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Medical Policy Manual Durable Medical Equipment, Policy No. 88

General Medical Necessity Guidance for Durable Medical Equipment, Prosthetic, Orthotics and Supplies (DMEPOS)

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

The Durable Medical Equipment, Prosthetic, and Orthotic Services (DMEPOS) benefit originated with the Medicare program as part of the home health benefit under the Social Security Act to assist with medical needs within the home environment. The Centers for Medicare and Medicaid Services (CMS) provide guidance regarding the medical appropriateness for medical equipment and supplies.

MEDICAL POLICY CRITERIA

Notes:

- Member contracts for covered equipment and services vary. Member contract language takes precedence over medical policy. Items that are not covered benefits do not necessarily mean the items are not appropriate for the member, but only that the item falls outside of the member benefit contract.
- The services described in this medical policy may not be subject to routine medical necessity review unless they are addressed by a separate medical policy (see Cross References below). However, utilization may be subject to audit.

- IMPORTANT: While an item or component may be dispensed by a durable medical equipment (DME) supplier or professional provider it may not meet the definition of or classification of “durable medical equipment” or be eligible for coverage. This applies to items with some remote medically related use.[1]
- The health plan may defer to current policies, guidelines, and/or interpretations established by CMS to determine appropriateness of equipment and supplies.
- Claim adjudication is subject to claim processing guidelines and provider contracts and therefore, an item that meets medically necessary criteria is not guaranteed reimbursement.

I. A DME, prosthetic, orthotic or supply (DMEPOS) item may be considered **medically necessary** when the requested item meets all of the following criteria (A. – D.):

   A. Approved for marketing and registered or listed as a medical device by the Food and Drug Administration (FDA)[2] (See Policy Guidelines);

   B. Meets all of the necessary requirements to satisfy the definition of DME, prosthetic or orthotic (See Policy Guidelines);

   C. Is generally considered to be safe and effective for the purpose intended and is reasonable and medically necessary for the individual member when one or more of the following are met:

      1. When the health plan has criteria for a given DME, prosthetic, or orthotic item, the applicable medical policy coverage criteria are met; or

      2. Supplies and accessories necessary for the effective use of medically necessary DME (e.g., drugs and biologicals put directly into the equipment in order to achieve the therapeutic benefit of the DME, batteries to assure the proper functioning of the equipment, etc.).

      3. In the absence of a specific medical policy, the health plan defers to current CMS coverage guidance (e.g., coverage manual, NCD, LCD, etc.). (See Policy Guidelines)

   D. Meets the minimum specification for, and is the least costly, reasonable and medically necessary item, that meets the medical needs of the individual member (i.e., the item is not considered an upgraded or deluxe item). *Note, while items that are measured, assembled, fitted, or adapted in consideration of a patient's body size, weight, disability, period of need, or intended use or which been assembled using available customized features, modifications or components are considered to be “custom-fitted items,” these items do not meet the definition of “custom made,” upgraded, or deluxe.*

II. DMEPOS items are considered **not medically necessary** for any of the following.

   A. Items that do not meet Criteria I.

   B. Requests for new equipment which include additional or deluxe items or components that are not reasonable or necessary to meet, or are in excess of meeting, the member's medical need (see Cross References for medical policies that address upgrades to existing equipment or replacement requests which involve upgrades).

C. Accessories for any non-covered DMEPOS item (See the health plan's Reimbursement Policy for "Associated Claims," Administrative 119). *Note, accessories in this situation would be non-covered regardless of whether the original DMEPOS item was billed to the health plan.*

D. Transportation restraint systems, protective/safety equipment, and accessories (examples include, but are not limited to, the following: Manual or electric safety bed systems [e.g., SleepSafe, Posey Bed Enclosure Safety System, Vail Enclosure beds; this exclusion does not apply to rails or enclosures used in conjunction with medically necessary hospital-grade beds], bed exit monitors or alarms, fall detection systems, non-medical mobility devices [e.g., strollers; this exclusion does not apply to pediatric wheelchairs], fire extinguishers, first aid kits, grab bars, harnesses, protective helmets used to prevent injury to the head [this does not apply to cranial molding helmets or orthoses used to provide active treatment, such as avoid the need for surgery and/or to facilitate a successful post-surgical outcome, which may be allowed as DME], knee and elbow pads, safety items to protect or affect performance in sports-related activities, belts, restraints, safety goggles, service animals, smoke and carbon monoxide detectors, telephone alert systems, and vehicular restraint systems [e.g., EZ-On Vest], and incontinence pads/protective covers).

