| CMS Manual System | Department of Health & Human Services (DHHS) |
|---|---|
| Pub 100-04 Medicare Claims Processing | Centers for Medicare & Medicaid Services (CMS) |
| **Transmittal 13608** | **Date: January 29, 2026** |
| | **Change Request 14108** |

**Transmittal 13317 issued July 24, 2025, is being rescinded and replaced by Transmittal 13608, dated January 29, 2026, to remove Business Requirement (BR)14108.4 and the associated manual update to 100-04, chapter 32, section 200.2. The Title, Summary, and Background sections have been updated accordingly. BR 14108.4 and the manual update are no longer required due to Change Request (CR) 13939.10. All other information remains unchanged.**

**SUBJECT: Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 32, Sections 150.4, 150.6, 200.2, 300.2, 400.2, 400.2.2, 400.2.3, 400.2.3.1, 400.2.4, and 400.3 for Coding Revisions to National Coverage Determinations (NCDs) - July 2025 Change Request (CR) 13939**

**I. SUMMARY OF CHANGES:** The purpose of this Change Request (CR) is to update the Pub. 100-04, Chapter 32, Sections 150.4, 150.6, 300.2, 400.2, 400.2.2, 400.2.3, 400.2.3.1, 400.2.4, and 400.3 of the Medicare Claims Processing Manual to coincide with the National Coverage Determination (NCD) updates in CR 13939, "International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs)-July 2025."

**EFFECTIVE DATE: August 25, 2025 - See Individual Business Requirements for Effective Dates**
**Unless otherwise specified, the effective date is the date of service.*
**IMPLEMENTATION DATE: August 25, 2025**

***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 | 32/150/150.4/ICD Diagnosis Codes for Bariatric Surgery |
| R | 32/150/150.6/ Claims Guidance for Payment |
| R | 32/300/300.2/Claims Processing Requirements for OPT with Verteporfin Services on Professional Claims and Outpatient Facility Claims |
| R | 32/400/400.2/Billing Requirements |
| R | 32/400/400.2.2/ A/B MAC (A) Revenue Code |
| R | 32/400/400.2.3/A/B MAC Billing HCPCS Codes |
| R | 32/400/400.2.3.1/A/B MAC (B) Places of Service (POS) |
| R | 32/400/400.2.4/ A/B MAC Diagnosis and Procedure Code Requirements |
| R | 32/400/400.3/ Payment Requirements |

**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 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.

**IV. ATTACHMENTS:**

**Business Requirements**
**Manual Instruction**

# Attachment - Business Requirements

| Pub. 100-04 | Transmittal: 13608 | Date: January 29, 2026 | Change Request: 14108 |
|---|---|---|---|

**Transmittal 13317 issued July 24, 2025, is being rescinded and replaced by Transmittal 13608, dated January 29, 2026, to remove Business Requirement (BR)14108.4 and the associated manual update to 100-04, chapter 32, section 200.2. The Title, Summary, and Background sections have been updated accordingly. BR 14108.4 and the manual update are no longer required due to Change Request (CR) 13939.10. All other information remains unchanged.**

**SUBJECT: Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 32, Sections 150.4, 150.6, 200.2, 300.2, 400.2, 400.2.2, 400.2.3, 400.2.3.1, 400.2.4, and 400.3 for Coding Revisions to National Coverage Determinations (NCDs) - July 2025 Change Request (CR) 13939**

**EFFECTIVE DATE: August 25, 2025 - See Individual Business Requirements for Effective Dates**
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**I. SUMMARY OF CHANGES:** The purpose of this Change Request (CR) is to update the Pub. 100-04, Chapter 32, Sections 150.4, 150.6, 300.2, 400.2, 400.2.2, 400.2.3, 400.2.3.1, 400.2.4, and 400.3 of the Medicare Claims Processing Manual to coincide with the National Coverage Determination (NCD) updates in CR 13939, "International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs)-July 2025."

## II. GENERAL INFORMATION

**A. Background:** The purpose of this Change Request (CR) is to update the billing requirements in Pub.100-04, chapter 32, sections 150.4, 150.6, 300.2, 400.2, 400.2.2, 400.2.3, 400.2.3.1, 400.2.4, and 400.3 for the Medicare Claims Processing Manual. The revisions listed below can be found in CR 13939, International Classification of Diseases,10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs)-July 2025.

