Coverage Summary

Durable Medical Equipment, Prosthetics, Corrective Appliances/Orthotics and Medical Supplies

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The benefit information in this Coverage Summary is based on existing national coverage policy, however, Local Coverage Determinations (LCDs) may exist and compliance with these policies are required where applicable.

INDEX TO COVERAGE SUMMARY

I. COVERAGE
   1. DME Rental or Purchase
   2. Prosthetic and Corrective Appliances/Orthotics
   3. Supplies for DME, Prosthetic Devices and Corrective Appliances
   4. Repairs, Maintenance and Replacement
   5. Medical Supplies
   6. Examples of Services that are Not Covered

II. DEFINITIONS

III. REFERENCES

IV. REVISION HISTORY

I. COVERAGE

Coverage Statement: Durable medical equipment (DME), prosthetic, corrective appliance/orthotic and medical supplies are covered when Medicare coverage criteria are met.

Guidelines/Notes:
1. DME maybe rented or purchased and must meet all of the following criteria:
   a. The equipment meets the definition of DME (see Definitions)
   b. The equipment is necessary and reasonable for the treatment of the member’s illness or injury or to improve the functioning of his/her malformed body member
   c. The equipment is used in the member’s home (see Definitions)

Note: See the Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/Orthotics (Non-Foot Orthotics) and Medical Supplies Grid for the list of items and specific coverage
information.

DME Face to Face Requirement: Effective July 1, 2013, Section 6407 of the Affordable Care Act (ACA) established a face-to-face encounter requirement for certain items of DME. For DME Face to Face Requirement information, refer to the Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/Orthotics (Non-Foot Orthotics) and Medical Supplies Grid. This does not apply to Power Mobility Devices (PMDs) as these items are covered under a separate requirement. See the Coverage Summary for Mobility Assistive Equipment (MAE).

2. Prosthetic devices and corrective appliances/orthotics must meet all of the following criteria:
   a. The item meets the definition of prosthetic or corrective appliances/orthotics (see Definitions).
   b. The item is furnished on a physician's order.

See the Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/Orthotics (Non-Foot Orthotics) and Medical Supplies Grid for the list of items and specific coverage information.


3. Supplies for DME Items, Prosthetic Devices and Corrective Appliances
   Supplies for DME items, prosthetic devices and corrective appliances (e.g., oxygen, batteries for an artificial larynx) are covered only when they are necessary for the effective use of the item/device. For specific coverage guideline, see the Medicare Benefit Policy Manual, Chapter 15, §110.3 - Coverage of Supplies and Accessories. (Accessed June 12, 2017)

4. Repairs, Maintenance and Replacement
   a. Durable Medical Equipment
      1) Repair
         Repairs to equipment which a beneficiary owns are covered when necessary to make the equipment serviceable. However, do not pay for repair of previously denied equipment or equipment in the frequent and substantial servicing or oxygen equipment payment categories. If the expense for repairs exceeds the estimated expense of purchasing or renting another item of equipment for the remaining period of medical need, no payment can be made for the amount of the excess.

      2) Maintenance
         Routine periodic servicing, such as testing, cleaning, regulating, and checking of the beneficiary’s equipment, is not covered. The owner is expected to perform such routine maintenance rather than a retailer or some other person who charges the beneficiary. Normally, purchasers of DME are given operating manuals which describe the type of servicing an owner may perform to properly maintain the equipment. It is reasonable to expect that beneficiaries will perform this maintenance. Thus, hiring a third party to do such work is for the convenience of the beneficiary and is not covered.

         However, more extensive maintenance which, based on the manufacturers’ recommendations, is to be performed by authorized technicians, is covered as repairs for medically necessary equipment which a beneficiary owns. This might
include, for example, breaking down sealed components and performing tests which require specialized testing equipment not available to the beneficiary.

3) **Replacement**

Replacement refers to the provision of an identical or nearly identical item. Situations involving the provision of a different item because of a change in medical condition are not addressed in this section.

Equipment which the beneficiary owns or is a capped rental item may be replaced in cases of loss or irreparable damage. Irreparable damage refers to a specific accident or to a natural disaster (e.g., fire, flood). A physician’s order and/or new Certificate of Medical Necessity (CMN), when required, is needed to reaffirm the medical necessity of the item.

