National Government Services

*A CMS Medicare Administrative Contractor*

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

# Medicare Monthly Review

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Contact information can be found on our website.
Medicare policies can be accessed from the Medical Policy Center section of our website. Providers without access to the Internet can request hard copies from National Government Services.



This bulletin should be shared with all health care practitioners and managerial members of the providers/suppliers staff. Bulletins issued during the last two years are available at no cost from our website.

CMS publishes the Quarterly Provider Update (QPU) at the beginning of each quarter to inform providers and suppliers:

- Regulations and major policies under development during the quarter
- Regulations and major policies completed or cancelled
- New or revised manual instructions

# National Government Services – Articles for Part A and Part B Providers

## Local Coverage Determination and Article Revisions: November–December 2019

### LCD Revisions

#### *B-type Natriuretic Peptide (BNP) Testing (L33573)*

Consistent with Change Request 10901, all coding information, National coverage provisions, and Associated Information (Documentation Requirements, Utilization Guidelines) were removed from the LCD and placed in the related Billing and Coding Article, A56826. There was no change in coverage with this LCD revision.

#### *Botulinum Toxins (L33646)*

The LCD has been revised to add the following indications which were inadvertently removed with the last update:

OnabotulinumtoxinA is indicated for the treatment of lower limb spasticity in adult patients to decrease the severity of increased muscle tone in ankle and toe flexors (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, and flexor digitorum longus).

AbobotulinumtoxinA is indicated for the treatment of lower limb spasticity in adults.

OnabotulinumtoxinA is indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.

#### *Drugs and Biologicals, Coverage of, for Label and Off-Label Uses (L33394)*

Consistent with Change Request 10901, all coding information, National coverage provisions, and Associated Information (Documentation Requirements, Utilization Guidelines) have been removed from the LCD and placed in the related Billing and Coding Article, A52855. There has been no change in coverage with this LCD revision.

#### *Heavy Metal Testing (L35074)*

Consistent with Change Request 10901, all coding information, National coverage provisions, and Associated Information (Documentation Requirements, Utilization Guidelines) were removed from the LCD and placed in the related Billing and Coding Article, A56767. There was no change in coverage with this LCD revision.

#### *Hospice - Determining Terminal Status (L33393)*

Consistent with Change Request 10901, all coding information, National coverage provisions, and Associated Information (Documentation Requirements, Utilization Guidelines) were from the LCD and placed in the related Billing and Coding Article, A52830. There was no change in coverage with this LCD revision.

#### *Nerve Conduction Studies and Electromyography (L35098)*

Consistent with Change Request 10901, all coding information, National coverage provisions, and Associated Information (Documentation Requirements, Utilization Guidelines) have been removed

from the LCD and placed in the related Billing and Coding Article, A57668. There has been no change in coverage with this LCD revision.

***Non-covered Services (L33629)***

Consistent with Change Request 10901, all coding information, National coverage provisions, and Associated Information (Documentation Requirements, Utilization Guidelines) have been removed from the LCD and placed in the related Billing and Coding Article, A57812. There has been no change in coverage with this LCD revision.

***Percutaneous Coronary Intervention (L33623)***

Consistent with Change Request 10901, all coding information, National coverage provisions, and Associated Information (Documentation Requirements, Utilization Guidelines) were removed from the LCD and placed in the related Billing and Coding Article, A56823. There was no change in coverage with this LCD revision.

***Peripheral Nerve Blocks (L36850)***

Consistent with Change Request 10901, all coding information, National coverage provisions, and Associated Information (Documentation Requirements, Utilization Guidelines) have been removed from the LCD and placed in the related Billing and Coding Article, A57452. There has been no change in coverage with this LCD revision.

***Proton Beam Therapy (L35075)***

Consistent with Change Request 10901, all coding information, National coverage provisions, and Associated Information (Documentation Requirements, Utilization Guidelines) were removed from the LCD and placed in the related Billing and Coding Article, A56827. There was no change in coverage with this LCD revision.

