



DURABLE MEDICAL EQUIPMENT, ORTHOTICS, OSTOMY SUPPLIES, MEDICAL SUPPLIES AND REPAIRS/REPLACEMENTS

Guideline Number: CDG.009.01
Effective Date: February 1, 2014

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INSTRUCTIONS FOR USE

This Coverage Determination Guideline provides assistance in interpreting certain standard UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee’s document (e.g., Certificates of Coverage (COCs), Schedules of Benefits (SOBs), or Summary Plan Descriptions (SPDs), and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this guideline is based. In the event of a conflict, the enrollee's specific benefit document supersedes these guidelines. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this guideline. Other coverage determination guidelines and medical policies may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its coverage determination guidelines and medical policies as necessary. This Coverage Determination Guideline does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

COVERAGE RATIONALE

Plan Document Language

Before using this guideline, please check enrollee's specific plan document and any federal or state mandates, if applicable.

For ASO plans with SPD language other than fully insured Generic COC language, please refer to the enrollee's specific SPD for coverage.

Essential Health Benefits for Individual and Small Group:

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage.

Indications for Coverage

1. Durable Medical Equipment (DME) is a Covered Health Service when the enrollee has a Durable Medical Equipment benefit, the equipment is ordered by a physician to treat an injury or sickness (illness) and the equipment is not otherwise excluded in the plan document.

DME must be:

- Ordered or provided by a physician for outpatient use primarily in a home setting;
 - Used for medical purposes;
 - Not consumable or disposable except as needed for the effective use of covered DME; and
 - Not of use to a person in the absence of a disease or disability.
2. Medical supplies that are used with covered DME are covered when the supply is necessary for the effective use of the item/device (e.g., oxygen tubing or mask, or tubing for a delivery pump).
 3. Orthotic braces that stabilize an injured body part and braces to treat curvature of the spine are considered Durable Medical Equipment. See #5 under Coverage Limitations and Exclusions. Examples of orthotic braces include but are not limited to:
 - Thoracic-lumbar-sacral orthotic (TLSO)
 - Lumbar-sacral orthotic (LSO)
 - Knee orthotics (KO)
 - Ankle Foot Orthotic (AFO)
 - Necessary adjustments to shoes to accommodate braces
 4. There are specific codes that are defined by HCPCS as orthotics that UnitedHealthcare covers as DME.
 5. Oral appliances for snoring are excluded. Coverage may be provided for oral appliances (prefabricated or custom fabricated) for sleep apnea (HCPCS E0485 and E0486). Please refer to the following Medical Policy [Non-Surgical Treatment of Obstructive Sleep Apnea](#)

- A letter of referral or prescription to the dentist for the appliance must be received from the treating physician; and
 - A polysomnography must be completed documenting obstructive sleep apnea.
6. Cranial helmets (cranial remolding orthosis, billed with S1040) used to facilitate a successful post-surgical outcome are covered as DME and are not subject to the orthotic device exclusion. Refer to the Medical Policy titled [Plagiocephaly and Craniosynostosis Treatment](#).
 7. Pleurx bottles and tubing are covered as DME.
 8. Repair and replacement of Durable Medical Equipment is covered when the enrollee has a Durable Medical Equipment benefit and any of the following:
 - The repairs, including the replacement of essential accessories, such as hoses, tubes, mouth pieces, etc., for necessary DME are covered when necessary to make the item/device serviceable;
 - The physician provides documentation that the condition of the enrollee changes e.g. impaired function necessitates an upgrade to an electric wheelchair from a manual one;
 - Routine wear on the equipment renders it non-functional and the enrollee still requires the equipment.
 9. Repairs, replacements and maintenance for rented items/devices are the contractual responsibility of the item/device provider.
 10. Coverage includes Durable Medical Equipment (DME) obtained in a physician's office, durable medical equipment vendor, or any other provider authorized to provide/dispense DME.
 11. Insulin pumps are considered DME. For state specific information on mandated coverage of diabetes supplies, please check state mandates.
 12. Tracheo-esophageal prosthetics and voice aid prosthetics are covered as Durable Medical Equipment.
 13. Ostomy Supplies. Supplies are limited to the following:
 - Pouches, face plates and belts
 - Irrigation sleeves, bags and ostomy irrigation catheters
 - Skin barriers

Benefits **are not available** for deodorants, filters, lubricants, tape, appliance cleaners, adhesive, adhesive remover, or other items not listed above.

