Regence

Medical Policy Manual Durable Medical Equipment, Policy No. 75

Durable Medical Equipment, Prosthetic and Orthotic Replacements, Duplicates, Repairs, and Upgrades to Existing Equipment

Effective: October 1, 2026

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

The Centers for Medicare and Medicaid Services (CMS) provide guidance regarding the medical appropriateness of replacement for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) due to irreparable damage or wear. In addition, CMS also provides guidance on the repair of DMEPOS (instead of replacement), upgrades, backup medical equipment, maintenance, and other services provided to ensure continued use of medically necessary items.

MEDICAL POLICY CRITERIA

Notes:

- The initial provision of a Group 3 power wheelchair should be reviewed with the DME37 policy (see Cross References).
- The services described in this medical policy may not be subject to routine medical necessity review unless they are addressed by a separate medical policy (see Cross References below). However, utilization may be subject to audit. The health plan may defer to current policies, guidelines, and/or interpretations established by

CMS to determine appropriateness of the replacement frequency of such equipment and supplies. Claim adjudication is subject to claim processing guidelines and provider contracts and therefore, an item that meets medically necessary criteria is not guaranteed for reimbursement.

- Clinical documentation to support criteria is required (See Required Documentation).

Medically Necessary

I. Replacement Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) may be **medically necessary** when any of the following Criterion (A. – C.) are met:

A. Supplies and accessories necessary for the effective use of DME, prosthetics, or orthotics (e.g., batteries, tubing, tape, etc.) if the primary DME, prosthetic, or orthotic item itself was determined to be medically necessary. Note: supplies and accessories are not generally subject to the requirements below; or

B. Replacement of all or part of a member-owned DME item when both of the following (1. and 2.) are met:

1. The DME item(s) continues to be medically necessary for the individual; and
2. One or more of the following (a. – d.) conditions are met:
   a. The current DME item(s) has been lost, stolen or irreparably damaged; or
   b. There is clinical evidence demonstrating a significant change in the individual's medical condition and both of the following (i. – ii.) are met:
      i. The current DME item(s) can no longer meet the individual's functional needs (See policy guidelines); and
      ii. It is the least costly option to replace the equipment to meet the individual's functional needs (See policy guidelines); or
   c. The current DME item(s) is irreparably worn **and** has exceeded the minimum five-year reasonable useful lifetime expectancy (excluding prosthetics [see below], some knee orthoses [see Policy Guidelines], and supplies); or
   d. An accessory required for the effective use of a DME item is irreparably worn and the replacement part needed is no longer available and cannot be substituted with another manufacturer's part. *Example: An electrical nerve stimulator unit's lead wires are no longer manufactured and cannot be substituted with another brand. Therefore, the nerve stimulator unit itself is effectively nonfunctional and must be replaced*; or

C. In the absence of a medical policy with specific coverage criteria, replacement of a prosthetic device that is an artificial limb or a replacement part of such a device may be considered **medically necessary** when one or more of the following (1. – 3.) conditions are met:

1. A change in the physiological condition of the individual; or

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.

II. A back-up DME item (a duplicate item that serves the same medical purpose) may be considered **medically necessary** when both of the following (A. and B.) are met (Note: identical or similar devices used to meet a different medical purpose do not fall under the above criteria and would not be considered a "back-up" item [See Policy Guidelines for definition and examples of different medical purpose]):

A. A break-down or malfunction of the item would result in immediate life-threatening consequences for the member (e.g. ventilator); and

B. The item is not being rented. Rented items are not owned by the member, but instead are considered owned by the supplier. The monthly rental payment includes a contingency plan that is expected to be in place by the supplier to ensure the medical needs of the equipment are met on an ongoing basis, including a plan to deal with interruptions in the use of the equipment that would be life-threatening. *Example: Providing a back-up unit while the original item is under repair.*

III. Repair, maintenance and items and services under warranty may be considered **medically necessary** when either of the following (A. or B.) are met:

A. Repair (labor and parts) of DME, prosthetics, or orthotics when all of the following (1. – 4.) are met:

1. Member-owned (purchased) equipment if the member meets the current coverage and documentation requirements as specified in the applicable medical policies (when they exist); and
2. When the repairs are necessary to make the equipment serviceable; and
3. The item is not under manufacturer or supplier warranty, unless a warranty specifically excludes an item (the health plan pays for reasonable and necessary labor and parts not otherwise covered under the manufacturer's or supplier's warranty); and
4. The supplier will use the least costly option to repair the equipment and not use excessive parts that are not required to restore the equipment to a serviceable condition (e.g., if a part is in a serviceable condition and can be reused, the supplier should reuse the existing part instead of billing for a replacement part/item); or

