Clinical Policy: Durable Medical Equipment, Orthotics and Prosthetics Guidelines

Reference Number: DE.CP.MP.107 Coding Implications
Date of Last Revision: 11/24 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

DME is defined as equipment that can stand repeated use, is primarily and customarily used to serve a medical purpose, and is generally not useful to a person in the absence of an illness or injury.[2] Orthotic devices are rigid and semi-rigid devices used for the purpose of supporting a weak or deformed body part or restricting or eliminating motion in a disease or injured body part.[3] Prosthetic devices are custom-made artificial limbs or other assistive devices that replace a body part or function as a result of traumatic injuries, vascular disease, diabetes, cancer or congenital disorders.

Policy/Criteria

I. It is the policy of Delaware First Health® that durable medical equipment, orthotics, and prosthetics are **medically necessary** when the general and applicable equipment-specific criteria in A and B are met:

A. General criteria: Both of the following have been provided to the member/enrollee and/or caregiver, as applicable:

1. Education regarding use of the device, with demonstrated understanding;
2. A trial of the requested device, with demonstrated ability to use it safely and effectively.

Note: *If a medically necessary, lesser cost item exists and will suit the member/enrollee's medical needs, a higher cost item will be denied.*

B. EQUIPMENT-SPECIFIC CRITERIA

CARDIAC EQUIPMENT	CRITERIA	HCPCS
Non-wearable external defibrillator with integrated ECG analysis [5]	Considered not medically necessary as it is primarily considered a safety device.	E0617

COMPRESSION THERAPY EQUIPMENT	CRITERIA	HCPCS
Non-pneumatic compression devices [6,7]	There is insufficient clinical evidence to support the safety and effectiveness of non-pneumatic compression devices over the use of standard pneumatic compression devices.	K1032 K1033

HEAT, COLD & LIGHT THERAPY EQUIPMENT	CRITERIA	HCPCS
Ultraviolet panel lights [8,9, 10]	Medically necessary when meeting both of the following: A. Refractory psoriasis; B. MD justifies treatment at home versus alternate sites (e.g. outpatient department at hospital). Panel lights should be considered, if several discrete body areas can be treated individually. Note: Cabinet style lights should be reserved for extensive involvement of body surface area.	E0691 E0692 E0693 E0694

OTHER EQUIPMENT	CRITERIA	HCPCS
Enclosed Beds [13, 14, 15, 16]	Requests will be reviewed by a medical director and/or therapy advisor to determine medical necessity, based on all of the following: A. Standard bed or standard hospital bed must be unable to meet the positioning needs due to disability; B. Less intensive alternatives to improve the member's/enrollee's safety have been tried and ruled out (to include documentation of why they could not meet medical needs). Considerations include, but are not limited to: 1. Bed rails; 2. Mattress placed on the floor; 3. Removal of all safety hazards; 4. Bed alarms; 5. Video/audio monitors; 6. Child protection devices such as locks on doors, windows, cabinets, furniture anchors, gates at steps and doors; 7. Physician-directed medication to address seizures, behaviors and sleep;	E0316 E1399 E0328 or E0329 (when combined with E0316 or E1399)

OTHER EQUIPMENT	CRITERIA	HCPCS
	8. Environmental modification to encourage calming behaviors and sleep; 9. Established routines addressing sensory needs and/or behavior modification to assist with improved naptime or night time behaviors and sleep; C. Medical diagnosis to include, but not limited to: 1. Cerebral palsy; 2. Developmental delay; 3. Genetic or neurological disorder that would cause vertigo, disorientation, or uncontrolled movement of the body or extremities; 4. Uncontrolled seizure disorder; 5. Severe behavior disorder; D. Healthcare provider evaluation (typically from an occupational or physical therapist) to include: 1. Specific information on functional status; 2. Documentation of home evaluation; 3. Documentation of education provided to caregivers on proper use of a bed enclosure, noting: they are to be used for medical support, improved safety transitioning in and out of the bed, and improved safety while sleeping; E. Name of and invoice for the bed or enclosure being requested. F. **If an enclosed bed is found to be medically necessary only a standard enclosed bed would be considered. Upgrades for aesthetic purposes or upgrades that do not meet the rules for Durable Medical equipment (DME) would not be covered as part of an enclosed bed purchase. These include, but are not limited to**: ○ special lights, sounds, fans, cameras, two-way talk monitors, vibration pads weighted blankets ○ custom wood types, finishes or engravings, special coverings on the outside of the bed ○ custom upgrades where lower cost alternatives are readily available Notes: **Enclosed beds should not be used as:** ○ a discipline measure ○ a restraint during times of high agitation or aggression ○ part of behavior therapy or training ○ a substitute for caregiver supervision **To limit sensory deprivation, enclosed beds should be used at night for sleeping and only for short rests or naps during the day.**	

