

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

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[Instructions for Use](#) ⓘ

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Medicare Advantage Coverage Summary

- [Durable Medical Equipment \(DME\), Prosthetics, Corrective Appliances/Orthotics \(Non-Foot Orthotics\) and Medical Supplies Grid](#)

COVERAGE RATIONALE

Indications for Coverage

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

DME must be:

- Not consumable or disposable except as needed for the effective use of covered DME;
- Not of use to a person in the absences of a disease or disability;
- Ordered or provided by a physician for outpatient use primarily in a home setting; and
- Used for medical purposes.

Breast Pumps

Breast pumps may be covered under the preventive care services benefit. Refer to the Coverage Determination Guideline titled [Preventive Care Services](#) for breast pump coverage indications.

Contact Lenses & Scleral Bandages (Shells)

Contact lenses or scleral shells that are used to treat an injury or disease (e.g., corneal abrasion, keratoconus or severe dry eye) are not considered DME and may be covered as a therapeutic service. In these situations, contact lenses and scleral shells are not subject to a plan's contact lens exclusion.

Cranial Remolding Orthosis

Cranial molding helmets (cranial remolding orthosis, billed with S1040) are excluded except when used to avoid the need for surgery, and/or to facilitate a successful post-surgical outcome are covered as DME and are not subject to the orthotic device exclusion. For all indications, refer to the Medical Policy titled [Plagiocephaly and Craniosynostosis Treatment](#).

Note: A protective helmet (HCPCS code A8000–A8004) is not a cranial remolding device. It is considered a safety device worn to prevent injury to the head rather than a device needed for active treatment; see [Coverage Limitations and Exclusions](#).

Enteral Pumps

Enteral pumps are covered as DME, even when the enteral nutrition formula is not covered. Check the member specific benefit plan document for coverage of enteral pumps.

Implanted Devices

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.)

Note: Cochlear Implant Benefit Clarification: If benefits exist for a cochlear implant, the external components (i.e., speech processor, microphone, and transmitter coil) are considered under the DME benefit, and the implantable components are considered under the medical-surgical benefit. The member specific benefit plan document must be referenced to determine if there are DME benefits for repair or replacement of external components.

Insulin Pumps

Insulin pumps are considered DME. For state specific information on mandated coverage of diabetes supplies, check state mandates.

Lymphedema Stockings for the Arm

Lymphedema stockings for the arm are covered on an unlimited basis as to number of items and dollar amounts covered consistent with the requirements of the [Women's Health and Cancer Rights Act \(WHCRA\) of 1998](#).

Medical Supplies

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, batteries for power wheelchairs and prosthetics, or tubing for a delivery pump).

Mobility Devices

Mobility Devices include manual wheelchair, electric wheelchairs, transfer chair or scooters/power-operated vehicles (POV) are a Covered Health Care Service when Medically Necessary. Check the member specific benefit plan document for coverage.

- Proof of the home evaluation is not required at the time of prior authorization. The on-site home evaluation can be performed prior to, or at the time of, delivery of a power Mobility Device. The written report of the home evaluation must be available on request post-delivery.

Oral Appliances

Oral appliances for snoring are excluded.

Coverage may be provided for oral appliances (prefabricated or custom fabricated) for sleep apnea (HCPCS E0485 and E0486). Refer to the Medical Policy titled [Obstructive Sleep Apnea Treatment](#).

- 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

Orthotic Braces

Orthotic braces that stabilize an injured body part and braces to treat curvature of the spine are considered DME (see [Coverage Limitations and Exclusions](#)). Examples of orthotic braces include but are not limited to:

- Ankle Foot Orthotic (AFO)
- Knee orthotics (KO)
- Lumbar-sacral orthotic (LSO)
- Necessary adjustments to shoes to accommodate braces
- Thoracic-lumbar-sacral orthotic (TLSO)

Note: There are specific codes that are defined by HCPCS as orthotics that UnitedHealthcare covers as DME.

Ostomy Supplies

Ostomy Supplies are limited to the following:

- Irrigation sleeves, bags and ostomy irrigation catheters
- Pouches, face plates and belts
- Skin barriers

Benefits are not available for deodorants, filters, lubricants, tape, appliance cleaners, adhesive, adhesive remover, or other items not listed above (check the member specific benefit plan document for coverage of ostomy supplies).

