic Addictions

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

Withdrawal is an accepted treatment for narcotic addiction, and Part B payment can be made for these services if they are provided by the physician directly or under his personal supervision and if they are reasonable and necessary. In reviewing claims, reasonableness and necessity are determined with the aid of the *B/Medicare Administrative Contractor's* medical staff.

Drugs that the physician provides in connection with this treatment are also covered if they cannot be self-administered and meet all other statutory requirements.

Cross-reference:

Medicare Benefit Policy Manual, Chapter 6, "Hospital Services Covered Under Part B," §20.4.1

140.5 - Laser Procedures

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

Medicare recognizes the use of lasers for many medical indications. Procedures performed with lasers are sometimes used in place of more conventional techniques. In the absence of a specific non-coverage instruction, and where a laser has been approved for marketing by the Food and Drug Administration, *Medicare Administrative Contractor* discretion may be used to determine whether a procedure performed with a laser is reasonable and necessary and, therefore, covered.

The determination of coverage for a procedure performed using a laser is made on the basis that the use of lasers to alter, revise, or destroy tissue is a surgical procedure. Therefore, coverage of laser procedures is restricted to practitioners with training in the surgical management of the disease or condition being treated.

150.5 - Diathermy Treatment

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

High energy pulsed wave diathermy machines have been found to produce some degree of therapeutic benefit for essentially the same conditions and to the same extent as standard diathermy. Accordingly, where the *Medicare Administrative Contractor's* medical staff has determined that the pulsed wave diathermy apparatus used is one which is considered therapeutically effective, the treatments are considered a covered service, but only for those conditions for which standard diathermy is medically indicated and only when rendered by a physician or incident to a physician's professional services.

Cross-reference: [§240.3](#).

(This NCD last reviewed June 2006.)

150.10 - Lumbar Artificial Disc Replacement (LADR) (Effective August 14, 2007)

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

A. General

The *lumbar artificial disc replacement (LADR)* is a surgical procedure on the lumbar spine that involves complete removal of the damaged or diseased lumbar intervertebral disc and implantation of an artificial disc. The procedure may be done as an alternative to lumbar spinal fusion and is intended to reduce pain,

increase movement at the site of surgery and restore intervertebral disc height. *The Food and Drug Administration* has approved the use of **LADR** for spine arthroplasty in skeletally mature patients with degenerative or discogenic disc disease at one level for L3 to S1.

B. Nationally Covered Indications

N/A

C. Nationally Non-Covered Indications

Effective for services performed from May 16, 2006 through August 13, 2007, the Centers for Medicare and Medicaid Services (CMS) has found that LADR with the Charite™ lumbar artificial disc is not reasonable and necessary for the Medicare population over 60 years of age; therefore, LADR with the Charite™ lumbar artificial disc is non-covered for Medicare beneficiaries over 60 years of age.

Effective for services performed 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.

D. Other

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 *Medicare Administrative Contractors*.

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.

160.1 - Induced Lesions of Nerve Tracts

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

Surgically induced lesions of nerve tracts which involve destruction of nerve *tissue are* primarily indicated for controlling the chronic or acute pain arising from conditions such as terminal cancer or lumbar degenerative arthritis. Induced lesions of nerve tracts may be produced by surgical cutting of the nerve (rhizolysis), chemical destruction of the nerve, or by creation of a radio-frequency lesion (electrocautery). Accordingly, program payment may be made for these denervation procedures when used in selected cases (concurrent in by *the Medicare Administrative Contractor's* medical staff) to treat chronic pain.

Note that these procedures differ from those employing implanted electrodes and associated equipment to control pain in that the nerve fibers are ablated rather than stimulated and no electronic equipment is required by the patient after the operation.

160.7 - Electrical Nerve Stimulators

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

Two general classifications of electrical nerve stimulators are employed to treat chronic intractable pain: peripheral nerve stimulators and central nervous system stimulators.

A. Implanted Peripheral Nerve Stimulators

Payment may be made under the prosthetic device benefit for implanted peripheral nerve stimulators. Use of this stimulator involves implantation of electrodes around a selected peripheral nerve. The stimulating

electrode is connected by an insulated lead to a receiver unit which is implanted under the skin at a depth not greater than 1/2 inch.

Stimulation is induced by a generator connected to an antenna unit which is attached to the skin surface over the receiver unit. Implantation of electrodes requires surgery and usually necessitates an operating room.

NOTE: Peripheral nerve stimulators may also be employed to assess a patient's suitability for continued treatment with an electric nerve stimulator. As explained in [§160.7.1](#), such use of the stimulator is covered as part of the total diagnostic service furnished to the beneficiary rather than as a prosthesis.

B. Central Nervous System Stimulators (Dorsal Column and Depth Brain Stimulators)

The implantation of central nervous system stimulators may be covered as therapies for the relief of chronic intractable pain, subject to the following conditions:

1. Types of Implantations

There are two types of implantations covered by this instruction:

- Dorsal Column (Spinal Cord) Neurostimulation - The surgical implantation of neurostimulator electrodes within the dura mater (endodural) or the percutaneous insertion of electrodes in the epidural space is covered.
- Depth Brain Neurostimulation - The stereotactic implantation of electrodes in the deep brain (e.g., thalamus and periaqueductal gray matter) is covered.

2. Conditions for Coverage

No payment may be made for the implantation of dorsal column or depth brain stimulators or services and supplies related to such implantation, unless all of the conditions listed below have been met:

- The implantation of the stimulator is used only as a late resort (if not a last resort) for patients with chronic intractable pain;
- With respect to item a, other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not prove satisfactory, or are judged to be unsuitable or contraindicated for the given patient;
- Patients have undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation. (Such screening must include psychological, as well as physical evaluation);
- All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and follow up of the patient (including that required to satisfy item c) must be available; and
- Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation.

Medicare Administrative Contractors may find it helpful to work with Quality Improvement *Organizations* to obtain the information needed to apply these conditions to claims.

See the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §120, and the following sections in this manual, [§§160.2](#) and [30.1](#).

160.13 - Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES)

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

Transcutaneous Electrical Nerve Stimulation (TENS) and/or Neuromuscular Electrical Stimulation (NMES) can ordinarily be delivered to patients through the use of conventional electrodes, adhesive tapes and lead wires. There may be times, however, where it might be medically necessary for certain patients receiving TENS or NMES treatment to use, as an alternative to conventional electrodes, adhesive tapes and lead wires, a form-fitting conductive garment (i.e., a garment with conductive fibers which are separated from the patients' skin by layers of fabric).

A form-fitting conductive garment (and medically necessary related supplies) may be covered under the program only when:

1. It has received permission or approval for marketing by the Food and Drug Administration;
2. It has been prescribed by a physician for use in delivering covered TENS or NMES treatment; and
3. One of the medical indications outlined below is met:
 - The patient cannot manage without the conductive garment because there is such a large area or so many sites to be stimulated and the stimulation would have to be delivered so frequently that it is not feasible to use conventional electrodes, adhesive tapes and lead wires;
 - The patient cannot manage without the conductive garment for the treatment of chronic intractable pain because the areas or sites to be stimulated are inaccessible with the use of conventional electrodes, adhesive tapes and lead wires;
 - The patient has a documented medical condition such as skin problems that preclude the application of conventional electrodes, adhesive tapes and lead wires;
 - The patient requires electrical stimulation beneath a cast either to treat disuse atrophy, where the nerve supply to the muscle is intact, or to treat chronic intractable pain; or
 - The patient has a medical need for rehabilitation strengthening (pursuant to a written plan of rehabilitation) following an injury where the nerve supply to the muscle is intact.

A conductive garment is not covered for use with a TENS device during the trial period specified in §160.3 unless:

4. The patient has a documented skin problem prior to the start of the trial period; and
5. The *A/B MAC (B)'s* medical consultants are satisfied that use of such an item is medically necessary for the patient.

(See conditions for coverage of the use of TENS in the diagnosis and treatment of chronic intractable pain in §§160.3, *160.13, and 160.27, and* the use of NMES in the treatment of disuse atrophy in §150.4.)

Medicare National Coverage Determinations Manual

Chapter 1, Part 3 (Sections 170 – 190.34)

Coverage Determinations

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(Rev. 173, Issued: 09-04-14,)

180.2 - Enteral and Parenteral Nutritional Therapy

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

Covered As Prosthetic Device

There are patients who, because of chronic illness or trauma, cannot be sustained through oral feeding. These people must rely on either enteral or parenteral nutritional therapy, depending upon the particular nature of their medical condition.

Coverage of nutritional therapy as a Part B benefit is provided under the prosthetic device benefit provision which requires that the patient must have a permanently inoperative internal body organ or function thereof. Therefore, enteral and parenteral nutritional therapy are *normally* not covered under Part B in situations involving temporary impairments.

Coverage of such therapy, however, does not require a medical judgment that the impairment giving rise to the therapy will persist throughout the patient's remaining years. If the medical record, including the judgment of the attending physician, indicates that the impairment will be of long and indefinite duration, the test of permanence is considered met.

If the coverage requirements for enteral or parenteral nutritional therapy are met under the prosthetic device benefit provision, related supplies, equipment and nutrients are also covered under the conditions in the following paragraphs and the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §120.

Parenteral Nutrition Therapy Daily parenteral nutrition is considered reasonable and necessary for a patient with severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition.

Since the alimentary tract of such a patient does not function adequately, an indwelling catheter is placed percutaneously in the subclavian vein and then advanced into the superior vena cava where intravenous infusion of nutrients is given for part of the day. The catheter is then plugged by the patient until the next infusion. Following a period of hospitalization, which is required to initiate parenteral nutrition and to train the patient in catheter care, solution preparation, and infusion technique, the parenteral nutrition can be provided safely and effectively in the patient's home by nonprofessional persons who have undergone special training. However, such persons cannot be paid for their services, nor is payment available for any services furnished by *non-physician* professionals except as services furnished incident to a physician's service.

For parenteral nutrition therapy to be covered under Part B, the claim must contain a physician's written order or prescription and sufficient medical documentation to permit an independent conclusion that the requirements of the prosthetic device benefit are met and that parenteral nutrition therapy is medically necessary. An example of a condition that typically qualifies for coverage is a massive small bowel resection resulting in severe nutritional deficiency in spite of adequate oral intake. However, coverage of parenteral nutrition therapy for this and any other condition must be approved on an individual, case-by-case

basis initially and at periodic intervals of no more than three months by the *Medicare Administrative Contractor (A/B MAC (B))* medical consultant or specially trained staff, relying on such medical and other documentation as the *A/B MAC (B)* may require. If the claim involves an infusion pump, sufficient evidence must be provided to support a determination of medical necessity for the pump. Program payment for the pump is based on the reasonable charge for the simplest model that meets the medical needs of the patient as established by medical documentation.

Nutrient solutions for parenteral therapy are routinely covered. However, Medicare pays for no more than one month's supply of nutrients at any one time. Payment for the nutrients is based on the reasonable charge for the solution components unless the medical record, including a signed statement from the attending physician, establishes that the beneficiary, due to his/her physical or mental state, is unable to safely or effectively mix the solution and there is no family member or other person who can do so. Payment will be on the basis of the reasonable charge for more expensive premixed solutions only under the latter circumstances.

Enteral Nutrition Therapy

Enteral nutrition is considered reasonable and necessary for a patient with a functioning gastrointestinal tract who, due to pathology to, or *non-function* of, the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition. Enteral therapy may be given by nasogastric, jejunostomy, or gastrostomy tubes and can be provided safely and effectively in the home by nonprofessional persons who have undergone special training. However, such persons cannot be paid for their services, nor is payment available for any services furnished by *non-physician* professionals except as services furnished incident to a physician's service.

Typical examples of conditions that qualify for coverage are head and neck cancer with reconstructive surgery and central nervous system disease leading to interference with the neuromuscular mechanisms of ingestion of such severity that the beneficiary cannot be maintained with oral feeding. However, claims for Part B coverage of enteral nutrition therapy for these and any other conditions must be approved on an individual, case-by-case basis. Each claim must contain a physician's written order or prescription and sufficient medical documentation (e.g., hospital records, clinical findings from the attending physician) to permit an independent conclusion that the patient's condition meets the requirements of the prosthetic device benefit and that enteral nutrition therapy is medically necessary. Allowed claims are to be reviewed at periodic intervals of no more than 3 months by the *A/B MAC (B)* medical consultant or specially trained staff, and additional medical documentation considered necessary is to be obtained as part of this review.

Medicare pays for no more than one month's supply of enteral nutrients at any one time.

If the claim involves a pump, it must be supported by sufficient medical documentation to establish that the pump is medically necessary, i.e., gravity feeding is not satisfactory due to aspiration, diarrhea, dumping syndrome. Program payment for the pump is based on the reasonable charge for the simplest model that meets the medical needs of the patient as established by medical documentation.

Nutritional Supplementation

Some patients require supplementation of their daily protein and caloric intake. Nutritional supplements are often given as a medicine between meals to boost protein-caloric intake or the mainstay of a daily nutritional plan. Nutritional supplementation is not covered under Medicare Part B.

Medicare National Coverage Determinations Manual

Chapter 1, Part 4 (Sections 200 – 310.1)

Coverage Determinations

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(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

220.6.13 - FDG *Positron Emission Tomography (PET)* for Dementia and Neurodegenerative Diseases
(Effective September 15, 2004)

220.9 - Digital Subtraction Angiography (**DSA**)

200.1 - Nesiritide for Treatment of Heart Failure Patients (Effective March 2, 2006)
(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

A. General

Nesiritide (Natrecor®) is Food and Drug Administration (*FDA*)-*approved* for the intravenous treatment of patients with acutely decompensated congestive heart failure (CHF) who have dyspnea (shortness of breath) at rest or with minimal activity. Nesiritide is not self-administered.

B. Nationally Covered Indications

N/A

C. Nationally Non-Covered Indications

Effective for dates of service on or after March 2, 2006, the Centers for Medicare & Medicaid *Services has* determined that there is sufficient evidence to conclude that the use of Nesiritide for the treatment of *CHF* is not reasonable and necessary for Medicare beneficiaries in any setting.

D. Other

Effective for dates of service on or after March 2, 2006, this determination applies only to the treatment of *CHF* and does not change *Medicare Administrative Contractor* discretion to cover other off-label uses of Nesiritide or use consistent with the current FDA indication for intravenous treatment of patients with acutely decompensated *CHF* who have dyspnea at rest or with minimal activity.

