Clinical Policy: Durable Medical Equipment and Orthotics and Prosthetics Guidelines

Reference Number: MC.CP.MP.107 Coding Implications
Date of Last Revision: 08/25 Revision Log

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

Description

Durable medical equipment (DME) is defined as equipment that can withstand repeated use, is primarily and customarily used to serve a medical purpose, is appropriate for use in the home, and is generally not useful to a person in the absence of an illness or injury.[1] 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.[2] 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.

The policy criteria is sourced from the Medicare benefit policy manual, chapter 15 – covered medical and other health services; the Medicare claims processing manual, chapter 20 – durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS); and scientific studies and systematic reviews. The criteria below aim to guide utilization of DME that can be used safely and effectively by the member/enrollee, reducing the risk of injury and increasing the likelihood of benefit from the intended use of the equipment. Additionally, the references utilized help to ensure members/enrollees receive the appropriate treatment for their specific clinical situation, taking into account the severity of their condition, need for the equipment, and the expected therapeutic outcomes.

Policy/Criteria

I. It is the policy of health plans affiliated with Centene Corporation® 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: All of the following:

1. Equipment is necessary and reasonable for the treatment of an illness or injury or to improve the functioning of a physical deficit;*
2. Both of the following have been provided to the member/enrollee and/or caregiver, as applicable:
   a. Education regarding use of the device, with demonstrated understanding;
      A trial of the requested device, with demonstrated ability to use it safely and effectively.

***Note:**[3,4]

- Equipment is necessary when it can be expected to make a meaningful contribution to the treatment of the patient's illness or injury or to the improvement of his or her malformed body member.
- Although an item of DME may serve a useful medical purpose, additional considerations should be made to whether the item is reasonable, such as, whether the expense of the item is disproportionate to the therapeutic benefits, whether it is substantially more costly than a medically appropriate and realistically feasible alternative plan of care, and/or whether the item will serve essentially the same purpose as equipment already available.

- Additional "deluxe" features or items that are rented or purchased for aesthetic reasons or added convenience, do not meet the reasonableness test.
- 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

COMPRESSION THERAPY EQUIPMENT	CRITERIA	HCPCS
Non-pneumatic compression devices [6-9]	Not medically necessary, as there is insufficient clinical evidence to support the safety and effectiveness of non-pneumatic compression devices over the use of standard pneumatic compression devices.	E0678 E0679 E0680 E0681

PROSTHETICS AND ORTHOTICS EQUIPMENT	CRITERIA	HCPCS
Spinal Orthotics	Requests for spinal orthotics require mandatory secondary review by a medical director and/or therapy advisor.	L0700, L0710, L0720, L0999, L1000, L1001, L1005, L1006
Hip orthotics[10]	Medically necessary when ordered by an orthopedic surgeon for the treatment of, or postoperatively for any of the following: A. Total hip arthroplasty; B. Hip labral tear. Requests for hip orthotics for hip osteoarthritis in patients who are not surgical candidates will be reviewed on a case by case basis by a medical director and/or therapy advisor.	L1640 L1680 L1685 L1686 L1690
Prosthetics and additions: Upper Extremity and Myoelectric	Requests for upper extremity and myoelectric prosthetics require mandatory secondary review by a medical director and/or therapy advisor.	L6000, L6010, L6020, L6026, L6028, L6029, L6031, L6032, L6033, L6037, L6050, L6055, L6100, L6110, L6120, L6130, L6200, L6205, L6250, L6300, L6310, L6320, L6350, L6360, L6370, L6380, L6382, L6384, L6386, L6388,

PROSTHETICS AND ORTHOTICS EQUIPMENT	CRITERIA	HCPCS
		L6400, L6450, L6500, L6550, L6570, L6580, L6582, L6584, L6586, L6588, L6590, L6623, L6624, L6625, L6628, L6638, L6646, L6647, L6648, L6689, L6690, L6692, L6693, L6700, L6704, L6707, L6708, L6709, L6711, L6712, L6713, L6714, L6715, L6721, L6722, L6885, L6895, L6900, L6905, L6910, L6915, L6920, L6930, L6940, L6950, L6960, L6965, L6970, L6975, L7040, L7170, L7185, L7186, L7405, L7406, L7499
Breast Prosthetics[11-13]	Medically necessary post-masectomy or for treatment of gender dysphoria. If the request is for a custom prosthetic, accompanying documentation must state the reason why a prefabricated device is not adequate.	L8030 L8035
Myoelectric Rehabilitation Systems[14-17]	Not medically necessary, as there is insufficient evidence in published peer-reviewed literature to support the effectiveness of these devices.	E0738 E0739

WHEELCHAIRS	CRITERIA	HCPCS
Robotic Arm, Wheelchair-mounted (JACO)[18,19]	Not medically necessary, as there is insufficient clinical evidence to support safety and improved health outcomes of the JACO Assistive Robotic Arm (Kinova, Inc.) over other technologies.	E1399

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.	08/25	08/25

References

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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.