NCD 80.3.1- Verteporfin: Add Current Procedural Terminology (CPT) code 92137 effective January 1, 2025. (IOM 100-04, Chapter 32, Section 300.2)

NCD 100.1 - Bariatric Surgery for Treatment of Co-morbid Conditions Related to Morbid Obesity: Add ICD-10 diagnosis (dx) codes E66.812 Obesity, class 2 and E66.813 Obesity, class 3 effective October 1, 2024. (IOM 100-04, Chapter 32, Section 150.4 and 150.6)

NCD 110.24 - CAR-T Cell Therapy: End date CPT codes 0537T, 0538T, 0539T, and 0540T effective December 31, 2024, and replaced with 38225, 38226, 38227, and 38228 effective January 1, 2025. Use ICD-10 procedure coding system codes XW0338A and XW0438A. (IOM 100-04, Chapter 32, Section 400.2, 400.2.2, 400.2.3, 400.2.3.1, 400.2.4, and 400.3)

**B. Policy:** This CR does not involve any changes to policy.

## III. BUSINESS REQUIREMENTS TABLE

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

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | MAC | FISS | MCS | VMS | CWF | |
| 14108.1 | Contractors shall be aware of the manual updates in Pub. 100-04, Chapter 32, Section 300.2.<br><br>Note: Add CPT 92137 as a covered code effective January 1, 2025. | X | X | | | | | | | |
| 14108.2 | Contractors shall be aware of the manual updates in Pub. 100-04, Chapter 32, Section 150.4 and 150.6.<br><br>Note: Add ICD-10 dx codes E66.812 and E66.813, effective October 1, 2024. | X | X | | | | | | | |
| 14108.3 | Contractors shall be aware of the manual updates in Pub. 100-04, Chapter 32, Section 400.2, 400.2.2, 400.2.3, 400.2.3.1, 400.2.4 and 400.3.<br><br>Note: End date CPT codes 0537T, 0538T, 0539T, and 0540T effective December 31, 2024, which will be replaced with CPT codes 38225, 38226, 38227, and 38228 effective January 1, 2025. Add coverage for Aucatzyl effective November 8, 2024. | X | X | | | | | | | |
| 14108.4 | This business requirement has been deleted. | X | X | | | | | | | |

## IV. PROVIDER EDUCATION

None

**Impacted Contractors:** None

## V. 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

## VI. CONTACTS

**Pre-Implementation Contact(s):** Cindy Pitts, Cindy.Pitts@cms.hhs.gov

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR).

## VII. 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 does 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.

**ATTACHMENTS: 0**

# Medicare Claims Processing Manual

## Chapter 32 – Billing Requirements for Special Services

**Table of Contents**

*(Rev. 13608; Issued: 01-29-26)*

## 150.4 - ICD Diagnosis Codes for Bariatric Surgery

**(*Rev. 13608; Issued: 01-29-26; Effective: 08-25-25; Implementation: 08-25-25)***

For services on or after October 1, 2015, the following ICD-10 diagnosis code is covered for bariatric surgery if certain other conditions are met:

E66.01 - Morbid (severe) obesity due to excess calories

*E66.812 - Obesity, class 2, effective October 1, 2024*

*E66.813 – Obesity, class 3, effective October 1, 2024*

Effective for services performed on and after February 12, 2009, type 2 diabetes mellitus (T2DM) is considered a comorbid condition related to morbid obesity for covered bariatric surgery procedures in Medicare beneficiaries with a BMI ≥35. When T2DM is the comorbid condition related to morbid obesity, the claim must include a covered ICD procedure code, ICD diagnosis code E66.01, *E66.812 or E66.813* as a primary diagnosis, a covered ICD diagnosis code indicating T2DM as a secondary diagnosis, and an ICD diagnosis code indicating a BMI ≥ 35 as a secondary diagnosis.