200.2 - Nebulized Beta Adrenergic Agonist Therapy for Lung Diseases – (Effective September 10, 2007)

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

A. General

Lung diseases such as chronic obstructive pulmonary disease (COPD) and asthma are characterized by airflow limitation that may be partially or completely reversible. Pharmacologic treatment with bronchodilators is used to prevent and/or control daily symptoms that may cause disability for persons with these diseases. These medications are intended to improve the movement of air into and from the lungs by relaxing and dilating the bronchial passageways. Beta adrenergic agonists are a commonly prescribed class of bronchodilator drug. They can be administered via nebulizer, metered dose inhaler, orally, or dry powdered inhaler.

Nebulized beta adrenergic agonist with racemic albuterol has been used for many years. More recently, levalbuterol, the (R) enantiomer of racemic albuterol, has been used in some patient populations. There are concerns regarding the appropriate use of nebulized beta adrenergic agonist therapy for lung disease.

B. Nationally Covered Indications

N/A

C. Nationally Non-Covered Indications

N/A

D. Other

After examining the available medical evidence, *the Centers for Medicare & Medicaid Services* determines that no national coverage *determination is* appropriate at this time. Section 1862(a)(1)(A) of the Social Security Act decisions should be made by local *Medicare Administrative Contractors* through a local coverage determination process or case-by-case adjudication. *See Heckler v. Ringer*, 466 U.S. 602, 617 (1984) (Recognizing that the Secretary has discretion to either establish a generally applicable rule or to allow individual adjudication.). See also, 68 Fed. Reg. 63692, 63693 (November 7, 2003).

210.2 - Screening Pap Smears and Pelvic Examinations for Early Detection of Cervical or Vaginal Cancer

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

Screening Pap Smear

A screening pap smear and related medically necessary services provided to a woman for the early detection of cervical cancer (including collection of the sample of cells and a physician's interpretation of the test results) and pelvic examination (including clinical breast examination) are covered under Medicare Part B when ordered by a physician (or authorized practitioner) under one of the following conditions:

- She has not had such a test during the preceding two years or is a woman of childbearing age (§1861(nn) of the *Social Security Act (the Act)*).
- There is evidence (on the basis of her medical history or other findings) that she is at high risk of developing cervical cancer and her physician (or authorized practitioner) recommends that she have the test performed more frequently than every two years.

High risk factors for cervical and vaginal cancer are:

- Early onset of sexual activity (under 16 years of age)
- Multiple sexual partners (five or more in a lifetime)
- History of sexually transmitted disease (including HIV infection)
- Fewer than three negative or any pap smears within the previous seven years; and
- DES (diethylstilbestrol) - exposed daughters of women who took DES during pregnancy.

NOTE: Claims for pap smears must indicate the beneficiary's low or high risk status by including the appropriate *diagnosis code* on the line item (Item 24E of the Form CMS-1500).

Definitions

- A woman as described in §1861(nn) of the Act is a woman who is of childbearing age and has had a pap smear test during any of the preceding 3 years that indicated the presence of cervical or vaginal cancer or other abnormality, or is at high risk of developing cervical or vaginal cancer.
- A woman of childbearing age is one who is premenopausal and has been determined by a physician or other qualified practitioner to be of childbearing age, based upon the medical history or other findings.

- Other qualified practitioner, as defined in 42 CFR 410.56(a) includes a certified nurse midwife (as defined in §1861(gg) of the Act), or a physician assistant, nurse practitioner, or clinical nurse specialist (as defined in §1861(aa) of the Act) who is authorized under State law to perform the examination.

Screening Pelvic Examination

Section 4102 of the Balanced Budget Act of 1997 provides for coverage of screening pelvic examinations (including a clinical breast examination) for all female beneficiaries, subject to certain frequency and other limitations. A screening pelvic examination (including a clinical breast examination) should include at least seven of the following eleven elements:

- Inspection and palpation of breasts for masses or lumps, tenderness, symmetry, or nipple discharge.
- Digital rectal examination including sphincter tone, presence of hemorrhoids, and rectal masses. Pelvic examination (with or without specimen collection for smears and cultures) including:
- External genitalia (for example, general appearance, hair distribution, or lesions).
- Urethral meatus (for example, size, location, lesions, or prolapse).
- Urethra (for example, masses, tenderness, or scarring).
- Bladder (for example, fullness, masses, or tenderness).
- Vagina (for example, general appearance, estrogen effect, discharge lesions, pelvic support, cystocele, or rectocele).
- Cervix (for example, general appearance, lesions, or discharge).
- Uterus (for example, size, contour, position, mobility, tenderness, consistency, descent, or support).
- Adnexa/parametria (for example, masses, tenderness, organomegaly, or nodularity).
- Anus and perineum.

This description is from Documentation Guidelines for Evaluation and Management Services, published in May 1997 and was developed by the Centers for Medicare & Medicaid Services and the American Medical Association.

220.1 - Computed Tomography (CT)

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

A. General

Diagnostic examinations of the head (head scans) and of other parts of the body (body scans) performed by computerized tomography (CT) scanners are covered if medical and scientific literature and opinion support the effective use of a scan for the condition, and the scan is: (1) reasonable and necessary for the individual patient; and (2) performed on a model of CT equipment that meets the criteria in C below.

The CT scans have become the primary diagnostic tool for many conditions and symptoms. CT scanning used as the primary diagnostic tool can be cost effective because it can eliminate the need for a series of other tests, is noninvasive and thus virtually eliminates complications, and does not require hospitalization.

B. Determining Whether a CT Scan Is Reasonable and Necessary

Sufficient information must be provided with claims to differentiate CT scans from other radiology services and to make coverage determinations. Carefully review claims to ensure that a scan is reasonable and necessary for the individual patient; i.e., the use must be found to be medically appropriate considering the patient's symptoms and preliminary diagnosis.

There is no general rule that requires other diagnostic tests to be tried before CT scanning is used. However, in an individual case the *Medicare Administrative Contractor (MAC)* medical staff may determine that use of a CT scan as the initial diagnostic test was not reasonable and necessary because it was not supported by the patient's symptoms or complaints stated on the claim form; e.g., "periodic headaches."

Claims for CT scans are reviewed for evidence of abuse, which might include the absence of reasonable indications for the scans, an excessive number of scans, or unnecessarily expensive types of scans considering the facts in the particular cases.

C. Approved Models of CT Equipment

1. Criteria for Approval

In the absence of evidence to the contrary, the *MAC* may assume that a CT scan for which payment is requested has been performed on equipment that meets the following criteria:

- a. The model must be known to the Food and Drug Administration (FDA), and
- b. Must be in the full market release phase of development.

Should it be necessary to confirm that those criteria are met, ask the manufacturer to submit the information in C.2. If manufacturers inquire about obtaining Medicare approval for their equipment, inform them of the foregoing criteria.

2. Evidence of Approval

- a. The letter sent by the Bureau of Radiological Health, FDA, to the manufacturer acknowledging the FDA's receipt of information on the specific CT scanner system model submitted as required under Public Law 90-602, "The Radiation Control for Health and Safety Act of 1968."
- b. A letter signed by the chief executive officer or other officer acting in a similar capacity for the manufacturer which:
 - i.. *Furnishes* the CT scanner system model number, all names that hospitals and physicians' offices may use to refer to the CT scanner system on claims, and the accession number assigned by FDA to the specific model;
 - ii. Specifies whether the scanner performs head scans only, body scans only (i.e., scans of parts of the body other than the head), or head and body scans;
 - iii. States that the company or corporation is satisfied with the results of the developmental stages that preceded the full market release phase of the equipment, that the equipment is in the full market release phase, and the date on which it was decided to put the product into the full market release phase.

D. Mobile CT Equipment

CT scans performed on mobile units are subject to the same Medicare coverage requirements applicable to scans performed on stationary units, as well as certain health and safety requirements recommended by the Health Resources and Services Administration. As with scans performed on stationary units, the scans must be determined medically necessary for the individual patient. The scans must be performed on types of CT scanning equipment that have been approved for use as stationary units (see C above), and must be in compliance with applicable State laws and regulations for control of radiation.

1. Hospital Setting

The hospital must assume responsibility for the quality of the scan furnished to inpatients and outpatients and must ensure that a radiologist or other qualified physician is in charge of the procedure. The radiologist or other physician (i.e., one who is with the mobile unit) who is responsible for the procedure must be approved by the hospital for similar privileges.

2. Ambulatory Setting

If mobile CT scan services are furnished at an ambulatory health care facility other than a hospital-based facility, e.g., a freestanding physician-directed clinic, the diagnostic procedure must be performed by, or under the direct personal supervision of, a radiologist or other qualified physician. In addition, the facility must maintain a record of the attending physician's order for a scan performed on a mobile unit.

3. Billing for Mobile CT Scans

Hospitals, hospital-associated radiologists, ambulatory health care facilities, and physician owner/operators of mobile units may bill for mobile scans as they would for scans performed on stationary equipment.

4. Claims Review

Evidence of compliance with applicable State laws and regulations for control of radiation should be requested from owners of mobile CT scan units upon receipt of the first claims. All mobile scan claims should be reviewed very carefully in accordance with instructions applicable to scans performed on fixed units, with particular emphasis on the medical necessity for scans performed in an ambulatory setting.

E. Multi-Planar Diagnostic Imaging (MPDI)

In usual CT scanning procedures, a series of transverse or axial images are reproduced. These transverse images are routinely translated into coronal and/or sagittal views. MPDI is a process which further translates the data produced by CT scanning by providing reconstructed oblique images which can contribute to diagnostic information. MPDI, also known as planar image reconstruction or reformatted imaging, is covered under Medicare when provided as a service to an entity performing a covered CT scan.

F. Computed Tomographic Angiography (CTA)

CTA is a general phrase used to describe a non-invasive method, using intravenous contrast, to visualize the coronary arteries (or other vessels) using high-resolution, high-speed CT.

After examining the medical evidence, the Centers for Medicare and Medicaid *Services has* determined that no national coverage *determination is* appropriate at this time (March 12, 2008). Section 1862(a)(1)(A) of the Social Security Act decisions should be made by local *MACs* through a local coverage determination process or case-by-case adjudication. See *Heckler v. Ringer*, 466 U.S. 602, 617 (1984) (Recognizing that the Secretary has discretion to either establish a generally applicable rule or to allow individual adjudication.). See also, 68 Fed. Reg. 63692, 63693 (November 7, 2003).

220.2 - Magnetic Resonance Imaging (MRI) (Various Effective Dates Below)

A. General

1. Method of Operation

Magnetic Resonance Imaging (MRI), formerly called nuclear magnetic resonance (NMR), is a non-invasive method of graphically representing the distribution of water and other hydrogen-rich molecules in the human body. In contrast to conventional radiographs or computed tomography (CT) scans, in which the image is produced by x-ray beam attenuation by an object, MRI is capable of producing images by several techniques. In fact, various combinations of MRI image production methods may be employed to emphasize particular characteristics of the tissue or body part being examined. The basic elements by which MRI produces an image are the density of hydrogen nuclei in the object being examined, their motion, and the relaxation times, and the period of time required for the nuclei to return to their original states in the main, static magnetic field after being subjected to a brief additional magnetic field. These relaxation times reflect the physical-chemical properties of tissue and the molecular environment of its hydrogen nuclei. Only hydrogen atoms are present in human tissues in sufficient concentration for current use in clinical MRI.

Magnetic Resonance Angiography (MRA) is a non-invasive diagnostic test that is an application of MRI. By analyzing the amount of energy released from tissues exposed to a strong magnetic field, MRA provides images of normal and diseased blood vessels, as well as visualization and quantification of blood flow through these vessels.

2. General Clinical Utility

Overall, MRI is a useful diagnostic imaging modality that is capable of demonstrating a wide variety of soft-tissue lesions with contrast resolution equal or superior to CT scanning in various parts of the body.

Among the advantages of MRI are the absence of ionizing radiation and the ability to achieve high levels of tissue contrast resolution without injected iodinated radiological contrast agents. Recent advances in technology have resulted in development and Food and Drug Administration (FDA) approval of new paramagnetic contrast agents for MRI which allow even better visualization in some instances. *Multi-slice* imaging and the ability to image in multiple planes, especially sagittal and coronal, have provided flexibility not easily available with other modalities. Because cortical (outer layer) bone and metallic prostheses do not cause distortion of MR images, it has been possible to visualize certain lesions and body regions with greater certainty than has been possible with CT. The use of MRI on certain soft tissue structures for the purpose of detecting disruptive, neoplastic, degenerative, or inflammatory lesions has now become established in medical practice.

Phase contrast (PC) and time-of-flight (TOF) are some of the available MRA techniques at the time these instructions are being issued. PC measures the difference between the phases of proton spins in tissue and blood and measures both the venous and arterial blood flow at any point in the cardiac cycle. TOF measures the difference between the amount of magnetization of tissue and blood and provides information on the structure of blood vessels, thus indirectly indicating blood flow. Two-dimensional (2D) and three-dimensional (3D) images can be obtained using each method.

Contrast-enhanced MRA (CE-MRA) involves blood flow imaging after the patient receives an intravenous injection of a contrast agent. Gadolinium, a non-ionic element, is the foundation of all contrast agents currently in use. Gadolinium affects the way in which tissues respond to magnetization, resulting in better visualization of structures when compared to un-enhanced studies. Unlike ionic (i.e., iodine-based) contrast agents used in conventional contrast angiography (CA), allergic reactions to gadolinium are extremely rare. Additionally, gadolinium does not cause the kidney failure occasionally seen with ionic contrast agents. Digital subtraction angiography (DSA) is a computer-augmented form of CA that obtains digital blood flow images as contrast agent courses through a blood vessel. The computer “subtracts” bone and other tissue

from the image, thereby improving visualization of blood vessels. Physicians elect to use a specific MRA or CA technique based upon clinical information from each patient.

B. Nationally Covered MRI and MRA Indications

1. MRI

Although several uses of MRI are still considered investigational and some uses are clearly contraindicated (see subsection C), MRI is considered medically efficacious for a number of uses. Use the following descriptions as general guidelines or examples of what may be considered covered rather than as a restrictive list of specific covered indications. Coverage is limited to MRI units that have received FDA premarket approval, and such units must be operated within the parameters specified by the approval. In addition, the services must be reasonable and necessary for the diagnosis or treatment of the specific patient involved.