B. Non-routine maintenance service or more extensive service, which is required to be performed by authorized technicians (based on the manufacturer's recommendations), is needed as repairs for member-owned, medically necessary equipment. *Example: Breaking down sealed components and performing tests which require specialized testing equipment not available to the beneficiary.*

Not Medically Necessary

IV. Replacement DMEPOS is **not medically necessary** for the following (A. – B):

A. Criterion I.B. above is not met; or

B. Replacement for any of the following (1. – 5.) situations:

1. Oxygen equipment replacement requests during the reasonable useful lifetime (RUL) of the equipment; or
2. Equipment that is being rented; or
3. Replacement of equipment due to member abuse, neglect or intentional damage; or
4. Items that are being or have been recalled (recalled items must be replaced at no charge to the member or the health plan); or
5. Replacement is covered under manufacturer warranty and maintenance services (See Criterion VII.).

V. **Upgrades:** Replacement requests for same/similar items which include upgraded features or components (additional or deluxe features which exceed the member's functional needs, see Policy Guidelines) or upgrades to DME, prosthetics, or orthotics already in use are **not medically necessary**.

VI. A backup or identical/similar item is **not medically necessary** for any of the following (A. – C.):

A. Item used for convenience, leisure or recreational activities of the member and/or caregiver (see Policy Guidelines); or

B. Item(s) that are being rented; or

C. For an individual who has a multi-function home ventilator (HCPCS code E0467), requests for separate component equipment as back-up items are not eligible for coverage (e.g., oxygen concentrator, cough stimulator, aspirator, nebulizer, positive airway pressure [PAP] devices, and custom fabricated oral appliances). Note: claims for code E0467 with a date(s) of service that overlaps date(s) of service in a rental month for any of the items listed above are considered as a claim for same or similar equipment.

VII. Repair (labor and parts) of DME, prosthetics or orthotics and maintenance service are considered **not medically necessary** for any of the following (A. – F.):

A. Any equipment covered under manufacturer or supplier warranty (A DMEPOS supplier must notify the member and the health plan of warranty coverage and honor all warranties under applicable State law. The supplier must repair or replace free of charge items that are under warranty); or

B. Equipment which was previously denied; or

C. Supplier-owned (rented) equipment, including oxygen; or

D. Because a multi-function ventilator (HCPCS E0467) describes a device that integrates the function of multiple types of equipment into a single device, any request for the repair of these integrated components on beneficiary-owned equipment (with or without replacement parts) is considered as unbundling if the date(s) of service for the repair overlaps any date(s) of service for code E0467; or

E. Routine periodic servicing, testing, cleaning, regulating, and checking of the member's equipment, among other services; or

F. Maintenance service for supplier owned (rented) equipment.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

POLICY GUIDELINES

Durable Medical Equipment Definition

Durable Medical Equipment (DME) is defined as equipment which:

- 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;
- Is appropriate for use in the home; and
- Has a minimum lifetime requirement (MLR) of at least three years (for items reviewed and categorized *on or after* January 1, 2012).

NOTE: The MLR is **different** from the reasonable useful lifetime (RUL) requirement for DME items.

All requirements of the definition must be met before an item is considered to be durable medical equipment.

Functional Needs

For member contracts subject to Washington HB 1699 or Oregon SB 699: Devices that meet the needs of the individual for purposes of performing physical activities, including but not limited to activities of daily living (ADLs), running, biking, swimming and strength training.

For all other contracts: Devices that meet the needs of the individual for purposes of performing activities of daily living (ADLs).

Reasonable Useful Lifetime (RUL)

The MLR used to determine if an item or piece of equipment meets the definition of "DME" is **not** the same as the reasonable useful lifetime, or RUL requirement for DME. The three-year MLR is a requirement for an item to be considered eligible for classification as DME because items with an MLR of less than three years are not considered DME because they do not meet the definition of the term "durable," and thus would be ineligible for coverage.

The RUL is used to determine how often it is reasonable to pay for the replacement of an item or component, which under Medicare, with some exceptions, is not generally less than five years. Exceptions include upper and lower extremity prosthetics (with no assigned RUL), as well as some knee orthoses, the latter of which have specified RUL requirements published in local contractor articles.

However, even if an item is not subject to the five-year RUL rule, replacement of these items remains subject to other medical necessity requirements (e.g., member still requires and

continues to use the item, the current item is irreparably worn or damaged, lost or stolen, or the member's physiological condition has changed to a significant extent that a different item is required, etc.).

Supplies and Accessories

Supplies and accessories that are necessary for the effective use of medically necessary DME are covered if the DME item itself is covered, but would not necessarily be subject to the same replacement rules since many supplies (e.g., batteries, tubes, tape, etc.) would not be expected to last five years, but would still be necessary to ensure proper function of the primary DME item.

