

Medical Policy Durable Medical Equipment (DME)

Policy Number: 018

	Commercial and Connector/Qualified Health Plans*	MassHealth*	Medicare Advantage
Authorization required Certain DME - See DME Prior Authorization List <u>DME Prior Authorization List</u>	Х	х	х
No Prior Authorization			
Not covered			

* Please refer to plan materials regarding individual coverage for DME.

Overview

The purpose of this document is to describe the guidelines Mass General Brigham Health Plan utilizes to determine the medical appropriateness of durable medical equipment (DME).

Coverage Guidelines

Mass General Brigham Health Plan provides coverage for FDA-approved DME when it is medically necessary for the treatment of illness or injury in order to improve or stabilize the member's condition or to improve functioning, can withstand repeated use over time, and when it is within the member's applicable benefit.

Coverage includes but is not limited to:

- 1. Purchase or rental: Mass General Brigham Health Plan determines whether it is appropriate to purchase or rent equipment for members
- 2. Replacement parts and repairs when the DME is no longer under warranty

A list of DME that requires prior authorization, including medical supplies, oxygen related equipment, orthotics, and hearing aids can be found under the <u>DME Prior Authorization List</u>.

DME requests should be submitted through a Mass General Brigham Health Plan contracted DME provider. Prior Authorization requests for DME submitted to Mass General Brigham Health Plan must include the following:

- 1. A written order signed and dated by the treating provider (who may be a physician, nurse practitioner, or physician assistant). Prior authorization requests can be written by someone other than the treating provider, but the treating provider must review, sign, and date the request before it is submitted to Mass General Brigham Health Plan.
- 2. The current treating provider's signature and NPI number with a signature date that is at least within 6 months of the request.
- 3. A description of the member's condition, abilities, limitations, and other factors contributing to the need for DME.
- 4. A summary of any previous treatment plan, including outcomes, that was used to treat the diagnosed condition for which the prescribed treatment is being recommended.



- 5. Medical justification for the specific item(s) being requested including a comparison evaluation of other similar equipment, and the expected outcome and therapeutic benefit of the requested item(s) or treatment.
- 6. A detailed description of the DME (brand names, model numbers, etc.), including all accessories and options that will be billed separately.
- 7. The quantity of the DME and the number of refills (if appropriate).
- 8. The equipment settings, hours to be used per day, options, or additional features, as they pertain to the DME.
- 9. How long the member will need the DME.
- 10. The start date of the order.
- 11. If applicable, documentation of a home trial/evaluation by a provider with certification in assistive technology who attests to the usability of the device in the member's home, and physical fit of the device in the home, including:
 - a. Adequate access for the DME into the home, access between rooms, maneuvering space, and surfaces for the operation of the DME.

Coverage Criteria for Durable Medical Equipment (DME)

Medical necessity for the following DME is determined through InterQual[®] criteria. To access the criteria, log into Mass General Brigham Health Plan's provider website at MassGeneralBrighamHealthPlan.org and click the InterQual[®] Criteria Lookup link under the Resources Menu.

- 1. Bone Growth Stimulators, Noninvasive
- 2. Cardioverter defibrillator, Wearable (WCD)
- 3. Continuous Glucose Monitors, Minimally Invasive¹
- 4. Hearing Aids²
- 5. Home Oxygen³
- 6. Hospital Beds⁴
- 7. Negative Pressure Wound Therapy (NPWT) Pump
- 8. Noninvasive Airway Assistive Devices (to treat Obstructive Sleep Apnea)
- 9. Orthoses, Cranial remodeling
- 10. Orthoses, Lower Extremity, Knee Family
- 11. Orthoses, Lower Extremity, Knee-Ankle-Foot (KAFO) and Ankle Foot (AFO)
- 12. Orthoses, Upper Extremity
- 13. Orthoses, Spinal (Thoracolumbosacral)
- 14. Patient Lift System
- 15. Pneumatic Compression Devices
- 16. Power Operated Vehicles (POV)
- 17. Prosthetics, Lower Extremity

⁴ The treating endocrinologist must sign a prescription for any requested insulin pump/supply at least yearly. In addition, the member's endocrinologist is responsible for providing all necessary clinical information for the determination of medical necessity including medical history, diabetes education received, treatment to date, glucose reading logs, pertinent laboratory testing, treatment plan, and medical necessity rational.