- a. Effective November 22, 1985, MRI is useful in examining the head, central nervous system, and spine. Multiple sclerosis can be diagnosed with MRI and the contents of the posterior fossa are visible. The inherent tissue contrast resolution of MRI makes it an appropriate standard diagnostic modality for general neuroradiology.
- b. Effective November 22, 1985, MRI can assist in the differential diagnosis of mediastinal and retroperitoneal masses, including abnormalities of the large vessels such as aneurysms and dissection. When a clinical need exists to visualize the parenchyma of solid organs to detect anatomic disruption or neoplasia, this can be accomplished in the liver, urogenital system, adrenals, and pelvic organs without the use of radiological contrast materials. When MRI is considered reasonable and necessary, the use of paramagnetic contrast materials may be covered as part of the study. MRI may also be used to detect and stage pelvic and retroperitoneal neoplasms and to evaluate disorders of cancellous bone and soft tissues. It may also be used in the detection of pericardial thickening. Primary and secondary bone neoplasm and aseptic necrosis can be detected at an early stage and monitored with MRI. Patients with metallic prostheses, especially of the hip, can be imaged in order to detect the early stages of infection of the bone to which the prosthesis is attached.
- c. Effective March 22, 1994, MRI may also be covered to diagnose disc disease without regard to whether radiological imaging has been tried first to diagnose the problem.
- d. Effective March 4, 1991, MRI with gating devices and surface coils, and gating devices that eliminate distorted images caused by cardiac and respiratory movement cycles are now considered state of the art techniques and may be covered. Surface and other specialty coils may also be covered, as they are used routinely for high resolution imaging where small limited regions of the body are studied. They produce high signal-to-noise ratios resulting in images of enhanced anatomic detail.

2. MRA (MRI for Blood Flow)

Currently covered indications include using MRA for specific conditions to evaluate flow in internal carotid vessels of the head and neck, peripheral arteries of lower extremities, abdomen and pelvis, and the chest. Coverage is limited to MRA units that have received FDA premarket approval, and such units must be operated within the parameters specified by the approval. In addition, the services must be reasonable and necessary for the diagnosis or treatment of the specific patient involved.

a. Head and Neck

Effective April 15, 2003, studies have proven that MRA is effective for evaluating flow in internal carotid vessels of the head and neck. However, not all potential applications of MRA have been shown to be reasonable and necessary. All of the following criteria must apply in order for Medicare to provide coverage for MRA of the head and neck:

- MRA is used to evaluate the carotid arteries, the circle of Willis, the anterior, middle or posterior cerebral arteries, the vertebral or basilar arteries or the venous sinuses;
- MRA is performed on patients with conditions of the head and neck for which surgery is anticipated and may be found to be appropriate based on the MRA. These conditions include, but are not limited to, tumor, aneurysms, vascular malformations, vascular occlusion or thrombosis. Within this broad category of disorders, medical necessity is the underlying determinant of the need for an MRA in specific diseases. The medical records should clearly justify and demonstrate the existence of medical necessity; and
- MRA and CA are not expected to be performed on the same patient for diagnostic purposes prior to the application of anticipated therapy. Only one of these tests will be covered routinely unless the physician can demonstrate the medical need to perform both tests.

b. Peripheral Arteries of Lower Extremities

Effective April 15, 2003, studies have proven that MRA of peripheral arteries is useful in determining the presence and extent of peripheral vascular disease in lower extremities. This procedure is non-invasive and has been shown to find occult vessels in some patients for which those vessels were not apparent when CA was performed. Medicare will cover either MRA or CA to evaluate peripheral arteries of the lower extremities. However, both MRA and CA may be useful in some cases, such as:

- A patient has had CA and this test was unable to identify a viable run-off vessel for bypass. When exploratory surgery is not believed to be a reasonable medical course of action for this patient, MRA may be performed to identify the viable runoff vessel; or
- A patient has had MRA, but the results are inconclusive.

c. Abdomen and Pelvis

i. Pre-operative Evaluation of Patients Undergoing Elective Abdominal Aortic Aneurysm (AAA) Repair

Effective July 1, 1999, MRA is covered for pre-operative evaluation of patients undergoing elective AAA repair if the scientific evidence reveals MRA is considered comparable to CA in determining the extent of AAA, as well as in evaluating aortoiliac occlusion disease and renal artery pathology that may be necessary in the surgical planning of AAA repair. These studies also reveal that MRA could provide a net benefit to the patient. If preoperative CA is avoided, then patients are not exposed to the risks associated with invasive procedures, contrast media, end-organ damage, or arterial injury.

ii. Imaging the Renal Arteries and the Aortoiliac Arteries in the Absence of AAA or Aortic Dissection

Effective July 1, 2003, MRA coverage is expanded to include imaging the renal arteries and the aortoiliac arteries in the absence of AAA or aortic dissection. MRA should be obtained in those circumstances in which using MRA is expected to avoid obtaining CA, when physician history, physical examination, and standard assessment tools provide insufficient information for patient management, and obtaining an MRA has a high probability of positively affecting patient management. However, CA may be ordered after obtaining the results of an MRA in those rare instances where medical necessity is demonstrated.

d. Chest

i. Diagnosis of Pulmonary Embolism

Current scientific data has shown that diagnostic pulmonary MRAs are improving due to recent developments such as faster imaging capabilities and gadolinium-enhancement. However, these advances in MRA are not significant enough to warrant replacement of pulmonary angiography in the diagnosis of pulmonary embolism for patients who have no contraindication to receiving intravenous iodinated contrast material. Patients who are allergic to iodinated contrast material face a high risk of developing complications if they undergo pulmonary angiography or computed tomography angiography. Therefore, Medicare will cover MRA of the chest for diagnosing a suspected pulmonary embolism when it is contraindicated for the patient to receive intravascular iodinated contrast material.

ii. Evaluation of Thoracic Aortic Dissection and Aneurysm

Studies have shown that MRA of the chest has a high level of diagnostic accuracy for pre-operative and post-operative evaluation of aortic dissection or aneurysm. Depending on the clinical presentation, MRA may be used as an alternative to other non-invasive imaging technologies, such as transesophageal echocardiography and CT. Generally, Medicare will provide coverage only for MRA or for CA when used as a diagnostic test. However, if both MRA and CA of the chest are used, the physician must demonstrate the medical need for performing these tests.

While the intent of this policy is to provide reimbursement for either RA or CA, *the Centers for Medicare & Medicaid Services (CMS)* is also allowing flexibility for physicians to make appropriate decisions concerning the use of these tests based on the needs of individual patients. CMS anticipates, however, low utilization of the combined use of MRA and CA. As a result, CMS encourages *the Medicare Administrative Contractors (MACs)* to monitor the use of these tests and, where indicated, require evidence of the need to perform both MRA and CA.

C. Contraindications and Nationally Non-Covered Indications

1. Contraindications

The MRI is not covered when the following patient-specific contraindications are present:

MRI is not covered for patients with cardiac pacemakers or with metallic clips on vascular aneurysms unless the Medicare beneficiary meets the provisions of the following exceptions:

Effective July 7, 2011, the contraindications will not apply to pacemakers when used according to the FDA-approved labeling in an MRI environment, or

Effective February 24, 2011, CMS believes that the evidence is promising although not yet convincing that MRI will improve patient health outcomes if certain safeguards are in place to ensure that the exposure of the device to an MRI environment adversely affects neither the interpretation of the MRI result nor the proper functioning of the implanted device itself. We believe that specific precautions (as listed below) could maximize benefits of MRI exposure for beneficiaries enrolled in clinical trials designed to assess the utility and safety of MRI exposure. Therefore, CMS determines that MRI will be covered by Medicare when provided in a clinical study under section 1862(a)(1)(E) (consistent with section 1142 of the *Social Security Act (the Act)*) through the Coverage with Study Participation (CSP) form of Coverage with Evidence Development (CED) if the study meets the criteria in each of the three paragraphs below:

The approved prospective clinical study of MRI must, with appropriate methodology, address one or more aspects of the following questions:

1. Do results of MRI in implanted permanent pacemaker (PM)/implantable cardioverter defibrillator (ICD) beneficiaries with implanted cardiac devices affect physician decision making related to:

- a. Clinical management strategy (e.g., in oncology, toward palliative or curative care)?
 - b. Planning of treatment interventions?; or
 - c. Prevention of unneeded diagnostic studies or interventions, or preventable exposures?
2. Do results of MRI in PM/ICD beneficiaries with implanted cardiac devices affect patient outcomes related to:
- a. Survival?
 - b. Quality of life?; or
 - c. Adverse events during and after MR scanning?

In addition, the prospective clinical study of MRI must include safety criteria for all participants. Such required safety measures for such studies, as further explained in guidance documents from professional societies must include, but are not limited to:

1. MRI should be done on a case-by-case and site-by-site basis.
2. MRI scan sequences, field intensity, and field(s) of exposure should be selected to minimize risk to the patient while gaining needed diagnostic information for diagnosis or for managing therapy.
3. MRI scanning should be done only if the site is staffed with individuals with the appropriate radiology and cardiology knowledge and expertise on hand.
4. Implanted device patients who are candidates for recruitment for an MRI clinical study should be advised that life-threatening arrhythmias might occur during MRI and serious device malfunction might occur, requiring replacement of the device.
5. Radiology and cardiology personnel and a fully stocked crash cart should be readily available throughout the procedure in case a significant arrhythmia develops during the examination that does not terminate with the cessation of the MRI study. The cardiologist should be familiar with the patient's arrhythmia history and the implanted device. A programmer that can be used to adjust the device as necessary should be readily available.
6. All such patients should be actively monitored for cardiac and respiratory function throughout the examination. At a minimum, ECG and pulse oximetry should be used. Visual and verbal contact with the patient must be maintained throughout the MRI scan. The patient should be instructed to alert the MRI staff on hand to any unusual sensations, pains, or to any problems.
7. At the conclusion of the examination, the cardiologist should examine the device to confirm that the function is consistent with its pre-examination state.
8. Follow-up should include a check of the patient's device at a time remote (1–6 weeks) after the scan to confirm appropriate function.
9. If the implanted device manufacturer has indicated additional safety precautions appropriate for safe MRI performance, these must be included in the study protocol.

The clinical study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

- a. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
- b. The research study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.

- c. The research study does not unjustifiably duplicate existing studies.
- d. The research study design is appropriate to answer the research question being asked in the study.
- e. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
- f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is regulated by the FDA, it must be in compliance with 21 CFR Parts 50 and 56.
- g. All aspects of the research study are conducted according to appropriate standards of scientific integrity (see <http://www.icmje.org>).
- h. The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for CED coverage.
- i. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR § 312.81(a) and the patient has no other viable treatment options.
- j. The clinical research study is registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.
- k. The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured, including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (<http://www.icmje.org>). However, a full report of the outcomes must be made public no later than three (3) years after the end of data collection.
- l. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
- m. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability, or Medicaid eligibility.

Consistent with section 1142 of the Act, the Agency for Healthcare Research and *Quality supports* clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

- MRI during a viable pregnancy is also contraindicated at this time.
- The danger inherent in bringing ferromagnetic materials within range of MRI units generally constrains the use of MRI on acutely ill patients requiring life support systems and monitoring devices that employ ferromagnetic materials.

- In addition, the long imaging time and the enclosed position of the patient may result in claustrophobia, making patients who have a history of claustrophobia unsuitable candidates for MRI procedures.

2. Nationally Non-Covered Indications

CMS has determined that MRI of cortical bone and calcifications, and procedures involving spatial resolution of bone and calcifications, are not considered reasonable and necessary indications within the meaning of section 1862(a)(1)(A) of the Act, and are therefore non-covered.

D. Other

Effective June 3, 2010, all other uses of MRI or MRA for which CMS has not specifically indicated coverage or non-coverage continue to be eligible for coverage through individual local *MAC* discretion.

220.5 - Ultrasound Diagnostic Procedures (Effective May 22, 2007)

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

A. General

Ultrasound diagnostic procedures utilizing low energy sound waves are being widely employed to determine the composition and contours of nearly all body tissues except bone and air-filled spaces. This technique permits noninvasive visualization of even the deepest structures in the body. The use of the ultrasound technique is sufficiently developed that it can be considered essential to good patient care in diagnosing a wide variety of conditions.

Ultrasound diagnostic procedures are listed below and are divided into two categories. Medicare coverage is extended to the procedures listed in Category I. Periodic claims review by *A/B MAC (A)* medical consultants should be conducted to ensure that the techniques are medically appropriate and the general indications specified in these categories are met. Techniques in Category II are considered experimental and should not be covered at this time.

B. Nationally Covered Indications

Category I - (Clinically effective, usually part of initial patient evaluation, may be an adjunct to radiologic and nuclear medicine diagnostic technique)

- Echoencephalography, (Diencephalic Midline) (A-Mode)
- Echoencephalography, Complete (Diencephalic Midline and Ventricular Size)
- Ocular and Orbital Echography (A-Mode)
- Covered procedures include efforts to determine the suitability of aphakic patients for implantation of an artificial lens (pseudophakoi) following cataract surgery.
- Ocular and Orbital Sonography (B-Mode)
- Echocardiography, Pericardial Effusion (M-Mode)
- Pericardiocentesis, by Ultrasonic Guidance
- Echocardiography, Cardiac Valve(s) (M-Mode)
- Echocardiography, Complete (M-Mode)
- Echocardiography, limited (e.g., follow-up or limited study) (M-Mode)
- Pleural Effusion Echography
- Thoracentesis, by Ultrasonic Guidance

- Abdominal Sonography, complete survey study (B-Scan)
- Abdominal Sonography, limited (e.g., follow-up or limited study) (B-Scan)
- Abdominal Sonography is not synonymous with ultrasound examination of individual organs.
- Renal Cyst Aspiration, by Ultrasonic Guidance
- Renal Biopsy, by Ultrasonic Guidance
- Pancreas Sonography (B-Scan)
- Pancreatic Sonography has proven effective in diagnosing pseudocysts.
- Spleen Sonography (B-Scan)
- Abdominal Aorta Echography (A-Mode)
- Abdominal Aorta Sonography (B-Scan)
- Retroperitoneal Sonography (B-Scan)
- Retroperitoneal Sonography does not include planning of fields for radiation therapy.
- Urinary Bladder Sonography (B-Scan)
- Urinary bladder Sonography does not include staging of bladder tumors.
- Pregnancy Diagnosis Sonography (B-Scan)
- Fetal Age Determination (Biparietal Diameter) Sonography (B-Scan)
- Fetal Growth Rate Sonography (B-Scan)
- Placenta Localization Sonography (B-Scan)
- Pregnancy Sonography, Complete (B-Scan)
- Molar Pregnancy Diagnosis Sonography (B-Scan)
- Ectopic Pregnancy Diagnosis Sonography (B-Scan)
- Passive Testing (Antepartum Monitoring of Fetal Heart Rate In the Resting Fetus)
- Intrauterine Contraceptive Device Sonography (B-Scan)
- Pelvic Mass Diagnosis Sonography (B-Scan)
- Amniocentesis, by Ultrasonic Guidance
- Arterial Flow Study, Peripheral (Doppler)
- Venous Flow Study, Peripheral (Doppler)
- Arterial Aneurysm, Peripheral (B-Scan)
- Radiation Therapy Planning Sonography (B-Scan)
- Thyroid Echography (A-Mode)
- Thyroid Sonography (B-Scan)
- Breast Echography (A-Mode)
- Breast Sonography (B-Scan)
- Hepatic Sonography (B-Scan)
- Gallbladder Sonography
- Renal Sonography
- Two-Dimensional Echocardiography (B-Mode)
- Monitoring of cardiac output (Esophageal Doppler) for ventilated patients in the ICU and operative patients with a need for intra-operative fluid optimization

C. Nationally Non-Covered Indications

Category II - (Clinical reliability and efficacy not proven)

- B-Scan for atherosclerotic narrowing of peripheral arteries.

