

## Coverage Summary

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

<b>Policy Number:</b> D-002	<b>Products:</b> UnitedHealthcare Medicare Advantage Plans	<b>Original Approval Date:</b> 04/15/2009
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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.**

*There are instances where this document may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG). In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)).*

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## 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*)

**Notes:**

- 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 \(MAE\)](#).
- **Capped-rental DME:** For payment rules for capped-rental DME, refer to the [42 CFR Title 42, Chapter IV, §414.229 Other durable medical equipment - capped rental](#). (Accessed June 12, 2019)

**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.

See the [Medicare Benefit Policy Manual, Chapter 15, §120 - Prosthetic Devices](#). (Accessed June 12, 2019)

**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, 2019)

**4. Repairs, Maintenance and Replacement**

**a. Durable Medical Equipment**

**1) Repair**

Repairs to equipment which a member 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 member'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 member. 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 member 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 member owns. This might include, for example, breaking down sealed components and performing tests which require specialized testing equipment not available to the member.

### 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 member 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 member 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 member, 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 member.**

Replacement of items due to malicious damage, neglect or wrongful disposition of item is not covered.

See the [Medicare Benefit Policy Manual, Chapter 15, §110.2 - Repairs, Replacement and Maintenance and Delivery](#). (Accessed June 12, 2019)

#### 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](#). (Accessed June 12, 2019)

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.

See the [Medicare Benefit Policy Manual, Chapter 15, §130 - Leg, Arm, Back, and Neck Braces, Trusses, and Artificial Legs, Arms, and Eyes](#). (Accessed June 12, 2019)

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, 2019)

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, 2019)

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.

For additional coverage guidelines, see the [Medicare Benefit Policy Manual, Chapter 15, §110 – §130](#). (Accessed June 11, 2019)

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 11, 2019)

## 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 11, 2019)

**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 11, 2019)

**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 and Medicare Claims Processing Manual, Chapter 4, §60.3 - Devices Eligible for Transitional Pass-Through Payments.](#) (Accessed June 11, 2019)

**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 11, 2019)

**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 11, 2019)

### III. REFERENCES

See above

## IV. REVISION HISTORY

06/18/2019

### **Guideline 1 [Durable Medical Equipment (DME) Rental or Purchase]**

- Updated language pertaining to payment rules for capped-rental DME; added reference link (relocated from the *Definitions* section) to the *Electronic Code of Federal Regulations (e-CFR)* data for other durable medical equipment – capped rental items §42 CFR 414.229

### **Guideline 4.a.3 (Durable Medical Equipment Replacement)**

- Added language (relocated from *Guideline 6*) to indicate replacement of items due to malicious damage, neglect or wrongful disposition of item is not covered

### **Guideline 6.a (Routine Maintenance)**

- Removed language pertaining to routine periodic maintenance services (refer to *Guideline 4.a.2*)

### **Guideline 6.b (Replacement of Items)**

- Removed/relocated language pertaining to the replacement of items due to malicious damage, neglect or wrongful disposition (refer to *Guideline 4.a.3*)

### **Guideline 6.c (Supplies or Accessories)**

- Removed language pertaining to 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 [Not covered (no CMS reference available)]

### **Definitions**

- Removed/replaced definition of “Other Durable Medical Equipment - Capped Rental” (refer to *Guideline 1*)