¹ The treating endocrinologist must sign a prescription for any requested continuous glucose monitor/supply at least yearly. In addition, the member's endocrinologist is responsible for providing all necessary clinical information for the determination of medical necessity including medical history, diabetes education received, treatment to date, glucose reading logs, pertinent laboratory testing, treatment plan, and medical necessity rational.

²Continue to use Mass General Brigham Health Plan's Hearing Devices Policy to review criteria for Bone-anchored healing devices and Brain stem implants.

³ Found under Home International Normalized Ratio (INR) Monitoring Device in InterQual

- 18. Prosthetics, Myoelectric, Upper Extremity⁵
- 19. Seat Lift Mechanism (covered for MassHealth members only)
- 20. Secretion Clearance Devices
- 21. Speech Generating Devices (SGD)
- 22. Standing Frames
- 23. Support Surfaces
- 24. Transcutaneous Electrical Nerve Stimulation (TENS)
- 25. Wheelchair cushions or seating system
- 26. Wheelchairs or strollers, pediatric
- 27. Wheelchairs, manual
- 28. Wheelchairs, power
- 29. Wheels, Power-Assist

Mass General Brigham Health Plan covers medically necessary FDA approved DME for members⁶ that meet General Eligibility Coverage Criteria and any applicable DME-specific criteria outlined in specific Mass General Brigham Health Plan medical policies or other plan documents. Mass General Brigham Health Plan covers medically necessary DME for all members when all the following are met:

- 1. It is not excluded in the member handbook or other plan documents.
- 2. It can withstand repeated use over an extended period of time or is a medical supply that is essential for the effective use of an approved DME item (e.g., oxygen tubing or mask).
 - a. The signed and dated treating provider's order must be within six months of the request.
- 3. The item should be used and is appropriate for use in a home setting. DME that is appropriate for use in the member's home may also be used in the community.
- 4. If applicable (e.g., power mobility devices), documentation of a home trial/evaluation must attest to the DME fit in the home, including: adequate access for the DME into the home and secure home storage, and adequate access between rooms, maneuvering space, and surfaces for the operation of the DME.
- 5. It is not serving a similar purpose as other DME already in use by the member, except when medical necessity supports a manual wheelchair back up to a power mobility system and when certain MassHealth regulations regarding power mobility systems apply.
- 6. It is part of a Mass General Brigham Health Plan-authorized home care program. DME, including rehabilitative and assistive technology items ordered for a member during an authorized home-health care plan, (see Mass General Brigham Health Plan's Home Health Care medical policy) is restricted to equipment that is:
 - a. Specifically related to the illness or injury for which skilled home health care plan is required
 - b. Integral to the skilled home health plan of care⁷
- 7. There is not an alternative service, sequence of services, device or equipment that is at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that member's illness, disease, or injury.
- 8. The requested DME is the most appropriate, least intensive, medically necessary model that adequately meets the medical needs of the member and/or allows the performance of activities of daily living.

⁶ If the member is a child, there must be social and clinical supports in place to assist in proper care and safe keeping of the DME and maintaining adherence. In the case of children, the burden of day-to-day management also rests with the caregivers, and every effort must be made to ensure that they are motivated and clearly committed to having the child gain the maximum benefit from the DME. ⁷DME needed beyond the authorized home care plan of care, or that is received after the authorized home care date span and exceeds the member benefit as outlined in member materials, is the responsibility of the member.



⁵ Continue to use Mass General Brigham Health Plan's Prostheses – Upper Limb for Body Powered Upper Limb Prosthesis.