D. Other

Uses for ultrasound diagnostic procedures not listed in Category I or II above are left to local *MAC* discretion. In view of the rapid changes in the field of ultrasound diagnosis, uses for ultrasound diagnostic procedures other than those listed under Categories I and II should be carefully reviewed before payment. Medical justification may be required.

Cross reference: §20.17

220.6.13 - FDG *Positron Emission Tomography (PET)* for Dementia and Neurodegenerative Diseases (Effective September 15, 2004)

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

A. General

Medicare covers FDG *Positron Emission Tomography (PET)* scans for either the differential diagnosis of fronto-temporal dementia (FTD) and Alzheimer's disease (AD) under specific requirements; OR, its use in a Centers for Medicare & Medicaid Services (CMS)-approved practical clinical trial focused on the utility of FDG PET in the diagnosis or treatment of dementing neurodegenerative diseases. Specific requirements for each indication are clarified below:

B. Nationally Covered Indications

1. FDG PET Requirements for Coverage in the Differential Diagnosis of AD and FTD

An FDG PET scan is considered reasonable and necessary in patients with a recent diagnosis of dementia and documented cognitive decline of at least 6 months, who meet diagnostic criteria for both AD and FTD. These patients have been evaluated for specific alternate neurodegenerative diseases or other causative factors, but the cause of the clinical symptoms remains uncertain.

The following additional conditions must be met before an FDG PET scan will be covered:

- a. The patient's onset, clinical presentation, or course of cognitive impairment is such that FTD is suspected as an alternative neurodegenerative cause of the cognitive decline. Specifically, symptoms such as social disinhibition, awkwardness, difficulties with language, or loss of executive function are more prominent early in the course of FTD than the memory loss typical of AD;
- b. The patient has had a comprehensive clinical evaluation (as defined by the American Academy of *Neurology encompassing* a medical history from the patient and a well-acquainted informant (including assessment of activities of daily living), physical and mental status examination (including formal documentation of cognitive decline occurring over at least 6 months) aided by cognitive scales or neuropsychological testing, laboratory tests, and structural imaging such as magnetic resonance imaging (MRI) or computed tomography (CT);
- c. The evaluation of the patient has been conducted by a physician experienced in the diagnosis and assessment of dementia;
- d. The evaluation of the patient did not clearly determine a specific neurodegenerative disease or other cause for the clinical symptoms, and information available through FDG PET is reasonably expected to help clarify the diagnosis between FTD and AD and help guide future treatment;

- e. The FDG PET scan is performed in a facility that has all the accreditation necessary to operate nuclear medicine equipment. The reading of the scan should be done by an expert in nuclear medicine, radiology, neurology, or psychiatry, with experience interpreting such scans in the presence of dementia;
- f. A brain single photon emission computed tomography (SPECT) or FDG PET scan has not been obtained for the same indication. (The indication can be considered to be different in patients who exhibit important changes in scope or severity of cognitive decline, and meet all other qualifying criteria listed above and below (including the judgment that the likely diagnosis remains *uncertain*.) The results of a prior SPECT or FDG PET scan must have been inconclusive or, in the case of SPECT, difficult to interpret due to immature or inadequate technology. In these instances, an FDG PET scan may be covered after 1 year has passed from the time the first SPECT or FDG PET scan was performed.)
- g. The referring and billing provider(s) have documented the appropriate evaluation of the Medicare beneficiary. Providers should establish the medical necessity of an FDG PET scan by ensuring that the following information has been collected and is maintained in the beneficiary medical record:
- Date of onset of symptoms;
 - Diagnosis of clinical syndrome (normal aging; mild cognitive impairment (MCI); mild, moderate or severe dementia);
 - Mini mental status exam (MMSE) or similar test score;
 - Presumptive cause (possible, probable, uncertain AD);
 - Any neuropsychological testing performed;
 - Results of any structural imaging (MRI or CT) performed;
 - Relevant laboratory tests (B12, thyroid hormone); and,
 - Number and name of prescribed medications.

The billing provider must furnish a copy of the FDG PET scan result for use by CMS and its *Medicare Administrative Contractors* upon request. These verification requirements are consistent with *Federal* requirements set forth in 42 Code of Federal Regulations, *section* 410.32 generally for diagnostic x-ray tests, diagnostic laboratory tests, and other tests. In summary, section 410.32 requires the billing physician and the referring physician to maintain information in the medical record of each patient to demonstrate medical necessity [410.32(d) (2)] and submit the information demonstrating medical necessity to CMS and/or its agents upon request [410.32(d)(3)(I)] (OMB number 0938-0685).

2. FDG PET Requirements for Coverage in the Context of a CMS-approved Practical Clinical Trial Utilizing a Specific Protocol to Demonstrate the Utility of FDG PET in the Diagnosis, and Treatment of Neurodegenerative Dementing Diseases

An FDG PET scan is considered reasonable and necessary in patients with MCI or early dementia (in clinical circumstances other than those specified in subparagraph 1) only in the context of an approved clinical trial that contains patient safeguards and protections to ensure proper administration, use and evaluation of the FDG PET scan.

The clinical trial must compare patients who do and do not receive an FDG PET scan and have as its goal to monitor, evaluate, and improve clinical outcomes. In addition, it must meet the following basic criteria:

- a. Written protocol on file;
- b. Institutional Review Board review and approval;
- c. Scientific review and approval by two or more qualified individuals who are not part of the research team; and,
- d. Certification that investigators have not been disqualified.

C. Nationally Non-Covered Indications

All other uses of FDG PET for patients with a presumptive diagnosis of dementia-causing neurodegenerative disease (e.g., possible or probable AD, clinically typical FTD, dementia of Lewy bodies, or Creutzfeldt-Jacob disease) for which CMS has not specifically indicated coverage continue to be non-covered.

D. Other

Not applicable.

220.6.17 - Positron Emission Tomography (FDG PET) for Oncologic Conditions (Effective June 11, 2013)

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

A. General

FDG (2-[F18] fluoro-2-deoxy-D-glucose) Positron Emission Tomography (PET) is a minimally-invasive diagnostic imaging procedure used to evaluate glucose metabolism in normal tissue as well as in diseased tissues in conditions such as cancer, ischemic heart disease, and some neurologic disorders. FDG is an injected radionuclide (or radiopharmaceutical) that emits sub-atomic particles, known as positrons, as it decays. FDG PET uses a positron camera (tomograph) to measure the decay of FDG. The rate of FDG decay provides biochemical information on glucose metabolism in the tissue being studied. As malignancies can cause abnormalities of metabolism and blood flow, FDG PET evaluation may indicate the probable presence or absence of a malignancy based upon observed differences in biologic activity compared to adjacent tissues.

The Centers for Medicare and Medicaid Services (CMS) was asked by the National Oncologic PET Registry (NOPR) to reconsider section 220.6 of the National Coverage Determinations (NCD) Manual to end the prospective data collection requirements under Coverage with Evidence Development (CED) across all oncologic indications of FDG PET imaging. The CMS received public input indicating that the current coverage framework of prospective data collection under CED be ended for all oncologic uses of FDG PET imaging.

1. Framework

Effective for claims with dates of service on and after June 11, 2013, CMS is adopting a coverage framework that ends the prospective data collection requirements by NOPR under CED for all oncologic uses of FDG PET imaging. CMS is making this change for all NCDs that address coverage of FDG PET for oncologic uses addressed in this decision. This decision does not change coverage for any use of PET imaging using radiopharmaceuticals NaF-18 (fluorine-18 labeled sodium fluoride), ammonia N-13, or rubidium-82 (Rb-82).

2. Initial Anti-Tumor Treatment Strategy

CMS continues to believe that the evidence is adequate to determine that the results of FDG PET imaging are useful in determining the appropriate initial anti-tumor treatment strategy for beneficiaries with suspected cancer and improve health outcomes and thus are reasonable and necessary under §1862(a)(1)(A) of the Social Security Act (the Act).

Therefore, CMS continues to nationally cover one FDG PET study for beneficiaries who have cancers that are biopsy proven or strongly suspected based on other diagnostic testing when the beneficiary's treating physician determines that the FDG PET study is needed to determine the location and/or extent of the tumor for the following therapeutic purposes related to the initial anti-tumor treatment strategy:

- To determine whether or not the beneficiary is an appropriate candidate for an invasive diagnostic or

therapeutic procedure; or

- To determine the optimal anatomic location for an invasive procedure; or
- To determine the anatomic extent of tumor when the recommended anti-tumor treatment reasonably depends on the extent of the tumor.

See the table at the end of this section for a synopsis of all nationally covered and non-covered oncologic uses of FDG PET imaging.

B.1. Initial Anti-Tumor Treatment Strategy Nationally Covered Indications

- a. CMS continues to nationally cover FDG PET imaging for the initial anti-tumor treatment strategy for male and female breast cancer only when used in staging distant metastasis.
- b. CMS continues to nationally cover FDG PET to determine initial anti-tumor treatment strategy for melanoma other than for the evaluation of regional lymph nodes.
- c. CMS continues to nationally cover FDG PET imaging for the detection of pre-treatment metastasis (i.e., staging) in newly diagnosed cervical cancers.

d. C.1 Initial Anti-Tumor Treatment Strategy Nationally Non-Covered Indications

- a. CMS continues to nationally non-cover initial anti-tumor treatment strategy in Medicare beneficiaries who have adenocarcinoma of the prostate.
- b. CMS continues to nationally non-cover FDG PET imaging for diagnosis of breast cancer and initial staging of axillary nodes.
- c. CMS continues to nationally non-cover FDG PET imaging for initial anti-tumor treatment strategy for the evaluation of regional lymph nodes in melanoma.
- d. CMS continues to nationally non-cover FDG PET imaging for the diagnosis of cervical cancer related to initial anti-tumor treatment strategy.

3. Subsequent Anti-Tumor Treatment Strategy

B.2. Subsequent Anti-Tumor Treatment Strategy Nationally Covered Indications

Three FDG PET scans are nationally covered when used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy. Coverage of more than three FDG PET scans to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy shall be determined by the local Medicare Administrative Contractors.

4. Synopsis of Coverage of FDG PET for Oncologic Conditions

Effective for claims with dates of service on and after June 11, 2013, the chart below summarizes national FDG PET coverage for oncologic conditions:

FDG PET for Cancers Tumor Type	Initial Treatment Strategy (formerly “diagnosis” & “staging”	Subsequent Treatment Strategy (formerly “restaging” & “monitoring response to treatment”
Colorectal	Cover	Cover
Esophagus	Cover	Cover

Head and Neck (not thyroid, CNS)	Cover	Cover
Lymphoma	Cover	Cover
Non-small cell lung	Cover	Cover
Ovary	Cover	Cover
Brain	Cover	Cover
Cervix	Cover with exceptions *	Cover
Small cell lung	Cover	Cover
Soft tissue sarcoma	Cover	Cover
Pancreas	Cover	Cover
Testes	Cover	Cover
Prostate	Non-cover	Cover
Thyroid	Cover	Cover
Breast (male and female)	Cover with exceptions *	Cover
Melanoma	Cover with exceptions *	Cover
All other solid tumors	Cover	Cover
Myeloma	Cover	Cover
All other cancers not listed	Cover	Cover

*Cervix: Nationally non-covered for the initial diagnosis of cervical cancer related to initial anti-tumor treatment strategy. All other indications for initial anti-tumor treatment strategy for cervical cancer are nationally covered.

*Breast: Nationally non-covered for initial diagnosis and/or staging of axillary lymph nodes. Nationally covered for initial staging of metastatic disease. All other indications for initial anti-tumor treatment strategy for breast cancer are nationally covered.

*Melanoma: Nationally non-covered for initial staging of regional lymph nodes. All other indications for initial anti-tumor treatment strategy for melanoma are nationally covered.

D. Other

N/A

220.9 - Digital Subtraction Angiography (DSA)

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

Digital subtraction angiography (DSA) is a diagnostic imaging technique that applies computer technology to fluoroscopy for the purpose of visualizing the same vascular structures observable with conventional angiography. Since the radiographic contrast material can be injected into a vein rather than an artery, the procedure reduces the risk to patients, and can be done on an outpatient basis.

Medicare Administrative Contractors should be alert to possible increases in utilization of DSA over conventional angiographic procedures, as well as to the fact that ordinarily patients should not require inpatient hospitalization solely to perform the procedure.

Payment for DSA should not exceed, and may be less than, that being paid for conventional angiographic techniques.

220.12 - Single Photon Emission Computed Tomograph (SPECT)

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

The *single photon emission computed tomograph (SPECT)* acquires information on the concentration of radionuclides introduced into the patient's body. It is useful in the diagnosis of several clinical conditions including:

- Stress fracture
- Spondylosis
- Infection (e.g., discitis)
- Tumor (e.g., osteoid osteoma)
- Analyze blood flow to an organ, as in the case of myocardial viability
- Differentiate ischemic heart disease from dilated cardiomyopathy.

Frequency limitations: *Medicare Administrative Contractor* discretion.

In the case of myocardial viability, FDG *positron emission tomography (PET)* may be used following a SPECT that was found to be inconclusive. However, SPECT may not be used following an inconclusive FDG PET performed to evaluate myocardial viability.

220.13 - Percutaneous Image-Guided Breast Biopsy

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

Percutaneous image-guided breast biopsy is a method of obtaining a breast biopsy through a percutaneous incision by employing image guidance systems. Image guidance systems may be either ultrasound or stereotactic.

The Breast Imaging Reporting and Data System (or BIRADS system) employed by the American College of Radiology provides a standardized lexicon with which radiologists may report their interpretation of a mammogram. The BIRADS grading of mammograms is as follows: Grade I-Negative, Grade II-Benign finding, Grade III-Probably benign, Grade IV-Suspicious abnormality, and Grade V-Highly suggestive of malignant neoplasm.