Irreparable wear refers to deterioration sustained from day-to-day usage over time and a specific event cannot be identified. Replacement of equipment due to irreparable wear takes into consideration the reasonable useful lifetime of the equipment. **If the item of equipment has been in continuous use by the patient on either a rental or purchase basis for the equipment’s useful lifetime, the beneficiary may elect to obtain a new piece of equipment. Replacement may be reimbursed when a new physician order and/or new CMN, when required, is needed to reaffirm the medical necessity of the item.**

The reasonable useful lifetime of durable medical equipment is determined through program instructions. In the absence of program instructions, UnitedHealthcare may determine the reasonable useful lifetime of equipment, but in no case can it be less than 5 years. Computation of the useful lifetime is based on when the equipment is delivered to the beneficiary, not the age of the equipment. **Replacement due to wear is not covered during the reasonable useful lifetime of the equipment. During the reasonable useful lifetime, Medicare does cover repair up to the cost of replacement (but not actual replacement) for medically necessary equipment owned by the beneficiary.**

*See the Medicare Benefit Policy Manual, Chapter 15, §110.2 - Repairs, Replacement and Maintenance and Delivery. (Accessed June 12, 2017)*

b. **Prosthetic Devices**

Payment may be made for the replacement of a prosthetic device that is an artificial limb, or replacement part of a device if the ordering physician determines that the replacement device or part is necessary because of any of the following:

1. A change in the physiological condition of the patient;
2. An irreparable change in the condition of the device, or in a part of the device; or
3. 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.

This provision is effective for items replaced on or after April 1, 2001. It supersedes any rule that that provided a 5-year or other replacement rule with regard to prosthetic devices.

*See the Medicare Benefit Policy Manual, Chapter 15, §120 - Prosthetic Devices.*
c. **Corrective Appliances**

Adjustment of corrective appliances are covered when required by wear or a change in the patient's condition and ordered by a physician.


5. **Medical Supplies**

a. Medical supplies are covered only when they are incident to a physician's professional services or authorized home health services and are furnished as an integral, although incidental, part of those services in the course of diagnosis or treatment of an injury or illness. *See the Medicare Benefit Policy Manual, Chapter 15, §60.1 - Incident to Physician’s Professional Services.* (Accessed June 12, 2017)

b. Medical supplies are expendable items required for care related to a medical illness or dysfunction. *See the Medicare Benefit Policy Manual, Chapter 15, §110.1 - Definition of Durable Medical Equipment.* (Accessed June 12, 2017)

c. Medical supplies may not be billed as implantable devices *(see Definitions)*

*See the Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/Orthotics (Non-Foot Orthotics) and Medical Supplies Grid for the list of items and specific coverage information.*

6. The following are examples of services that are not covered:

a. Routine periodic maintenance (e.g., testing, cleaning, regulating and checking equipment) for which the owner is generally responsible.

*See the Medicare Benefit Policy Manual, Chapter 15, §110.2 - Repairs, Replacement and Maintenance and Delivery.* (Accessed June 12, 2017)

b. Replacement of items due to malicious damage, neglect or wrongful disposition of item.

*See the Medicare Benefit Policy Manual, Chapter 15, §110.2 - Repairs, Replacement and Maintenance and Delivery.* (Accessed June 12, 2017)

c. Additional accessories to DME, corrective appliances or prosthetics which are primarily for the comfort or convenience of the member, including home remodeling or modification to home or vehicle.

*See the Medicare Benefit Policy Manual, Chapter 15, §110.3 - Coverage of Supplies and Accessories.* (Accessed June 12, 2017)

For additional coverage guidelines, see the Medicare Benefit Policy Manual, Chapter 15, §110 – §130. (Accessed June 12, 2017)

For general instructions on billing and claims processing, refer to the Medicare Claims Processing Manual, Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). (Accessed June 12, 2017)

**II. DEFINITIONS**

**Corrective Appliances/Orthotic:** Devices that are designed to support a weakened body part.
These appliances are manufactured or custom-fitted to an individual member. [This definition does not include foot orthotics or specialized footwear which may be covered for member with diabetic foot disease.] *Medicare Claims Processing Manual, Chapter 20, §10.1.3 – Prosthetics and Orthotics (Leg, Arm, Back, and Neck Braces, Trusses, and Artificial Legs, Arms, and Eyes) - Coverage Definition*. (Accessed June 12, 2017)

**Durable Medical Equipment (DME):** Equipment that 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, and is appropriate for use in the home. *Medicare Benefit Policy Manual, Chapter 15, §110.1 - Definition of Durable Medical Equipment*. (Accessed June 12, 2017)

**Implantable Devices:** Defined by the FDA as a device that is placed into a surgically or naturally formed cavity of the human body if the device is intended to remain there for a period of 30 days or more. In order to protect public health, the FDA may determine that devices placed in subjects for shorter periods of time are also implants.