***Psychiatric Inpatient Hospitalization (L33624)***

Consistent with Change Request 10901, all coding information, National coverage provisions, and Associated Information (Documentation Requirements, Utilization Guidelines) were removed from the LCD and placed in the related Billing and Coding Article, A56865. There was no change in coverage with this LCD revision.

***Psychiatric Partial Hospitalization Programs (L33626)***

Consistent with Change Request 10901, all coding information, National coverage provisions, and Associated Information (Documentation Requirements, Utilization Guidelines) were removed from the LCD and placed in the related Billing and Coding Article, A56850. There was no change in coverage with this LCD revision.

***Psychiatry and Psychology Services (L33632) Effective: 07/01/2019***

LCD was revised to include Documentation Requirements which were inadvertently omitted in a previous version.

***Psychiatry and Psychology Services (L33632)***

Consistent with Change Request 10901, all coding information, National coverage provisions, and Associated Information (Documentation Requirements, Utilization Guidelines) were removed from the LCD and placed in the related Billing and Coding Article, A56937. There was no change in coverage with this LCD revision.

***Venous Angioplasty with or without Stent Placement for the Treatment of Chronic Cerebrospinal Venous Insufficiency (L35028)***

Consistent with Change Request 10901, all coding information, National coverage provisions, and Associated Information (Documentation Requirements, Utilization Guidelines) were removed from the LCD and placed in the related Billing and Coding Article, A56845. There was no change in coverage with this LCD revision.

***Vitamin D Assay Testing (L37535)***

Consistent with Change Request 10901, all coding information, National coverage provisions, and Associated Information (Documentation Requirements, Utilization Guidelines) have been removed from the LCD and placed in the related Billing and Coding Article, A57736. There has been no change in coverage with this LCD revision.

## LCDs effective 12/1/2019

***Biomarker Testing (Prior to Initial Biopsy) for Prostate Cancer Diagnosis (L37733)***

Consistent with Change Request 10901, all coding information, National coverage provisions, and Associated Information (Documentation Requirements, Utilization Guidelines) have been removed from the LCD and placed in the related Billing and Coding Article, A56609.

Based on a reconsideration request, coverage for EPI (0005U) was added for patients with moderately elevated PSA levels.

***Micro-Invasive Glaucoma Surgery (MIGS) (L37244)***

Consistent with Change Request 10901, all coding information, National coverage provisions, and Associated Information (Documentation Requirements, Utilization Guidelines) have been removed from the LCD and placed in the related Billing and Coding Article, A56588.

Based on a reconsideration request, added coverage for iStent inject.

***Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (L33569)***

The LCD has been revised to address Percutaneous Vertebral Augmentation (PVA) only for Osteoporotic Vertebral Compression Fracture (VCF). Specific inclusion and exclusion criteria have been added to Indications and Limitation of Coverage.

Consistent with Change Request 10901, all coding information, National coverage provisions, and Associated Information (Documentation Requirements, Utilization Guidelines) have been removed from the LCD and placed in the related Billing and coding Article, A56178.

***Water Vapor Thermal Therapy for LUTS/BPH (L37808)***

Consistent with Change Request 10901, all coding information, National coverage provisions, and Associated Information (Documentation Requirements, Utilization Guidelines) have been removed from the LCD and placed in the related Billing and coding Article, A56590.

Based on a reconsideration request, the obstructing median lobe requirement was removed from the LCD.

## The following LCDs were converted to the new "no-codes" format. There has been no change in coverage with these revisions:

- Osteopathic Manipulative Treatment (L33616)

- Treatment of Varicose Veins of the Lower Extremity (L33575)