A. *Non-Palpable* Breast Lesions

Effective January 1, 2003, Medicare covers percutaneous image-guided breast biopsy using stereotactic or ultrasound imaging for a radiographic abnormality that is *non*-palpable and is graded as a BIRADS III, IV, or V.

B. Palpable Breast Lesions

Effective January 1, 2003, Medicare covers percutaneous image guided breast biopsy using stereotactic or ultrasound imaging for palpable lesions that are difficult to biopsy using palpation alone. *Medicare Administrative Contractors* have the discretion to decide what types of palpable lesions are difficult to biopsy using palpation.

230.3 - Sterilization

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

A. *Nationally Covered Conditions*

- Payment may be made only where sterilization is a necessary part of the treatment of an illness or injury, e.g., removal of a uterus because of a tumor or removal of diseased ovaries.
- Sterilization of a mentally challenged beneficiary is covered if it is a necessary part of the treatment of an illness or injury (bilateral oophorectomy or bilateral orchidectomy in a case of cancer of the

prostate). The Medicare Administrative Contractor denies claims when the pathological evidence of the necessity to perform any such procedures to treat an illness or injury is absent; and

- Monitor such surgeries closely and obtain the information needed to determine whether in fact the surgery was performed as a means of treating an illness or injury or only to achieve sterilization.

B. Nationally Non-Covered Conditions

- Elective hysterectomy, tubal ligation, and vasectomy, if the primary indication for these procedures is sterilization;
- A sterilization that is performed because a physician believes another pregnancy would endanger the overall general health of the woman is not considered to be reasonable and necessary for the diagnosis or treatment of illness or injury within the meaning of §1862(a)(1) of the Social Security Act. The same conclusion would apply where the sterilization is performed only as a measure to prevent the possible development of, or effect on, a mental condition should the individual become pregnant; and sterilization of a mentally retarded person where the purpose is to prevent conception, rather than the treatment of an illness or injury.

230.7 - Water Purification and Softening Systems Used in Conjunction *with* Home Dialysis

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

A. Water Purification Systems

Water used for home dialysis should be chemically free of heavy trace metals and/or organic contaminants that could be hazardous to the patient. It should also be as free of bacteria as possible but need not be biologically sterile. Since the characteristics of natural water supplies in most areas of the country are such that some type of water purification system is needed, such a system used in conjunction with a home dialysis (either peritoneal or hemodialysis) unit is covered under Medicare.

There are two types of water purification systems that will satisfy these requirements:

- Deionization - The removal of organic substances, mineral salts of magnesium and calcium (causing hardness), compounds of fluoride and chloride from tap water using the process of filtration and ion exchange; or
- Reverse Osmosis (*RO*) - The process used to remove impurities from tap water utilizing pressure to force water through a porous membrane.

Use of both a deionization unit and *RO* unit in series, theoretically to provide the advantages of both systems, has been determined medically unnecessary since either system can provide water which is both chemically and bacteriologically pure enough for acceptable use in home dialysis. In addition, spare deionization tanks are not covered since they are essentially a precautionary supply rather than a current requirement for treatment of the patient.

Activated carbon filters used as a component of water purification systems to remove unsafe concentrations of chlorine and chloramines are covered when prescribed by a physician.

B. Water Softening System

Except as indicated below, a water softening system used in conjunction with home dialysis is excluded from coverage under Medicare as not being reasonable and necessary within the meaning of §1862(a)(1) of

the *Social Security* Act. Such a system, in conjunction with a home dialysis unit, does not adequately remove the hazardous heavy metal contaminants (such as arsenic) which may be present in trace amounts.

A water softening system may be covered when used to pretreat water to be purified by a *RO* unit for home dialysis where:

The manufacturer of the RO unit has set standards for the quality of water entering the RO (e.g., the water to be purified by the RO must be of a certain quality if the unit is to perform as intended);

The *patient's* water is demonstrated to be of a lesser quality than required; *and*,

The softener is used only to soften water entering the RO unit, and thus, used only for dialysis. (The softener need not actually be built into the RO unit, but must be an integral part of the dialysis system.)

C. Developing Need When a Water Softening System is Replaced with a Water Purification Unit in an Existing Home Dialysis System

The medical necessity of water purification units must be *carefully* developed when they replace water softening systems in existing home dialysis systems. A purification system may be ordered under these circumstances for a number of reasons. For example, changes in the medical community's opinions regarding the quality of water necessary for safe dialysis may lead the physician to decide the quality of water previously used should be improved, or the water quality itself may have deteriorated. Patients may have dialyzed using only an existing water softener previous to Medicare *end-stage renal disease* coverage because of inability to pay for a purification system. On the other hand, in some cases, the installation of a purification system is not medically necessary. Thus, when such a case comes to the *Medicare Administrative Contractor's (MAC's)* attention, the *MAC* asks the physician to furnish the reason for the changes. Supporting documentation, such as the *suppliers'* recommendations or water analysis, may be required. All such cases should be reviewed by the *MAC's* medical consultants.

Cross reference: - The Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §110.

240.2 - Home Use of Oxygen

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

A. General

Medicare coverage of home oxygen and oxygen equipment under the durable medical equipment (DME) benefit (see §1861(s)(6) of the *Social Security* Act) is considered reasonable and necessary only for patients with significant hypoxemia who meet the medical documentation, laboratory evidence, and health conditions specified in subsections B, C, and D. This section also includes special coverage criteria for portable oxygen systems. Finally, a statement on the absence of coverage of the professional services of a respiratory therapist under the DME benefit is included in subsection F.

B. Medical Documentation

Initial claims for oxygen services must include a completed Form CMS-484 (Certificate of Medical Necessity: Oxygen) to establish whether coverage criteria are met and to ensure that the oxygen services provided are consistent with the physician's prescription or other medical documentation. The treating physician's prescription or other medical documentation must indicate that other forms of treatment (e.g., medical and physical therapy directed at secretions, bronchospasm and infection) have been tried, have not been sufficiently successful, and oxygen therapy is still required. While there is no substitute for oxygen therapy, each patient must receive optimum therapy before long-term home oxygen therapy is ordered. Use

Form CMS-484 for recertifications. (See the Medicare Program Integrity Manual, Chapter 5, for completion of Form CMS-484.)

The medical and prescription information in section B of Form CMS-484 can be completed only by the treating physician, the physician's employee, or another clinician (e.g., nurse, respiratory therapist, etc.) as long as that person is not the DME supplier. Although hospital discharge coordinators and medical social workers may assist in arranging for physician-prescribed home oxygen, they do not have the authority to prescribe the services. Suppliers may not enter this information. While this section may be completed by non-physician clinician or a physician employee, it must be reviewed and the Form CMS-484 signed by the attending physician.

A physician's certification of medical necessity for oxygen equipment must include the results of specific testing before coverage can be determined.

Claims for oxygen must also be supported by medical documentation in the patient's record. Separate documentation is used with electronic billing. This documentation may be in the form of a prescription written by the patient's attending physician who has recently examined the patient (normally within a month of the start of therapy) and must specify:

- A diagnosis of the disease requiring home use of oxygen;
- The oxygen flow rate; and
- An estimate of the frequency, duration of use (e.g., 2 liters per minute, 10 minutes per hour, 12 hours per day), and duration of need (e.g., 6 months or lifetime).

NOTE: A prescription for "Oxygen PRN" or "Oxygen as needed" does not meet this last requirement. Neither provides any basis for determining if the amount of oxygen is reasonable and necessary for the patient.

A member of the *A/B MAC (B)* medical staff should review all claims with oxygen flow rates of more than four liters per minute before payment can be made.

The attending physician specifies the type of oxygen delivery system to be used (i.e., gas, liquid, or concentrator) by signing the completed Form CMS-484. In addition, the supplier or physician may use the space in section C for written confirmation of additional details of the physician's order. The additional order information contained in section C may include the means of oxygen delivery (mask, nasal, cannula, etc.), the specifics of varying flow rates, and/or the *non-continuous* use of oxygen as appropriate. The physician confirms this order information with their signature in section D.

New medical documentation written by the patient's attending physician must be submitted to the *A/B MAC (B)* in support of revised oxygen requirements when there has been a change in the patient's condition and need for oxygen therapy.

A/B MACs(B) are required to conduct periodic, continuing medical necessity reviews on patients whose conditions warrant these reviews and on patients with indefinite or extended periods of necessity as described in the Medicare Program Integrity Manual, Chapter 5, "Items and Services Having Special DMERC Review Considerations." When indicated, *A/B MACs* may also request documentation of the results of a repeat arterial blood gas or oximetry study.

NOTE: Section 4152 of OBRA 1990 requires earlier recertification and retesting of oxygen patients who begin coverage with an arterial blood gas result at or above a partial pressure of 55 or an arterial oxygen saturation percentage at or above 89. (See the Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS)," §100.2.3, for certification and retesting schedules.)

C. Laboratory Evidence

Initial claims for oxygen therapy must also include the results of a blood gas study that has been ordered and evaluated by the attending physician. This is usually in the form of a measurement of the partial pressure of oxygen (PO₂) in arterial blood. A measurement of arterial oxygen saturation obtained by ear or pulse oximetry, however, is also acceptable when ordered and evaluated by the attending and performed under his or her supervision or when performed by a qualified provider or supplier of laboratory services.

When the arterial blood gas and the oximetry studies are both used to document the need for home oxygen therapy and the results are conflicting, the arterial blood gas study is the preferred source of documenting medical need. A DME supplier is not considered a qualified provider or supplier of laboratory services for purposes of these guidelines.

This prohibition does not extend to the results of blood gas test conducted by a hospital certified to do such tests. The conditions under which the laboratory tests are performed must be specified in writing and submitted with the initial claim, i.e., at rest, during exercise, or during sleep.

The preferred sources of laboratory evidence are, existing physician and/or hospital records that reflect the patient's medical condition. Since it is expected that virtually all patients who qualify for home oxygen coverage for the first time under these guidelines have recently been discharged from a hospital where they submitted to arterial blood gas tests, the *A/B MAC (B)* needs to request that such test results be submitted in support of their initial claims for home oxygen. If more than one arterial blood gas test is performed during the patient's hospital stay, the test result obtained closest to, but no earlier than two days prior to the hospital discharge date is required as evidence of the need for home oxygen therapy.

For those patients whose initial oxygen prescription did not originate during a hospital stay, blood gas studies should be done while the patient is in the chronic stable state, i.e., not during a period of an acute illness or an exacerbation of their underlying disease.

A/B MACs (B) may accept an attending physician's statement of recent hospital test results for a particular patient, when appropriate, in lieu of copies of actual hospital records.

A repeat arterial blood gas study is appropriate when evidence indicates that an oxygen recipient has undergone a major change in their condition relevant to home use of oxygen. If the *A/B MAC (B)* has reason to believe that there has been a major change in the patient's physical condition, it may ask for documentation of the results of another blood gas or oximetry study.

D. Health Conditions

Coverage is available for patients with significant hypoxemia in the chronic stable state, i.e., not during a period of acute illness or an exacerbation of their underlying disease, if:

- 1) The attending physician has determined that the patient has a health condition outlined in subsection D.1,
- 2) The patient meets the blood gas evidence requirements specified in subsection D.3, and
- 3) The patient has appropriately tried other treatment without complete success. (See subsection B.)

1. Conditions for Which Oxygen Therapy May Be Covered

- A severe lung disease, such as chronic obstructive pulmonary disease, diffuse interstitial lung disease, cystic fibrosis, bronchiectasis, widespread pulmonary neoplasm, or

- Hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy. Examples of these symptoms and findings are pulmonary hypertension, recurring congestive heart failure due to chronic cor pulmonale, erythrocytosis, impairment of the cognitive process, nocturnal restlessness, and morning headache.

2. Conditions for Which Oxygen Therapy Is Not Covered

- Angina pectoris in the absence of hypoxemia. This condition is generally not the result of a low oxygen level in the blood, and there are other preferred treatments;
- Breathlessness without cor pulmonale or evidence of hypoxemia. Although intermittent oxygen use is sometimes prescribed to relieve this condition, it is potentially harmful and psychologically addicting;
- Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities. There is no evidence that increased PO₂ improves the oxygenation of tissues with impaired circulation; or
- Terminal illnesses that do not affect the lungs.

3. Covered Blood Gas Values

If the patient has a condition specified in subsection D.1, the *A/B MAC (B)* must review the medical documentation and laboratory evidence that has been submitted for a particular patient (see subsections B and C) and determine if coverage is available under one of the three group categories outlined below.

(a) - Group I - Except as modified in subsection d, coverage is provided for patients with significant hypoxemia evidenced by any of the following:

- An arterial PO₂ at or below 55 mm Hg, or an arterial oxygen saturation at or below 88%, taken at rest, breathing room air.
- An arterial PO₂ at or below 55 mm Hg, or an arterial oxygen saturation at or below 88%, taken during sleep for a patient who demonstrates an arterial PO₂ at or above 56 mm Hg, or an arterial oxygen saturation at or above 89%, while awake; or a greater than normal fall in oxygen level during sleep (a decrease in arterial PO₂ more than 10 mm Hg, or decrease in arterial oxygen saturation more than 5%) associated with symptoms or signs reasonably attributable to hypoxemia (e.g., impairment of cognitive processes and nocturnal restlessness or insomnia). In either of these cases, coverage is provided only for use of oxygen during sleep, and then only one type of unit will be covered. Portable oxygen, therefore, would not be covered in this situation.
- An arterial PO₂ at or below 55 mm Hg or an arterial oxygen saturation at or below 88%, taken during exercise for a patient who demonstrates an arterial PO₂ at or above 56 mm Hg, or an arterial oxygen saturation at or above 89%, during the day while at rest. In this case, supplemental oxygen is provided for during exercise if there is evidence the use of oxygen improves the hypoxemia that was demonstrated during exercise when the patient was breathing room air.

(b) - Group II - Except as modified in subsection d, coverage is available for patients whose arterial PO₂ is 56-59 mm Hg or whose arterial blood oxygen saturation is 89%, if there is evidence of:

- Dependent edema suggesting congestive heart failure;
- Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVF); or

- Erythrocythemia with a hematocrit greater than 56%.

(c) - Group III - Except as modified in subsection d, *A/B MACs (B)* must apply a rebuttable presumption that a home program of oxygen use is not medically necessary for patients with arterial PO₂ levels at or above 60 mm Hg, or arterial blood oxygen saturation at or above 90%. In order for claims in this category to be reimbursed, the *A/B MAC (B)'s* reviewing physician needs to review any documentation submitted in rebuttal of this presumption and grant specific approval of the claims.

The *Centers for Medicare & Medicaid Services* expects few claims to be approved for coverage in this category.