Please check the enrollee specific plan document for coverage of ostomy supplies.
 14. Contact lenses that are used to treat a Sickness or Injury of the cornea (e.g. corneal abrasion or keratoconus), are covered as a therapeutic service and not as DME or subject to the contact lens exclusion.
 15. Scleral bandages (shells) that are used to treat a Sickness or Injury to the cornea (scratch or burn), are covered as a therapeutic service and not as DME or subject to the vision exclusion.
 16. Speech generating devices are covered as Durable Medical Equipment when they are not explicitly excluded from coverage in the benefit document (Certificate of Coverage or Summary Plan Description) and the treating physician determines that the enrollee suffers from a severe speech impairment and that the medical condition warrants the use of a device

based upon the definitions below. The physician attestation must be consistent with and based upon the recommendation of a qualified speech and language pathologist. The speech and language pathology evaluation must reach all of the following conclusions:

- The enrollees medical condition is one resulting in a severe expressive speech impairment;
- The enrollees speaking needs cannot be met using natural communication methods;
- Other forms of treatment have been attempted or considered and ruled out.

Examples of a speech generating device are: Dynavox, Freedom, Say-it!

Please check the enrollee specific plan document for coverage of speech generating devices.

17. Mobility devices (manual wheel chair, electric wheelchairs, transfer chair or scooters) are a Covered Health Service. Please check the enrollee specific plan document for coverage of mobility devices.
18. Breast pumps may be covered as DME. Please refer to Coverage Determination Guideline titled [Preventive Care Services](#) for breast pump coverage indications.
19. Enteral pumps are covered as DME, even when the enteral nutrition formula is not covered. Please check the enrollee specific plan document for coverage of enteral pumps.

Medical Necessity Plans

On October 1, 1993, the Health Care Financing Administration (HCFA), now known as Center for Medicare and Medicaid Services (CMS), began using *four* Durable Medical Equipment Medicare Administrative Contracts (DME MAC) to process Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) claims for Medicare payment. Prior to the DME MACs, HCFA/CMS used 34 carriers to process all Part B claims, including DMEPOS. The change to four DME MACs for processing DMEPOS claims was a HCFA/CMS effort to improve ineffective and costly claims processing under the 34 carrier system.)

HCFA/ CMS required the DME MACs to:

- Establish standardized medical policies for the 100 DMEPOS items that had the highest allowed charges,
- Implement comprehensive educational outreach programs,
- Develop aggressive fraud detection and prevention programs, and
- Improve claims processing expertise and efficiency.

Durable Medical Equipment (DME) and Related Supplies, Prosthetics and Orthotics are medically necessary when:

- Ordered by a physician; and
- The item(s) meets the plans medically necessary definition (refer to the plan specific document(s); and
- CMS DME MAC criteria are met; and
- Item is not otherwise excluded from coverage.

The following are the four current DME MAC Carriers:

- [CIGNA Government Services \(CGS\)](#)
- [National Government Services \(NGS\)](#)

- [National Heritage Insurance Company \(NHIC\)](#)
- [Noridian Administrative Services](#)

Coverage Limitations and Exclusions

1. When more than one piece of Durable Medical Equipment can meet the enrollee's functional needs, benefits are available only for the equipment that meets the minimum specifications for enrollee needs. Examples include but are not limited to: standard electric wheelchair vs. custom wheelchair; standard bed vs semi-electric bed vs fully electric or flotation system. This limitation is intended to exclude coverage for deluxe or additional components of a DME item, not necessary to meet the enrollee's minimal specifications to treat an Injury or Sickness.
2. When the enrollee rents or purchases a piece of Durable Medical Equipment that exceeds this guideline, the enrollee will be responsible for any cost difference between the piece he/she rents or purchases and the piece we have determined is the most cost-effective.
3. Additional accessories to DME items or devices which are primarily for the comfort or convenience of the enrollee are not covered. Examples include but not limited to: air conditioners, humidifiers, air purifiers and filters, remodeling or modification to home or vehicle to accommodate DME or patient condition.
4. Any device, appliance, pump, machine, stimulator, or monitor that is fully implanted into the body is not covered as DME. **(If covered, the device is covered as part of the surgical service.)** Some devices include both a DME component and an implanted component, e.g., cochlear implant.
5. Orthotic braces that straighten or change the shape of a body part are excluded from coverage.
6. Upgrade or replacement of Durable Medical Equipment when the existing equipment is still functional is not covered.
7. Replacement of items due to malicious damage, neglect or abuse is not covered.
8. Replacement of lost or stolen items is not covered.
9. Routine periodic maintenance (e.g., testing, cleaning, regulating and checking of equipment) for which the owner or vendor is generally responsible.
10. Durable Medical Equipment and supplies that are explicitly excluded in the enrollee specific plan document are not covered.
11. Elastic splints, sleeves or bandages **unless part of a covered health service**, e.g., sleeve used in conjunction with a lymphedema pump or bandages used with complex decongestive therapy are not covered.
12. Devices used specifically as safety items or to affect performance in sports-related activities are not covered.
13. The following items are excluded even if prescribed by a physician. Please refer to the enrollee specific plan document.
 - a. Blood pressure cuff/monitor
 - b. Enuresis alarm