Pleurx Bottles and Tubing

Pleurx bottles and tubing are covered as DME.

Repair and Replacement

Repair and replacement of DME is covered when the member has a DME 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 member 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 member still requires the equipment.
 - Vendors/manufacturers are responsible for repairs, replacements, and maintenance for rented equipment and for purchased equipment covered by warranty
 - Coverage includes DME obtained in a physician's office, DME vendor, or any other provider authorized to provide/dispense DME
- Replacement of DME is for the same or similar type of equipment
- Unless otherwise stated, DME has a Reasonable Useful Lifetime (RUL) of 5 years
- Pediatric equipment should allow room for growth with 3 inches of depth and width available for adjustments

Equipment Upgrades

- A change in the member's medical condition and equipment needs requires the same documentation as a new request
- Equipment upgrades are equivalent to a new service

Speech Generating Devices

Speech Generating Devices are covered as DME when:

- The device(s) are not explicitly excluded from coverage in the member specific benefit plan document (COC or SPD); and
- The treating physician determines that the member suffers from severe speech impairment (impediment) or lack of speech directly due to sickness or injury; and
- 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 member's medical condition is one resulting in a severe expressive speech impairment (impediment) or lack of speech directly related to Sickness or Injury;
- The member's 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!TM

Note: Most benefit plans require a 3-month rental period before a purchase can be made.

Trachea-Esophageal and Voice Aid Prosthetics

Trachea-esophageal prosthetics and voice aid prosthetics are covered as DME.

Ventilators and Respiratory Assist Devices

For adult or pediatric members, UnitedHealthcare uses the Medicare policy for coverage determinations for home ventilators. Home ventilators are:

- Not covered for non-life-threatening conditions
- Not covered when used as Respiratory Assistance Devices (RAD)

Regardless of the member's age, any type of ventilator would not be eligible for reimbursement for any of the conditions described in the [Medicare RAD criteria](#) even though the ventilator may have the capability of operating in a bi-level PAP (E0470, E0471) mode.

- The conditions that qualify for use of a RAD are not life-threatening conditions where interruption of respiratory support would quickly lead to serious harm or death.
- Claims for ventilators, such as Trilogy mechanical ventilators, (E0465, E0466) used for the treatment of conditions described in the Medicare RAD criteria are not covered. Bi-level PAP devices (E0470, E0471) are considered as Medically Necessary in those clinical scenarios.
- Ventilators must not be billed using codes for CPAP (E0601) or bi-level PAP (E0470, E0471, and E0472). The use of CPAP or bi-level PAP HCPCS codes to bill a ventilator is incorrect coding, even if the ventilator is only being used in CPAP or bi-level mode.

PAP Therapy

Note: For the evaluation of PAP therapy, hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in airflow and with at least a 3% decrease in oxygen saturation from pre-event baseline or the event is associated with an arousal (AASM Scoring Manual, 2017).

Medical Necessity Plans

In the absence of a related policy or coverage indication from above, UnitedHealthcare uses available criteria from the [DME MAC](#).

DME, related supplies, and orthotics are Medically Necessary when:

- Ordered by a physician; and
- The item(s) meets the plans Medically Necessary definition (refer to the member specific benefit plan document); and
- CMS DME MAC criteria are met (see above link); and
- The item is not otherwise excluded from coverage

Coverage Limitations and Exclusions

When more than one piece of DME can meet the member's functional needs, benefits are available only for the item that meets the minimum specifications for member 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 which are not necessary to meet the member's minimal specifications to treat an Injury or Sickness.

When the member rents or purchases a piece of DME that exceeds this guideline, the member 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.

The following services are excluded from coverage:

- Additional accessories to DME items or devices which are primarily for the comfort or convenience of the member are not covered. Examples include but are not limited to:
 - Air conditioners
 - Air purifiers and filters
 - Batteries for non-medical equipment (e.g., flashlights, smoke detectors, telephones, watches, weight scales)
 - Humidifiers
 - Remodeling or modification to home or vehicle to accommodate DME or patient condition (e.g., Ramps, stair lifts and stair glides, wheelchair lifts, bathroom modifications, door modifications)
- Cranial molding helmets and cranial banding except when used to avoid the need for surgery and/or to facilitate a successful surgical outcome.