(d) - Variable Factors That May Affect Blood Gas Values - In reviewing the arterial PO₂ levels and the arterial oxygen saturation percentages specified in subsections D. 3.a, *b*, and *c*, the *A/B MAC (B)* medical staff must take into account variations in oxygen measurements that may result from such factors as the patient's age, the altitude level, or the patient's decreased oxygen carrying capacity.

E. Portable Oxygen Systems

A patient meeting the requirements specified below may qualify for coverage of a portable oxygen system either (1) by itself, *or*, (2) to use in addition to a stationary oxygen system. Portable oxygen is not covered when it is provided only as a backup to a stationary oxygen system. A portable oxygen system is covered for a particular patient if:

- The claim meets the requirements specified in subsections A-D, as appropriate; and
- The medical documentation indicates that the patient is mobile in the home and would benefit from the use of a portable oxygen system in the home. Portable oxygen systems are not covered for patients who qualify for oxygen solely based on blood gas studies obtained during sleep.

F. Respiratory Therapists

Respiratory therapists' services are not covered under the provisions for coverage of oxygen services under the Part B *DME* benefit as outlined above. This benefit provides for coverage of home use of oxygen and oxygen equipment, but does not include a professional component in the delivery of such services.

(See §280.1, and the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §110.)

240.8 - Pulmonary Rehabilitation Services - (Effective September 25, 2007)

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

A. General

Pulmonary rehabilitation was defined in a 1999 joint statement of the American Thoracic Society and the European Respiratory Society as a multi-disciplinary program of care for patients with chronic respiratory impairment that is individually tailored and designed to optimize physical and social performance and autonomy and an evidence-based, multidisciplinary, and comprehensive intervention for patients with chronic respiratory diseases who are symptomatic and often have decreased daily life activities. Integrated into the individualized treatment of the patient, pulmonary rehabilitation is designed to reduce symptoms, optimize functional status, increase participation, and reduce health care costs through stabilizing or reversing systematic manifestations of the disease.

Although services that make up pulmonary rehabilitation individually may be covered under Medicare and fall into various applicable benefit categories, the Centers for Medicare & Medicaid Services (CMS) has determined that the Social Security Act (the Act) does not expressly define a comprehensive Pulmonary Rehabilitation Program as a Part B benefit. In addition, respiratory therapy services are identified as covered services under the Comprehensive Outpatient Rehabilitation Facility benefit and defined in 42 CFR 410.100(e)(1) to (2)(vi).

B. Nationally Covered Indications

N/A

C. Nationally Non-Covered Indications

N/A

D. Other

The CMS has determined that a national coverage determination (NCD) for pulmonary rehabilitation is not appropriate at this time. Local *Medicare Administrative Contractors* should continue to make decisions under §1862(a)(1)(A) of the Act through their local coverage determination (LCD) process or by case-by-case adjudication. See *Heckler v. Ringer*, 466 U.S. 602, 617 (1984) (Recognizing that the Secretary has discretion to either establish a generally applicable rule or to allow individual adjudication.). See also, 68 Fed. Reg. 63692, 63693 (November 7, 2003). LCDs can be accessed from the CMS search engine located at: <http://www.cms.hhs.gov/mcd/search.asp>.

250.1 - Treatment of Psoriasis

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

Psoriasis is a chronic skin disease, for which several conventional methods of treatment have been recognized as covered. These include topical application of steroids or other drugs; ultraviolet light (actinotherapy); and coal tar alone or in combination with ultraviolet B light (Goeckerman treatment).

A newer treatment for psoriasis uses a psoralen derivative drug in combination with ultraviolet A light, known as PUVA. PUVA therapy is covered for treatment of intractable, disabling psoriasis, but only after the psoriasis has not responded to more conventional treatment. The *Medicare Administrative Contractor* should document this before paying for PUVA therapy.

In addition, reimbursement for PUVA therapy should be limited to amounts paid for other types of photochemotherapy; ordinarily, payment should not be allowed for more than 30 days of treatment, unless improvement is documented.

250.3 - Intravenous Immune Globulin for the Treatment of Autoimmune Mucocutaneous Blistering Diseases

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

Intravenous immune globulin (IVIg) is a blood product prepared from the pooled plasma of donors. It has been used to treat a variety of autoimmune diseases, including mucocutaneous blistering diseases. It has fewer side effects than steroids or immunosuppressive agents.

Effective October 1, 2002, IVIg is covered for the treatment of biopsy-proven: (1) Pemphigus Vulgaris, (2) Pemphigus Foliaceus, (3) Bullous Pemphigoid, (4) Mucous Membrane Pemphigoid (a.k.a., Cicatricial Pemphigoid), and, (5) Epidermolysis Bullosa Acquisita for the following patient subpopulations:

- Patients who have failed conventional therapy. *Medicare Administrative Contractors (MACs)* have the discretion to define what constitutes failure of conventional therapy;
- Patients in whom conventional therapy is otherwise contraindicated. conventional therapy; or
- Patients with rapidly progressive disease in whom a clinical response could not be affected quickly enough using conventional agents. In such situations IVIg therapy would be given along with conventional treatment(s) and the IVIg would be used only until the conventional therapy could take effect.

In addition, IVIg for the treatment of autoimmune mucocutaneous blistering diseases must be used only for short-term therapy and not as a maintenance therapy. *MACs* have the discretion to decide what constitutes short-term therapy.

270.1 - Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds – (Effective July 1, 2004)

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

Electrical stimulation (ES) and electromagnetic therapy have been used or studied for many different applications, one of which is accelerating wound healing. ES for the treatment of wounds is the application of electrical current through electrodes placed directly on the skin in close proximity to the wound. Electromagnetic therapy uses a pulsed magnetic field to induce current. *The Centers for Medicare & Medicaid Services (CMS)* was asked to reconsider its national *non-coverage* determination for electromagnetic therapy. After thorough review, CMS determined that the results from the use of electromagnetic therapy for the treatment of wounds were similar to the results from the use of ES. Therefore, effective July 1, 2004, Medicare will cover electromagnetic therapy for the same settings and conditions for which ES is covered. This means Medicare will allow either one covered ES therapy or one covered electromagnetic therapy for the treatment of wounds.

A. Nationally Covered Indications

The use of ES and electromagnetic therapy for the treatment of wounds are considered adjunctive therapies, and will only be covered for chronic Stage III or Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers. Chronic ulcers are defined as ulcers that have not healed within 30 days of occurrence. ES or electromagnetic therapy will be covered only after appropriate standard wound therapy has been tried for at least 30 days and there are no measurable signs of improved healing. This 30-day period may begin while the wound is acute.

Standard wound care includes: optimization of nutritional status, debridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, and necessary treatment to resolve any infection that may be present. Standard wound care based on the specific type of wound includes: frequent repositioning of a patient with pressure ulcers (usually every 2 hours), off-loading of pressure and good glucose control for diabetic ulcers, establishment of adequate circulation for arterial ulcers, and the use of a compression system for patients with venous ulcers.

Measurable signs of improved healing include: a decrease in wound size (either surface area or volume), decrease in amount of exudates, and decrease in amount of necrotic tissue. ES or electromagnetic therapy must be discontinued when the wound demonstrates 100% *epithelialized* wound bed.

The ES and electromagnetic therapy services can only be covered when performed by a physician, physical therapist, or incident to a physician service. Evaluation of the wound is an integral part of wound therapy. When a physician, physical therapist, or a clinician incident to a physician, performs ES or electromagnetic therapy, the practitioner must evaluate the wound and contact the treating physician if the wound worsens.

If ES or electromagnetic therapy is being used, wounds must be evaluated at least monthly by the treating physician.

B. Nationally *Non-Covered* Indications

1. ES and electromagnetic therapy will not be covered as an initial treatment modality.
2. Continued treatment with ES or electromagnetic therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.
3. Unsupervised use of ES or electromagnetic therapy for wound therapy will not be covered, as this use has not been found to be medically reasonable and necessary.

C. Other

All other uses of ES and electromagnetic therapy not otherwise specified for the treatment of wounds remain at local *Medicare Administrative Contractor* discretion.

280.1 - Durable Medical Equipment Reference List (Effective May 5, 2005)

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

The durable medical equipment (DME) list that follows is designed to facilitate the *Medicare Administrative Contractor's (MAC's)* processing of DME claims. This section is designed as a quick reference tool for determining the coverage status of certain pieces of DME and especially for those items commonly referred to by both brand and generic names. The information contained herein is applicable (where appropriate) to all DME national coverage determinations (NCDs) discussed in the DME portion of this manual. The list is organized into two columns. The first column lists alphabetically various generic categories of equipment on which NCDs have been made by the Centers for Medicare & Medicaid Services (CMS); the second column notes the coverage status.

In the case of equipment categories that have been determined by CMS to be covered under the DME benefit, the list outlines the conditions of coverage that must be met if payment is to be allowed for the rental or purchase of the DME by a particular patient, or cross-refers to another section of the manual where the applicable coverage criteria are described in more detail. With respect to equipment categories that cannot be covered as DME, the list includes a brief explanation of why the equipment is not covered. This DME list will be updated periodically to reflect any additional NCDs that CMS may make with regard to other categories of equipment.

When the *MAC* receives a claim for an item of equipment which does not appear to fall logically into any of the generic categories listed, the *MAC* has the authority and responsibility for deciding whether those items are covered under the DME benefit.

These decisions must be made by each *MAC* based on the advice of its medical consultants, taking into account:

- The Medicare Claims Processing Manual, Chapter 20, “Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS).”
- Whether the item has been approved for marketing by the Food and Drug Administration (FDA) and is otherwise generally considered to be safe and effective for the purpose intended; and
- Whether the item is reasonable and necessary for the individual patient.

The term DME is defined as equipment which:

- Can withstand repeated use; i.e., could normally be rented and used by successive patients;
- Is primarily and customarily used to serve a medical purpose;
- Generally is not useful to a person in the absence of illness or injury; and,
- Is appropriate for use in a patient's home.

Durable Medical Equipment Reference List

<i>Item</i>	Coverage
Air Cleaners	Deny--environmental control equipment; not primarily medical in nature (§1861(n) of the Act).
Air Conditioners	Deny--environmental control equipment; not primarily medical in nature (§1861(n) of the Act).
Air-Fluidized Beds	(See Air-Fluidized Beds §280.8 of this manual.)
Alternating Pressure Pads, Mattresses and <i>Lamb's</i> Wool Pads	Covered if patient has, or is highly susceptible to, decubitus ulcers and patient's physician specifies that he/she will be supervising the course of treatment.
Audible/Visible Signal/Pacemaker Monitors	(See Self-Contained Pacemaker Monitors.)
Augmentative Communication Devices	(See Speech-Generating Devices §50.1 of this manual.)
Bathtub Lifts	Deny--convenience item; not primarily medical in nature (§1861(n) of the Act).
Bathtub Seats	Deny--comfort or convenience item; hygienic equipment; not primarily medical in nature (§1861(n) of the Act).
Bead Beds	(See §280.8 .)
Bed Baths (home type)	Deny--hygienic equipment; not primarily medical in nature (§1861(n) of the Act).
Bed Lifters (bed elevators)	Deny--not primarily medical in nature (§1861(n) of the Act).
Bedboards	Deny--not primarily medical in nature (§1861(n) of the Act).
Bed Pans (autoclavable hospital type)	Covered if patient is bed-confined.
Bed Side Rails	(See Hospital Beds §280.7 of this manual.)
Beds-Lounges (power or manual)	Deny--not a hospital bed; comfort or convenience item; not primarily medical in nature (§1861(n) of the Act).
Beds (Oscillating)	Deny--institutional equipment; inappropriate for home use.

<i>Item</i>	Coverage
Bidet Toilet Seats	(See Toilet Seats.)
Blood Glucose Analyzers (Reflectance Colorimeter)	Deny--unsuitable for home use (see §40.2 of this manual).
Blood Glucose Monitors	Covered if patient meets certain conditions (see §40.2 of this manual).
Braille Teaching Texts	Deny--educational equipment; not primarily medical in nature (§1861(n) of the Act).
Canes	Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual).
Carafes	Deny--convenience item; not primarily medical in nature (§1861(n) of the Act).
Catheters	Deny—non-reusable disposable supply (§1861(n) of the Act). (See Medicare Claims Processing Manual, Chapter 20, DMEPOS).
Commodes	Covered if patient is confined to bed or room. NOTE: The term “room-confined” means that patient’s condition is such that leaving the room is medically contraindicated. The accessibility of bathroom facilities generally would not be a factor in this determination. However, confinement of a patient to a home in a case where there are no toilet facilities in the home may be equated to room confinement. Moreover, payment may also be made if a patient’s medical condition confines him to a floor of the home and there is no bathroom located on that floor.
Communicators	(See §50.1 of this manual, Speech Generating Devices.)
Continuous Passive Motion Devices	Continuous passive motion devices are devices covered for patients who have received a total knee replacement. To qualify for coverage, use of the device must commence within 2 days following surgery. In addition, coverage is limited to that portion of the 3-week period following surgery during which the device is used in the patient’s home. There is insufficient evidence to justify coverage for longer periods of time or for other applications.
Continuous Positive Airway Pressure (CPAP) Devices	(See §240.4 of this manual.)
Crutches	Covered if patient meets Mobility Assistive Equipment clinical criteria (see section 280.3 of this manual).
Cushion Lift Power Seats	(See Seat Lifts.)
Dehumidifiers (room or central heating system type)	Deny--environmental control equipment; not primarily medical in nature (§1861(n) of the Act).