- 9. The member does not exceed the manufacturer's recommended weight or height restrictions for the requested DME.
- 10. The requested DME can be safely and effectively managed by the member regarding the DME weight, stability, and power.
- 11. In the case of children who are still growing, the requested DME or its components are designed to optimize use over time by optimally adjusting to growth.
- 12. The member³ is highly motivated and able to gain the maximum benefit from the requested DME.
- 13. If the DME is for function, the member³ will reach or maintain a predicted improved functional state, with the use of the prescribed DME within a reasonable and predictable period of time.
- 14. The member³ is expected to be highly adherent in the use of the DME.
- 15. The member³ understands the DME functional limits and physical limitations, and understands and can demonstrate and ensure proper care, use, and safe keeping of the DME.
- 16. When specific medical policies and criteria have not been developed by Mass General Brigham Health Plan or by MassHealth, Mass General Brigham Health Plan may use relevant criteria from CMS National and Local Coverage Determination criteria specific to DME for medical necessity if deemed relevant.

Exclusions

Mass General Brigham Health Plan does not cover DME including but not limited to the following, when:

- 1. It is excluded in the member handbook or other plan documents
- 2. It is solely for non-medical purposes or in the absence of illness or injury, such as protective equipment, including eye wear, body protection and mouth guards used for sports and recreation
- 3. Services are not medically necessary (e.g., scalp cooling caps to prevent hair loss)
- 4. It will not improve or stabilize the member's condition or improve functioning, or it is suboptimal in producing the desired results and other acceptable options that can produce the desired outcome
- 5. It cannot withstand repeated use over an extended period of time, or it is not a medical supply that is essential (e.g., oxygen tubing or mask) for the effective use of an approved DME item
- 6. Coverage of power operated vehicles (scooters) when used for community use only (Commercial and qualified health plans only)
- 7. It is solely for the use in a school program
- 8. It is serving a similar purpose as other DME already in use by the member except when medical necessity supports a manual wheelchair back up to a power mobility system and when certain MassHealth regulations regarding power mobility systems apply
- 9. There is an alternative service, sequence of services, device or equipment that is at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that member's illness, disease, or injury
- 10. There is a more appropriate, less intensive model that adequately meets the medical needs of the member and/or allows the performance of activities of daily living
- 11. The DME or DME features/accessories would be principally used for convenience or would provide a non-medically necessary attribute, including but not limited to:
 - Standard ("off the shelf") batteries (e.g., including but not limited to battery sizes AAA, AA, A, C, D, etc.) except when used for and billed specifically for insulin pumps and/or continuous glucose monitors
 - b. Batteries for power mobility devices or wheelchairs that are not sealed
 - c. Exercise equipment, etc.
 - d. Massage devices
 - e. Air conditioners, dehumidifiers, whirlpools
 - f. Speed upgrade for power mobility device or power wheelchair
 - g. Therapeutic/molded shoes and molded inserts, except for diabetics when within benefit limits



- h. Orthotics/support devices for the feet for **commercial and qualified health plan** members. Please refer to Commercial plan materials for orthotic coverage as it varies by plan.
- 12. Home or vehicle modifications such as ramps, elevators, or stair lifts
- 13. The DME or DME features/accessories is/are primarily for recreational or avocational use
- 14. The DME or DME features/accessories is/are considered experimental and investigational per the Mass General Brigham Health Plan Experimental and Investigational Medical Policy
- 15. It is not FDA approved
- 16. Furniture and other items which are used to support covered DME
- 17. Functional electrical stimulation (FES) devices for home use as they are considered not medically necessary based on insufficient proof of long-term efficacy in current literature. Examples of these devices include but not limited to:
 - a. Bionicare Knee System
 - b. WalkAide
 - c. Odstock Dropped Foot Stimulator (ODFS) Pace
 - d. FES bikes
- 18. Myoelectric Orthosis (i.e., Myomo, Ottobock C-brace)

Mass General Brigham Health Plan does not cover certain services related to DME including but not limited to the following:

- 1. The replacement or repair of DME or its parts when:
 - a. It is still under manufacture warranty
 - b. It has not surpassed a reasonable useful lifetime of five years
 - c. It is lost, stolen or damaged due to improper care, or misuse, or neglect (Mass General Brigham Health Plan may require proof of the stolen or damaged item. Proof consists of a police report, pictures, or corroborating statement)
 - d. The member has a functioning model and a newer or upgraded model is not medically necessary
 - e. The cost of the repair is equal to or more than the cost of purchasing a replacement
- 2. The routine periodic testing, cleaning, regulating, or checking of DME
- 3. The evaluation or diagnostic tests conducted by the DME provider to establish the medical need for the DME

