Durable Medical Equipment, Prosthetics and Orthotics

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<tr>
<th>Policy Number:</th>
<th>Current Effective Date:</th>
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<tr>
<td>MM.01.002</td>
<td>September 27, 2019</td>
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<tr>
<th>Lines of Business:</th>
<th>Original Effective Date:</th>
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<tr>
<td>HMO; PPO</td>
<td>May 21, 1999</td>
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<tr>
<th>Place of Service:</th>
<th>Precertification:</th>
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<td>Home</td>
<td>Required, see Section IV</td>
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I. Description
Durable medical equipment (DME) is equipment that can withstand repeated use, is primarily and customarily used to serve a medical purpose, is generally not useful to a person in the absence of a medical condition, and is appropriate for use in the home.

Prosthetics are artificial substitutes that replace all or part of a body organ, or replace all or part of the function of a permanently inoperative, absent, or malfunctioning body part.

Orthotics are rigid or semi-rigid supportive devices used to protect, restore, or improve body function.

II. Policy Criteria
Durable medical equipment, prosthetics and orthotics are covered (subject to Limitations and Administrative Guidelines) when all of the following criteria are met:
A. The item meets the definition of DME, prosthetics or orthotics as described above (see Description).
B. The item is used in the home. Home means the place where the member lives, other than a hospital or skilled or intermediate nursing facility.
C. The item is ordered by the treating physician.
D. The item is FDA approved for the purpose that it is being prescribed.
E. Criteria for the specific DME, orthotic or prosthetic as stated in the sources below are met:
   1. HMSA has developed specific policies for the following items. Click on the link to be directed to the policy located in the Provider E-library.
      - Continuous Glucose Monitoring System
      - Compression Garments (Gradient) for the Extremities
      - High Frequency Chest Wall Oscillation Devices
      - Insulin Pumps - External
      - Knee Orthoses for Osteoarthritis
      - Negative Pressure Wound Therapy (NPWT)
      - Oxygen and Oxygen Equipment
      - Positive Airway Pressure and Oral Devices for the Treatment of Obstructive Sleep Apnea
      - Pulse Oximeter for Children
      - Breast Pumps
   2. In the absence of an HMSA medical policy addressing specific durable medical equipment (DME), orthotic or prosthetic coverage determination criteria in the following sources will be used to determine medical necessity:
      a. Medical necessity criteria under Hawaii Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes § 432E-1.4), which state that the drug must be:
i. For the purpose of treating a medical condition;
ii. The most appropriate delivery or level of service, considering potential benefits and harms to the patient;
iii. Known to be effective in improving health outcomes; provided that:
   a. Effectiveness is determined first by scientific evidence;
   b. If no scientific evidence exists, then by professional standards of care; and
   c. If no professional standards of care exist or if they exist but are outdated or contradictory, then by expert opinion; and
iv. Cost-effective for the medical condition being treated compared to alternative health interventions, including no intervention. For purposes of this paragraph, cost-effective shall not necessarily mean the lowest price.

b. Noridian - Durable Medical Equipment
c. Medicare National Coverage Determinations
d. Noridian - Part A/B

III. Limitations
The following items are not covered:
A. Items that do not meet the definition of DME, prosthetics or orthotics as noted above.
B. Items that are excluded under the patient's plan benefits.
C. Items that represents a duplicative piece of equipment that is intended to be used as a back-up device, for multiple residences, or for traveling, etc. (e.g., back-up manual wheelchair when a power wheelchair is the member's primary means of mobility, a second wheeled mobility device specifically for work or school use); or
D. Items that meet the same medical need as the current item, but in a more efficient manner or is more convenient, when there is no change in the member's condition.
E. Items that are not primarily medical in nature (e.g., environmental control equipment, comfort or convenience item, hygienic equipment, exercise equipment and educational equipment), with the exception of Quest Integration, which covers hygienic equipment when medically necessary.
F. Items used primarily for participation in sports, exercise, or leisure activities.
G. Institutional equipment that will be used in the home setting with the exception of breast pumps and pulse oximeters for children (subject to member benefits).
H. Items that are not therapeutic in nature (e.g., emergency first-aid or precautionary equipment including but not limited to back-up equipment).
I. Items that are only necessary for use outside the home and not necessary for use inside the home.
J. Supplies and accessories used with DME when criteria are not met for the DME.