## 150.6 Claims Guidance for Payment

**(*Rev. 13608; Issued: 01-29-26; Effective: 08-25-25; Implementation: 08-25-25)***

**Covered Bariatric Surgery Procedures for Treatment of Co-Morbid Conditions Related to Morbid Obesity**

Contractors shall process covered bariatric surgery claims as follows:

**C.** Identify bariatric surgery claims.

Contractors identify inpatient bariatric surgery claims by the presence of ICD-10 diagnosis code E66.01, *E66.812 or E66.813* as the primary diagnosis (for morbid obesity) and one of the covered ICD-10 procedure codes listed in §150.3.

Contractors identify practitioner bariatric surgery claims by the presence of ICD-10 diagnosis code E66.01, *E66.812 or E66.813* as the primary diagnosis (for morbid obesity) and one of the covered HCPCS procedure codes listed in §150.2.

**D.** Perform facility certification validation for all bariatric surgery claims on a pre-pay basis up to and including date of service September 23, 2013.

A list of approved facilities is found at the link noted in section 150.1, section A, above.

**E.** Review bariatric surgery claims data and determine whether a pre- or post-pay sample of bariatric surgery claims needs further review to assure that the beneficiary has a BMI ≥35 (Z68.35-Z68.45) (see ICD-10 equivalents above in section 150.5), and at least one co-morbidity related to obesity.

The A/B MAC medical director may define the appropriate method for addressing the obesity-related co-morbid requirement.

Effective for dates of service on and after September 24, 2013, CMS has removed the certified facility requirements for Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity. **NOTE:** If ICD-10 diagnosis code E66.01*, E66.812 or E66.813* is present, but a covered procedure code (listed in §150.2 or §150.3) is/are not present, the claim is not for bariatric surgery and should be processed under normal procedures.

## 300.2 - Claims Processing Requirements for OPT with Verteporfin Services on Professional Claims and Outpatient Facility Claims

***(Rev. 13608; Issued: 01-29-26; Effective: 08-25-25; Implementation: 08-25-25)***

OPT with Verteporfin is a covered service when billed with the below ICD-10-CM codes
**Nationally Covered ICD-10-CM codes**

| | |
|---|---|
| H35.3210 | Exudative age-related macular degeneration, right eye, stage unspecified |
| H35.3211 | Exudative age-related macular degeneration, right eye, with active choroidal neovascularization |
| H35.3212 | Exudative age-related macular degeneration, right eye, with inactive choroidal neovascularization |
| H35.3213 | Exudative age-related macular degeneration, right eye, with inactive scar |
| H35.3220 | Exudative age-related macular degeneration, left eye, stage unspecified |
| H35.3221 | Exudative age-related macular degeneration, left eye, with active choroidal neovascularization |
| H35.3222 | Exudative age-related macular degeneration, left eye, with inactive choroidal neovascularization |
| H35.3223 | Exudative age-related macular degeneration, left eye, with inactive scar |
| H35.3230 | Exudative age-related macular degeneration, bilateral, stage unspecified |
| H35.3231 | Exudative age-related macular degeneration, bilateral, with active choroidal neovascularization |
| H35.3232 | Exudative age-related macular degeneration, bilateral, with inactive choroidal neovascularization |
| H35.3233 | Exudative age-related macular degeneration, bilateral, with inactive scar |

**ICD-10- Codes for OPT with Verteporfin for other ocular indications are eligible for local coverage determinations through individual contractor discretion.**

| | |
|---|---|
| B39.4 | Histocapsulati, unspecified |
| | (Translates to combination of both B39.4 & H32) |
| B39.5 | Histoplasmosis duboisii |
| | (Requires H32 coverage) |
| B39.9 | Histoplasmosis, unspecified |
| | (Requires H32 coverage) |
| H32 | Chorioretinal disorders in diseases classified elsewhere |
| | (Requires B39.4 coverage) |
| H44.2A1 | Degenerative myopia with choroidal neovascularization, right eye |

