Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements (for Louisiana Only)

Guideline Number: CS032LA.Q
Effective Date: October 1, 2020

Instructions for Use

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Application

This Coverage Determination Guideline only applies to the state of Louisiana.

Coverage Rationale

Indications for Coverage

Durable Medical Equipment (DME), related supplies, and orthotics are covered when Medically Necessary and the following requirements are met:

- Medicare National Coverage Determination (NCD), CMS DME MAC Local Coverage Determination (LCD), Local Coverage Article (LCA), or other Medicare coverage guidance criteria are met (see link below); and
- Consistent with the state definition of DME and/or Orthotic; and
- Ordered by a physician; and
- The item is not otherwise excluded from coverage

UnitedHealthcare Community Plan uses available criteria from the (DME MAC).

Breast Pumps

Breast pumps may be covered. Refer to the federal, state or contractual requirements for coverage.

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. Please check the federal, state or contractual requirements for coverage.

Cranial Remolding Orthosis

Cranial molding helmets (cranial remolding orthosis, billed with S1040) used to facilitate a successful post-surgical outcome are covered.

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.

Enteral Pumps

Enteral pumps are covered as DME, even when the enteral nutrition formula is not covered. Please check the federal, state or contractual requirements for coverage.

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.)

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. Reference the federal, state or contractual requirements 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, reference the federal, state or contractual requirements.

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).

Coverage of Ostomy Supplies is limited to the following:

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

Note: Deodorants, filters, lubricants, tape, appliance cleaners, adhesive, adhesive remover, or other items not listed above, are not covered items, except as otherwise required by federal, state or contractual requirements for coverage.

For coverage of urinary catheters, refer to the federal, state or contractual requirements.

Other supplies are not covered unless required under applicable federal, state or contractual requirements.

For additional supply information, reference the Coverage Limitations and Exclusions section.

Mobility Devices

Mobility Devices include manual wheelchairs, electric wheelchairs, transfer chair, or scooters/power-operated vehicles (POV). Reference the federal, state or contractual requirements 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). Reference the federal, state or contractual requirements for coverage.

- 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. 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

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

Repair or replacement of DME is not covered for the following:

- Repairs, replacements and maintenance for items/devices required during a rental period or a Maintenance & Service agreement. These are the contractual responsibility of the item/device provider.
- Replacement and repairs of items are required due to malicious damage, neglect or abuse.

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

Safety Enclosure with Beds

Safety enclosure with beds (e.g., pediatric enclosed bed, adult bed, safety enclosure) are covered as DME for individuals that have a risk for safety in bed when all of the following criteria are met:

- Use of equipment is required due to a diagnosis related to cognitive impairment (e.g., traumatic brain injury, cerebral palsy, seizure disorder) or a severe behavioral disorder

- There is a safety risk that includes but is not limited to any of the following:
  - Claustrophobia
  - High risk of falls due to a clinical condition
  - Uncontrolled movements
  - Violent or self-destructive behaviors such as uncontrolled head banging
- Less restrictive alternatives methods such as the following have been tried and have not been successful or are contraindicated:
  - A mattress on the floor
  - Protective helmet
  - Side rails
  - Weighted blankets

The physician documentation must include:
- A signed physicians order for the enclosed bed
- Behavioral Management Program, if applicable
- Evaluation for contraindications to use of the equipment
- Member assessment for physical, environmental, and behavioral factors
- Name and model of protective or enclosure bed with a valid HCPCS code
- Physician directed written monitoring plan
- The medical, neurologic, or behavioral diagnosis

Speech Generating Devices

Speech Generating Devices are covered as DME when:
- The device(s) are not explicitly excluded from coverage (refer to the federal, state or contractual requirements); and
- The treating physician determines that the member suffers from severe speech impairment (impediment); 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;
- 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 Dedicated Speech Generating Device include but are not limited to:
  - Dynavox
  - Freedom
  - Say-it!™

Note: Reference the federal, state or contractual requirements for coverage of Speech Generating Devices.

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, home ventilators are:
- Not covered for non-life-threatening conditions
- Not covered when used as respiratory assist devices (RAD)

Regardless of the member's age, any type of ventilator would not be Medically Necessary for any of the conditions described in the DME Medicare Administrative Contracts (DME MAC) RAD criteria even though the ventilator may have the capability of operating in a bi-level PAP (E0470, E0471) mode.
- Ventilators, such as Trilogy mechanical ventilators (E0465, E0466), used for the treatment of conditions described in the DME MAC RAD criteria that deliver continuous or intermittent positive airway pressure are not Medically Necessary. Bi-level PAP devices (E0470, E0471) are considered as medically necessary in those clinical scenarios.

- 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.
- Ventilators must not be billed using codes for CPAP (E0601) or bi-level PAP (E0470, E0471, 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

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).

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.

Unless identified for coverage by the federal, state or contractual requirements, the following 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
    - Non-medical mobility devices (e.g., commercial stroller). This exclusion does not apply to pediatric wheelchairs.
    - 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)
- Dental braces unless identified for coverage by the federal, state or contractual requirements
- 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 (e.g., blood pressure monitor, oximeters) unless the service is identified for coverage by the federal, state or contractual requirements (e.g., oximeter use with a ventilator).
- Elastic splints, sleeves or bandages are not covered, unless identified for coverage by the federal, state or contractual requirements (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.
- Personal Care, Comfort and Convenience items and supplies unless identified for coverage by the state contract or state guidelines.
- 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 are not covered:
    - Items and supplies that are not Medically Necessary
    - 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.