IV. Administrative Guidelines
A. Precertification is required for the following items. To precertify, complete HMSA's Precertification Request and mail or fax the form and all applicable documentation from the medical record, including the signed and dated written order by the treating physician, as indicated.
   1. Continuous glucose monitoring system
   2. Custom-fabricated knee orthosis
   3. External Prosthetic devices exceeding $10,000 in charges
   4. High frequency chest wall oscillation device
   5. Hospital grade breast pump
6. Insulin pump, external
7. Negative pressure wound therapy (NPWT)
8. Oral Appliances for the Treatment of Obstructive Sleep Apnea
9. Oxygen and oxygen equipment (as specified in the policy)
10. Pneumatic compression device
11. Pulse oximeter for children
12. Respiratory assist device (bi-level positive airway pressure device)
13. Spinal cord stimulator for pain management
14. TENS unit
15. Ventilators
16. Items that are uniquely constructed or substantially modified based on the member’s specific need. Please include a complete and clear description of the item.
17. Adult wheelchairs with HCPCS codes K0004, K0005, K0008 and K0009
18. Power mobility devices (PMDs) with HCPCS codes K0013, K0800-K0898 and push-rim activated power assist devices with HCPCS code E0986
19. Standing frames with HCPCS codes E0637, E0638, E0641 and E0642
20. Gait trainers with HCPCS codes E8000, E8001 and E8002
21. Replacement external speech processor for cochlear implants with HCPCS codes L8619, L8627 and L8628
22. Any DME coded with a miscellaneous HCPCS code (i.e., E1399, K0108 and/or K0900)

B. For items that do not require precertification, documentation supporting medical necessity should be legible, maintained in the patient’s medical record and must be made available to HMSA upon request. HMSA reserves the right to perform retrospective review using the above criteria to validate if services rendered met payment determination criteria.

C. DME can be rented or purchased, depending on the length of time the equipment is needed. The decision whether to rent or purchase durable medical equipment is made by HMSA. HMSA has adopted the Medicare category for capped rental items which are available as rentals only.

D. In general, Medicare criteria for repairs, maintenance, and replacement apply.
   1. For DME, this information is available in Noridian/Medicare Jurisdiction D DME Supplier Manual, Chapter 5, DMEPOS. Of note is that if an item of DME is in good working order and meets the patient’s medical needs, it should not automatically be replaced based on the age of the DME.
   2. Replacement of an orthotic, prosthetic device that is an artificial limb, or replacement part of a prosthetic device is covered if the ordering physician determines that the device is still medically necessary and that the replacement device or part is necessary because of any of the following:
      a. A significant change in the physiological condition of the patient;
      b. Irreparable wear of the device, or in a part of the device;
      c. The condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost of a replacement device, or, as the case may be, of the part being replaced;
      d. Loss; or
      e. Irreparable accidental damage.
   3. In general, the cost of repair will be covered when it is more cost effective to repair than replace the item.
4. HMSA will only pay for one month of a loaner item per repair incident. If at a later time the equipment needs to be fixed again, HMSA may consider payment for another loaner item.

E. Suppliers are responsible for monitoring utilization of DMEPOS rental items and supplies. Suppliers must discontinue billing when rental items or ongoing supply items are no longer used by the patient.

F. Break in service
   1. For an item described by the same code, a new capped rental period begins if there has been an interruption in the medical necessity for the item and the interruption lasted for 60-plus consecutive days. A 60-plus consecutive day interruption is defined as a period including two full rental months plus whatever days are remaining in the rental month during which the need ends.
   2. For an item described by a different code, a new capped rental period would begin if there is a substantive change in the patient’s condition that necessitates a significantly different item. The claim for these items must include, but is not limited to:
      a. A description of the patient’s prior medical condition that necessitated the previous item
      b. A statement explaining when and why the medical necessity for the previous item ended; and
      c. A statement explaining the patient’s new or changed medical condition and when the new need began.

V. Important Reminder
   The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

   Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VI. References
2. Noridian/Medicare Durable Medical Equipment website- Noridian DME.