| | |
|---|---|
| H44.2A2 | Degenerative myopia with choroidal neovascularization, left eye |
| H44.2A3 | Degenerative myopia with choroidal neovascularization, bilateral eye |
| H44.2B1 | Degenerative myopia with macular hole, right eye |
| H44.2B2 | Degenerative myopia with macular hole, left eye |
| H44.2B3 | Degenerative myopia with macular hole, bilateral eye |
| H44.2C1 | Degenerative myopia with retinal detachment, right eye |
| H44.2C2 | Degenerative myopia with retinal detachment, left eye |
| H44.2C3 | Degenerative myopia with retinal detachment, bilateral eye |
| H44.2D1 | Degenerative myopia with foveoschisis, right eye |
| H44.2D2 | Degenerative myopia with foveoschisis, left eye |
| H44.2D3 | Degenerative myopia with foveoschisis, bilateral eye |
| H44.2E1 | Degenerative myopia with other maculopathy, right eye |
| H44.2E2 | Degenerative myopia with other maculopathy, left eye |
| H44.2E3 | Degenerative myopia with other maculopathy, bilateral eye |
| H44.21 | Degenerative Myopia, right eye |
| H44.22 | Degenerative Myopia, left eye |
| H44.23 | Degenerative Myopia, bilateral |
| H35.711 | Central serous chorioretinopathy, right eye |
| H35.712 | Central serous chorioretinopathy, left eye |
| H35.713 | Central serous chorioretinopathy, bilateral |

**Coverage is denied when billed with the below Nationally Non-Covered ICD-10-CM codes Nationally Non-Covered ICD-10-CM codes:**

| | |
|---|---|
| H35.30 | Unspecified macular degeneration |
| H35.3110 | Nonexudative age-related macular degeneration, right eye, stage unspecified |
| H35.3111 | Nonexudative age-related macular degeneration, right eye, early dry stage |
| H35.3112 | Nonexudative age-related macular degeneration, right eye, intermediate dry stage |
| H35.3113 | Nonexudative age-related macular degeneration, right eye, advanced atrophic without subfoveal involvement |
| H35.3114 | Nonexudative age-related macular degeneration, right eye, advanced atrophic with subfoveal involvement |
| H35.3120 | Nonexudative age-related macular degeneration, left eye, stage unspecified |
| H35.3121 | Nonexudative age-related macular degeneration, left eye, early dry stage |
| H35.3122 | Nonexudative age-related macular degeneration, left eye, intermediate dry stage |
| H35.3123 | Nonexudative age-related macular degeneration, left eye, advanced atrophic without subfoveal involvement |
| H35.3124 | Nonexudative age-related macular degeneration, left eye, advanced atrophic with subfoveal involvement |
| H35.3130 | Nonexudative age-related macular degeneration, bilateral, stage unspecified |
| H35.3131 | Nonexudative age-related macular degeneration, bilateral, early dry stage |
| H35.3132 | Nonexudative age-related macular degeneration, bilateral, intermediate dry stage |
| H35.3133 | Nonexudative age-related macular degeneration, bilateral, advanced atrophic without subfoveal involvement |
| H35.3134 | Nonexudative age-related macular degeneration, bilateral, advanced atrophic with subfoveal involvement |

Payment for OPT service (CPT code 67221/67225) must be billed on the same claim as the drug (J3396) for the same date of service.

Claims for OPT with Verteporfin for dates of service prior to April 3, 2013, are covered at the initial visit as determined by a fluorescein angiogram (FA) CPT code 92235. Subsequent follow-up visits also require a FA prior to treatment.

For claims with dates of service on or after April 3, 2013, contractors shall accept and process claims for subsequent follow-up visits with either a FA, CPT code 92235, or optical coherence tomography (OCT), CPT codes 92133, 92134 *or 92137 (effective 01/01/2025)* prior to treatment. Regardless of the date of service of the claim, the FA or OCT is not required to be submitted on the claim for OPT and can be maintained in the patient's file for audit purposes.

## 400.2 - Billing Requirements

***(Rev. 13608; Issued: 01-29-26; Effective: 08-25-25; Implementation: 08-25-25)***

Effective for dates of service on or after August 7, 2019, contractors shall pay for line-item professional claims from approved providers for the administration of autologous treatment for cancer with T-cells expressing at least one CAR with Current Procedural Terminology (CPT) code 0540T *end date 12/31/24 replaced with 38228 effective 01/01/25.*

