| CMS Manual System | **Department of Health & Human Services (DHHS)** |
|---|---|
| Pub 100-02 Medicare Benefit Policy | **Centers for Medicare & Medicaid Services (CMS)** |
| **Transmittal 11769** | **Date: December 30, 2022** |
| | **Change Request 13028** |

**SUBJECT: Manual Update Pub. 100-02 Medicare Benefit Policy, Chapter 15, Section 110.8 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Benefit Category Determinations**

**I. SUMMARY OF CHANGES:** The purpose of this Change Request (CR) is to update Pub. 100-02 Medicare Benefit Policy Manual to add Chapter 15, Section 110.8 DMEPOS Benefit Category Determinations.

**EFFECTIVE DATE: January 31, 2023**
**Unless otherwise specified, the effective date is the date of service.*
**IMPLEMENTATION DATE: January 31, 2023**

***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 |
|---|---|
| N | 15/110/.8/DMEPOS Benefit Category Determinations |

**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. 100-02 | Transmittal: 11769 | Date: December 30, 2022 | Change Request: 13028 |
|---|---|---|---|

**SUBJECT: Manual Update Pub. 100-02 Medicare Benefit Policy, Chapter 15, Section 110.8 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Benefit Category Determinations**

**EFFECTIVE DATE: January 31, 2023**
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**IMPLEMENTATION DATE: January 31, 2023**

## I. GENERAL INFORMATION

**A. Background:** The purpose of this Change Request (CR) is to update Pub. 100-02 Medicare Benefit Policy Manual to add Chapter 15, Section 110.8 DMEPOS Benefit Category Determinations. This manual section is a quick reference tool for benefit categories determinations on or after September 26, 2022 in accordance with the procedures at 42 CFR §414.114 and §414.240. More information on the items and services evaluated using these procedures is available at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings

**B. Policy:** No new policy. The CR updates the manual to reflect current policy.

## II. BUSINESS REQUIREMENTS TABLE

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

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | |
| 13028.1 | Contractors shall be aware of this manual update to Pub.100-02 Medicare Benefit Policy to add Chapter 15, Section 110.8 DMEPOS Benefit Category Determinations. | X | X | X | X | | | | | |

## III. PROVIDER EDUCATION TABLE

| Number | Requirement | Responsibility | | | | |
|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | CEDI |
| | | A | B | HHH | | |
| 13028.2 | Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the | X | X | X | X | |

| Number | Requirement | Responsibility | | | | |
|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | CEDI |
| | | A | B | HHH | | |
| | CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the "MLN Connects" listserv to get MLN content notifications. You don't need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above. | | | | | |

## 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):** Anita Greenberg, Anita.Greenberg@cms.hhs.gov

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

## 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 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 Benefit Policy Manual

## Chapter 15 – Covered Medical and Other Health Services

## Table of Contents

*(Rev. 11769, 12-22)*

## *110.8 – DMEPOS Benefit Category Determinations*

***(Rev11769, Issued: 12-30-2022, Effective: 01-31-2023, Implementation: 01-31-23)***

*Whether or not an item or service falls under a Medicare benefit category, such as the Medicare Part B benefit category for DME, is a necessary step in determining whether an item may be covered under the Medicare program and, if applicable, what statutory and regulatory payment rules apply to the items and services. If the item is excluded from coverage by the Act or does not fall within the scope of a defined benefit category, the item cannot be covered under Medicare Part B.*

*Medicare Durable Medical Equipment, Prosthetic Devices, Prosthetics, Orthotics and Supplies (DMEPOS) benefit category determinations established on or after September 26, 2022, in accordance with the procedures at 42 CFR §414.114 and §414.240, are listed below. These procedures consider public consultation furnished at public meetings and in writing in accordance with requirements for new DME items by section 531(b) of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub L. 106-554). This section is a quick reference tool for the benefit categories of items and services evaluated using the procedures described above. The section is organized alphabetically by the categories of items and services and then by the benefit category status of each category of items and services.*

*Special note: the benefit category and payment rules for items and services that are assigned to an existing HCPCS code(s) are determined by the benefit category and payment rules for that HCPCS code(s). More information on the final determinations for items and services reviewed using the process described above is available at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings.*