Replacement

Replacement of true durable medical equipment refers to the provision of an identical (same) or nearly identical (similar) DMEPOS item which is used or may be used to serve the same medically necessary function or purpose.

Under the DME benefit, the member is eligible for the least costly reasonable or medically necessary equipment. By definition, this excludes same or similar duplicate DMEPOS items that serve or may serve the same medically necessary function.

Example: Both manual wheelchairs and power wheelchairs fall under the broad category of Mobility Assistive Equipment (MAE) and are used to serve the same medical purpose of restoring the individual's mobility limitation so the member may complete their mobility-related activities of daily living (MRADLs; toileting, feeding, dressing, grooming, bathing, etc.). As such, the member is eligible for the least costly alternative that meets this medical need, but not both. Prior to *replacing* durable medical equipment, prosthetics or orthotics, *repairs* of existing equipment may be attempted to make the item serviceable until it becomes irreparable**.**

Backup/Identical or Similar Devices

Backup medical equipment is defined as an identical or similar device that is used to meet the same medical purpose for the beneficiary but is provided for precautionary reasons to deal with an emergency in which the primary piece of equipment malfunctions. Identical or similar devices required to serve a different purpose, determined by the individual's medical needs, are not considered backup devices.[1] Examples of situations in which multiple items serve a different medical purpose and would *not* be considered backup items:

- One type of ventilator (e.g., a negative pressure ventilator with a chest shell) is needed for part of the day, but a different type of ventilator is needed during the rest of the day (e.g., a positive pressure respiratory assist device with a nasal mask)
- A wheelchair-mounted ventilator is needed for use during the day, but another ventilator of the same type is needed for use in bed to ensure safe use of the medical equipment, prevent medical complications that could occur without both pieces of equipment, or to achieve appropriate medical outcomes
- One type of infusion pump is required for a particular drug (e.g., a pump with patient control features for parenteral morphine), and a different type of pump is required for another drug (e.g., continuous infusion chemotherapy)

Examples of situations in which multiple items serve the same medical purpose and would be considered backup medical equipment:

- A second ventilator of the same or similar type is requested at the bedside as a precaution in case of malfunction of the primary ventilator
- A second identical Continuous Positive Airway Pressure (CPAP) machine is requested for at-home use in case the primary unit fails

Upgrades

Upgrades may be requested either as part of a replacement request or as a request of its own, usually due to member or caregiver convenience. This may include a component piece of equipment, or an extra feature or service offered for the item. It may be supplied in addition to the primary equipment or is a whole new piece of equipment that is more extensive and/or more expensive than the medically reasonable item. An item can be considered an upgrade even if the physician has prescribed the item. As an item that goes beyond what is medically necessary according to the coverage criteria, these are not covered unless there are specific coverage criteria available in a medical policy.

REQUIRED DOCUMENTATION

The following information is not required with every claim submission but may be requested for audit of DME items. Requested information may include, but is not limited to, the following:

All requests should include documentation in the medical records and/or chart notes to support the continued medical need for the item in question.

- Lost DME: The request for replacement should include a written explanation regarding the circumstances of the loss.
- Stolen DME: For DME items that have been stolen, a police report should be provided.
- Replacement due to Irreparable Damage: Equipment that is irreparably damaged or worn should include verification of how the equipment was damaged and a physician's order and/or new Certificate of Medical Necessity (CMN) to reaffirm the medical necessity of the item.
- Replacement due to Irreparable Wear: To demonstrate the equipment is irreparably worn, the DME supplier should conduct a comprehensive repair evaluation that documents specifically what is wrong with the equipment down to the part level. When applicable, the evaluation should include as much objective evidence to demonstrate the items requested are necessary to restore the equipment to a serviceable condition. A physician’s order and/or new CMN is also needed to reaffirm the medical necessity of the item.
    - When DME needs to be replaced due to irreparable wear of an accessory and the replacement accessory is no longer available and unable to be substituted with another available item, the supplier must obtain and submit with the claim a current detailed written physician's order with an explanation of why the item must be replaced. For items that require a CMN, a current CMN may serve as the detailed written order if the narrative description is sufficiently detailed.

- Replacement due to change in the individual's condition: Documentation must document what has changed for the member, why the existing equipment is inadequate, and include physician's order and/or new CMN is also needed to reaffirm the medical necessity of the item.

- Repair: For repairs, the DME supplier must include a repair evaluation and demonstrate the item/part requested is medically or reasonably necessary to restore the equipment to a serviceable condition. There must also be a statement attesting that the item or part is not covered under manufacturer warranty.