Contractors shall not require the NCD 110.24 -KX modifier and diagnosis codes for clinical trials under NCD 310.1. These claims shall bill with the NCT number for the specific trial, the -Q0 clinical trial modifier, and the Z00.6 clinical trial diagnosis code on the *0540T claim line effective for dates of service on or after August 7, 2019. *(*0540T end date 12/31/24 and replaced with 38228 effective 01/01/25.)*
For Part A Outpatient (OPPS) contractors shall not require NCD 110.24 REMS facility and diagnosis codes for CAR T-cell therapy CPT code *0540T in clinical trials under NCD 310.1 billed with the NCT number for the specific trial, the -Q0 clinical trial modifier, condition code 30, value code D4, and the Z00.6 clinical trial diagnosis code effective for dates of service on or after August 7, 2019. *(*0540T end date 12/31/24 and replaced with 38228 effective 01/01/25.)*

## 400.2.2 - A/B MAC (A) Revenue Code

***(Rev. 13608; Issued: 01-29-26; Effective: 08-25-25; Implementation: 08-25-25)***

The following Revenue Codes are used for billing inpatient and outpatient CAR T-cell therapy services:

0871 – Cell Collection w/CPT code 0537T *end date 12/31/24 and replaced with 38225 effective 01/01/25.*

0872 – Specialized Biologic Processing and Storage – Prior to Transport w/CPT code 0538T *end date 12/31/24 and replaced with 38226 effective 01/01/25.*

0873 – Storage and Processing after Receipt of Cells from Manufacturer w/CPT code 0539T *end date 12/31/24 and replaced with 38227 effective 01/01/25.*

0874 – Infusion of Modified Cells w/CPT code 0540T *end date 12/31/24 and replaced with 38228 effective 01/01/25.*

0891 – Special Processed Drugs – FDA Approved Cell Therapy w/ Healthcare Common Procedure Coding System (HCPCS) codes Q2041, Q2042, C9073 (replaced with Q2053 April 1, 2021), C9076 (replaced with Q2054 October 1, 2021), C9081 (replaced with Q2055 January 1, 2022), C9098 (replaced with Q2056 October 1, 2022), or C9399

## 400.2.3 - A/B MAC Billing HCPCS Codes

***(Rev. 13608; Issued: 01-29-26; Effective: 08-25-25; Implementation: 08-25-25)***

The following HCPCS/CPT procedure codes are used for billing outpatient CAR T-cell therapy services:

HCPCS Code Q2041 for Axicabtagene Ciloleucel

HCPCS Code Q2042 for Tisagenlecleucel

HCPCS Code Q2053 for Brexucabtagene Autoleucel (effective April 1, 2021)

HCPCS Code Q2054 for Lisocabtagene Maraleucel (effective October 1, 2021)

HCPCS Code Q2055 for Idecabtagene Vicleucel (effective January 1, 2022)

HCPCS Code Q2056 for Ciltacabtagene Autoleucel (effective October 1, 2022)

HCPCS Code C9073 for Brexucabtagene Autoleucel (prior to April 1, 2021)

HCPCS Code C9076 for Lisocabtagene maraleucel (prior to October 1, 2021)

HCPCS Code C9081 for Idecabtagene Vicleucel (prior to January 1, 2022)

HCPCS Code C9098 for Ciltacabtagene Autoleucel (prior to October 1, 2022)

HCPCS Code C9399, J3490, J3590, or J9999 for unclassified drugs or biologicals when dose of CAR T-cell therapy exceeds code descriptor or when other CAR T-cell therapy obtains FDA approval but has not yet received a specific HCPCS code

CPT Code 0537T collection/handling* *end date 12/31/24 and replaced with 38225 effective 01/01/25.*

CPT Code 0538T preparation for transport* *end date 12/31/24 and replaced with 38226 effective 01/01/25.*

CPT Code 0539T receipt and preparation* *end date 12/31/24 and replaced with 38227 effective 01/01/25.*

CPT Code 0540T the provider (physician/NPP) procedure to administer CAR T-cells *end date 12/31/24 and replaced with 38228 effective 01/01/25.*

* Procedure represents the various steps required to collect and prepare the genetically modified T-cells, and these steps are not paid separately under the Outpatient Prospective Payment System (OPPS)/Medicare Physician Fee Schedule (MPFS).