*DMEPOS Benefit Category Determinations*

| *Item* | *Benefit Category Determination* |
|---|---|
| *Addition, Endoskeletal Knee-Shin System, 4 Bar Linkage or Multiaxial, Fluid Swing and Stance Phase Control* | *Artificial Leg--This item is a microprocessor-controlled knee added to a prosthetic leg that utilizes a 4-bar geometry with hydraulic control of both stance and swing phases of gait. Final determination established on 09-26-22.* |
| *Addition to Lower Extremity Prosthesis, Endoskeletal Knee Disarticulation, Above Knee, Hip Disarticulation, Positional Rotation Unit* | *Artificial Leg--This item is added to a prosthetic leg and provides 360-degree rotation of the prosthetic limb to accommodate specific environmental situations. Final determination established on 09-26-22.* |
| *Automated Lateral Turning System: Positioned Beneath Patient's Mattress* | *DME--Decubitus care equipment which uses alternating pressure pad placed under the mattress rather than on top of the mattress. Final determination established on 09-26-22.* |
| *Cranial Electrotherapy Stimulation System* | *DME--These devices utilize a microcurrent to deliver proprietary low-level electrical signals trans cranially to treat insomnia, depression, anxiety, and pain. Final determination established on 09-26-22.* |
| *Disposable Collection and Storage Bag for Breast Milk, Any Size* | *No DMEPOS Benefit Category--There is no DMEPOS benefit category for disposable supplies. Also, electric breast pumps are not classified as DME. Therefore, disposable supplies used with these items would not fall under a DMEPOS benefit category. With regard to manual breast pumps and related supplies, the Medicare Administrative Contractor processing claims for these items would determine whether or not the pump is DME on a claim by claim basis. Final determination established on 09-26-22.* |
| *Distal Transcutaneous Electrical Nerve Stimulator, Stimulates Peripheral Nerves of the Upper Arm* | *No DMEPOS Benefit Category--Minimum lifetime requirement of at least three years not met. Final determination established on 09-26-22.* |
| *Electronic Positional Obstructive Sleep Apnea Treatment Equipment, With Sensor* | *DME--These items are classified as DME if FDA clearance expressly states it is for the treatment of positional obstructive sleep apnea and is not clinically indicated or marketed for anti-snoring or other non-medical uses and all other requirements for classification as DME in accordance with §414.202 are met. Final determination established on 09-26-22.* |
| *Enema Tube, With or Without Adapter* | *No DMEPOS Benefit Category--These items cannot withstand repeated use and are therefore not DME. Rectal catheters or tubes are not prosthetic devices because they do not replace all or part of an internal body organ or all or* |

| Item | Benefit Category Determination |
| --- | --- |
| | *part of the function of a permanently inoperative or malfunctioning internal body organ.*<br>*Final determination established on 09-26-22.* |
| *External Upper Limb Tremor Stimulator of the Peripheral Nerves of the Wrist* | *DME--These devices deliver electrical stimulation to the nerves in the wrist to stimulate the peripheral nervous system for the treatment of essential tremors.*<br>*Final determination established on 09-26-22.* |
| *Foot Adductus Positioning Device, Adjustable* | *Leg Brace--These are foot positioning devices that stabilize the heel in the heel cage and the rest of the foot in the device while applying corrective pressures to the midfoot, thereby realigning the malformed pediatric foot. This is considered to be an alternative to serial casting. The devices treat newborns with semiflexible and rigid metatarsus adductus/varus, as well as flexible metatarsus adductus/varus that does not respond to stretching.*<br>*Final determination established on 09-26-22.* |
| *Hydrophilic, Dual Focus Contact Lens* | *No DMEPOS Benefit Category--Contact lens used for the correction of myopic ametropia and for slowing the progression of myopia in children. These lenses do not qualify as prosthetic devices under any of the categories for prosthetic lenses under section 120.B of chapter 15 of the Medicare Benefit Policy Manual.*<br>*Final determination established on 09-26-22.* |
| *Hydrophilic, Spherical Contact Lens with Photochromic Additive* | *Prosthetic Device--Refractive lenses are covered as prosthetic lenses under the benefit category for prosthetic devices when they are used to restore the vision normally provided by the natural lens of the eye of an individual lacking the organic lens because of surgical removal or congenital absence. Covered diagnoses are limited to pseudophakia (condition in which the natural lens has been replaced with an artificial intraocular lens [IOL]), aphakia (condition in which the natural lens has been removed but there is no IOL), and congenital aphakia. Lenses provided for other diagnoses will be denied as noncovered. Coverage may be limited to one pair of eyeglasses or contact lenses. Because coverage of refractive lenses is based upon the prosthetic device benefit category, there is no coverage for frames or lens add-on codes unless there is a covered lens(es). Tinted lenses, including photochromatic lenses, used as sunglasses, which are prescribed in addition to regular prosthetic lenses to a pseudophakic beneficiary, will be denied as noncovered.*<br>*Final determination established on 09-26-22.* |
| *Knee Ankle Foot Device, Any Material, Single or Double Upright, Swing and Stance Phase Microprocessor Control* | *Leg Brace--Rigid device used for the purpose of supporting a weak or deformed leg.*<br>*Final determination established on 09-26-22.* |