## Article Revisions for November–December 2019

***These Articles were revised to convert to the new coding format, and to remove Bill Types and Revenue Codes:***

- Billing and Coding: Botulinum Toxins (A52848)
- Billing and Coding: Bevacizumab and biosimilars (A52370)
- Billing and Coding: Bortezomib (A52371)
- Billing and Coding: Denosumab (Prolia ™, Xgeva ™) (A52399)
- Billing and Coding: Drugs and Biologicals (A52855)
- Billing and Coding: Eculizumab (A54548)
- Billing and Coding: Filgrastim, Pegfilgrastim, Tbo-filgrastim and biosimilars (A52408)
- Billing and Coding: Hyaluronans Intra-articular Injections of (A52420)
- Billing and Coding: Ibandronate Sodium (A52421)
- Billing and Coding: Infliximab and biosimilars (A52423)
- Billing and Coding: Intravenous Immune Globulin (IVIG) (A52446)
- Billing and Coding: Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (A52453)
- Billing and Coding: Nivolumab (A54862)
- Billing and Coding: Omalizumab (A52448)
- Billing and Coding: Paclitaxel (e.g., Taxol®/Abraxane ™) (A52450)
- Billing and Coding: Ranibizumab and Aflibercept (A52451)
- Billing and Coding: Rituximab, Rituximab-abbs and Rituximab and hyaluronidase human (Rituxan Hycela™) (A52452)
- Billing and Coding: Treatment of Varicose Veins of the Lower Extremity (A52870)

***New Billing and Coding Articles***

- Billing and Coding: B-type Natriuretic Peptide (BNP) Testing (A56826)
- Billing and Coding: Heavy Metal Testing (A56767)
- Billing and Coding: Hospice - Determining Terminal Status (A52830)
- Billing and Coding: Nerve Conduction Studies and Electromyography (A57668)
- Billing and Coding: Osteopathic Manipulative Treatment (A56954)
- Billing and Coding: Percutaneous Coronary Intervention (A56823)
- Billing and Coding: Peripheral Nerve Blocks (A57452)
- Billing and Coding: Proton Beam Therapy (A56827)
- Billing and Coding: Psychiatric Inpatient Hospitalization (A56865)
- Billing and Coding: Psychiatric Partial Hospitalization Programs (A56850)
- Billing and Coding: Psychiatry and Psychology Services (A56937)
- Billing and Coding: RAST Type Tests (A56844)
- Billing and Coding: Reduction Mammaplasty (A56837)
- Billing and Coding: Venous Angioplasty with or without Stent Placement for the Treatment of Chronic Cerebrospinal Venous Insufficiency (A56845)
- Billing and Coding: Non-covered Services (57812)
- Billing and Coding: Vitamin D Assay Testing (A57736)

## Chimeric Antigen Receptor (CAR) T-Cell Therapy Reminder

National Government Services (NGS) is receiving certain CAR T-Cell therapy claims that are billed incorrectly resulting in claim rejection or erroneous claim adjudication. Please note that a rejected claims does not have appeal rights.

Providers billing Medicare Administrative Contractors (MACs) for Chimeric Antigen Receptor (CAR) T-Cell Therapy services provided to Medicare patients are reminded to follow the billing guidelines provided in MLN Matters Article SE19009 to prevent claim denials.

On August 7, 2019, CMS finalized the decision to cover Food and Drug Administration (FDA)-approved Chimeric Antigen Receptor T-cell (CAR T-cell) therapy, which is a form of cancer treatment that uses a patient's own genetically-modified immune cells to fight disease. FDA-approved CAR T-cell therapies are approved to treat some people with specific types of cancer – certain types of non-Hodgkin lymphoma and B-cell precursor acute lymphoblastic leukemia.

Refer to the Resources section at the end of this article for links to the CMS Decision Memo and National Coverage Analysis Tracking Sheet for additional information.

Medicare will cover CAR T-cell therapies when provided in health care facilities enrolled in the FDA Risk Evaluation and Mitigation Strategies for FDA-approved indications (according to the FDA-approved label). In addition, Medicare will cover FDA-approved CAR T-cell therapies for off-label uses that are recommended by CMS-approved compendia.

Currently there are only two (2) drugs approved by the FDA for use in this therapy for the following conditions and age limitations:

Tisagenlecleucel, received FDA approval on August 30, 2017 for the treatment of patients up to 25 years of age (age limitation) with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse.

A second FDA indication for tisagenlecleucel was granted on May 1, 2018 for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma.

Additional information about the FDA approval of tisagenlecleucel, including the Risk Evaluation Mitigation Strategy (REMS) program, is available on the FDA website.