- c. Non-wearable external defibrillator
 - d. Trusses or girdle
 - e. Ultrasonic nebulizers
14. Devices and computers to assist in communication and speech are not covered. However, see #16 under [Indications for Coverage](#) for information on speech generating devices.
 15. Oral appliances for snoring are not covered. See #5 under [Indications for Coverage](#) for oral appliances for sleep apnea.
 16. Personal Care, Comfort and Convenience items and supplies. Please check the enrollee specific plan document for the list of excluded items.
 17. Dental braces are also excluded from coverage. Please check the enrollee specific plan document and State Mandates.
 18. Items and supplies that do not meet the definition of a Covered Health Service are not covered.
 19. Ostomy Supplies are not covered unless specifically stated as covered. Please check the enrollee specific plan document. See #13 under [Indications for Coverage](#).
 20. Medical supplies (except those described in #2) above under Indications for Coverage are excluded. This includes, but is not limited to bandages, gauze, dressings, cotton balls and alcohol wipes.
 21. Urinary catheters are excluded unless specifically stated as covered. Please check the enrollee specific plan document.
 22. Cranial helmets used for other indications other than those in #6 in the [Indications for Coverage](#) are excluded from coverage under the orthotics exclusion.

For ASO plans with SPD language other than fully-insured Generic COC language
Please refer to the enrollee's plan specific SPD for coverage.

DEFINITIONS

Covered Health Service(s): Health services, including services, supplies, or Pharmaceutical Products, which we determine to be all of the following:

- Provided for the purpose of preventing, diagnosing or treating a Sickness, Injury, Mental Illness, substance abuse, or their symptoms.
- Consistent with nationally recognized scientific evidence as available, and prevailing medical standards and clinical guidelines as described below.
- Not provided for the convenience of the Covered Person, Physician, facility or any other person.
- Described in the *Certificate of Coverage* under *Section 1: Covered Health Services* and in the *Schedule of Benefits*.
- Not otherwise excluded in the *Certificate of Coverage* under *Section 2: Exclusions and Limitations*.
- In applying the above definition, "scientific evidence" and "prevailing medical standards" shall have the following meanings:

- "Scientific evidence" means the results of controlled clinical trials or other studies published in peer-reviewed, medical literature generally recognized by the relevant medical specialty community.
- "Prevailing medical standards and clinical guidelines" means nationally recognized professional standards of care including, but not limited to, national consensus statements, nationally recognized clinical guidelines, and national specialty society guidelines.

We maintain clinical protocols that describe the scientific evidence, prevailing medical standards and clinical guidelines supporting our determinations regarding specific services. These clinical protocols (as revised from time to time), are available to Covered Persons on www.myuhc.com or by calling *Customer Care* at the telephone number on your ID card, and to Physicians and other health care professionals on UnitedHealthcareOnline.

Durable Medical Equipment: Medical equipment that is all of the following:

- Can withstand repeated use
- Is not disposable
- Is used to serve a medical purpose with respect to treatment of a Sickness, Injury or their symptoms
- Is generally not useful to a person in the absence of a Sickness, Injury or their symptoms
- Is appropriate for use, and is primarily used, within the home
- Is not implantable within the body

Medical Supplies: Expendable items required for care related to a medical illness or dysfunction.

Mobility Device: A manual wheelchair, electric wheelchair, transfer chair or scooter.