According to Medicare, these devices are used as an integral and subordinate part of the procedure performed, are used for one patient only, are single use, come in contact with human tissue, and are surgically implanted or inserted whether or not they remain with the patient when the patient is released from the hospital outpatient department. The following are not considered to be implantable devices: sutures, customized surgical kits, or clips, other than radiological site markers, furnished incident to a service or procedure. They are also not materials such as biologicals or synthetics that may be used to replace human skin. *FDA - Medical Devices, IDE Definitions and Acronyms, Medicare Claims Processing Manual, Chapter 4, §60.3 - Devices Eligible for Transitional Pass-Through Payments*. (Accessed June 12, 2017)

**Member’s Home:** For the purposes of rental and purchase of DME, the member’s home may be his own dwelling, an apartment, a relative’s home, a home for the aged, or some other type of institution. However, an institution may not be considered the member’s home if it:

Meets at least the basic requirement in the definition of a hospital (i.e., it is primarily engaged in providing, by or under the supervision of physicians, to inpatients, diagnostic and therapeutic services for medical diagnosis, treatment, and care of injured, disabled and sick persons, or rehabilitation services for the rehabilitation of injured, disabled or sick persons).

Meets at least the basic requirement in the definition of a skilled nursing facility (i.e., it is primarily engaged in providing skilled nursing care and related services to inpatients who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled or sick persons). *Medicare Benefit Policy Manual, Chapter 15, §110.1 - Definition of Durable Medical Equipment (4)(D)*. (Accessed June 12, 2017)

**Prosthetic Device:** Articles or equipment, other than dental, that replace all or part of an internal body organ (including contiguous tissue) or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ. In this policy the test of permanence is met if the medical record, including the judgment of the attending physician, indicates that the member’s condition is of long and indefinite duration. *Medicare Benefit Policy Manual, Chapter 15, §120 - Prosthetic Devices*. (Accessed June 12, 2017)

**Other durable medical equipment - capped rental:**

(a) **General payment rule.** Payment is made for other durable medical equipment that is not subject to the payment provisions set forth in §414.220 through §414.228 as follows:
(1) For items furnished prior to January 1, 2006, payment is made on a rental or purchase option basis in accordance with the rules set forth in paragraphs (b) through (e) of this section.

(2) For items other than power-driven wheelchairs furnished on or after January 1, 2006, payment is made in accordance with the rules set forth in paragraph (f) of this section.

(3) For power-driven wheelchairs furnished on or after January 1, 2006 through December 31, 2010, payment is made in accordance with the rules set forth in paragraphs (f) or (h) of this section.

(4) For power-driven wheelchairs that are not classified as complex rehabilitative power-driven wheelchairs, furnished on or after January 1, 2011, payment is made in accordance with the rules set forth in paragraph (f) of this section.

(5) For power-driven wheelchairs classified as complex rehabilitative power-driven wheelchairs, furnished on or after January 1, 2011, payment is made in accordance with the rules set forth in paragraphs (f) or (h) of this section.

(b) Fee schedule amounts for rental.

(1) For 1989 and 1990, the monthly fee schedule amount for rental of other covered durable medical equipment equals 10 percent of the purchase price recognized as determined under paragraph (c) of this section subject to the following limitation: For 1989 and 1990, the fee schedule amount cannot be greater than 115 percent nor less than 85 percent of the prevailing charge, as determined under §405.504 of this chapter, established for rental of the item in January 1987, as adjusted by the change in the level of the CPI-U for the 6-month period ending December 1987.

(2) For 1991 and subsequent years, the monthly fee schedule amount for rental of other covered durable medical equipment equals 10 percent of the purchase price recognized as determined under paragraph (c) of this section for each of the first 3 months and 7.5 percent of the purchase price for each of the remaining months.

(c) Determination of purchase price. The purchase price of other covered durable medical equipment is determined as follows:

(1) For 1989 and 1990. (i) The carrier determines a base local purchase price amount equal to the average of the purchase prices submitted on an assignment-related basis of new items supplied during the 6-month period ending December 1986. (ii) The purchase price is equal to the base local purchase price adjusted by the change in the level of the CPI-U for the 6-month period ending December 1987.