    - Ostomy Supplies unless identified for coverage by federal, state or contractual requirements. See Indications for Coverage.
- The following items are excluded even if prescribed by a physician unless identified for coverage by the federal, state or contractual requirements
    - 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 is not covered. Refer to Repair/Replacement section.

Definitions

Check the federal, state or contractual definitions that supersede the definitions below.

Behavioral Management Program: Recommended guidelines for behavior management include direct behavioral observations, systematic assessment of environmental and within-patient variables associated with aberrant behavior, antecedent management to minimize the probability of aberrant behavior, provision of functionally equivalent alternative means of controlling the environment, and differential reinforcement to shape positive behavior and coping strategies while not inadvertently shaping emergent, disruptive sequelae.

Durable Medical Equipment (DME): Medical equipment that is all of the following:
- Can withstand repeated use
- Is generally not useful to a person in the absence of a sickness, injury or their symptoms
- Is not disposable
- Is not implantable within the body
- Is used to serve a medical purpose with respect to treatment of a sickness, injury or their symptoms
- Meets the state definition of DME

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, scooter, gait trainer, walker, crutch or cane.

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 established pursuant to Medicare requirements 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 be software that allows a laptop computer, desktop computer or personal digital assistant (PDA) to function as a Speech Generating Device
- May have digitized speech output, using pre-recorded messages, greater than 8 minutes recording time
- May have digitized speech output, using pre-recorded messages, less than or equal to 8 minutes recording time
- May have synthesized speech output, which permits multiple methods of message formulation and multiple methods of device access
- May have synthesized speech output, which requires message formulation by spelling and device access by physical contact with the device-direct selection techniques

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 a source for correct coding and coding clarification.

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

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Guideline History/Revision Information

Date	Summary of Changes
04/01/2021	**Template Update** • Removed *Related Policies* section • Updated *Instructions for Use*; replaced reference to "MCG™ Care Guidelines" with "InterQual® criteria"
02/09/2021	**Template Update** • Reformatted policy; transferred content to new template
01/01/2021	**Related Policies** • Removed reference link to the policy titled *Electrical and Ultrasound Bone Growth Stimulators (for Louisiana Only)* (retired Jan. 1, 2021)

10/01/2020	**Coverage Rationale**
	Indications for Coverage
	• Combined and reformatted content/language previously included in the sections titled Medical Supplies and Ostomy Supplies
	• Added instruction to refer to federal, state or contractual requirements for coverage of urinary catheters
	• Added coverage guidelines for Safety Enclosure with Beds to indicate:
	  ○ Safety enclosure with beds (e.g., pediatric enclosed bed, adult bed, safety enclosure) are covered as DME for individuals that have a risk for safety in bed when all of the following criteria are met:
	  ▪ Use of equipment is required due to a diagnosis related to cognitive impairment (e.g., traumatic brain injury, cerebral palsy, seizure disorder) or a severe behavioral disorder
	  ▪ There is a safety risk that includes but is not limited to any of the following:
	  – Claustrophobia
	  – High risk of falls due to a clinical condition
	  – Uncontrolled movements
	  – Violent or self-destructive behaviors such as uncontrolled head banging
	  ▪ Less restrictive alternatives methods such as the following have been tried and have not been successful or are contraindicated;
	  – A mattress on the floor
	  – Protective helmet
	  – Side rails
	  – Weighted blankets
	  ○ The physician documentation must include:
	  ▪ A signed physicians order for the enclosed bed
	  ▪ Behavioral Management Program, if applicable
	  ▪ Evaluation for contraindications to use of the equipment
	  ▪ Member assessment for physical, environmental, and behavioral factors

Date	Summary of Changes
	▪ Name and model of protective or enclosure bed with a valid HCPCS code ▪ Physician directed written monitoring plan ▪ The medical, neurologic, or behavioral diagnosis *Coverage Limitations and Exclusions* • Revised list of services excluded from coverage: ○ Updated list of examples of accessories to DME items or devices which are primarily for the comfort or convenience of the member and not covered; added "non-medical mobility devices (e.g., commercial stroller); this exclusion does not apply to pediatric wheelchairs" ○ Replaced "diagnostic or monitoring equipment purchased for home use unless identified for coverage by the federal, state or contractual requirements (e.g., blood pressure monitor, oximeters)" with "diagnostic or monitoring equipment purchased for home use (e.g., blood pressure monitor, oximeters) unless *the service is* identified for coverage by the federal, state or contractual requirements *(e.g., oximeter use with a ventilator)*" Definitions • Added definition of "Behavioral Management Program" Supporting Information • Updated *References* section to reflect the most current information • Archived previous policy version CS032LA.P

Instructions for Use

This Coverage Determination Guideline provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this guideline, please check the federal, state or contractual requirements for benefit plan coverage. 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.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The 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.