- Dental braces. Check the member specific benefit plan document and State Mandates.
- Devices and computers to assist in communication and speech. However, see [Indications for Coverage](#) for information on Speech Generating Devices.
- Devices used specifically as safety items or to affect performance in sports-related activities.
- Diagnostic or monitoring equipment purchased for home use unless otherwise described as a Covered Health Care Service (e.g., blood pressure monitor, oximeters).
- Elastic splints, sleeves or bandages, unless part of a Covered Health Care Service (e.g., sleeve used in conjunction with a lymphedema pump or bandages used with complex decongestive therapy).
- Oral appliances for snoring. See [Indications for Coverage](#) for oral appliances for sleep apnea.
- Orthotic braces that straighten or change the shape of a body part.
- Personal Care, Comfort and Convenience items and supplies. Check the member specific benefit plan document for the list of excluded items.
- Powered and non-powered exoskeleton devices.
- Prescribed or non-prescribed publicly available devices, software applications and/or monitors that can be used for non-medical purposes (e.g., smart phone applications, software applications).
- Replacement of items due to malicious damage, neglect or abuse.
- Replacement of lost or stolen items.
- Routine periodic maintenance (e.g., testing, cleaning, regulating and checking of equipment) for which the owner or vendor is generally responsible.
- The following items and supplies:
 - DME and supplies that are explicitly excluded in the member specific benefit plan document
 - Medical Supplies (except those described above under Indications for Coverage). This includes, but is not limited to bandages, gauze, dressings, cotton balls and alcohol wipes.
 - Items and supplies that do not meet the definition of a Covered Health Care Service.
 - Ostomy Supplies unless specifically stated as covered. Check the member specific benefit plan document. See [Indications for Coverage](#).
- The following items are excluded even if prescribed by a physician. Refer to the member specific benefit plan document.
 - Blood pressure cuff/monitor
 - Enuresis alarm
 - Non-wearable external defibrillator
 - Trusses or girdle
 - Ultrasonic nebulizers
- Upgrade or replacement of DME when the existing equipment is still functional. Refer to [Repair/Replacement](#) section
- Urinary catheters unless specifically stated as covered. Check the member specific benefit plan document.

DEFINITIONS

The following definitions may not apply to all plans. Refer to the member specific benefit plan document for applicable definitions.

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

- Provided for the purpose of preventing, evaluating, diagnosing or treating a Sickness, Injury, Mental Illness, substance-related and addictive disorders, condition, disease or its symptoms.
- Medically Necessary
- Described as a Covered Health Care Service in the *COC* under *Section 1: Covered Health Care Services* and in the *Schedule of Benefits*
- Not excluded in the *COC* under *Section 2: Exclusions and Limitations*

Durable Medical Equipment (DME): Medical Equipment that is all of the following:

- 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
- Not of use to a person in the absence of a disease or disability
- Serves a medical purpose for the treatment of a Sickness or injury
- Primarily used within the home

Injury: Damage to the body, including all related conditions and symptoms.

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

Medically Necessary: Health Care Services that are all of the following as determined by us or our designee.

- In accordance with *Generally Accepted Standards of Medical Practice*
- Clinically appropriate, in terms of type, frequency, extent, service site and duration, and considered effective for your Sickness, Injury, Mental Illness, substance-related and addictive disorders, disease or its symptoms
- Not mainly for your convenience or that of your doctor or other health care provider
- Not more costly than an alternative drug, service(s), service site or supply that is at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of your Sickness, Injury, disease or symptoms

Mental Illness: Those mental health or psychiatric diagnostic categories that are listed in the current edition of the International Classification of Diseases section on Mental and Behavioral Disorders or Diagnostic and Statistical Manual of the American Psychiatric Association. The fact that a condition is listed in the current edition of the International Classification of Diseases section on Mental and Behavioral Disorders or Diagnostic and Statistical Manual of the American Psychiatric Association does not mean that treatment for the condition is a Covered Health Care Service.

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

Reasonable Useful Lifetime: RUL is the expected minimum lifespan for the item. It starts on the initial date of service and runs for the defined length of time. The default RUL for durable medical equipment is set at 5 years. RUL is also applied to other non-DME items such as orthoses and prostheses. RUL is not applied to supply items.

Sickness: Physical illness, disease or Pregnancy. The term Sickness as used in this Certificate includes Mental Illness or substance-related and addictive disorders, regardless of the cause or origin of the Mental Illness or substance-related and addictive disorder.

