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MEDICAL POLICY



Medical Policy Title	Durable Medical Equipment (DME) and Devices, Standard and Non-Standard
Policy Number	1.01.00
Current Effective Date August 21, 2025	
Next Review Date	August 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to <u>Product Disclaimer</u>)

POLICY STATEMENT(S)

- I. Requests for Durable Medical Equipment (DME) or medical devices will be considered in accordance with any existing corporate medical policy criteria. Similarly, any existing applicable medical policies specific to a DME or device being considered will supersede this policy.
- II. The rental or purchase of standard (i.e., not designed or customized for a specific individual's use) DME is eligible for coverage, if determined to be medically necessary, when the equipment meets ALL of the following criteria:
 - A. is medically useful;
 - B. is generally not useful in the absence of illness or injury;
 - C. is ordered by a physician;
 - D. is primarily for use in the home;
 - E. can withstand repeated use;
 - F. can be used by successive individuals;
 - G. provides therapeutic benefits that cannot be achieved by other customary/standard methods.
 - **Please refer to the Policy Guideline section for additional information**
- III. Duplicate equipment is considered **not medically necessary**. Having more than one DME item that serves the same or similar function is considered a matter of member convenience.
- IV. DME Repair
 - A. Repair of a medically necessary DME or components not under warranty will be considered **medically appropriate** when the following criteria are met:
 - 1. Physician documentation includes **ALL** the following:
 - a. Date of DME initiation:
 - b. Manufacturer warranty information, if applicable;
 - c. Attestation that the individual has been compliant with the use of the DME and will

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continue to benefit from the use of the DME;

2. The DME is no longer functioning adequately; and **BOTH** of the following criteria are met:

- a. Inadequate DME function interferes with activities of daily living; and
- b. Repair is expected to make the equipment fully functional (as defined by manufacturer).
- B. Repair of equipment damaged due to individual neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

V. <u>DME Replacement</u>

- A. Replacement of a medically necessary DME or components not under warranty will be considered **medically appropriate** when **EITHER** of the following criteria are met:
 - 1. The DME is no longer functioning adequately and has been determined to be non-repairable, or the cost of the repair is in excess of the replacement cost;
 - 2. There is documentation that a change in the individual's condition makes the present unit non-functional and improvement is expected with a replacement unit.
- B. The replacement of a properly functioning DME, its components or accessories is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or to make the DME more aesthetically pleasing;
- C. The replacement of equipment damaged or lost due to individual neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.
- VI. Accessories or components for DME that are considered not medically necessary or investigational by peer-reviewed literature will also be considered as **not medically necessary** or **investigational** by the Health Plan.

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VII. The rental or purchase of standard (i.e., not designed or customized for a specific individual's use) medical devices is **eligible for coverage**, if determined to be **medically necessary**, when the specific criteria for that device are met.

VIII. <u>Device Repair</u>

- A. Repair of a medically necessary device or components not under warranty will be considered **medically appropriate** when the following criteria are met:
 - 1. Physician documentation includes **ALL** of the following:
 - a. Date of device implantation/initiation;

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b. Manufacturer warranty information, if applicable;

- c. Attestation that the individual has been compliant with the use of device and will continue to benefit from the use of device;
- 2. The device is no longer functioning adequately; and **BOTH** of the following criteria are met:
 - a. Inadequate device function interferes with activities of daily living; and
 - b. Repair is expected to make the equipment fully functional (as defined by manufacturer).
- B. Repair of equipment damaged due to individual neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage.**

IX. <u>Device Replacement</u>

- A. Replacement of a medically necessary device or components not under warranty will be considered **medically appropriate** when **EITHER** of the following criteria are met:
 - 1. The device is no longer functioning adequately and has been determined to be non-repairable, or the cost of the repair is in excess of the replacement cost;
 - 2. There is documentation that a change in the individuals condition makes the present unit non-functional and improvement is expected with a replacement unit.
- B. The replacement of a properly functioning device, its components or accessories is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or in order to make the device more aesthetically pleasing;
- C. The replacement of equipment damaged or lost due to individual neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.
- X. Accessories or components for a device that are considered not medically necessary or investigational by peer-reviewed literature will also be considered as **not medically necessary** or investigational by the Health Plan.

