

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-02 Medicare Benefit Policy</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 12684</b>	<b>Date: June 13, 2024</b>
	<b>Change Request 13651</b>

**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, Chapter 15, Section 110.8 DMEPOS Benefit Category Determinations.

**EFFECTIVE DATE: January 1, 2024 - for 3 orthotic brace determinations; April 1, 2024 - For all other items, equipment and devices**

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

**IMPLEMENTATION DATE: July 15, 2024**

*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.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
R	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: 12684	Date: June 13, 2024	Change Request: 13651
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### I. GENERAL INFORMATION

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

**B. Policy:** Additional information on new DMEPOS Benefit Category Determinations made as part of the 2023 Second Biannual (B2) 2023 Healthcare Common Procedure Coding System (HCPCS) coding cycle in accordance with the procedures at 42 CFR §414.114, §414.240 and §414.1670 is available at: [www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings](http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings)

### 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	
13651.1	Contractors shall be aware of updates to Pub.100-02, Chapter 15, Section 110.8 DMEPOS Benefit Category Determinations.			X	X					

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13651.2	Medicare Learning Network® (MLN): CMS will develop and release national provider education content and market it through the MLN Connects® newsletter shortly after we issue the CR. MACs shall link to relevant information on your website and follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 for distributing the newsletter to providers. When you	X	X	X	X	X

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	follow this manual section, you don't need to separately track and report MLN content releases. You may supplement with your local educational content after we release the newsletter.					

**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**

**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 *(Rev12684; Issued: 06-13-24)*

#### 110.8 – DMEPOS Benefit Category Determinations

*(Rev12684; Issued:06-13-24, Effective: 04-01-24, Implementation: 07-15-24)*

##### ***A. General***

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, *through rulemaking or* in accordance with the procedures at 42 CFR §414.114, §414.240 and §414.1670, 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). These procedures are often performed in coordination with Healthcare Common Procedure Coding System (HCPCS) code decisions. 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 determination with effective date.

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). *Additional benefit category determinations established before 2022 for DME items are available in CMS Pub. 100-03 Chapter 1, Part 4, Section 280.1 Durable Medical Equipment Reference List.* More information on *HCPCS code decisions and* benefit category determinations for items and services reviewed using the process described above is available at <https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system>

#### DMEPOS Benefit Category Determinations

Item	Benefit Category Determination	Effective Date
Addition, Endoskeletal Knee-Shin System, 4 Bar Linkage or Multiaxial, Fluid Swing and Stance Phase Control	Prosthetic (Artificial Leg)-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.	<b>10-1-22</b>
<i>Addition, Endoskeletal Knee-Shin System, Polycentric,</i>	<i>Prosthetic (Artificial Leg)-Prosthetic endoskeletal knee-shin system that provides pneumatic swing and stance control.</i>	<i>4-1-24</i>

<i>Pneumatic Swing, and Stance Phase Control</i>		
Addition to Lower Extremity Prosthesis, Endoskeletal Knee Disarticulation, Above Knee, Hip Disarticulation, Positional Rotation Unit	Prosthetic (Artificial Leg)-Added to a prosthetic leg to provide 360-degree rotation of the prosthetic limb to accommodate specific environmental situations.	<b>10-1-22</b>
Addition to Lower Extremity Prosthesis, Osseointegrated External Prosthetic Connector	Prosthetic (Artificial Leg)-Connection device between implantable components and external prosthetic components such as prosthetic knee and foot.	<b>10-1-23</b>
<i>Addition to Lower Extremity, User Adjustable, Mechanical, Residual Limb Volume Management System</i>	<i>Prosthetic (Artificial Leg)-Added to a lower extremity prosthetic socket.</i>	<i><b>4-1-24</b></i>
<i>Adhesive clip applied to the skin to secure external electrical nerve stimulator controller</i>	<i>Prosthetic Supply-Supply used with Prosthetic Device</i>	<i><b>4-1-24</b></i>
<i>Bilateral hip, knee, ankle, foot device, powered, includes pelvic component, single or double upright(s), knee joints any type, with or without ankle joints any type, includes all components and accessories, motors, microprocessors, sensors</i>	<i>Orthotic (Leg Brace)-Lower body exoskeleton system worn to enable ambulation for user with disorders such as paralysis.</i>	<i><b>1-1-24</b></i>

