Clinical UM Guideline

Subject: Durable Medical Equipment

Guideline #: CG-DME-10Publish Date: 10/01/2024Status: ReviewedLast Review Date: 08/08/2024

Description

This document defines general principles used to determine the medical necessity of durable medical equipment (DME) **and** includes a general definition of DME, which is based on standard contract definitions of DME and the definition from the Centers for Medicare & Medicaid Services (CMS).

Note: As these criteria may not be the criteria used in the definition of DME within the covered individual's plan document, these criteria are not to be used for benefit determinations for a covered individual. Please see the definition of "durable medical equipment" in the covered individual's plan document for the purpose of making benefit determinations.

- Please check appropriate state mandates for laws that will supersede this document when applicable, such as those
 governing prosthetics.
- Any corporate medical policy or clinical UM guideline addressing the specific type of DME requested takes precedence
 over this guideline.
- Verify benefits and benefit exclusions. This document shall not be construed to require coverage for any device when the benefit plan excludes coverage of the device.
- This document shall not be construed to require coverage for any device when the FDA has determined its use to be contraindicated.

Clinical Indications

Definition:

Durable medical equipment is any equipment that meets all the following requirements:

- 1. Provides therapeutic benefits or enables the individual to perform certain tasks that the individual is unable to undertake otherwise due to certain medical conditions or illnesses; **and**
- 2. Can withstand repeated use: and
- 3. Is primarily and customarily used to serve a medical purpose; and
- 4. Generally is not useful to a person in the absence of an illness or injury; and
- 5. Is appropriate for use in the home but may be transported to other locations to allow the individual to complete instrumental activities of daily living (IADL), which are more complex tasks required for independent living.

DME must meet the following definitions of "durable" and "medical equipment":

- A. <u>Durable</u>. --An item is considered durable if it can withstand repeated use, that is, the type of item which could normally be rented. Medical supplies of an expendable nature such as incontinence pads, lambswool pads, catheters, ace bandages, elastic stockings, surgical face masks, irrigating kits, sheets and bags are not considered "durable" within the meaning of the definition. There are other items, which, although durable in nature, may fall into other benefit categories such as braces, prosthetic devices, artificial arms, legs, and eyes.
- B. <u>Medical Equipment</u>. --Medical equipment is equipment which is 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 determine 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 (hospitals, medical schools, medical societies) 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.

Medically Necessary:

Durable medical equipment is considered medically necessary when all of the following criteria are met:

- A. The requested item meets the definition of DME above; and
- B. The requested item has not otherwise been identified as not medically necessary or investigational and not medically necessary by a specific document; **and**
- C. There is adequate documentation in the medical records or in the claim submission of all of the following:
 - 1. The documentation substantiates that the physician exercised prudent clinical judgment to order or provide this equipment for an individual for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and in accordance with generally accepted standards of medical practice. Generally accepted

- standards of medical practice means standards that are based on credible scientific evidence published in peerreviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations and the views of physicians practicing in relevant clinical areas and any other relevant factors; **and**
- 2. There is a clinical assessment and associated rationale for the requested DME in the home setting, as evaluated by a physician, licensed physical therapist, occupational therapist, or nurse; **and**
- 3. There is documentation substantiating that the DME is clinically appropriate, in terms of type, quantity, frequency, extent, site and duration and is considered effective for the individual's illness, injury or disease; **and**
- 4. The documentation supports that the requested DME will restore or facilitate participation in the individual's usual IADL's and life roles; and
- 5. The requested DME is not primarily for the convenience of the individual, physician, caregiver, or other health care provider; **and**
- 6. The DME is not more costly than an alternative service, sequence of services, device or equipment, at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that covered individual's illness, injury or disease.

The information should include the individual's diagnosis and other pertinent functional information including, but not limited to, duration of the individual's condition, clinical course (static, progressively worsening, or improving), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc.

Not Medically Necessary:

Items not meeting the above criteria are considered **not medically necessary** including, but not limited to **any** of the following situations:

- 1. The item is intended to be used for athletic, exercise, or recreational activities as opposed to assisting the individual in the activities of daily living (either ADLs or IADLs); **or**
- 2. The item is intended for environmental control or a home modification (for example, electronic door openers, air cleaners, ramps, elevators, stair glides, wheelchair attachments or accessories for stair-climbing, etc.); **or**
- 3. The item includes an additional feature or accessory, or is a non-standard or deluxe item that is primarily for the comfort and convenience of the individual (for example, customized options on wheelchairs, hand controls to drive, electric vehicle lifts for wheelchairs, etc.); or
- 4. The item is specifically designed for outdoor use (for example, specially designed manual wheelchairs for beach access, specially designed power mobility devices for rough terrain, manual wheelchairs for sports, etc.); **or**
- 5. The item represents a duplicative piece of equipment that is intended to be used as a backup device, for multiple residences, or for traveling, etc. (for example, back-up manual wheelchair when a power wheelchair is the individual's primary means of mobility, a second wheeled mobility device specifically for work or school use, car seats); or
- 6. The item represents a product upgrade to a current piece of equipment that is either fully functional or replacement of a device when the item can be cost-effectively repaired.