OTHER EQUIPMENT	CRITERIA	HCPCS
Positioning seat	Requests should have a physician or therapy advisor review to determine medical necessity. Medically necessary with therapist evaluation and ongoing treatment and *all* of the following criteria are met: A. Commercial device must be unable to meet the positioning needs due to height, weight, or disability; B. Other positioning devices in the home must be reviewed to ensure a duplication of devices is not already in place.	T5001 E1399
Specialized supply or equipment	Requests for not otherwise specified supplies or miscellaneous equipment codes will have a physician or therapy advisor review to determine medical necessity.	E0240 T2028 T2029 K0108 K0739 E1399 (For wheelchair seating refer to CP.MP.99)
ROMTech® PortableConnect® Device [17]	Not medically necessary, as there is insufficient evidence in published peer-reviewed literature to support the use of this technology over currently available alternatives.	E1399, A9900

PROSTHETICS AND ORTHOTICS EQUIPMENT	CRITERIA	HCPCS
Cervical traction equipment [11]	Medically necessary when all of the following are met: A. The appropriate use of the selected home cervical traction device has been demonstrated and was tolerated; B. One of the following: 1. Diagnosis of temporomandibular joint (TMJ) dysfunction and has received treatment for TMJ condition; 2. Distortion of the lower jaw and neck anatomy (e.g. radical neck dissection) such that a chin halter is unable to be utilized; 3. The treating physician orders and/or documents the medical necessity for greater than 20 pounds of cervical traction in the home setting.	E0849
Halo procedure equipment & Fracture Frames	Halo and fracture frame placement is generally performed on an emergent or inpatient basis and will be reviewed at the appropriate level of care using nationally recognized decision support tools.	E0947 E0948 L0810 L0820 L0830 L0859
Cervical collar, custom molded	Requests for custom molded cervical collar will be reviewed by a licensed physical or occupational therapist. Documentation	L0170 L0190

PROSTHETICS AND ORTHOTICS EQUIPMENT	CRITERIA	HCPCS
	accompanying the request must state reason why pre-fabricated collar not adequate.	L0200
Hip orthotics	Medically necessary when ordered by an orthopedist for treatment of, or postoperatively for any of the following: A. Total hip arthroplasty; B. Slipped capital femoral epiphysis; C. Legg-Calvé-Perthes disease; D. Hip labral tear; E. Hip dysplasia for Charcot-Marie-Tooth disease. Lateral replacements due to growth are considered medically necessary in pediatrics for diagnoses such as hip dysplasia with Charcot-Marie-Tooth disease.	L1640 L1680 L1685 L1686 L1690
Legg Perthes orthotics	Medically necessary when ordered by an orthopedist for use in the treatment for Legg-Calvé-Perthes disease in children.	L1700 L1710 L1720 L1730 L1755
Orthotic components	Requests for orthotic components listed will be reviewed using relevant nationally recognized decision support tool criteria for similar codes.	L2570 L2580 L2627 L2628
MyoPro® Orthosis [26]	Not medically necessary, as there is insufficient evidence in published peer-reviewed literature to support the use of this technology over other technologies and currently available alternatives.	L8701 L8702

PUMPS	CRITERIA	HCPCS
Vacuum erection device[18, 19]	A vacuum erection device (VED) and tension ring are medically necessary for the treatment of erectile dysfunction when prescribed by a physician.	L7900 L7902

RESPIRATORY EQUIPMENT	CRITERIA	HCPCS
IPPB & supplies	Medically necessary for member/enrollee with respiratory disease when an incentive spirometer is ineffective.	E0500 E0550
Intrapulmonary percussive ventilation devices (Volara™, Percussionaire-TRUE-IPV®)[20, 21, 22, 23]	Current evidence does not support the effectiveness of intrapulmonary percussive ventilation (IPV).	E1399

Surgical Supplies	Criteria	HCPCS
Other surgical supplies	These items are used as part of a surgical procedure and will be reviewed according to the relevant surgical procedure or level of care.	L8040, L8041, L8042, L8043, L8044, L8045, L8046, L8047, L8499, L8600, L8609, L8610, L8612, L8615, L8631, L8659