<i>Item</i>	Coverage
Diathermy Machines (standard pulses wave types)	Deny--inappropriate for home use (see §150.5 of this manual).
Digital Electronic Pacemaker Monitors	(See Self-Contained Pacemaker Monitors).
Disposable Sheets and Bags	Deny— <i>non-reusable</i> disposable supplies (§1861(n) of the Act).
Elastic Stockings	Deny— <i>non-reusable</i> supply; not rental-type items (§1861(n) of the Act.) (See §270.5 of this manual.)
Electric Air Cleaners	Deny--(see Air Cleaners.) (§1861(n) of the Act).
Electric Hospital Beds	(See Hospital Beds §280.7 of this manual.)
Electrical Stimulation for Wounds	Deny--inappropriate for home use. (See §270.1 of this manual.)
Electrostatic Machines	Deny--(see Air Cleaners and Air Conditioners.) (§1861(n) of the Act).
Elevators	Deny--convenience item; not primarily medical in nature (§1861(n) of the Act).
Emesis Basins	Deny--convenience item; not primarily medical in nature (§1861(n) of the Act).
Esophageal Dilators	Deny--physician instrument; inappropriate for patient use.
Exercise Equipment	Deny--not primarily medical in nature (§1861(n) of the Act).
Fabric Supports	Deny—non-reusable supplies; not rental-type items (§1861(n) of the Act).
Face Masks (oxygen)	Covered if oxygen is covered. (See §240.2 of this manual.)
Face Masks (surgical)	Deny—non-reusable disposable items (§1861(n) of the Act).
<i>Flow Meters</i>	(See Medical Oxygen Regulators.) (See §240.2 of this manual.)
Fluidic Breathing Assisters	(See Intermittent Positive Pressure Breathing Machines.)
Fomentation Devices	(See Heating Pads.)
Gel Flotation Pads and Mattresses	(See Alternating Pressure Pads and Mattresses.)
Grab Bars	Deny--self-help device; not primarily medical in nature (§1861(n) of the Act).
Heat and Massage Foam	Deny--not primarily medical in nature; personal comfort

<i>Item</i>	Coverage
Cushion Pads	item (§1861(n) and 1862(a)(6) of the Act).
Heating and Cooling Plants	Deny--environmental control equipment not primarily medical in nature (§1861(n) of the Act).
Heating Pads	Covered if <i>MAC</i> 's medical staff determines patient's medical condition is one for which the application of heat in the form of a heating pad is therapeutically effective.
Heat Lamps	Covered if <i>MAC</i> 's medical staff determines patient's medical condition is one for which the application of heat in the form of a heat lamp is therapeutically effective.
Hospital Beds	(See §280.7 of this manual.)
Hot Packs	(See Heating Pads.)
Humidifiers (oxygen)	(See Oxygen Humidifiers.)
Humidifiers (room or central heating system types)	Deny--environmental control equipment; not medical in nature (§1861(n) of the Act).
Hydraulic Lifts	(See Patient Lifts.)
Incontinent Pads	Deny—non-reusable supply; hygienic item (§1861(n) of the Act).
Infusion Pumps	For external and implantable pumps, see §40.2 of this manual. If pump is used with an enteral or parenteral nutritional therapy system, see §180.2 of this manual for special coverage rules.
Injectors (hypodermic jet)	Deny--not covered self-administered drug supply; pressure-powered devices (§1861(s)(2)(A) of the Act) for injection of insulin.
Intermittent Positive Pressure Breathing Machines	Covered if patient's ability to breathe is severely impaired.
Iron Lungs	(See Ventilators.)
Irrigating Kits	Deny—non-reusable supply; hygienic equipment (§1861(n) of the Act).
<i>Lamb's</i> Wool Pads	(See Alternating Pressure Pads, Mattresses, and <i>Lamb's</i> Wool Pads.)
Leotards	Deny--(See Pressure Leotards.) (§1861(n) of the Act).
Lymphedema Pumps	Covered (See Pneumatic Compression Devices §280.6 of this manual.)
Massage Devices	Deny--personal comfort items; not primarily medical in

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nature ([§1861\(n\)](#) and [1862\(a\)\(6\)](#) of the Act).

Mattresses	Covered only where hospital bed is medically necessary. (Separate Charge for replacement mattress should not be allowed where hospital bed with mattress is rented.) (See §280.7 of this manual.)
Medical Oxygen Regulators	Covered if patient's ability to breathe is severely impaired. (See §240.2 of this manual.)
Mobile Geriatric Chairs	Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual). (See Rolling Chairs).
Motorized Wheelchairs	Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual).
Muscle Stimulators	Covered for certain conditions. (See §250.4 of this manual.)
Nebulizers	Covered if patient's ability to breathe is severely impaired.
Oscillating Beds	Deny--institutional equipment; inappropriate for home use.
Over-bed Tables	Deny--convenience item; not primarily medical in nature (§1861(n) of the Act).
Oxygen	Covered if oxygen has been prescribed for use in connection with medically necessary DME. (See §240.2 of this manual.)
Oxygen Humidifiers	Covered if oxygen has been prescribed for use in connection with medically necessary DME for purposes of moisturizing oxygen. (See §240.2 of this manual.)
Oxygen Regulators (Medical)	(See Medical Oxygen Regulators.)
Oxygen Tents	(See §240.2 of this manual.)
Paraffin Bath Units (Portable)	(See Portable Paraffin Bath Units.)
Paraffin Bath Units (Standard)	Deny--institutional equipment; inappropriate for home use.
Parallel Bars	Deny--support exercise equipment; primarily for institutional use; in the home setting other devices (e.g., walkers) satisfy patient's need.
Patient Lifts	Covered if MAC 's medical staff determines patient's condition is such that periodic movement is necessary to effect improvement or to arrest/retard deterioration in condition .
Percussors	Covered for mobilizing respiratory tract secretions in patients with chronic obstructive lung disease, chronic bronchitis, or emphysema, when patient/operator of powered

Item

Coverage

percussor receives appropriate training by a physician/therapist, and no one competent to administer manual therapy is available.

Portable Oxygen Systems	<ol style="list-style-type: none">1. Regulated Covered (adjustable covered under conditions specified in a flow rate). Refer all claims to medical staff for this determination.2. Preset Deny (flow rate deny emergency, first-aid, or not adjustable) precautionary equipment; essentially not therapeutic in nature.
Portable Paraffin Bath Units	Covered when patient has undergone a successful trial period of paraffin therapy ordered by a physician and patient's condition is expected to be relieved by long-term use of this modality.
Portable Room Heaters	Deny--environmental control equipment; not primarily medical in nature (§1861(n) of the Act).
Portable Whirlpool Pumps	Deny--not primarily medical in nature; personal comfort items (§§1861(n) and 1862(a)(6) of the Act).
Postural Drainage Boards	Covered if patient has a chronic pulmonary condition.
Preset Portable Oxygen Units	Deny--emergency, first-aid, or precautionary equipment; essentially not therapeutic in nature.
Pressure Leotards	Deny--non-reusable supply, not rental-type item (§1861(n) of the Act).
Pulse Tachometers	Deny--not reasonable or necessary for monitoring pulse of homebound patient with/without a cardiac pacemaker.
Quad-Canes	Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual).
Raised Toilet Seats	Deny--convenience item; hygienic equipment; not primarily medical in nature (§1861(n) of the Act).
Reflectance Colorimeters	(See Blood Glucose Analyzers.)
Respirators	(See Ventilators.)
Rolling Chairs	<p>Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual). Coverage is limited to those roll-about chairs having casters of at least 5 inches in diameter and specifically designed to meet the needs of ill, injured, or otherwise impaired individuals.</p> <p>Coverage is denied for the wide range of chairs with smaller casters as are found in general use in homes, offices, and institutions for many purposes not related to the care/treatment of ill/injured persons. This type is not</p>

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	primarily medical in nature. (§1861(n) of the Act.)
Safety Rollers	Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual).
Sauna Baths	Deny--not primarily medical in nature; personal comfort items (§§1861(n) and (1862(a)(6) of the Act).
Seat Lifts	Covered under conditions specified in §280.4 of this manual. Refer all to medical staff for this determination.
Self-Contained Pacemaker Monitors	Covered when prescribed by a physician for a patient with a cardiac pacemaker. (See §§20.8.1 and 280.2 of this manual.)
Sitz Baths	Covered if MAC 's medical staff determines patient has an infection/injury of the perineal area and the item has been prescribed by the patient's physician as part of planned regimen of treatment in patient's home.
Spare Tanks of Oxygen	Deny--convenience or precautionary supply.
Speech Teaching Machines	Deny--education equipment; not primarily medical in nature (§1861(n) of the Act).
Stairway Elevators	Deny--(See Elevators.) (§1861(n) of the Act).
Standing Tables	Deny--convenience item; not primarily medical in nature (§1861(n) of the Act).
Steam Packs	These packs are covered under same conditions as heating pads. (See Heating Pads.)
Suction Machines	Covered if MAC 's medical staff determines that the machine specified in the claim is medically required and appropriate for home use without technical/professional supervision.
Support Hose	Deny (See Fabric Supports.) (§1861(n) of the Act).
Surgical Leggings	Deny--non-reusable supply; not rental-type item (§1861(n) of the Act).
Telephone Alert Systems	Deny--these are emergency communications systems and do not serve a diagnostic/therapeutic purpose.
Toilet Seats	Deny--not medical equipment (§1861(n) of the Act).
Traction Equipment	Covered if patient has orthopedic impairment requiring traction equipment that prevents ambulation during period of use. (Consider covering devices usable during ambulation; e.g., cervical traction collar, under brace provision.)
Trapeze Bars	Covered if patient is bed-confined and needs a trapeze bar to sit up because of respiratory condition, to change body

<i>Item</i>	Coverage
	position for other medical reasons, or to get in/out of bed.
Treadmill Exercisers	Deny--exercise equipment; not primarily medical in nature (§1861(n) of the Act).
Ultraviolet Cabinets	Covered for selected patients with generalized intractable psoriasis. Using appropriate consultation, <i>the MAC</i> should determine whether medical/other factors justify treatment at home rather than at alternative sites, e.g., outpatient department of a hospital.
Urinals autoclavable	Covered if patient is bed-confined (hospital type).
Vaporizers	Covered if patient has a respiratory illness.
Ventilators	Covered for treatment of neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease. Includes both positive/negative pressure types. (See §240.5 of this manual.)
Walkers	Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual).
Water and Pressure Pads and Mattresses	(See Alternating Pressure Pads, Mattresses, and <i>Lamb's Wool Pads</i> .)
Wheelchairs (manual)	Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual).
Wheelchairs (power-operated)	Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual).
Wheelchairs (scooter/POV)	Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual).
Wheelchairs (specially-sized)	Covered if patient meets Mobility Assistive Equipment clinical criteria (see §280.3 of this manual).
Whirlpool Bath Equipment	Covered if patient is homebound and has a (standard) condition for which the whirlpool bath can be expected to provide substantial therapeutic benefit justifying its cost. Where patient is not homebound but has such a condition, payment is restricted to the cost of providing the services elsewhere; e.g., an outpatient department of a participating hospital, if that alternative is less costly. In all cases, refer claim to medical staff for determination.
Whirlpool Pumps	Deny--(See Portable Whirlpool Pumps.) (§1861(n) of the Act).
White Canes	Deny-- (See §280.2 of this manual.) (Not considered Mobility Assistive Equipment)

Cross-references: Medicare Benefit Policy Manual, Chapters 13, “Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Services,” 15, “Covered Medical and Other Health Services.”

Medicare Claims Processing Manual, Chapters 12, “Physician/Practitioner Billing,” 20, “Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS),” 23, “Fee Schedule Administration and Coding Requirements.”

280.7 - Hospital Beds

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

A. General Requirements for Coverage of Hospital Beds

A physician’s *prescription and* such additional documentation as the *Medicare Administrative Contractor (MAC)* medical *staff* may consider necessary, including medical records and physicians’ reports, must establish the medical necessity for a hospital bed due to one of the following reasons:

- *The patient’s condition requires positioning of the body; e.g., to alleviate pain, promote good body alignment, prevent contractures, avoid respiratory infections, in ways not feasible in an ordinary bed; or*
- *The patient’s condition requires special attachments that cannot be fixed and used on an ordinary bed.*

B. Physician’s Prescription

The physician’s prescription which must accompany the initial claim, and supplementing documentation when required, must establish that a hospital bed is medically necessary. If the stated reason for the need for a hospital bed is the patient’s condition requires positioning, the prescription or other documentation must describe the medical condition, e.g., cardiac disease, chronic obstructive pulmonary disease, quadriplegia or paraplegia, and also the severity and frequency of the symptoms of the *condition that* necessitates a hospital bed for positioning.

If the stated reason for requiring a hospital bed is the patient’s condition requires special attachments, the prescription must describe the patient’s condition and specify the attachments that require a hospital bed.

C. Variable Height Feature

In well documented cases, the *MAC* medical *staff* may determine that a variable height feature of a hospital bed, approved for coverage under subsection A above, is medically necessary and, therefore, covered, for one of the following conditions:

- *Severe arthritis and other injuries to lower extremities; e.g., fractured hip - The condition requires the variable height feature to assist the patient to ambulate by enabling the patient to place his or her feet on the floor while sitting on the edge of the bed;*
- *Severe cardiac conditions - For those cardiac patients who are able to leave bed, but who must avoid the strain of “jumping” up or down;*
- *Spinal cord injuries, including quadriplegic and paraplegic patients, multiple limb amputee and stroke patients. For those patients who are able to transfer from bed to a wheelchair, with or without help; or,*
- *Other severely debilitating diseases and conditions, if the variable height feature is required to assist the patient to ambulate.*

D. Electric Powered Hospital Bed Adjustments

Electric powered adjustments to lower and raise head and foot may be covered when the **MAC** medical staff determines that the patient's condition requires frequent change in body position and/or there may be an immediate need for a change in body position (i.e., no delay can be tolerated) and the patient can operate the controls and cause the adjustments. Exceptions may be made to this last requirement in cases of spinal cord injury and brain damaged patients.

E. Side Rails

If the patient's condition requires bed side rails, they can be covered when an integral part of, or an accessory to, a hospital bed.

280.14 - Infusion Pumps

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

A. General

Infusion pumps are medical devices used to deliver solutions containing parenteral drugs under pressure at a regulated flow rate.

B. Nationally Covered Indications

The following indications for treatment using infusion pumps are covered under Medicare:

1. External Infusion Pumps

a. *Iron Poisoning (Effective for Services Performed On or After September 26, 1984)*

When used in the administration of deferoxamine for the treatment of acute iron poisoning and iron overload, only external infusion pumps are covered.

b. *Thromboembolic Disease (Effective for Services Performed On or After September 26, 1984)*

When used in the administration of heparin for the treatment of thromboembolic disease and/or pulmonary embolism, only external infusion pumps used in an institutional setting are covered.

c. *Chemotherapy for Liver Cancer (Effective for Services Performed On or After January 29, 1985)*

The external chemotherapy infusion pump is covered when used in the treatment of primary hepatocellular carcinoma or colorectal cancer where this disease is unresectable; OR, where the patient refuses surgical excision of the tumor.

d. *Morphine for Intractable Cancer Pain (Effective for Services Performed On or After April 22, 1985)*

Morphine infusion via an external infusion pump is covered when used in the treatment of intractable pain caused by cancer (in either an inpatient or outpatient setting, including a hospice).

e. *Continuous Subcutaneous Insulin Infusion (CSII) Pumps (Effective for Services Performed On or after December 17, 2004)*

Continuous subcutaneous insulin infusion (CSII) and related drugs/supplies are covered as medically reasonable and necessary in the home setting for the treatment of diabetic patients who: (1) either meet the updated fasting C-Peptide testing requirement, or, are beta cell autoantibody positive; and, (2) satisfy the

remaining criteria for insulin pump therapy as described below. Patients must meet either Criterion A or B as follows:

Criterion A: The patient has completed a comprehensive diabetes education program, and has been on a program of multiple daily injections of insulin (i.e., at least 3 injections per day), with frequent self-adjustments of insulin doses for at least 6 months prior to initiation of the insulin pump, and has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump, and meets one or more of the following criteria while on the multiple daily injection regimen:

- Glycosylated hemoglobin level (HbA1c) **>7.0%**;
- History of recurring hypoglycemia;
- Wide fluctuations in blood glucose before mealtime;
- Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl; **or,**
- History of severe glycemic excursions.