E. Items not expected to significantly improve the basic health status of the member as determined by a health plan medical director, contracted vendor, or consultant, for example items, supplies, and accessories which are not required for effective use of the device, even if the base equipment item itself is medically reasonable and necessary.

F. Items not approved for reimbursement by CMS, unless the health plan otherwise determines a HCPCS code to be approved for reimbursement or specifically includes a HCPCS code within a provider contract as potentially eligible for reimbursement (general requirements for coverage may still be applied). (See Policy Guidelines)

G. Items requested by or for an individual determined to be non-compliant with treatment.

H. Items requested for recreational purposes or which are inappropriate or not required for use in the member's home (e.g., a wheelchair or wheelchair equipment requested for use outside the home) or items determined to fall under the category of "exercise equipment."

I. Items requested for convenience or comfort of the member or caregiver, items requested to improve appearance, or that are not primarily medical in nature (e.g., massage devices, heat and massage pads, room or space heaters, whirlpool pump, sauna baths, air conditioners or purifiers, etc.).

J. Home or vehicle remodeling or modification to accommodate DME or patient condition (e.g., ramps, stair lifts, elevators, stair glides, wheelchair lifts, bathroom modifications, door modifications, etc.)

K. Medical supplies such as bandages, gauze, dressing, alcohol wipes used in the home unless used for a surgical or surgically treated wound or home dialysis.

L. Publicly available devices or software applications or monitoring used for non-medical purposes (e.g., home wireless internet [WiFi]).

M. Personal care items not specifically listed as a covered benefit. Examples include, but are not limited to, enuresis alarms, girdles, etc., even if ordered by a physician.

N. Equipment that duplicates the function of existing home equipment (e.g., adaptive seating devices [floor sitter, corner chair, etc.] for an individual with a wheelchair).

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

POLICY GUIDELINES

REGULATORY STATUS

All devices intended for human use require some level of regulation, however, not all devices and accessories will require specific FDA approval, depending on which "class" they fall under. Some devices require a Premarket Approval application (PMA). When a PMA is not required, then a 510(k) must be submitted to the FDA to demonstrate the device is as safe and effective (aka, substantially equivalent) to a legally marketed device, but some devices are exempt from this requirement as well.[3, 4]

The FDA categorizes medical devices and accessories into one of three classes – Class I, II, or III – based on their risks and the regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. Class I devices generally pose the lowest risk to the patient and/or user and Class III devices pose the highest risk.[5] Most Class I and some Class II devices are exempt from 510(k) requirements if the FDA determines that a 510(k) is not required to provide reasonable assurance of safety and effectiveness for the device; however, these devices are still subject to certain limitations or regulations, such as Medical Device Good Manufacturing Practices (GMPs).

This regulation extends to device *accessories*, which are devices intended to support, supplement, and/or augment the performance of one or more parent devices. Accessories are reviewed to evaluate "the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness of the accessory…" This review looks at the safety and effectiveness of the accessory only – it does not base any decision on the classification of any device the accessory is intended to be used with. Of note, while an item **can** be used in conjunction with a parent device, this does **not** automatically qualify it to be defined as an "accessory." For example, a mobile smart phone would not be considered an accessory, even if it is used for the purpose of downloading a medical application (app) because while the mobile smart phone may be compatible with medical devices, the mobile smart phone was not specifically intended for use with any single medical device.[6]

The classification and exemption status of an item can be found by searching by device name in the FDA Product Classification Database. In addition, FDA-approved indications and substantially equivalent decisions can be found by searching by device name in the FDA 510(k) Premarket Notification Database and viewing the Summary. Many common items will likely be considered FDA-approved without confirmation, assuming the item is requested for use consistent with the intended purpose (e.g., a wheelchair seat cushion may not have FDA

approval confirmed if requested for its intended purpose, as a seat cushion component of a wheelchair). However, utilization may be subject to audit as necessary.