Note: To the extent a particular type of DME is considered not medically necessary or investigational and not medically necessary, it may be addressed in a specific Medical Policy or Clinical UM Guideline.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

HCPCS

Including, but not limited to:

K0900 Customized durable medical equipment, other than wheelchair

Note: applies to any code for durable medical equipment when there is

not a more specific document available

ICD-10 Diagnosis

All diagnoses

When services are Not Medically Necessary:

For the procedure codes listed above when criteria are not met or for situations designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

The medical necessity of DME is based on an analysis of the following factors:

- 1. Whether or not the requested item is considered a piece of DME.
- 2. Whether or not the requested DME is considered medically necessary for the individual's specific clinical situation includes establishing the severity of the individual's condition and the immediate and long-term need for the equipment and the therapeutic benefits that the individual is expected to realize from its use. A claim of therapeutic effectiveness or benefit based on speculation or theory alone cannot be accepted. When restoration of function is cited as a reason for use of DME, the exact nature of the deformity or medical problem should be clear from the medical evidence submitted. Also, the manner in which the equipment or device will restore or improve the bodily function should be explained.

Definitions

Activities of daily living (ADLs): Self-care activities such as transfers, toileting, grooming and hygiene, dressing, bathing, and eating.

Instrumental activities of daily living (IADLs): Activities related to independent living and include preparing meals, managing money, shopping, doing housework and using a telephone; IADLs do not involve personal care activities.

References

Government Agency, Medical Society, and Other Authoritative Publications:

- 1. Centers for Medicare and Medicaid Services. Medicare Benefit Policy Manual. Available at: http://www.cms.hhs.gov/Manuals/downloads/bp102c15.pdf. Accessed on May 24, 2024.
- 2. Centers for Medicare and Medicaid Services. Durable Medical Equipment (DME) Center. Available at: http://www.cms.hhs.gov/center/dme.asp. Accessed on May 24, 2024.
- 3. Centers for Medicare and Medicaid Services. National Coverage Determination: Durable Medical Equipment Reference List. NCD #280.1. Effective May 5, 2005. Available at: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=190&ncdver=2&bc=AgAAgAAAAAA&. Accessed on May 24, 2024.

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History	D-4-	A - 45 - 11
Status	Date	Action
Reviewed	08/08/2024	Medical Policy & Technology Assessment Committee (MPTAC)
	00/40/0000	review. Updated References section.
Revised	08/10/2023	MPTAC review. Revised gender-specific language in the Clinical
		Indications and updated References section.
Reviewed	08/11/2022	MPTAC review. Updated References section.
Reviewed	08/12/2021	MPTAC review. Updated References section.
Reviewed	08/13/2020	MPTAC review. Updated References section. Reformatted Coding
		section.
Reviewed	11/07/2019	MPTAC review. Updated References section.
Reviewed	01/24/2019	MPTAC review. Updated References section.
Reviewed	02/27/2018	MPTAC review. Updated header language from "Current Effective
		Date" to "Publish Date." Updated Description and References
		sectios.
Reviewed	02/02/2017	MPTAC review. Updated formatting in Clinical Indications section.
		Updated Description and References sections.
Revised	02/04/2016	MPTAC review. Defined abbreviation in clinical indications criteria
		section. Updated References section. Removed ICD-9 codes from
		Coding section.
Reviewed	02/05/2015	MPTAC review. Updated Description.
Reviewed	02/13/2014	MPTAC review. Updated Description and Websites.
	07/01/2013	Updated Coding section with 07/01/2013 HCPCS changes.
Revised	02/14/2013	MPTAC review. Clarified not medically necessary statement and
		criteria deleting term DME and replacing with "item". Updated
		Websites.
Reviewed	02/16/2012	MPTAC review. Updated websites.
Reviewed	02/17/2011	MPTAC review. Clarified Note in clinical indication section. Update
· - · · - · · - · ·		Websites and References.
Revised	02/25/2010	MPTAC review.

		Clarified definition of durable medical equipment in Clinical Indications section and clarified Medically Necessary statement. Updated description, background and references.
Reviewed	02/26/2009	MPTAC review. References updated.
Reviewed	02/21/2008	MPTAC review. References updated.
Revised	03/08/2007	MPTAC review. Clarified definition, medically necessary criteria, not

medically necessary criteria and the discussion section.

Reviewed 12/07/2006 MPTAC review. References updated. New 12/01/2005 MPTAC initial guideline development.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

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