Criterion B: The patient with diabetes has been on a pump prior to enrollment in Medicare and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to Medicare enrollment.

General CSII Criteria

In addition to meeting Criterion A or B above, the following general requirements must be met:

The patient with diabetes must be insulinopenic per the updated fasting C-peptide testing requirement, or, as an alternative, must be beta cell autoantibody positive.

Updated fasting C-peptide testing requirement:

- Insulinopenia is defined as a fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method.
- For patients with renal insufficiency and creatinine clearance (actual or calculated from age, gender, weight, and serum creatinine) ≤ 50 ml/minute, insulinopenia is defined as a fasting C-peptide level that is less than or equal to 200% of the lower limit of normal of the laboratory's measurement method.
- Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose ≤ 225 mg/dL.
- Levels only need to be documented once in the medical records.

Continued coverage of the insulin pump would require that the patient be seen and evaluated by the treating physician at least every 3 months.

The pump must be ordered by and follow-up care of the patient must be managed by a physician who manages multiple patients with CSII and who works closely with a team including nurses, diabetes educators, and dietitians who are knowledgeable in the use of CSII.

Other Uses of CSII

The *Centers for Medicare & Medicaid Services* will continue to allow coverage of all other uses of CSII in accordance with the Category B investigational device *exemption clinical* trials regulation (42 CFR 405.201) or as a routine cost under the clinical trials policy (Medicare National Coverage *Determinations Manual* 310.1).

f. Other Uses

Other uses of external infusion pumps are covered if the *Medicare Administrative Contractor (MAC)* medical staff verifies the appropriateness of the therapy and the prescribed pump for the individual patient.

NOTE: Payment may also be made for drugs necessary for the effective use of a covered external infusion pump as long as the drug being used with the pump is itself reasonable and necessary for the patient's treatment.

2. Implantable Infusion Pumps

a. Chemotherapy for Liver Cancer (Effective for Services Performed On or After September 26, 1984)

The implantable infusion pump is covered for intra-arterial infusion of 5-FUdR for the treatment of liver cancer for patients with primary hepatocellular carcinoma or Duke's Class D colorectal cancer, in whom the metastases are limited to the liver, and where: (1) the disease is unresectable, *or*, (2) the patient refuses surgical excision of the tumor.

b. Anti-Spasmodic Drugs for Severe Spasticity

An implantable infusion pump is covered when used to administer anti-spasmodic drugs intrathecally (e.g., baclofen) to treat chronic intractable spasticity in patients who have proven unresponsive to less invasive medical therapy as determined by the following criteria:

As indicated by at least a 6-week trial, the patient cannot be maintained on *non-invasive* methods of spasm control, such as oral anti-spasmodic drugs, either because these methods fail to control adequately the spasticity or produce intolerable side *effects*. *And* prior to pump implantation, the patient must have responded favorably to a trial intrathecal dose of the anti-spasmodic drug.

c. Opioid Drugs for Treatment of Chronic Intractable Pain

An implantable infusion pump is covered when used to administer opioid drugs (e.g., morphine) intrathecally or epidurally for treatment of severe chronic intractable pain of malignant or nonmalignant origin in patients who have a life expectancy of at least 3 months, and who have proven unresponsive to less invasive medical therapy as determined by the following criteria:

The patient's history must indicate that he/she would not respond adequately to noninvasive methods of pain control, such as systemic opioids (including attempts to eliminate physical and behavioral abnormalities which may cause an exaggerated reaction to pain); and a preliminary trial of intraspinal opioid drug administration must be undertaken with a temporary intrathecal/epidural catheter to substantiate adequately acceptable pain relief and degree of side effects (including effects on the activities of daily living) and patient acceptance.

d. Coverage of Other Uses of Implanted Infusion Pumps

Determinations may be made on coverage of other uses of implanted infusion pumps if the *MAC* medical staff verifies that:

- The drug is reasonable and necessary for the treatment of the individual patient;

- It is medically necessary that the drug be administered by an implanted infusion pump; and,
- The Food and Drug *Administration-approved* labeling for the pump must specify that the drug being administered and the purpose for which it is administered is an indicated use for the pump.

e. Implantation of Infusion Pump Is Contraindicated

The implantation of an infusion pump is contraindicated in the following patients:

With a known allergy or hypersensitivity to the drug being used (e.g., oral baclofen, morphine, etc.); *or*,

Who have an *active* infection; *or*,

Whose body size is insufficient to support the weight and bulk of the device; *or*,

With other implanted programmable devices since crosstalk between devices may inadvertently change the prescription.

NOTE: Payment may also be made for drugs necessary for the effective use of an implantable infusion pump as long as the drug being used with the pump is itself reasonable and necessary for the patient's treatment.

C. Nationally Non-Covered Indications

The following indications for treatment using infusion pumps are not covered under Medicare:

1. External Infusion Pumps

Vancomycin (Effective for Services Beginning On or After September 1, 1996)

Medicare coverage of vancomycin as a durable medical equipment infusion pump benefit is not covered. There is insufficient evidence to support the necessity of using an external infusion pump, instead of a disposable elastomeric pump or the gravity drip method, to administer vancomycin in a safe and appropriate manner.

2. Implantable Infusion Pump

a. Thromboembolic Disease (Effective for Services Performed On or After September 26, 1984)

There is insufficient published clinical data to support the safety and effectiveness of the heparin implantable pump. Therefore, the use of an implantable infusion pump for infusion of heparin in the treatment of recurrent thromboembolic disease is not covered.

b. Diabetes

An implanted infusion pump for the infusion of insulin to treat diabetes is not covered. The data does not demonstrate that the pump provides effective administration of insulin.

D. Other

Not applicable.

300.1 - Obsolete or Unreliable Diagnostic Tests

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

A. Diagnostic Tests

Do not routinely pay for the following diagnostic tests because they are obsolete and have been replaced by more advanced procedures. The listed tests may be paid for only if the medical need for the procedure is satisfactorily justified by the physician who performs it. When the services are subject to the Quality Improvement Organization (QIO) review, the QIO is responsible for determining that satisfactory medical justification exists.

When the services are not subject to QIO review, the *A/B Medicare Administrative Contractor* is responsible for determining that satisfactory medical justification exists. This includes:

- Amylase, blood isoenzymes, electrophoretic,
- Chromium, blood,
- Guanase, blood,
- Zinc sulphate turbidity, blood,
- Skin test, cat scratch fever,
- Skin test, lymphopathia venereum,
- Circulation time, one test,
- Cephalin flocculation,
- Congo red, blood,
- Hormones, adrenocorticotropin quantitative animal tests,
- Hormones, adrenocorticotropin quantitative bioassay,
- Thymol turbidity, blood,
- Skin test, actinomycosis,
- Skin test, brucellosis,
- Skin test, psittacosis,
- Skin test, trichinosis,
- Calcium, feces, 24-hour quantitative,
- Starch, feces, screening,
- Chymotrypsin, duodenal contents,
- Gastric analysis, pepsin,
- Gastric analysis, tubeless,
- Calcium saturation clotting time,
- Capillary fragility test (Rumpel-Leede),
- Colloidal gold,
- Bendien's test for cancer and tuberculosis,
- Bolen's test for cancer,
- Rehfuss test for gastric acidity, and
- Serum seromuroid assay for cancer and other diseases.

B. Cardiovascular Tests

Do not pay for the following phonocardiography and vectorcardiography diagnostic tests because they have been determined to be outmoded and of little clinical value. They include:

- Phonocardiogram with or without ECG lead; with supervision during recording with interpretation and report (when equipment is supplied by the physician),
- Phonocardiogram; tracing only, without interpretation and report (e.g., when equipment is supplied by the hospital, clinic),
- Phonocardiogram; interpretation and report,

- Phonocardiogram with ECG lead, with indirect carotid artery and/or jugular vein tracing, and/or apex cardiogram; with interpretation and report,
- Phonocardiogram; without interpretation and report,
- Phonocardiogram; interpretation and report only,
- Intracardiac,
- Vectorcardiogram (VCG), with or without ECG; with interpretation and report,
- Vectorcardiogram; tracing only, without interpretation and report, *and*,
- Vectorcardiogram; interpretation and report only.

310.1 - Routine Costs in Clinical *Trials* (Effective July 9, 2007)

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD – 10, Implementation: Upon Implementation of ICD 10)

Effective for items and services furnished on or after July 9, 2007, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.

Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:

- The investigational item or service, itself unless otherwise covered outside of the clinical trial;
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- Items and services customarily provided by the research sponsors *free-of-charge* for any enrollee in the trial.

Routine costs in clinical trials include:

- Items or services that are typically provided absent a clinical trial (e.g., conventional care);
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service--in particular, for the diagnosis or treatment of complications.

This policy does not withdraw Medicare coverage for items and services that may be covered according to local medical review policies (LMRPs) or the regulations on category B investigational device *exemptions found* in 42 CFR 405.201-405.215, 411.15, and 411.406. For information about LMRPs, refer to www.lmrp.net, a searchable database of Medicare *Administrative Contractor* local policies.

For non-covered items and services, including items and services for which Medicare payment is statutorily prohibited, Medicare only covers the treatment of complications arising from the delivery of the non-covered item or service and unrelated reasonable and necessary care. However, if the item or service is not covered by virtue of a national non-coverage policy in Pub. 100-03, *National Coverage Determination (NCD) Manual*, *and* is the focus of a qualifying clinical trial, the routine costs of the clinical trial (as defined above) will be covered by Medicare but the non-covered item or service, itself, will not.

A. Requirements for Medicare Coverage of Routine Costs

Any clinical trial receiving Medicare coverage of routine costs must meet the following three requirements:

- The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
- The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.
- Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

The three requirements above are insufficient by themselves to qualify a clinical trial for Medicare coverage of routine costs. Clinical trials also should have the following desirable characteristics; however, some trials, as described below, are presumed to meet these characteristics and are automatically qualified to receive Medicare coverage:

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;
2. The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;
3. The trial does not unjustifiably duplicate existing studies;
4. The trial design is appropriate to answer the research question being asked in the trial;
5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
6. The trial is in compliance with Federal regulations relating to the protection of human subjects; and
7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

B. Qualification Process for Clinical Trials

Using the authority found in §1142 of the *Social Security Act (the Act)* (cross-referenced in §1862(a)(1)(E) of the Act), the Agency for Healthcare Research and Quality (AHRQ) will convene a multi-agency Federal panel (the "panel") composed of representatives of the Department of Health and Human Services research agencies (National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), AHRQ, and the Office of Human Research Protection), and the research arms of the Department of Defense (DOD) and the Department of Veterans Affairs (VA) to develop qualifying criteria that will indicate a strong probability that a trial exhibits the desirable characteristics listed above. These criteria will be easily verifiable, and where possible, dichotomous. Trials that meet these qualifying criteria will receive Medicare coverage of their associated routine costs. This panel is not reviewing or approving individual trials. The multi-agency panel will meet periodically to review and

evaluate the program and recommend any necessary refinements to *the Centers for Medicare & Medicaid Services (CMS)*.

Clinical trials that meet the qualifying criteria will receive Medicare coverage of routine costs after the trial's lead principal investigator certifies that the trial meets the criteria. This process will require the principal investigator to enroll the trial in a Medicare clinical trials registry, currently under development.

Some clinical trials are automatically qualified to receive Medicare coverage of their routine costs because they have been deemed by AHRQ, in consultation with the other agencies represented on the multi-agency panel to be highly likely to have the above-listed seven desirable characteristics of clinical trials. The principal investigators of these automatically qualified trials do not need to certify that the trials meet the qualifying criteria, but must enroll the trials in the Medicare clinical trials registry for administrative purposes, once the registry is established.

Effective September 19, 2000, clinical trials that are deemed to be automatically qualified are:

1. Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA;
2. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, *DOD*, and VA;
3. Trials conducted under an investigational new drug application (IND) reviewed by the FDA; and
4. Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) will be deemed automatically qualified until the qualifying criteria are developed and the certification process is in place. At that time the principal investigators of these trials must certify that the trials meet the qualifying criteria in order to maintain Medicare coverage of routine costs. This certification process will only affect the future status of the trial and will not be used to retroactively change the earlier deemed status.

The CMS, through *the NCD* process, through an individualized assessment of benefits, risks, and research potential, may determine that certain items and services for which there is some evidence of significant medical benefit, but for which there is insufficient evidence to support a "reasonable and necessary" determination, are only reasonable and necessary when provided in a clinical trial that meets the requirements defined in that NCD.

Medicare will cover the routine costs of qualifying trials that either have been deemed to be automatically qualified, have certified that they meet the qualifying criteria, or are required through the NCD process, unless CMS's Chief Clinical Officer subsequently finds that a clinical trial does not meet the qualifying criteria or jeopardizes the safety or welfare of Medicare beneficiaries.

Should CMS find that a trial's principal investigator misrepresented that the trial met the necessary qualifying criteria in order to gain Medicare coverage of routine costs, Medicare coverage of the routine costs would be denied under §1862(a)(1)(E) of the Act. In the case of such a denial, the Medicare beneficiaries enrolled in the trial would not be held liable (i.e., would be held harmless from collection) for the costs consistent with the provisions of §§1879, 1842(l), or 1834(j)(4) of the Act, as applicable. Where appropriate, the billing providers would be held liable for the costs and fraud investigations of the billing providers and the trial's principal investigator may be pursued.

Medicare regulations require Medicare+Choice (M+C) organizations to follow *CMS NCDs*. This NCD raises special issues that require some modification of most M+C organizations' rules governing provision of items and services in and out of network. The items and services covered under this NCD are inextricably linked to the clinical trials with which they are associated and cannot be covered outside of the context of those clinical trials. M+C organizations therefore must cover these services regardless of whether they are available through in-network providers. M+C organizations may have reporting requirements when enrollees participate in clinical trials, in order to track and coordinate their members' care, but cannot require prior authorization or approval.