Medicare Variation

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies, including InterQual criteria as noted above, are used for coverage determinations. At the time of Mass General Brigham Health Plan's most recent policy review, Medicare has the following NCDs and LCDs for DME:

- Ankle-Foot/Knee-Ankle-Foot Orthosis (L33686)
- Automatic External Defibrillators (L33690)
- Bowel Management Devices (L36267)
- Canes and Crutches (L33733)
- Cervical Traction Devices (L33823)
- Cold Therapy (L33735)
- Commodes (L33736)
- Durable Medical Equipment Reference List (280.1)
- External Breast Prostheses (L33317)



- External Upper Limb Tremor Stimulatory Therapy (L39591)
- Eye Prostheses (L33737)
- Facial Prostheses (L33738)
- Heating Pads and Heat Lamps (L33784)
- High Frequency Chest Wall Oscillation Devices (L33785)
- Home Use of Oxygen (240.2)
- Hospital Beds and Accessories (L33820)
- INDEPENDENCE iBOT 4000 Mobility System (280.15)
- Infrared Heating Pad Systems (L33825)
- Intrapulmonary Percussive Ventilation System (L33786)
- Knee Orthoses (L33318)
- Manual Wheelchair Bases (L33788)
- Mechanical In-exsufflation Devices (L33795)
- Mobility Assistive Equipment (280.3)
- Nebulizers (L33370)
- Negative Pressure Wound Therapy Pumps (L33821)
- Neuromuscular Electrical Stimulation (NMES; 160.12)
- Oral Appliances for Obstructive Sleep Apnea (L33611)
- Orthopedic Footwear (L33641)
- Osteogenesis Stimulators (L33796)
- Ostomy Supplies (L33828)
- Oxygen and Oxygen Equipment (L33797)
- Patient Lifts (L33799)
- Power Mobility Devices (L33789)
- Pressure Reducing Support Surfaces Group 1 (L33830)
- Pressure Reducing Support Surfaces Group 2 (L33642)
- Pressure Reducing Support Surfaces Group 3 (L33692)
- Respiratory Assist Devices (L33800)
- Seat Elevation Equipment (Power Operated) on Power Wheelchairs (280.16)
- Seat Lift Mechanisms (L33801)
- Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (L36377)
- Spinal Orthoses: TLSO and LSO (L33790)
- Suction Pumps (L33612)
- Surgical Dressings (L33831)
- Therapeutic Shoes for Persons with Diabetes (L33369)
- Tracheostomy Care Supplies (L33832)
- Transcutaneous Electrical Joint Stimulation Devices (TEJSD; L34821)
- Transcutaneous Electrical Nerve Stimulators (TENS; L33802)
- Tumor Treatment Field Therapy (TTFT; L34823)
- Urological Supplies (L33803)
- Vacuum Erection Devices (VED; L34824)
- Walkers (L33791)
- Wheelchair Options/Accessories (L33792)
- Wheelchair Seating (L33312)
- Wound and Ulcer Care (L38902)



- Wound and Ulcer Care (L38904)
- Wound Care (L37228)

MassHealth Variation

Mass General Brigham Health Plan uses guidance from MassHealth for coverage determinations for its MassHealth members.

 In addition to the criteria above, see guidelines, inclusions, and exclusions for DME found in the MassHealth Provider Regulation and Provider Manuals, including but not limited to: Audiology, Durable Medical Equipment, Hearing Instrument Specialist, Orthotics, Oxygen and Respiratory Therapy Equipment, Podiatrist, and Prosthetics found at: <u>https://www.mass.gov/lists/masshealth-providermanuals</u> and MassHealth Guidelines for Medical Necessity Determination found at: <u>http://www.mass.gov/eohhs/provider/insurance/masshealth/clinical-treatment/medical-necessitydetermination</u>