RELATED POLICIES

Corporate Medical Policy

#1.01.02 Continuous Passive Motion Device in the Home Setting

#1.01.03 Augmentative and Alternative Communication Systems (e.g., Speech- generating Devices)

#1.01.08 Patient Lifts, Seat Lift Chair Mechanisms, and Ceiling Lifts

#1.01.16 Wheelchairs and Power Operated Vehicles (POVs)

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#1.01.17 Powered Compression Devices/Lymphedema Pumps

#1.01.18 External Prosthetic Devices

#1.01.25 Orthotics

#1.01.46 Standing Devices and Gait Trainers

#1.01.51 Limb Pneumatic Compression Devices for Venous Thromboembolism Prophylaxis

#1.01.52 Vitrectomy Chair/Face-down Positioning System

#1.01.55 Electrical Stimulation as a Treatment for Pain and Other Medical Conditions

#1.01.56 Specialty Enclosure Bed Systems

#11.01.11 Comfort, Convenience, Custodial or Cosmetic Services

POLICY GUIDELINE(S)

- I. Eligibility for reimbursement is based upon:
 - A. The benefits set forth in the member's subscriber contract;
 - B. For items of DME not addressed by a specific Corporate Medical Policy, the decision to cover standard and/or non-standard items will be based on the medical necessity criteria set forth in this policy. Documentation and the individuals' situation will be considered in these determinations.
 - C. To qualify as standard DME, the following is required:
 - 1. Durable: The item must be able to withstand repeated use (e.g., it could normally be rented) and used by successive individuals;
 - 2. Used at home: The individual must live in one of the following places:
 - a. "private residence" where the individual receives care;
 - b. The individuals "dwelling," i.e., a house or an apartment;
 - c. A "relative's home:"
 - d. A "place of residence used as a home;" or
 - e. A "home for the aged" or retirement home;
 - **(Many institutions do not qualify as a "home." For example, a skilled nursing facility (SNF) or a hospital cannot be a DME "home;" however, a residential nursing home where the individuals reside can be.) **

D. <u>Medically useful</u>

1. The item's primary use must be medical. It must be ordered by a physician and is something that a healthy person would not ordinarily need.

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- 2. DME is not used solely for the purpose of hygiene (e.g., a shower chair). A bedside commode (or appropriate toileting device for those individuals unable to use a commode) is only considered DME for an individual who is bed bound, room-confined, or without toileting facilities in the home; or whose condition confines him/her to a floor of the home where no toileting facilities are located.
- 3. A signed physician order (e.g., prescription) is required to document that a physician orders the item.
- 4. DME is primarily and customarily used for a medical purpose and generally is not useful to a person in the absence of illness or injury; and
- E. Standard DME is not designed or customized for a specific individual's use.
- II. Medical supplies needed for the routine use of a DME item are eligible for coverage if the DME item is covered, even though the supplies, themselves, are not durable.
- III. Non-standard Durable Medical Equipment is any item of DME that has certain convenience or luxury features that make it more expensive than a standard item that will adequately meet the medical needs of the individuals.
- IV. Non-standard DME will be covered only when necessary and reasonable, as described more fully below. When a request is received for equipment with extra aesthetic features, or medical features that are not required by the individuals condition; or when there is a reasonably feasible and medically appropriate alternative pattern of care that is considered standard compared to the equipment requested, the Health Plan will authorize coverage of standard equipment or alternative treatment that meets the individuals medical needs.
 - A. Reasonableness Although an item of DME may serve a useful medical purpose, it must also be reasonable for coverage. The following will be considered:
 - 1. Would coverage of the non-standard item be clearly disproportionate to the therapeutic benefits that could ordinarily be derived from the use of the standard alternative pattern of care?
 - 2. Does the item serve essentially the same purpose as the standard equipment or pattern of care already available to the individual?
 - B. Medical Equipment Medical equipment is primarily and customarily used for medical purposes and is not generally useful in the absence of illness or injury. Equipment that can be useful in the absence of illness or injury (e.g., a blood pressure cuff) is **ineligible for coverage**.
 - C. Equipment that is presumptively non-medical in nature and used primarily and customarily for a non-medical purpose, even though the item may have some remote medically related use, will be considered a convenience item and not "medical equipment." Convenience items are **ineligible for coverage.**

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For example, devices and equipment used for environmental control or to enhance the environmental setting of the individual are not covered DME. While a cardiac individual may use an air conditioner to lower room temperature in an effort to reduce fluid loss or to maintain the proper fluid balance, the primary and customary use of the air conditioner is non-medical; therefore, the air conditioner is not considered medical equipment and is **ineligible for coverage**.