Durable Medical Equipment Definition

Durable Medical Equipment (DME) is defined as equipment furnished by a DMEPOS supplier/provider or a home health agency which:

- Can withstand repeated use;
- Is primarily and customarily used to serve a medical purpose;
- Generally, is not useful to a person in the absence of an illness or injury;
- Is appropriate for use in the home; and
- Has a minimum lifetime requirement (MLR) of at least 3 years (for items reviewed and categorized on or after January 1, 2012).

Note: The 3-year MLR is a requirement for an item to be considered eligible for classification as DME. Items with an MLR of less than 3 years are ineligible to be considered DME because they do not meet the definition of the term “durable.” However, the MLR is not the reasonable useful lifetime (RUL) requirement for DME items. The RUL is used to determine how often it is reasonable to pay for the replacement of an item or component (see Cross References).

Of note, while an item or component may be supplied by a DMEPOS provider, or is useful to an individual or benefit them in some manner, that does not mean the item would be appropriately classified as "durable medical equipment" or would be eligible for coverage, even if the item has some remote medically-related use.

Prosthetics and Orthotics

Prosthetic devices are items which replace all or part of a body organ or limb. Examples include, but are not limited to, artificial limbs, parenteral and enteral (PEN) nutrition, cardiac pacemakers, prosthetic lenses, breast prostheses (including a surgical brassiere) for postmastectomy patients, maxillofacial devices, and devices which replace all or part of the ear or nose. However, dental items, such as dentures, are not considered prosthetic devices.

Orthoses are rigid or semi-rigid devices used for supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. Items that are not sufficiently rigid to be capable of providing the necessary immobilization or support to the body part for which it is designed would not meet this definition and therefore, would be noncovered.

MEDICARE COVERAGE GUIDANCE

Medicare coverage policies include, but may not be limited to, coverage manuals (e.g., the Medicare Benefit Policy Manual), national coverage determinations (NCDs), local coverage determinations (LCDs) and articles (LCAs).

- NCDs related to DMEPOS *(§280.1-280.15 addresses many DMEPOS items, but other sections of the NCD manual may also be used, including but not limited to, §10.2, §40.2-40.4, §50.1-50.4, §80.1, §80.4, §80.5, §80.12, §150.2, electrical stimulators in §160, home oxygen in §240, and wound treatment devices in §270).*
- Active Noridian LCDs and LCAs related to DMEPOS *(Many items addressed in NCDs also have applicable LCDs and LCAs).*
- The Noridian web page for Noncovered Items

Note: Not all items may have specific coverage criteria, but all items are still required to be medically reasonable **and** necessary according to the policy guidelines above, including meeting the definition of DMEPOS.

LIST OF INFORMATION NEEDED FOR REVIEW

DOCUMENTATION:

The following information is not required with every claim submission, but may be requested for audit of DME items. Requested information may include, but is not limited to, the following:

- Make/model and manufacturer name of equipment/device;
- Written and signed order or prescription (also referred to as Standard Written Order, or SWO) or certificate of medical necessity (CMN) from the treating provider;
- Medical records and chart notes relevant to the item or equipment requested; and,
- Other documentation as appropriate for the specific item or equipment under review.

CROSS REFERENCES

1. Definitive Lower Limb Prostheses, Durable Medical Equipment, Policy No. 18
2. Power Wheelchairs: Group 3, Durable Medical Equipment, Policy No. 37
3. Durable Medical Equipment, Prosthetic and Orthotic Upgrades, Replacements, Duplicates, and Repairs, Durable Medical Equipment, Policy No. 75
4. Durable Medical Equipment Policies, Medical Policy Manual Index
5. Reimbursement Policy Manual Web Page

BACKGROUND

The Durable Medical Equipment, Prosthetic, and Orthotic Services (DMEPOS) benefit originated with the Medicare program as part of the home health benefit under the Social Security Act, and as such, DMEPOS is limited to medical needs within the home environment.