| *Item* | *Benefit Category Determination* |
| --- | --- |
| *with Adjustability, Includes All Components (e.g., Sensors, Batteries, Charger), Any Type Activation, with or without Ankle Joint(s), Custom Fabricated* | |
| *Low Frequency Ultrasonic Diathermy Treatment Device for Home Use* | *No DMEPOS Benefit Category--Minimum lifetime requirement of at least three years not met. These items are not the standard pulses wave types of diathermy machines referenced in section 280.1 of chapter 1, part 4 of the National Coverage Determinations Manual. However, the equipment must be able to be rented and used by multiple patients for a minimum of three years in order to be classified as DME.*<br>*Final determination established on 09-26-22.* |
| *Mechanical Allergen Particle Barrier/Inhalation Filter, Cream, Nasal, Topical* | *No DMEPOS Benefit Category--Minimum lifetime requirement of at least three years not met.*<br>*Final determination established on 09-26-22.* |
| *Non-Invasive Vagus Nerve Stimulator* | *DME--These devices stimulate the cervical branch of the vagus nerve when applied to the side of the neck through two stainless steel stimulation surfaces.*<br>*Final determination established on 09-26-22.* |
| *Non-Pneumatic Compression Controller* | *DME--These devices use non-pneumatic compression to treat and manage lymphedema.*<br>*Final determination established on 09-26-22.* |

| | |
|---|---|
| *Oral Device/Appliance for Neuromuscular Electrical Stimulation of the Tongue Muscle for the Reduction of Snoring and Obstructive Sleep Apnea, Controlled by Phone Application* | *No DMEPOS Benefit Category--The component that performs the medically necessary function of the device is a smartphone which is useful to an individual in the absence of an illness or injury. Final determination established on 09-26-22.* |
| *Prescription Digital Therapy* | *No DMEPOS Benefit Category--Digital therapies or computer software are housed on non-medical devices like smartphones or computers and the equipment and software as a whole are not DME. Final determination established on 09-26-22.* |
| *Speech Volume Modulation System* | *DME--These devices are worn behind the ear and play background noise (multi-talker babble) in the patient's ear only when the patient speaks. The noise elicits the Lombard Effect, automatically increasing the patient's vocal intensity, slowing their speech rate, and/or increasing the clarity of their speech. Final determination established on 09-26-22.* |
| *Suction Pump, Home Model, Portable or Stationary, Electric, for Use with External Urine Management System* | *DME--Home suction pumps have been classified as DME under the HCPCS since 1984 or earlier. This type of home suction pump is used for urine collection or drainage. Final determination established on 09-26-22.* |
| *Transcutaneous Electrical Nerve Stimulator for Electrical Stimulation of the Trigeminal Nerve* | *DME--These devices are used during sleep for the treatment for pediatric attention deficit hyperactivity disorder (ADHD). Final determination established on 09-26-22.* |
| *Wheelchair Accessory: Dynamic Positioning Hardware for Back* | *DME--These items are hardware added to the wheelchair to absorb the force of a patient's uncontrollable backward jerking motions is classified as DME if necessary for the effective use of a wheelchair classified as DME. Final determination established on 09-26-22.* |
| *Whirlpool Tub, Walk-In, Portable* | *No DMEPOS Benefit Category--A portable hydrotherapy unit or whirlpool is useful to individuals in the absence of an illness or injury for relaxation and soothing sore muscles. Per section 280.1 of chapter 1, part 4 of the Medicare National Coverage Determinations Manual, portable whirlpool pumps are not DME because they are not primarily medical in nature and are personal comfort items excluded from Medicare coverage (§1862(a)(6) of the Act). Final determination established on 09-26-22.* |