Cranial Electrotherapy Stimulation System	DME--These devices utilize a microcurrent to deliver proprietary low-level electrical signals transcranially to treat insomnia, depression, anxiety, and pain.	<b>10-1-22</b>
<i>Complex Rehabilitative Power Wheelchair Accessory, Power Seat Elevation System, Any Type</i>	<i>DME--Component of a complex rehabilitative power wheelchair that raises and lowers a user while in a seated position to varying amounts of vertical height.</i>	<b>4-1-24</b>
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. For 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	<b>10-1-22</b>
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	<b>10-1-22</b>
Electrical stimulator supplies (external) for use with implantable neurostimulator, per month	Prosthetic Device--Accessories for neuromodulation systems indicated for pain management in adults who have severe intractable pain of peripheral nerve origin.	<b>4-1-23</b>
Electronic Positional Obstructive Sleep Apnea Treatment Equipment, With Sensor	DME--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.	<b>10-1-22</b>
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 part of the function of a permanently inoperative or malfunctioning internal body organ.	<b>10-1-22</b>
Enteral feeding supply kit; elastomeric control fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape	Prosthetic Device--Portable, lightweight, non-electronic, disposable enteral feeding system.	<b>10-1-23</b>
Expiratory Positive Airway Pressure Intranasal Resistance Valve	No DMEPOS Benefit Category--These are single-patient, reusable expiratory positive airway pressure (EPAP) devices for the treatment of obstructive sleep apnea. These single-patient items cannot withstand repeated use and therefore are not DME.	<b>4-1-23</b>
External Upper Limb Tremor Stimulator of the Peripheral Nerves of the Wrist	DME--Delivers electrical stimulation to the nerves in the wrist to stimulate the peripheral nervous system for the treatment of essential tremors.	<b>10-1-22</b>

<i>Fertility cycle (contraception &amp; conception) tracking software application, fda cleared, per month, includes accessories (e.g., thermometer)</i>	<i>No DMEPOS Benefit Category—Software applications (apps) are not devices, equipment, or supplies and do not fall under a DMEPOS benefit category.</i>	<b>4-1-24</b>
Foot Adductus Positioning Device, Adjustable	Orthotic (Leg Brace)-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.	<b>10-1-22</b>
Hip orthosis, bilateral hip joints and thigh cuffs, adjustable flexion, extension, abduction control of hip joint, postoperative hip abduction type, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	Orthotic (Leg Brace)-Prefabricated, custom fitted, hip orthosis designed for bilateral post-operative hip range of motion control.	<b>10-1-23</b>
<i>Home Ventilator, dual-function respiratory device, also performs additional function of cough stimulation, includes all accessories, components and supplies for all functions</i>	<i>DME-- Assists with ventilation and cough stimulation and falls under the multi-function ventilator definition in 42 CFR §414.222(f)(1).</i>	<b>4-1-24</b>

Hydrophilic, with Blue-Violet Filter Contact Lens	No DMEPOS Benefit Category --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.	<b>10-1-23</b>
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.	<b>10-1-22</b>
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.	<b>10-1-22</b>
Indwelling intraurethral drainage device with valve, patient inserted	Prosthetic Device--Urethral insert with a valve for bladder drainage. The intraurethral device replaces the function of a permanently inoperative bladder.	<b>4-1-23</b>
<i>Integrated lancing and blood sample testing cartridges for home blood glucose monitor, per month</i>	<i>DME--Supply used with Durable Medical Equipment.</i>	<b><i>4-1-24</i></b>



Knee Ankle Foot Device, Any Material, Single or Double Upright, Swing and Stance Phase Microprocessor Control with Adjustability, Includes All Components (e.g., Sensors, Batteries, Charger), Any Type Activation, with or without Ankle Joint(s), Custom Fabricated	Orthotic (Leg Brace)-Rigid device used for the purpose of supporting a weak or deformed leg.	10-1-22
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.	10-1-22
Mechanical Allergen Particle Barrier/Inhalation Filter, Cream, Nasal, Topical	No DMEPOS Benefit Category--Minimum lifetime requirement of at least three years not met.	10-1-22
<i>Mechanical Vibration Device for Massage Stimulation</i>	<i>No DMEPOS Benefit Category--Mechanical vibration devices for massage stimulation are personal comfort items excluded from Medicare coverage by section 1862(a)(6) of the Social Security Act.</i>	<i>4-1-24</i>
Molecular diagnostic test reader, nonprescription self-administered and self-collected use, fda approved, authorized or cleared	No DMEPOS Benefit Category--In vitro diagnostic medical device for analyzing specimens in the home collected with the single-use cartridges.	4-1-23
<i>Neuromodulation Stimulator System, adjunct to rehabilitation therapy regime</i>	<i>DME--Neuromodulation stimulator device designed to assist with gait deficit.</i>	<i>4-1-24</i>
<i>Neuromodulation Stimulator System, adjunct to rehabilitation therapy regime, mouthpiece</i>	<i>DME--Supply used with Durable Medical Equipment</i>	<i>4-1-24</i>
Neuromuscular electrical stimulator (nmes), disposable, replacement only	No DMEPOS Benefit Category— These single-patient items cannot withstand repeated use and therefore are not DME.	4-1-23
Non-Invasive Vagus Nerve Stimulator	DME--Devices to stimulate the cervical branch of the vagus nerve when applied to the side of the neck through two stainless steel stimulation surfaces.	10-1-22
Non-Pneumatic Compression Controller	DME--These devices use non-pneumatic compression to treat and manage lymphedema.	10-1-22
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.	10-1-22