    - Note: Parts that are not reasonable or medically necessary should not be included with the estimate for the replacement or repair request (e.g., a plastic shroud on a power wheelchair with aesthetic value only would not be required to make the chair serviceable and should not be included in the estimate).

CROSS REFERENCES

1. Definitive Lower Limb Prostheses, Durable Medical Equipment, Policy No. 18
2. Power Wheelchairs: Group 2 and Group 3, Durable Medical Equipment, Policy No. 37
3. General Medical Necessity Guidance for Durable Medical Equipment, Prosthetic, Orthotics and Supplies (DMEPOS), Durable Medical Equipment, Policy No. 88
4. Mechanical Residual Limb Volume Management System for Upper Extremity Prostheses, Durable Medical Equipment, Policy No 98
5. Durable Medical Equipment Policies, Medical Policy Manual Index
6. Reimbursement Policy Manual: Home web page

BACKGROUND

Durable Medical Equipment (DME) is defined as equipment which:[2]

- 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;
- Is appropriate for use in the home; and
- Has a minimum lifetime requirement (MLR) of at least 3 years (for items reviewed and categorized *on or after* January 1, 2012).

Note: The MLR is not the reasonable useful lifetime (RUL) requirement for DME items. The RUL is used to determine how often it is reasonable to pay for the replacement of an item or component (see Cross References). The 3-year MLR is a requirement for an item to be considered eligible for classification as DME. Items with an MLR of less than 3 years are ineligible to be considered DME because they do not meet the definition of the term "durable."

All requirements of the definition must be met before an item is considered to be durable medical equipment. This policy is based on requirements established by the Centers for Medicare & Medicaid Services (CMS). The following definitions are applicable per CMS and in support of this policy.[1, 3-11]

Backup Medical Equipment: Is defined as an identical or similar device that is used to meet the same medical need for the member but is provided for precautionary reasons to deal with an emergency in which the primary piece of equipment malfunctions.

Identical or Similar Devices: Refers to an identical or similar device that is already in the member's possession, that is still within the reasonable useful lifetime of the equipment and/or still in a serviceable condition and meets the medical needs of the member. Generally the item(s) are within the same benefit category, but not always.

Irreparable Damage: Irreparable damage refers to a specific accident or to a natural disaster (e.g., fire, flood), for example, a wheelchair falling out of the back of a truck while traveling down the highway. While the term irreparable damage means the item is not repairable, in the context of this policy, irreparable damage also refers to equipment that is not cost effective to repair.

Irreparable Wear: Refers to deterioration sustained from day-to-day usage over time and a specific event cannot be identified. Irreparable wear means the item is not repairable. However, in the context of this policy, irreparable wear also means equipment is not cost effective to repair. Replacement of equipment due to irreparable wear takes into consideration the reasonable useful lifetime of the equipment.

Upgrades: An upgrade is defined as an item that goes beyond what is medically necessary according to the coverage criteria. This includes excess components (either a device or an extra feature or service) supplied in addition to, or is more extensive and/or more expensive than, the medically reasonable item. An item can be considered an upgrade even if the physician has prescribed the item.

Reasonable Useful Lifetime (RUL): The RUL is used to determine how often it is reasonable to pay for the replacement of DME. Computation of the RUL is based on when the equipment is delivered to the member, not the age of the equipment. Per the federal definition found in 42 CFR 414.210(f) and the national standard, in no case can the reasonable useful lifetime of durable medical equipment be less than 5 years.

Repairs: To fix or mend and to put the equipment back in serviceable condition after damage or wear. The term serviceable means to "fulfill its function adequately" or to make the item "usable". It does not include restoring the equipment to "like new" condition and does not include items or features that are aesthetic in nature only.

Maintenance: Maintenance services include routine periodic servicing, testing, cleaning, regulating, and checking of the member's equipment, as well as breaking down sealed components and performing tests which require specialized testing equipment not available to the beneficiary.

SUMMARY

Medically Necessary

According to the U.S. Centers for Medicare & Medicaid Services, repair, replacement, and non-routine maintenance of DME, prosthetics and orthotics may be considered medically reasonable and necessary when specific policy criteria are met.

Not Medically Necessary

According to the U.S. Centers for Medicare & Medicaid Services, repair, replacement, and non-routine maintenance of DME, prosthetics and orthotics are considered not medically necessary when policy criteria are not met.

Routine maintenance, upgrades, and back-up/duplicate items are considered not medically necessary.

REFERENCES

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CODES

NOTE: Some equipment, prosthetics, orthotics, supplies and accessories will have specific codes for use when the item is a replacement. As with all services and items, providers and suppliers are expected to report all items with the appropriate Healthcare Common Procedure Coding System (HCPCS) code.

Codes	Number	Description
CPT	None	
HCPCS	None	

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