2. Repair of retired serviceable power wheelchairs is covered in accordance with the Commonwealth of Massachusetts Executive Office of Health and Human Services, Office of Medicaid's administrative bulletin 22-14 effective July 1, 2022, under the following circumstances:

a) the DME provider must obtain prior authorization from the MassHealth agency or its designee as a prerequisite for any repair of a member's serviceable retired backup power wheelchair;

(b) the member's medical complexity prevents them from being able to use a manual wheelchair or suitable loaner power wheelchair when the primary mobility system needs repair;

(c) the total cost of the repair of the serviceable backup power wheelchair does not exceed \$1,000.00 per calendar year unless the MassHealth agency exercises discretion to approve the total cost of the repair. The MassHealth agency will review requests exceeding \$1,000.00 on a case-by-case basis;
(d) the MassHealth agency will only pay for the repair of one serviceable backup power wheelchair per calendar year;

(e) DME providers must document the serial number of the repaired serviceable backup power wheelchair and submit the documentation listed at 130 CMR 409.420(D)(2)(c), (d) and (e); and (f) all documentation regarding the repaired serviceable backup power wheelchair must remain in the member's file.

Definitions

<u>Accessories</u>: Products that are fabricated primarily and customarily to modify or enhance the usefulness or functional capability of another piece of equipment and that are generally not useful in the absence of that other piece of equipment.

<u>Customized Equipment</u>: Durable medical equipment that:

- 1. Is uniquely constructed, adapted, or modified solely for the full-time use of the patient for whom it is purchased;
- 2. Is made-to-order or adapted to meet the specific needs of the patient; and
- 3. The unique construction, adaptation or modification of the equipment permanently precludes the use of such equipment by another individual.

Durable medical equipment (DME) is defined as equipment which:

- 1. Can withstand repeated use
- 2. Is primarily and customarily used to serve a medical purpose
- 3. Generally, is not useful to a person in the absence of an illness or injury
- 4. Is appropriate for home use
- 5. Is principally for use in the home



Note: Equipment that Mass General Brigham Health Plan determines to be non-medical in nature and used primarily for non-medical purposes (even though that equipment may have limited medical use) will not be considered DME.

<u>Home Setting:</u> Any place where the member has established his/her place of residence for the time period when home care services are being provided. This may include his/her own dwelling, an apartment, the home of a friend or family member, a group home, a homeless shelter or other temporary place of residency or a community setting. It does not include hospitals, skilled nursing facilities, intermediate care facility for the developmentally disabled, or any other institutional facility providing medical, nursing, rehabilitative, or related care. A day care setting, adult day care, or adult medical care does not meet the definition of a home setting.

<u>Mobility System</u>: A manual or power wheelchair or other wheeled device, such as a scooter, including a base, a seating system, its components, accessories, and modifications.

<u>Seating Systems</u>: A seated positioning system, including its components, accessories, and modifications, which may be attached to a base wheelchair and is designed to meet the individualized medical needs of the patient.

<u>Used Equipment</u>: Any item that has been previously purchased or rented, including equipment that was:

- 1. Used by a patient for a trial period
- 2. Used by the supplier as a demonstrator
- 3. Rented by a patient who now wants to buy it

Relevant Regulation

MassHealth ACO Contract §2.6D

Massachusetts General Law: General or blanket policies; power to issue; non- applicability of sec. 108 (Home Care and DME); M.G.L.c. 176 § 110, K.

Massachusetts General Law: Coverage for prosthetic devices and repairs: M.G.L.c. 176 § 4S

Massachusetts General Law: Scalp hair prostheses necessary due to cancer or leukemia treatment, M.G.L. c.176 § 47T

Related Policies

- <u>Continuous Glucose Monitors</u>
- Home Health Care
- Hearing Devices
- Insulin Pumps
- Oral Maxillofacial Surgery and Procedures
- Oral and Maxillofacial Surgery Provider Payment Guidelines
- Durable Medical Equipment Provider Payment Guidelines

Effective

May 2025: Annual Review. Updated Medicare variation and added LCDs.

January 2025: Ad hoc Review. Added MassHealth variation language. Clarified exclusions to include scalp cooling caps. Fixed link to MassHealth provider manuals.