<p>Oral Device/Appliance for Neuromuscular Electrical Stimulation of the Tongue Muscle for the Reduction of Snoring and Obstructive Sleep Apnea, Controlled by Hardware Remote</p>	<p>DME--The component that performs the medically necessary function of the device is a durable control unit and a hardware remote.</p>	<p><b>10-1-23</b></p>
<p>Oral mucoadhesive, any type (liquid, gel, paste, etc)</p>	<p>No DMEPOS Benefit Category--Oral mucoadhesive is not a surgical dressing covered under Section 1861(s)(5) of the Act and does not fall under any other DMEPOS benefit category.</p>	<p><b>10-1-23</b></p>
<p><i>Pessary, disposable, any type</i></p>	<p><i>Prosthetic Device--Pessary for temporary, nonsurgical management of pelvic organ prolapse in females.</i></p>	<p><i>4-1-24</i></p>
<p>Powered Pressure Reducing Underlay/pad, Alternating, With Pump</p>	<p>DME--Decubitus care equipment which uses alternating turning pressure pad placed under the mattress rather than on top of the mattress.</p>	<p><b>10-1-22</b></p>

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.	<b>10-1-22</b>
Programable, transient, orally ingested capsule, for use with external programmer, per month	No DMEPOS Benefit Category--The component that performs the medically necessary function of the device is a non-durable capsule.	<b>10-1-23</b>
<i>Powered upper extremity range of motion assist device, elbow, wrist, hand with single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated</i>	<i>Orthotic (Arm Brace)-Motorized, microprocessor controlled, elbow-wrist-hand device used for patients experiencing complications of stroke or other neurological/neuromuscular injury and illness.</i>	<i><b>1-1-24</b></i>
<i>Powered upper extremity range of motion assist device, elbow, wrist, hand, finger, single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated</i>	<i>Orthotic (Arm Brace)-Motorized, microprocessor controlled, elbow-wrist-hand-finger device used for patients experiencing complications of stroke or other neurological/neuromuscular injury and illness.</i>	<i><b>1-1-24</b></i>
<i>Rehab system with interactive Interface Providing Active Assistance in Rehabilitation Therapy, includes all components and accessories, motors, microprocessors, sensors</i>	<i>DME--Device provides rehabilitation to hand or foot.</i>	<i><b>4-1-24</b></i>
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.	<b>10-1-22</b>
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.	<b>10-1-22</b>
<i>Thoracic, pectus carinatum orthosis, sternal compression, rigid circumferential frame with anterior and posterior rigid pads, custom fabricated</i>	<i>Orthotic (Brace)</i>	<i><b>4-1-24</b></i>

Transcutaneous Electrical Nerve Stimulator for Electrical Stimulation of the Trigeminal Nerve	DME--Devices used during sleep for the treatment for pediatric attention deficit hyperactivity disorder (ADHD).	<b>10-1-22</b>
<i>Transcutaneous tibial nerve simulator</i>	<i>DME--Device performs transcutaneous tibial nerve stimulation.</i>	<i>4-1-24</i>
Upper extremity medical tubing/lines enclosure or covering device, restricts elbow range of motion	No DMEPOS Benefit Category--The device is safety equipment to prevent patient entanglement when stationary or mobile with vital tubes, lines and catheters. There is not a benefit category under Medicare Part B for safety equipment used in the home.	<b>4-1-23</b>
<i>Upper extremity rehabilitation system providing active assistance to facilitate muscle re-education, include microprocessor, all components and accessories</i>	<i>DME--Device assists to facilitate muscle re-education.</i>	<i>4-1-24</i>
Virtual reality cognitive behavioral therapy device (cbt), including pre-programmed therapy software	DME--The device delivers a clinically based multimodal pain self-management program incorporating evidence-based principles of Cognitive Behavioral Therapy (CBT).	<b>4-1-23</b>
<i>Walker component for extra power to ambulate harder terrain outside the home, folding, adjustable or fixed height</i>	<i>No DMEPOS benefit category--Item assists with extra power to ambulate harder terrain outside the home (i.e. uphill, grassy field, longer distances). Item does not serve a medical purpose for use in the home.</i>	<i>4-1-24</i>
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.	<b>10-1-22</b>
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).	<b>10-1-22</b>

### ***B. DMEPOS Benefit category Determinations for Miscellaneous Items and Services***

*The instructions in section A. apply to all claims for items and services billed using HCPCS codes for specific items and services that have national BCDs. For claims for items and services billed using HCPCS codes for miscellaneous DMEPOS items and services (e.g., A9999, B9999, E1399, K0108, L3999), the contractors must determine if the item or service falls within one of the benefit categories for DMEPOS and whether or not the item or service is excluded from coverage in accordance with the rules of section 1862 of the Social Security Act and other Medicare laws, regulations, and program instructions. These determinations are made on an individual, claim-by-claim basis.*