- V. Precise rationale is required for consideration of DME items for coverage. When non-standard DME items are requested, the individual medical condition of the member will be considered in determining medical necessity.
- VI. Coverage is limited to DME items that adequately meet the individuals medical needs. If non-standard equipment (e.g., with special features), is determined to be medically necessary for the individuals, coverage of the non-standard item will be authorized.
 - A. If the individual purchases or rents an item of DME having more non-standard features than the individuals condition requires, coverage is limited to the DME that is determined to be medically necessary to adequately meet the individual's needs.
- VII. DME may include coverage for the following:
 - A. Rental charges for equipment that can be rented for a cost less than the purchase price of the equipment;
 - B. Purchased equipment, when rental equipment is unavailable or when it is less expensive to purchase than to rent the equipment;
 - C. Supplies and accessories necessary for the effective functioning of the equipment;
 - D. Repair, adjustment or replacement of parts and accessories necessary for the normal and effective functioning of purchased equipment.

DESCRIPTION

Durable Medical Equipment

Durable Medical Equipment (DME) is any equipment that provides therapeutic benefits to an individual in need due to certain medical conditions and/or illness. DME consists of items, usually "equipment," that individuals use at home. Many in the industry find the term "home medical equipment" (HME) to be more representative of the products supplied, and the terms are often used interchangeably. Walkers, wheelchairs, ventilators, and hospital beds are examples of DME. DME excludes structural changes to an individual's home (e.g., ramps). DME refers to medical devices and equipment that can withstand repeated use (i.e., is durable), it's primarily and customarily used for medical purposes, is not generally useful to a person in the absence of illness or injury, is appropriate for use in the home, and is prescribed by a licensed healthcare provider.

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Medical devices are instruments, machines, implants, or other similar articles that are used to diagnose, prevent, monitor, treat, or alleviate diseases or medical conditions in humans. They work by physical, mechanical, or chemical, means unlike medications which work through metabolic or chemical actions in the body. Medical devices range from simple tongue depressors and bedpans to complex programmable pacemakers, nerve stimulators, and closed looped artificial pancreas systems. Medical devices can include in vitro diagnostic products such as reagents, test kits, and blood glucose meters. Certain radiation emitting electronic products that have a medical use or make medical claims are also considered medical devices.

SUPPORTIVE LITERATURE

Not Applicable

PROFESSIONAL GUIDELINE(S)

Not Applicable

REGULATORY STATUS

Medical Devices

The United States Food and Drug Administration (FDA) regulates medical devices. All medical devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Jul 18]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2025 Jul 18]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
Multiple codes	

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HCPCS Codes

Code	Description
Multiple codes	

ICD10 Codes

Code	Description
Multiple codes	

REFERENCES

Centers for Medicare & Medicaid Services [Internet]. Durable medical equipment, prosthetic devices, prosthetics, orthotics, & supplies. [modified 2025 May 5; accessed 2025 Jul 21]. Available from: <u>Durable Medical Equipment, Prosthetic Devices, Prosthetics, Orthotics, & Supplies | CMS</u>

U.S. Food & Drug Administration [Internet]. How to determine if your product is a medical device. [accessed 2025 Jul 21]. Available from: https://www.fda.gov/medical-devices/classify-your-medical-device#step1

SEARCH TERMS

Durable Medical Equipment (DME), Home Medical Equipment (HME)

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

NCD - Durable Medical Equipment Reference List (280.1) [accessed 2025 Jul 18]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

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• If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

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POLICY HISTORY/REVISION		
Committee Approval Dates		
04/25/02, 03/27/03, 05/22/03, 08/26/04, 02/24/05, 02/23/06, 12/07/06, 04/24/08, 04/23/09, 04/29/10, 08/25/11, 08/23/12, 08/22/13, 08/28/14, 08/27/15, 08/25/16, 08/25/17, 08/23/18, 08/22/19, 08/27/20, 08/19/21, 08/18/22, 08/17/23, 08/22/24, 08/21/25		
Date	Summary of Changes	
08/21/25	Annual review. Title was updated to include "medical devices". Policy statements were added for medical devices and also DME/Device repair and replacement.	
01/01/25	Summary of changes tracking implemented.	
10/18/01	Original effective date	