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

Women's Health and Cancer Rights Act of 1998, § 713 (a): "In general - a group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, that provides medical and surgical benefits with respect to a Mastectomy shall provide, in case of a participant or beneficiary who is receiving benefits in connection with a Mastectomy and who elects breast reconstruction in connection with such Mastectomy, coverage for (1) reconstruction of the breast on which the Mastectomy has been performed; (2) surgery and reconstruction of the other breast to produce symmetrical appearance; and (3) prostheses and physical complications all stages of Mastectomy, including lymphedemas in a manner determined in consultation with the attending physician and the patient."

APPLICABLE CODES

UnitedHealthcare has adopted the requirements and intent of the National Correct Coding Initiative. The Centers for Medicare & Medicaid Services (CMS) has contracted with Palmetto to manage Pricing, Data and Coding (PDAC) for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). This notice is to confirm UnitedHealthcare has established the PDAC as its definitive source for correct coding and coding clarification.

REFERENCES

Centers for Disease Control and Prevention. https://www.cdc.gov/growthcharts/clinical_charts.htm. Accessed July 15, 2019.

Centers for Medicare and Medicaid Services (CMS), "Correct Coding and Coverage of Ventilators" Revised January 1, 2019; available at <https://www.dmepdac.com/palmetto/PDAC.nsf/DID/4OYYZRE0B0>. Accessed January 25, 2019.

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 Durable Medical Equipment – General.

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

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.

Noridian Healthcare Solutions. <https://med.noridianmedicare.com/web/jddme/article-detail/-/view/2230703/reasonable-useful-lifetime-and-duplicate-items-billing-reminder>. Accessed July 16, 2019.

Women's Health and Cancer Rights Act of 1998. Available at: https://www.cms.gov/ccio/programs-and-initiatives/other-insurance-protections/whcra_factsheet.html. Accessed May 2, 2019.

GUIDELINE HISTORY/REVISION INFORMATION

Date	Action/Description
10/01/2019	<p>Coverage Rationale</p> <ul style="list-style-type: none"> • Revised coverage guidelines for: <ul style="list-style-type: none"> Cranial Remolding Orthosis <ul style="list-style-type: none"> ○ Updated language to clarify cranial molding helmets (cranial remolding orthosis, billed with S1040) <i>are excluded except when used to avoid the need for surgery, and/or to facilitate a successful post-surgical outcome</i> are covered as DME and are not subject to the orthotic device exclusion Lymphedema Stockings for the Arm <ul style="list-style-type: none"> ○ Updated language to clarify lymphedema stockings for the arm are covered on an unlimited basis as to number of items and dollar amounts covered <i>consistent with the requirements of the Women’s Health and Cancer Rights Act (WHCRA) of 1998</i> Repair and Replacement <ul style="list-style-type: none"> ○ Added language to indicate repair and replacement of DME is covered when the member has a DME benefit and: <ul style="list-style-type: none"> ▪ Replacement of DME is for the same or similar type of equipment ▪ Unless otherwise stated, DME has a Reasonable Useful Lifetime (RUL) of 5 years ▪ Pediatric equipment should allow room for growth with 3 inches of depth and width available for adjustments ○ Removed language indicating frequency and timeframe limits for DME repair or replacement are specified in the member specific benefit plan document Equipment Upgrades <ul style="list-style-type: none"> ○ Added language to indicate: <ul style="list-style-type: none"> ▪ A change in the member’s medical condition and equipment needs requires the same documentation as a new request ▪ Equipment upgrades are equivalent to a new service • Reorganized list of services excluded from coverage (no change to exclusions) <p>Definitions</p> <ul style="list-style-type: none"> • Added definition of: <ul style="list-style-type: none"> ○ Injury ○ Mental Illness ○ Reasonable Useful Lifetime ○ Sickness <p>Supporting Information</p> <ul style="list-style-type: none"> • Updated <i>References</i> section to reflect the most current information • Archived previous policy version CDG.009.14

INSTRUCTIONS FOR USE

This Coverage Determination Guideline provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this guideline, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Coverage Determination Guideline is provided for informational purposes. It does not constitute medical advice.

This Coverage Determination Guideline may also be applied to Medicare Advantage plans in certain instances. 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](#)).

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Coverage Determination 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.

For self-funded plans with SPD language other than fully-insured Generic COC language, please refer to the member specific benefit plan document for coverage.