May 2024: Annual Review.

May 2023: Annual Review. Medicare Advantage added to table on page 1. Medicare Variation language added. References updated.

June 2022: Annual Review. The following changes were made:

 On page 2 under Coverage Criteria for Durable Medical Equipment, removed "Continuous Passive Motion Device (CPM)", "Home Prothrombin Time Monitoring Devices", "Insulin Pump, Ambulatory", and "orthoses or shoes for persons with diabetes" as these no longer require prior authorization.



- On page 5 under Exclusions:
 - Removed "It is not used and is not appropriate for use in a home setting", and its associated footnote.
 - Added language "Coverage of power operated vehicles (scooters) when use for community use only (Commercial and qualified health plans only)"

May 2021: Annual Review. References updated.

October 2020: Coverage criteria section changed; #23 Seat Lift Mechanism added text "Covered for MassHealth members only"

June 2020: Annual Review. Under General coverage criteria, changed item #3; language on appropriate for use in a home setting. Under Exclusions; revised #6 to reflect language on home setting. Under Exclusion; added the Ottobock C-Brace.

October 2019: Annual Review.

October 2018: Annual Review. Removed footnote on item 11 on page 2 under subheading Coverage Criteria for Durable Medical Equipment (DME) that restricted devices for OSA for MassHealth members. Revised exclusion 11 h specifying orthotic coverages varies by plan design.

August 2017: Annual Review. Added two DME items to InterQual criteria list; Home Prothrombin Time Monitoring Devices, and Noninvasive Airway Assistive Devices (to treat Obstructive Sleep Apnea). Added Functional electrical stimulation devices as an exclusion. Moved language regarding MassHealth members to page 1 for clarity. Added reference.

April 2017: Ad hoc Review. Changes reflect the addition of InterQual[®] criteria for the applicable DME listed in this policy.

April 2016: Effective date

References:

MassHealth Provider Manuals

http://www.mass.gov/eohhs/gov/laws-regs/masshealth/provider-library/provider-manual/

MassHealth Guidelines for Medical Necessity Determination: <u>https://www.mass.gov/lists/masshealth-guidelines-for-medical-necessity-determination</u>

CMS Local Coverage Determination for Massachusetts for DME

Local Coverage Determinations (LCDs) for Noridian Healthcare Solutions, LLC. (DME MAC, 16013, Jurisdiction A)

Centers for Medicare & Medicaid Services. National Coverage Determination (NCD): Durable Medical Equipment Reference List (280.1) Implementation Date: 07/05/2005. Available: https://www.cms.gov/medicare-coverage-database/search.aspx

Hayes, Inc. Health Technology Assessment. Functional Electrical Stimulation for Rehabilitation Following Spinal Cord Injury. Lansdale, PA: Hayes, Inc. November 16, 2017. Annual Review February 26, 2020.

Hayes, Inc. Health Evidence Analysis Research Brief. MyoPro Orthosis (Myomo Inc.) to Improve Upper Extremity Function and Elbow Range of Motion in Patients with Cerebral Palsy. Lansdale, PA: Hayes, Inc. July 21, 2020.

Hayes, Inc. Health Evidence Analysis Research Brief. MyoPro Orthosis (Myomo Inc.) for Upper Extremity Paralysis/Paresis After Stroke. Lansdale, PA: Hayes, Inc. July 21,2020.

Hayes, Inc. Health Technology Brief. Functional Electrical Stimulation (FES) for Treatment of Foot Drop in Multiple Sclerosis Patients. Lansdale, PA: Hayes, Inc. July 16, 2015, Annual Review June 27, 2017. Archived August 16, 2018



Hayes, Inc. Hayes Technology Review. BioniCare Knee System (VQ OrthoCare) for Treatment of Osteoarthritis of the Knee. October 18, 2013, Archived November 17, 2014.

Hayes, Inc. Evidence Analysis Research Brief. C-Brace (Ottobock) for Mobility and Stability Following Paralysis of the Lower Extremity. Lansdale, PA: Hayes, Inc. January 17, 2020.