## 400.2.3.1 – A/B MAC (B) Places of Service (POS)

***(Rev. 13608; Issued: 01-29-26; Effective: 08-25-25; Implementation: 08-25-25)***

The following places of service (POS) are covered for CAR T-cells product HCPCS codes (Q2041, Q2042, Q2053-Q2056, J3490, J3590, and J9999):

11 (Office)

49 (Independent clinic)

Professional claims for the procedure to administer CAR T-cells (0540T) *end date 12/31/24 and replaced with 38228 effective 01/01/25* may include (but are not necessarily limited to):

11 (Office)

19 (Off Campus-Outpatient Hospital)

21 (Inpatient Hospital)

22 (On Campus-Outpatient Hospital)

49 (Independent Clinic)

## 400.2.4 - A/B MAC Diagnosis and Procedure Code Requirements

***(Rev. 13608; Issued: 01-29-26; Effective: 08-25-25; Implementation: 08-25-25)***

Please see NCD spreadsheet for the applicable International Classification of Disease (ICD)-10-CM diagnosis codes for CAR T-cell therapy coverage.

The following are the applicable ICD-10-PCS procedure codes for CAR T-cell therapy coverage for inpatient claims:

**For dates of service on or after October 1, 2021:**

CARVYKTI™ - XW033A7: Introduction of Ciltacabtagene Autoleucel into Peripheral Vein, Percutaneous Approach, New Technology Group 7

CARVYKTI™ - XW043A7: Introduction of Ciltacabtagene Autoleucel into Central Vein, Percutaneous Approach, New Technology Group 7

When other CAR T-cell therapy obtains FDA approval but has not yet received a specific PCS code, and for use in clinical trials FDA-approved under NCD 310.1 – XW033C7: Introduction of Autologous Engineered Chimeric Antigen Receptor T-cell Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7

When other CAR T-cell therapy obtains FDA approval but has not yet received a specific PCS code, and for use in clinical trials FDA-approved under NCD 310.1 – XW043C7: Introduction of Autologous Engineered Chimeric Antigen Receptor T-cell Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7

Yescarta® - XW033H7: Introduction of Axicabtagene Ciloleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7

Yescarta® - XW043H7: Introduction of Axicabtagene Ciloleucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7

Kymriah® - XW033J7: Introduction of Tisagenlecleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7

Kymriah® - XW043J7: Introduction of Tisagenlecleucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7

ABECMA® - XW033K7: Introduction of Idecabtagene Vicleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7

ABECMA® - XW043K7: Introduction of Idecabtagene Vicleucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7

Tecartus™ - XW033M7: Introduction of Brexucabtagene Autoleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7

Tecartus™ - XW043M7: Introduction of Brexucabtagene Autoleucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7

Breyanzi® - XW033N7: Introduction of Lisocabtagene Maraleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 7

Breyanzi® - XW043N7: Introduction of Lisocabtagene Maraleucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 7
*Aucatzyl® - XW0338A: Introduction of Obecabtagene Autoleucel into Peripheral Vein, Percutaneous Approach, New Technology Group 10 (FDA Approval date of November 8, 2024). This code is covered in a clinical trial, see below.*

*Aucatzyl® - XW0438A: Introduction of Obecabtagene Autoleucel into Central Vein, Percutaneous Approach, New Technology Group 10 (FDA Approval date of November 8, 2024). This code is covered in a clinical trial, see below.*

**For dates of service prior to October 1, 2021:**

Yescarta®, ABECMA®, Kymriah® - XW033C3: Introduction of Engineered Autologous Chimeric Antigen Receptor T-cell Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 3

Yescarta®, ABECMA®, Kymriah® - XW043C3: Introduction of Engineered Autologous Chimeric Antigen Receptor T-cell Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 3

Tecartus™ - XW23346 - Transfusion of Brexucabtagene Autoleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 6

Tecartus™ - XW24346 - Transfusion of Brexucabtagene Autoleucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 6

Breyanzi® - XW23376 – Transfusion of lisocabtagene maraleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 6

Breyanzi®- XW24376 – Transfusion of lisocabtagene maraleucel immunotherapy into central vein, percutaneous approach, new technology 6

**NOTE:** Since allogenic T-cells are by definition not autologous CAR T-cells, it is inappropriate to use any of the above autologous CAR T-cell ICD-10 PCS procedure codes for allogenic T-cell treatments.
For Part A Inpatient contractors shall not require NCD 110.24 REMS facility and diagnosis codes for autologous CAR T-cell therapy ICD-10-PCS codes XW033A7/XW043A7, XW033H7/XW043H7, XW033J7/XW043J7, XW033K7/XW043K7, XW033M7/XW043M7, XW033N7/XW043N7, *and XW0338A/XW0438A* in clinical trials under NCD 310.1 billed with the NCT number for the specific trial, condition code 30, value code D4, and the Z00.6 clinical trial diagnosis code effective for dates of service on or after August 7, 2019.