Wheelchairs	Criteria	HCPCS
Robotic Arm, Wheelchair-mounted (JACO) [25]	There is insufficient clinical evidence to support safety and improved health outcomes of the JACO Assistive Robotic Arm (Kinova, Inc.) over other technologies.	E1399
Rollabout chair	Medically necessary when used in lieu of a wheelchair for those who would qualify for a wheelchair (except for the ability to self-propel a manual wheelchair).	E1031
Wheelchair repair	Requests for wheelchair repairs specifically using codes K0108, K0739, or E1399, are medically necessary when reviewed by a physician or therapy advisor and when meeting the following criteria: A. Wheelchair is less than 5 years old (as evident by the age/date of purchase information provided); B. Cost of repairs is less than the cost of replacement; C. Information is provided to support the need for repairs due to normal wear and tear, as opposed to abuse/misuse or overutilization (as based on review of previous repair history, age and overall condition). One month's rental for a standard manual wheelchair is considered medically necessary if a member/enrollee owned wheelchair is being repaired.[31]	K0108 K0739 E1399

Wound Care	Criteria	HCPCS
Whirlpool tub	Considered not medically necessary.	E1310

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

Background

DME items have the following characteristics:

- The equipment is prescribed by a physician;
- The equipment meets the definition of DME;
- The equipment is necessary and reasonable for the treatment of an illness or injury;
- The equipment is manufactured primarily for use in the home environment, but is not limited to use in the home.

Member/Enrollee's Home

For purposes of rental and purchase of DME, a member/enrollee's home may be their own dwelling, an apartment, a relative's home, a home for the aged or some other type of institution. However, an institution may not be considered a member/enrollee's home if the following are met:

- Meets at least the basic requirement in the definition of a hospital, i.e., it is primarily engaged in providing by or under the supervision of physicians, inpatient, diagnostic and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, and sick persons, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons; or
- Meets at least the basic requirement in the definition of a skilled nursing facility, i.e., it is primarily engaged in providing to inpatients skilled nursing care and related services for members/enrollees who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.

Members/enrollees who have been permanently admitted to an inpatient skilled nursing facility or inpatient hospice and who have changed their home address to that of the SNF or hospice will have the SNF or hospice defined as their home.

Products

Products is defined as a listing of the most common items, or group of items, that are or may be perceived as home medical equipment. This listing, while reasonably complete, is not intended to quantify the entire spectrum of products that may be considered DME either now or in the future.

Durability

An item is considered durable if it can withstand repeated use, i.e., the type of item that could normally be rented. Medical supplies of an expendable nature, such as incontinence pads, lamb's wool pads, catheters, ace bandages, elastic stockings, surgical facemasks, sheets and bags are not considered "durable" within the meaning of the definition. There are other items that although durable in nature, may fall into other coverage categories such as supplies and orthotics and prosthetics. Orthotics and Prosthetics items include, but are not limited to, braces, artificial limbs and eyes.

Medical Equipment
Medical equipment is defined as equipment primarily and customarily used for medical purposes and is not generally useful in the absence of illness or injury. In most instances, no documentation will be needed to support whether a specific item of equipment is medical in nature. However, some cases will require documentation to determine whether the item constitutes medical equipment. This documentation would include the advice of local medical organizations and facilities and specialists in the field of physical medicine and rehabilitation. If the equipment is new on the market, it may be necessary, prior to seeking professional advice, to obtain information from the supplier or manufacturer explaining the design, purpose, effectiveness and method of using the equipment in the home as well as the results of any tests or clinical studies that have been conducted.

Personal computers or mobile technology such as iPads, smart phones, iPods, personal digital assistants, etc., may be considered as medical equipment when used for the purpose of speech generating equipment when other non-medical functions are limited or disabled and that device is used as the primary source of communication for those qualifying for a speech generating device.

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy created.	05/24	06/24
Added criteria F. under Other Equipment: Enclosed beds. References reviewed and updated.	11/24	12/24

References
1. CP.MP.107 Durable Medical Equipment and Orthotics and Prosthetics Guidelines
2. National coverage determination: Durable medical equipment (DME) reference list (280.1). Centers for Medicare and Medicaid Services w, ebsite. https://www.cms.gov/medicare-coverage-database/search.aspx. Published May 16, 2023. Accessed September 4, 2024.
3. Local coverage article. Knee orthoses – policy article (A52465). Centers for Medicare & Medicaid Services website. http://www.cms.hhs.gov/mcd/search.asp. Published October 1, 2015 (revised January 23, 2024). Accessed October 15, 2024.
4. Local coverage article. Surgical dressings (A54563). Centers for Medicare & Medicaid Services website. http://www.cms.hhs.gov/mcd/search.asp. Published October 1, 2015 (revised January 1, 2024). Accessed September 4, 2024.
5. Rea TD, Eisenberg MS. Automated external defibrillators. UpToDate. http://www.uptodate.com. Published March 5, 2024. Accessed September 6, 2024.
6. National coverage determination. Pneumatic compression devices (280.6). Centers for Medicare & Medicaid Services website. http://www.cms.hhs.gov/mcd/search.asp. Published January 14, 2002. Accessed September 6, 2024.