Obstructive Sleep Apnea: The American Academy of Sleep Medicine (AASM) defines obstructive sleep apnea as a sleep related breathing disorder that involves a decrease or complete halt in airflow despite an ongoing effort to breathe.

OSA severity is defined as:

- mild for AHI or RDI ≥ 5 and < 15
- moderate for AHI or RDI ≥ 15 and ≤ 30
- severe for AHI or RDI > 30 /hr

Speech Generating Device: Speech generating devices are characterized by the following:

- Are of use only by an individual who has severe speech impairment.
- May have digitized speech output, using pre-recorded messages, less than or equal to 8 minutes recording time
- May have digitized speech output, using pre-recorded messages, greater than 8 minutes recording time.
- May have synthesized speech output, which requires message formulation by spelling and device access by physical contact with the device-direct selection techniques.
- May be software that allows a laptop computer, desktop computer or personal digital assistant (PDA) to function as a speech generating device.
- May have synthesized speech output, which permits multiple methods of message formulation and multiple methods of device access.

Speech generating devices are not:

- Devices that are capable of running software for purposes other than for speech generation, e.g., devices that can also run a word processing package, an accounting program, or perform other non-medical function

- Laptop computers, desktop computers, or PDAs which may be programmed to perform the same function as a speech generating device
- Useful to someone without severe speech impairment

REFERENCES

Centers for Medicare and Medicaid Services (CMS). Medicare National Coverage Determinations Manual (Pub. 100-3), Chapter 1, Part 4 (Sections 200 – 310.1), § 280

Medical and Surgical Supplies Coverage Determinations Medicare Coverage Issues Manual, Pub. 6, §60-9

Centers for Medicare and Medicaid Services (CMS). Medicare Benefit Policy Manual, Pub. 100-2, Chapter 15, §110 Durable Medical Equipment – General

Centers for Medicare and Medicaid Services (CMS). Medicare Benefit Policy Manual, Pub. 100-2, Chapter 14, §10, Coverage of Medical Devices

Centers for Medicare and Medicaid Services (CMS). Medicare Benefit Policy Manual, Pub. 100-2, Chapter 15, §110.4 Repairs, Maintenance, Replacement, and Delivery.

GUIDELINE HISTORY/REVISION INFORMATION

Date	Action/Description
04/11/2014	<ul style="list-style-type: none"> • Reformatted table of contents (no change to policy content/coverage determination guidelines): <ul style="list-style-type: none"> ○ Added new policy guideline number assignment for document archive management purposes; guideline number previously listed as CDG-A-030 ○ Removed applicable products grid (<i>Note: Policy document no longer applies to Community Plan membership; Community Plan specific policy documents now available</i>)
02/01/2014	<ul style="list-style-type: none"> • Reformatted policy; added content previously outlined in Utilization Review Guideline titled <i>Durable Medical Equipment and Related Supplies, Prosthetics and Orthotics</i> (retired 02/01/2014) • Revised coverage rationale/indications for coverage: <ul style="list-style-type: none"> ○ Added examples of orthotic braces that stabilize an injured body part or treat curvature of the spin ○ Added language to indicate speech generating devices are covered as Durable Medical Equipment when they are not explicitly excluded from coverage in the benefit document (Certificate of Coverage or Summary Plan Description) and the treating physician determines that the enrollee suffers from a severe speech impairment and that the medical condition warrants the use of a device based upon the definitions outlined in the policy <ul style="list-style-type: none"> ▪ The physician attestation must be consistent with and based upon the recommendation of a qualified speech and language pathologist; the speech and language pathology evaluation must reach all of the following conclusions: <ul style="list-style-type: none"> - The enrollees medical condition is one resulting in a severe expressive speech impairment; - The enrollees speaking needs cannot be met using

Date	Action/Description
02/01/2014	<p>natural communication methods;</p> <ul style="list-style-type: none"> - Other forms of treatment have been attempted or considered and ruled out <ul style="list-style-type: none"> ▪ Examples of a speech generating device are Dynavox, Freedom, and Say-it! ▪ Check the enrollee specific plan document for coverage of speech generating devices • Revised coverage limitations/exclusions; added language to indicate urinary catheters are excluded unless specifically stated as covered (check the enrollee specific plan document) • Removed definition of: <ul style="list-style-type: none"> ○ Brace ○ Prosthetic ○ Orthotic (CMS) ○ Orthotic (UHC fully insured products) ○ Non-Essential DME.