(2) For 1991. (i) The local payment amount is the purchase price for the preceding year adjusted by the covered item update for 1991 and decreased by the percentage by which the average of the reasonable charges for claims paid for all other items described in §414.229, is lower than the average of the purchase prices submitted for such items during the final 9 months of 1988. (ii) The purchase price for 1991 is the national limited payment amount as determined using the methodology contained in §414.220(f).

(3) For years after 1991. The purchase price is determined using the methodology contained in paragraphs (d) through (f) of §414.220.

(d) Purchase option. Suppliers must offer a purchase option to beneficiaries during the 10th continuous rental month and, for power-driven wheelchairs, the purchase option must also be made available at the time the equipment is initially furnished.

(1) Suppliers must offer beneficiaries the option of purchasing power-driven wheelchairs at the time the supplier first furnishes the item. On or after January 1, 2011, this option is available only for complex rehabilitative power-driven wheelchairs. Payment must be on a lump-sum fee schedule purchase basis if the beneficiary chooses the purchase option. The purchase fee is the
amount established in §414.229(c).

(2) Suppliers must offer beneficiaries the option of converting capped rental items (including power-driven wheelchairs not purchased when initially furnished) to purchased equipment during their 10th continuous rental month. Beneficiaries have one month from the date the supplier makes the offer to accept the purchase option. (i) If the beneficiary does not accept the purchase option, payment continues on a rental basis not to exceed a period of continuous use of longer than 15 months. After 15 months of rental payments have been paid, the supplier must continue to provide the item without charge, other than a charge for maintenance and servicing fees, until medical necessity ends or Medicare coverage ceases. A period of continuous use is determined under the provisions in §414.230. (ii) If the beneficiary accepts the purchase option, payment continues on a rental basis not to exceed a period of continuous use of longer than 13 months. On the first day after 13 continuous rental months during which payment is made, the supplier must transfer title to the equipment to the beneficiary.

(e) **Payment for maintenance and servicing.**

(1) The carrier establishes a reasonable fee for maintenance and servicing for each rented item of other durable medical equipment. The fee may not exceed 10 percent of the purchase price recognized as determined under paragraph (c) of this section.

(2) Payment of the fee for maintenance and servicing of other durable medical equipment that is rented is made only for equipment that continues to be used after 15 months of rental payments have been made and is limited to the following: (i) For the first 6-month period, no payments are to be made. (ii) For each succeeding 6-month period, payment may be made during the first month of that period.

(3) Payment for maintenance and servicing DME purchased in accordance with paragraphs (d)(1) and (d)(2)(ii) of this section, is made on the basis of reasonable and necessary charges.

(f) **Rules for capped rental items furnished beginning on or after January 1, 2006.**

(1) For items furnished on or after January 1, 2006, payment is made based on a monthly rental fee schedule amount during the period of medical need, but for no longer than a period of continuous use of 13 months. A period of continuous use is determined under the provisions in §414.230.

(2) The supplier must transfer title to the item to the beneficiary on the first day that begins after the 13th continuous month in which payments are made under paragraph (f)(1) of this section.

(3) Payment for maintenance and servicing of beneficiary-owned equipment is made in accordance with §414.210(e).

(g) **Additional supplier requirements for capped rental items that are furnished beginning on or after January 1, 2007**

(1) The supplier that furnishes an item for the first month during which payment is made using the methodology described in paragraph (f)(1) of this section must continue to furnish the equipment until medical necessity ends, or the 13-month period of continuous use ends, whichever is earlier, unless — (i) The item becomes subject to a competitive acquisition program implemented in accordance with section 1847(a) of the Act; (ii) The beneficiary relocates to an area that is outside the normal service area of the supplier that initially furnished the equipment; (iii) The beneficiary elects to obtain the equipment from a different supplier prior to the expiration of the 13-month rental period; or (iv) CMS or the carrier determines that an exception should apply in an individual case based on the circumstances.

(2) A capped rental item furnished under this section may not be replaced by the supplier prior to the expiration of the 13-month rental period unless: (i) The supplier replaces an item with the same, or equivalent, make and model of equipment because the item initially furnished was
lost, stolen, irreparably damaged, is being repaired, or no longer functions; (ii) A physician orders different equipment for the beneficiary. If the need for different equipment is based on medical necessity, then the order must indicate why the equipment initially furnished is no longer medically necessary and the supplier must retain this order in the beneficiary's medical record; (iii) The beneficiary chooses to obtain a newer technology item or upgraded item and signs an advanced beneficiary notice (ABN); or (iv) CMS or the carrier determines that a change in equipment is warranted.