7. Evidence analysis research brief: Dayspring (Koya Medical Inc.) for treatment of lymphedema. Hayes. www.hayesinc.com. Published March 27, 2023. Accessed September 6, 2024.
8. National coverage determination. Treatment of psoriasis (250.1). http://www.cms.hhs.gov/mcd/search.asp. Published January 1, 1966. Accessed September 6, 2024.
9. Elmets CA, Lim HW, Stoff B, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy. J Am Acad Dermatol. 2019; 81(3):775-804.
10. Local coverage determination: Heating pads and heat lamps (L33784). Centers for Medicare and Medicaid Services website. https://www.cms.gov/medicare-coverage-database/search.aspx. Published October 1, 2015 (updated January 1, 2020). Accessed September 10, 2024.
11. Local coverage determination. Cervical traction devices (L33823). Centers for Medicare & Medicaid Services website. http://www.cms.hhs.gov/mcd/search.asp. Published October 1, 2015 (revised January 1, 2020). Accessed November 19, 2024.
12. DMEPOS quality standards. Centers for Medicare & Medicaid Services website. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/DMEPOSQuality/DMEPOSQualBooklet-905709.html. Published December 2022. Accessed September 23,2024.
13. Restraint and seclusion - Enclosure beds, side rails and mitts. The Joint Commission website. https://www.jointcommission.org/standards/standard-faqs/critical-access-hospital/provision-of-care-treatment-and-services-pc/000001668/. Published April 11, 2016 (updated July 20, 2022). Accessed September 23, 2024.
14. Enclosure bed: A protective and calming restraint. American Nurse Association website. https://www.myamericannurse.com/use-enclosure-beds/. Published January 13, 2015. Accessed September 23, 2024.
15. State Operations Manual Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals. Centers for Medicare & Medicaid Services. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf. Published May 21, 2004 (revised July 21, 2023). Accessed September 23, 2024.
16. Local coverage determination: hospital bed and accessories (L33820). Centers for Medicare and Medicaid Services website. http://www.cms.hhs.gov/mcd/search.asp. Published October 1, 2015 (revised January 1, 2020). Accessed November 19, 2024.
17. Evolving evidence review: ROMTech/PortableConnect (ROM Technologies Inc.) for telerehabilitation following total knee arthroplasty. Hayes. https://www.hayesinc.com/. Published March 10, 2022 (annual review August 15, 2024). Accessed September 23, 2024.
18. Local coverage determination. Vacuum erection devices (L34824). Centers for Medicare & Medicaid Services website. http://www.cms.hhs.gov/mcd/search.asp. Published October 1, 2015 (revised January 1, 2020). Accessed October 1, 2024.
19. Khera M. Treatment of male sexual dysfunction. UpToDate. www.uptodate.com. Published October 24, 2023. Accessed October 1, 2024.
20. Evidence analysis research brief: Volara (Hillrom) for respiratory therapy. Hayes. www.hayesinc.com. Published March 18, 2024. Accessed October 2, 2024.

21. Lauwers E, Ides K, Van Hoorenbeeck K, Verhulst S. The effect of intrapulmonary percussive ventilation in pediatric patients: A systematic review. *Pediatr Pulmonol*. 2018;53(11):1463 to 1474. doi:10.1002/ppul.24135
22. Huynh TT, Liesching TN, Cereda M, et al. Efficacy of Oscillation and Lung Expansion in Reducing Postoperative Pulmonary Complication. *J Am Coll Surg*. 2019;229(5):458 to 466.e1. doi:10.1016/j.jamcollsurg.2019.06.004
23. Aboussouan LS. Role of mucoactive agents and secretion clearance techniques in COPD. UpToDate. www.uptodate.com. Updated November 16, 2023. Accessed October 2, 2024.
24. Schiappa V, Piriano J, Bernhardt L, et al. RESNA Position on the Application of Seat-Elevation Devices for Power Wheelchair Users Literature Update. Rehabilitation Engineering and Assistive Technology Society of North America. https://www.resna.org/Portals/0/Documents/Position%20Papers/RESNA_App%20of%20Seat%20Elevation%20Devices%202019.pdf. Published September 25, 2019. Accessed October 2, 2024.
25. Beaudoin M, Lettre J, Routhier F, Archambault PS, Lemay M, Gélinas I. Long-term use of the JACO robotic arm: a case series. *Disabil Rehabil Assist Technol*. 2019;14(3):267 to 275. doi:10.1080/17483107.2018.1428692
26. Evolving evidence review: MyoPro Orthosis (Myomo Inc.) for Upper Extremity Paralysis/Paresis After Stroke. Hayes. www.hayesinc.com. Published March 6, 2023 (annual review March 18, 2024). Accessed November 19, 2024.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to

applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.