Axicabtagene ciloleucel received FDA approval on October 18, 2017 for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL, not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma.

Additional information about the FDA approval of axicabtagene ciloleucel, including the REMS program, is available on the FDA website.

### Hospital Outpatient Billing:

- Report CPT code 0540T with revenue code 0874 for the administration with:

- HCPCS Q2041 (Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose; registered name is Yescarta)

  or

- Q2042 (Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose; registered name is Kymriah) for the drug/biological with revenue code 0891.

- Report value code 86 (Invoice Cost)

Bundled Services: Medicare payment for the various steps required to collect and prepare CAR-T is included in payment for the biological. Providers should choose one method for including the charges for the various steps. Do not report the same charge(s) twice

- Either include the charges for these various steps in the charge submitted for the biological

  or

- Report these charges separately, as noncovered services, for tracking purposes using the following as applicable:
  - HCPCS 0537T with revenue code 0871
  - HCPCS 0538T with revenue code 0872
  - HCPCS 0539T with revenue code 0873
- Do not include charges for pre-infusion steps in both the drug revenue code (0891) and separately listed for the pre-infusion revenue codes (0871, 0872, and 0873).

## Hospital Inpatient Billing:

***FDA approved indication:***

If the CAR-T service is for an FDA approved indication, no national clinical trial (NCT) number is included on the claim. Note that in addition to reimbursement for DRG 016, these claims, when properly coded and billed, will receive additional payment for the appropriate CAR-T drug.

***Indication is Not FDA approved:***

When the CAR-T service is not for an FDA approved indication, then the appropriate NCT number must be included on the claim along with all applicable clinical trial requirements. When properly coded and billed, these claims will receive reimbursement for DRG 016**.** However, the claim will not receive any additional payment for the CAR-T drug.

When CAR T-cell preparation services are initiated and furnished in the hospital outpatient setting, but the CAR T-cells are administered in the inpatient setting following an inpatient admission to the hospital more than 3- days after the related outpatient services are furnished, do not report the drug Q-code.

Note: When the cells are collected in the hospital outpatient 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.

Report the charge associated with the various steps to collect and prepare the CAR T-cells on the inpatient claim (Type of Bill 11x) in one of two ways:

- Report separately using revenue codes 0871, 0872, or 0873

  or

- 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.

***CAR T-Cell Therapy Codes***

| HCPCS Code | Long Descriptors | Status Indicator | APC |
|---|---|---|---|
| Q2041 | Axicabtagene ciloleucel, up to 200 million autologous anticd 19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose | G | 9035 |
| Q2042 | Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose | G | 9194 |
| 0537T | Chimeric antigen receptor t-cell (car-t) therapy; harvesting of blood-derived t lymphocytes for development of genetically modified autologous cart cells, per day | B | N/A |
| 0538T | Chimeric antigen receptor t-cell (car-t) therapy; preparation of blood-derived t lymphocytes for transportation (eg, cryopreservation, storage) | B | N/A |
| 0539T | Chimeric antigen receptor t-cell (car-t) therapy; receipt and preparation of car-t cells for administration | B | N/A |
| 0540T | Chimeric antigen receptor t-cell (car-t) therapy; car-t cell administration, autologous | S | 5694 |

| Status Indicator | Item/Code/Service | OPPS Payment Status |
|---|---|---|
| B | Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x). | Not paid under OPPS. |
| | | • May be paid by MACs when submitted on a different bill type, for example, 75x (CORF), but not paid under OPPS.<br>• An alternate code that is recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x) may be available. |
| G | Pass-Through Drugs and Biologicals | Paid under OPPS; separate APC payment. |
| S | Procedure or Service, Not Discounted When Multiple | Paid under OPPS; separate APC payment. |

***Related Content:***

- CMS Change Request 11216 “April 2019 Update of the Hospital Outpatient Prospective Payment System (OPPS)”
- CMS Decision Memo for Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers (CAG-00451N)
- National Coverage Analysis (NCA) Tracking Sheet for Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers (CAG-00451N)