(3) Before furnishing a capped rental item, the supplier must disclose to the beneficiary its intentions regarding whether it will accept assignment of all monthly rental claims for the duration of the rental period. A supplier's intentions could be expressed in the form of a written agreement between the supplier and the beneficiary.

(4) No later than two months before the date on which the supplier must transfer title to a capped rental item to the beneficiary, the supplier must disclose to the beneficiary whether it can maintain and service the item after the beneficiary acquires title to it. CMS or its carriers may make exceptions to this requirement on a case-by-case basis.

(h) Purchase of power-driven wheelchairs furnished on or after January 1, 2006.
(1) Suppliers must offer beneficiaries the option to purchase power-driven wheelchairs at the time the equipment is initially furnished.
(2) Payment is made on a lump-sum purchase basis if the beneficiary chooses this option.
(3) On or after January 1, 2011, this option is available only for complex rehabilitative power-driven wheelchairs.

42 CFR Title 42 Chapter IV, §414.229 Other durable medical equipment - capped rental.
(Accessed June 12, 2017)

III. REFERENCES

See above

IV. REVISION HISTORY

6/21/2017 Annual review with the following updates:

Guideline 5 (Medical Supplies)
- Removed “Surgical dressings are also covered when obtained on the order of a physician or other authorized healthcare professional from an authorized supplier” as the statement is already addressed in the Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/Orthotics (Non-Foot Orthotics) and Medical Supplies Grid.
- Added (from Definition section) “Medical supplies are expendable items required for care related to a medical illness or dysfunction”, including the referenced link to the Medicare Benefit Policy Manual, Chapter 15, §110.1 - Definition of Durable Medical Equipment.

Definitions

Implantable Devices – removed reference link to Medicare Claims Processing Manual, Chapter 20, §10.1.2 - Prosthetic Devices - Coverage Definition. (incorrect reference); added reference links to FDA - Medical Devices, IDE Definitions and Acronyms and Medicare Claims Processing Manual, Chapter 4, §60.3 - Devices Eligible for Transitional Pass-Through Payments.
Medical Supplies – moved to Guideline 5 (Medical Supplies)

06/21/2016  Annual review; no updates.

07/21/2015  Annual review with the following update:
Guideline 5 (Medical Supplies) - Added reference link to the Medicare Benefit Policy Manual, Chapter 15, §60.1 - Incident To Physician’s Professional Services

10/21/2014  Removed detailed DME Face-to-Face Requirement information and replaced with a reference link to the DME, Prosthetics, Corrective Appliances/Orthotic and Medical Supplies Grid.

07/15/2014  Annual review with the following updates to Definitions:
• Corrective Appliances/Orthotic: Added the reference link to the Medicare Claims Processing Manual Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Section 10.1.3 Prosthetics and Orthotics (Leg, Arm, Back, and Neck Braces, Trusses, and Artificial Legs, Arms, and Eyes) Coverage Definition
• Durable Medical Equipment (DME): Added the reference link to the Medicare Benefit Policy Manual Chapter 15, Section 110.1 Definition of Durable Medical Equipment
• Implantable Devices: Added the reference link to the Medicare Claims Processing Manual, Chapter 20, Section 10.1.2 Prosthetic Devices Coverage Definition
• Medical Supplies: Added the reference link to the Medicare Benefit Policy Manual Chapter 15, Section 110.1 Definition of Durable Medical Equipment
  (D)
• Prosthetic Device: Added the reference link to the Medicare Benefit Policy Manual Chapter 15, Section 120 Prosthetic Devices
• 42 CFR § 414.229 Other durable medical equipment-capped rental items: Updated the definition and reference link to the Code of Federal Regulations

08/20/2013  Annual review with the following update: Added a note pertaining to the DME Face-to-Face Requirement in accordance with Section 6407 of the Affordable Care Act as defined in the 42 CFR 410.38(g).

08/20/2012  Guidelines # 4 updated to further clarify the coverage guidelines for repairs, maintenance and replacements of DME, prosthetic and corrective appliances based on the Medicare Benefit Policy Manual, Chapter 15 Medical and Other Health Services.

08/29/2011  Annual review; no updates.