All requirements of the definition must be met before an item is considered to be durable medical equipment. Supplies and accessories that are necessary for the effective use of medically necessary DME are covered if the DME item itself is covered. The term "durable medical equipment" includes but is not limited to, items such as wheelchairs, hospital beds, traction equipment, canes, crutches, walkers, CPAP/BiPAP devices, ventilators, oxygen services, home infusion pumps, pressure mattresses and patient lifts.

This policy is based on requirements established by the Centers for Medicare & Medicaid Services (CMS). The following definitions are applicable per CMS and in support of this policy.

> **Activities of Daily Living (ADLs):** Activities performed during a normal day, including but are not limited to, tasks such as eating, toileting, grooming, dressing, and bathing that are necessary to maintain or improve the client's health.[2]
>
> **Custom DME:** In order to be considered a customized DME item, the item (including a wheelchair) must be:
>
> > (a) uniquely constructed or substantially modified for a specific beneficiary according to a physician's description and orders (e.g., one-of-a-kind item, fabricated to meet specific needs) and

(b) so different from another item used for the same purpose that the two items cannot be grouped together for pricing purposes.[7]

Example: A wheelchair that must be custom built or substantially fabricated to accommodate the needs of wheelchair-confined conjoined twins facing each other. Such a chair would require significant modifications or custom fabrication to meet specific needs and would be unable to be grouped together with other types of wheelchairs.

Items which are measured, assembled, fitted, or adapted in consideration of a patient's body size, weight, disability, period of need, or intended use (i.e., custom *fitted* items) or items which have been assembled by a supplier, or ordered from a manufacturer, using available customized features, modifications or components do **not** meet the definition of "customized" because these items are not uniquely constructed or substantially modified and can be grouped with other items for pricing purposes. The use of "customized" options, custom ordered options/accessories or custom fitting of certain parts does not result in the equipment being considered as custom DME.

Home Setting: For purposes of rental and purchase of DME, a "home" is defined as the member's place of permanent residence. Permanent residence may include an individual's own dwelling (e.g., home or apartment), a relative's home, a home for the aged, or some other type of institution (such as an assisted living facility, or an intermediate care facility for individuals with intellectual disabilities (ICF/IID)). **Note**: Hospitals, skilled nursing facilities (SNFs), or any setting that exists primarily for the purpose of providing medical/nursing care are **not** considered a "home" for purposes of DME rental or purchase. ***IMPORTANT****: Medicare place of service (POS) rules with respect to DMEPOS claims will be applied during the claim adjudication process*.[8]

Medical Records: Means the physician's office records, hospital records, nursing facility records, home health agency records, records from other healthcare professionals, and diagnostic and test reports. For the purpose of payment, medical records do not include prescriptions or any records produced by the DMEPOS supplier/provider. Letters of "medical necessity" must be supported by clinical evidence in the actual medical records.

Practitioner/Clinician: Means an individual licensed pursuant to federal and state law to engage in the provision of health care services within the scope of the practitioner's license and certification. **Note:** Medicare rules regarding ordering providers will apply. While Medicare and member benefits within EOCs may allow coverage to see certain provider types (e.g., chiropractors, naturopaths, etc.), these providers may not be eligible to *order or supply* DMEPOS items under Medicare federal payment rules.[9]

Used equipment (DME): Any equipment that has been purchased or rented by someone before the current purchase transaction and equipment that has been used under circumstances where there has been no commercial transaction (e.g. equipment used for trial periods or as a demonstrator).[10]

MEDICAL NECESSITY

In order to be considered for coverage, DME items must be both medically necessary ***and*** reasonable.

Necessary and Reasonable

Although an item may be classified as DME, it may not be covered in every instance. Coverage in a particular case is subject to the requirement that the equipment be necessary and reasonable for treatment of an illness or injury, or to improve the functioning of a malformed body member. These considerations will bar payment for equipment which cannot reasonably be expected to perform a therapeutic function in an individual case or will permit only partial therapeutic function in an individual case. Equipment furnished that substantially exceeds the medical need for the treatment of the illness or injury involved will be denied.

Medical Necessity for the Equipment

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.