## 400.3 - Payment Requirements

***(Rev. 13608; Issued: 01-29-26; Effective: 08-25-25; Implementation: 08-25-25)***

Inpatient

The A/ B MAC billing requirements will allow for CAR T-cell therapy when the services are submitted on

the following TOB: 11X. Type of facility and setting determines the basis of payment:

For services performed in inpatient hospitals, TOB 11X, under the Inpatient PPS is based on the Medicare Severity-Diagnosis Related Group (MS-DRG).

For services performed in Critical Access Hospital (CAH) inpatient TOB 11X, payment is based on 101% of reasonable cost.

Outpatient

The A/B MAC billing requirements will pay for CAR T-cell therapy when the services are submitted on the TOBs: 13X and 85x. Type of facility and setting determines the basis of payment:

For services performed in hospital outpatient departments (HOPDs), TOBs 13X, or inpatient ancillary TOB 12X, payment is based on OPPS.

For services performed in CAH OPDs, TOB 85X, payment is based on reasonable cost.

For services performed in CAH Method II with revenue code 096X, 097X, and 098X, TOB 85X, payment is based on the lesser of the actual charge or the Medicare Physician Fee Schedule (115% of the lesser of the fee schedule amount and submitted charge).

HOPDs may report CPT codes 0537T, 0538T, and 0539T *(end date 12/31/24 replaced with 38225, 38226, and 38227 effective 01/01/25)* to allow tracking of these services when furnished in the outpatient setting. Medicare will reject these lines as Medicare does not separately pay for these services under the OPPS.

These following scenarios present further clarification on how to report items and services related to CAR-T in various clinical scenarios.

**Scenario 1: CAR-T Dosing and Preparation Services and Viable T-cells Administered in HOPDs**:

In instances when you administer the CAR-T drug in the HOPD setting, report CPT code 0540T (*end date 12/31/24 and replaced with 38228 effective 01/01/25)* for the administration and HCPCS Q2041, Q2042, Q2053 (effective April 1, 2021), C9073 (prior to April 1, 2021), C9076, or, if a more specific code is unavailable, the most appropriate unclassified drug code (e.g., C9399 for unclassified drugs or biologicals). NOTE: the drug codes will be denied as a Part A service even if billed with the administration.) For specific instructions on billing unclassified drug codes, refer to Chapter 26, Section 10.4 of the "Medicare Claims Processing Manual" on the CMS website at: Regulations-and-Guidance.Ch26. As discussed in the Calendar Year (CY) 2019 OPPS/Ambulatory Surgery Center final rule (83 FR 58904), the procedures described by CPT *0537T (collection/handling), 0538T (preparation for transport), and 0539T (receipt and preparation) *(*0537T, 0538T, and 0539T end date 12/31/24 and replaced with 38225, 38226, and 38227 effective 01/01/25)* represent the various steps required to collect and prepare the genetically modified T-cells, and these steps are not paid separately under the OPPS. However, you may report the charges for these various steps to collect and prepare the CAR T-cells separately and Medicare will reject them on the HOPD claim, or they may be included in the charge reported for the biological.

**Note**: When including the charges for collection and preparation of the CAR-T cells in the charge for the CAR-T product, outpatient providers should code the CAR-T product service on the date that the CAR-T administration took place and not on the date when the cells were collected.

**Scenario 2: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Not Administered:**

In instances when the CAR-T drug is not ultimately administered to the beneficiary, but the CAR-T preparation services are initiated or performed in the HOPD facility, the hospital may not report the drug Q

code (which only applies when the T-cells are administered in the HOPD setting). HOPDs may report CPT *0537T, 0538T, and 0539T (as appropriate) and *(*0537T, 0538T, and 0539T end date 12/31/24 and replaced with 38225, 38226, and 38227 effective 01/01/25)* the charges associated with each code under the appropriate revenue code on the HOPD claim. Medicare will reject these codes.