Reasonableness of the Equipment

Even though an item of DME may serve a useful medical purpose, the health plan will also consider to what extent, if any, it would be reasonable to pay for the item prescribed. The following considerations will enter into the determination of reasonableness:

1. Would the expense of the item to the program be clearly disproportionate to the therapeutic benefits which could ordinarily be derived from use of the equipment?
2. Is the item substantially more costly than a medically appropriate and realistically feasible alternative pattern of care?
3. Does the item serve essentially the same purpose as equipment already available to the beneficiary?

Equipment or items which contain features that are aesthetic in nature or which may be medical in nature but which are **not** required for the patient's condition or where there exists a reasonably feasible and medically appropriate alternative pattern of care which is less costly than the equipment requested, will be denied.

SUMMARY

According to the U.S. Centers for Medicare & Medicaid Services, the provision of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) may be considered medically reasonable and necessary when specific policy criteria are met, but are considered not medically reasonable or necessary when policy criteria are not met.

In addition, some items or accessories may be supplied by a DMEPOS provider, or are useful to an individual with some sort of benefit, but that does not mean the item would be appropriately classified as "durable medical equipment" or would be eligible for coverage, even if the item has some remote medically-related use.

REFERENCES

1. Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services, §110.1 - Definition of Durable Medical Equipment *(see all subsections)*. [cited 11/14/2023]. 'Available from:' https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.
2. National Coverage Determination (NCD) for *Durable Medical Equipment Reference List* (280.1). [cited 11/14/2023]. 'Available from:' https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=190&ncdver=2&DocID=280.1&bc=gAAAAAgAAAAA&.
3. U.S. Food & Drug Administration (FDA) Premarket Notification 510(k). [cited 11/14/2023]. 'Available from:' https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k.
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5. U.S. Food & Drug Administration (FDA) Overview of Medical Device Classification and Reclassification. [cited 11/14/2023]. 'Available from:' https://www.fda.gov/about-fda/cdrh-transparency/overview-medical-device-classification-and-reclassification.
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7. Social Security Act (SSA) Section 1862(a)(2).
8. Noridian DME web page for *Place of Service*. [cited 11/14/2023]. 'Available from:' https://med.noridianmedicare.com/web/jddme/claims-appeals/claim-submission/pos.
9. Noridian DME web page for *Orders*. [cited 11/14/2023]. 'Available from:' https://med.noridianmedicare.com/web/jadme/topics/documentation/orders.
10. CMS Glossary Web page. [cited 11/14/2023]. 'Available from:' https://www.cms.gov/apps/glossary/.
11. SSA §1861(s)(8) and (9).
12. Customized items; CFR §414.224(a).
13. Medicare Benefit Policy Manual, Chapter 20 - Medicare Claims Processing Manual, Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), §30.1.1 - Used Equipment *(see all subsections)*. [cited 11/14/2023]. 'Available from:' https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c20.pdf.
14. Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services, §120 - Prosthetic Devices. [cited 11/14/2023]. 'Available from:' https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.
15. Centers for Medicare and Medicaid Services (CMS) criteria. [cited 11/14/2023]. 'Available from:' https://www.cms.gov/medicare-coverage-database/search.aspx.
16. Noridian Local Coverage Article (LCA) for *Standard Documentation Requirements for All Claims Submitted to DME MACs* (A55426). [cited 11/14/2023]. 'Available from:' https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55426.

CODES

NOTE: Most DME, prosthetics, orthotics, and accessories have an applicable, specific HCPCS code available. Only when there is no appropriate descriptive code to use may an “unlisted code” (e.g., HCPCS codes E1399 or K0108) be reported. Inappropriate use of unlisted codes or failure to use specific codes when available may result in inaccurate reviews, denials, and/or recoupment of monies paid. This includes appropriate coding for customized equipment or components. Items that are measured, assembled, fitted, or adapted in consideration of a patient's body size, weight, disability, period of need, or intended use (i.e., custom *fitted* items) or which been assembled by a supplier, or ordered from a manufacturer using available customized features, modification or components do not meet the definition of customized items and the HCPCS code(s) for the standard version of the item should be used.

Codes	Number	Description
CPT	None	
HCPCS	None	

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