**Scenario 3: CAR-T Dosing and Preparation Services Administered in HOPD Setting, but Viable T-cells Administered in the Hospital Inpatient Setting:**

When CAR T-cell preparation services are initiated and furnished in the HOPD setting, but the CAR T-cells are administered in the inpatient setting, the hospital may not report the drug Q code (which only applies when the T-cells are administered in the HOPD setting). Report the charge associated with the various steps to collect and prepare the CAR T-cells on the inpatient claim (TOB 11x) separately using revenue codes 0871, 0872, or 0873. Alternatively, the hospital may include the charges for these various steps in the charge reported for the biological using revenue code 0891 – Special Processed Drugs – FDA (U.S. Food and Drug Administration) Approved Cell Therapy – Charges for Modified cell therapy.

**Note**: When the cells are collected in the HOPD setting and the CAR-T is administered in the hospital inpatient setting, inpatient providers should report the date that the CAR-T administration took place and not the date the cells were collected.

Physician Office or Non-Hospital Clinic

The A/B MAC billing requirements will pay for CAR T-cell therapy when the services are submitted on the Form CMS-1500 or electronic 837P.

**Scenario 1: CAR-T Dosing and Preparation Services and Viable T-cells Administered in Physician Office or Non-Hospital Clinic**:

In instances when you administer the CAR-T drug in the physician office setting or other non-hospital clinic setting that is enrolled in the REMS program as a REMS participating site, report CPT code 0540T (*end date 12/31/24 and replaced with 38228 effective 01/01/25)* for the administration and HCPCS Q2041, Q2042, Q2053 (effective April 1, 2021), C9073 (prior to April 1, 2021), C9076, or, if a more specific code is unavailable, the most appropriate unclassified drug code (e.g., J3590 for unclassified biologics). For specific instructions on billing unclassified drug codes, refer to Chapter 26, Section 10.4 of the "Medicare Claims Processing Manual" on the CMS website at: *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf*

The procedures described by CPT *0537T (collection/handling), 0538T (preparation for transport), and 0539T (receipt and preparation) represent the various steps required to collect and prepare the genetically modified T-cells, and these steps are not paid separately under the MPFS. However, you may report them separately, and Medicare will reject them on the professional claim. *(*0537T, 0538T, and 0539T end date 12/31/24 and replaced with 38225,38226, and 38227 effective 01/01/25.)*

**Note**: Practitioners should code the CAR-T product service on the date that the CAR-T administration took place and not on the date when the cells were collected.

**Scenario 2: CAR-T Dosing and Preparation Services Administered in Physician Office or Non-Hospital Clinic, but Viable T-cells Not Administered:**

In instances when the CAR-T drug is not ultimately administered to the beneficiary, but the CAR-T preparation services are initiated or performed in the physician office or other non-hospital clinic facility, the practitioner may not report the drug HCPCS code (which only applies when the T-cells are administered in the setting). The practitioner may report CPT 0537T, 0538T, and 0539T. *(0537T, 0538T, and 0539T end date 12/31/24 and replaced with 38225, 38226, and 38227 effective 01/01/25.)*

**Scenario 3: CAR T-cells Dosing and Preparation Services in Physician Office or Non-Hospital Clinic, but Viable T-cells Administered in the Hospital Inpatient Setting:**

When CAR T-cell preparation services are initiated and furnished in the physician office or other non-hospital clinic setting, but the CAR T cells are administered in the hospital inpatient setting, the practitioner may not report the drug HCPCS code (which only applies when viable T-cells are administered in the setting). The hospital that administers the T-cells will report the charge associated with the various steps to collect and prepare the CAR T-cells on the inpatient claim (TOB 11x) separately using revenue codes 0871, 0872, or 0873. Alternatively, the hospital may include the charges for these various steps in the charge reported for the biological using revenue code 0891 – Special Processed Drugs – FDA (U.S. Food and Drug Administration) Approved Cell Therapy – Charges for Modified cell therapy.
**Note:** When the cells are collected in the physician office setting and the CAR T-cell is administered in the hospital inpatient setting, inpatient providers shall report the date that the CAR T-cell administration took place and not the date the cells were collected.