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Medicare Advantage Policy Manual **Policy ID:** M-DME75

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

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

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.

MEDICARE ADVANTAGE POLICY CRITERIA

Note:

- 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. However, utilization may be subject to audit.
- See "Policy Guidelines" below for Medicare-based definitions of terms used in this medical policy.

Procedure(s):	CMS Coverage Manuals and National Coverage Determinations (NCDs)
Replacement (DME, non-limb prosthetics, and orthotics)	**Medicare Benefit Policy Manual, Pub. No. 100-02** **Chapter 15 - Covered Medical and Other Health Services** *See Section 110.2, Subsection C, in the following link:* §110.2 Repairs, Maintenance, Replacement, and Delivery

Important Notes:

- The following scenarios for replacement are not covered:
  - Equipment that is being rented (this includes equipment in the frequent and substantial servicing or oxygen equipment payment categories because items in these categories are rented)[1];
  - Replacement of equipment due to member abuse, neglect or intentional damage;
  - Items that are being or have been recalled (recalled items must be replaced at no charge to the member or health plan); or
  - Items still covered under manufacturer warranty (see below).
  - Replacement due to irreparable wear during the 5-year reasonable useful lifetime (RUL) period is not covered. (Note, there are exceptions to the 5-year RUL for some knee orthoses noted in the LCA (A52465)
  - Replacement items or accessories that are beneficial primarily in allowing the patient to perform leisure or recreational activities are noncovered.
- Replacement is defined by Medicare as the provision of an entire identical or nearly identical item when it is lost, stolen or irreparably damaged.[2] The Noridian "Same or Similar Chart" can be useful in making this distinction.

	• The item must be lost, stolen, irreparably worn or damaged (if repairs can be made reasonably to the item, it should **not** be replaced). In addition, for irreparably worn items, the equipment must also have exceeded the minimum 5-year RUL expectancy. (See note regarding knee orthoses above.) • Cases suggesting malicious damage, culpable neglect, or wrongful disposition of equipment may be investigated and denied when the health plan determines it is unreasonable to make program payment under the circumstances. • In rare situations, 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: A 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.*
Limb Prosthetic Replacement	**Medicare Benefit Policy Manual, Pub. No. 100-02** **Chapter 15 - Covered Medical and Other Health Services** *See Section 120, Subsection A, in the following link:* §120 Prosthetic Devices, A. General **Important Notes:** • For general limb prosthetic replacement, see the noted Medicare reference. • If the existing equipment is no longer functioning, but the replacement request includes upgraded technology or features, even if the replacement base device is medically necessary, the upgraded components may not be approved based on Medicare guidance for “Upgrades” below. • If the existing equipment is no longer functioning and is adequate for the individual’s needs, but a prosthetic replacement is requested as an upgrade, see below.
Warranties	**Medicare Benefit Policy Manual, Pub. No. 100-02** **Chapter 16 - General Exclusions from Coverage** *See Section 40.4 in the following link:* §40.4 - Items Covered Under Warranty **Important Notes:**

	• 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.[2] If equipment or a device is replaced free of charge by the warrantor, no payment may be made, since there was no charge involved.
Repairs and Maintenance Services	**Medicare Benefit Policy Manual, Pub. No. 100-02** **Chapter 15 - Covered Medical and Other Health Services** *See Section 110.2, Subsection C, in the following link:* §110.2 Repairs, Maintenance, Replacement, and Delivery, A. Repairs **Important Notes:** • Repair or maintenance of equipment in the frequent and substantial servicing or oxygen equipment payment categories is not eligible for coverage under Medicare because equipment in these categories is paid on a rental basis only.[1] In addition, coverage of repairs or replacement part charges is not allowed for supplier-owned (rented) equipment. • The supplier must 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). • Repairs are not covered for equipment which was previously denied (non-covered equipment). • 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. • Some warranties may specifically exclude an item or service from being covered under the warranty. The health plan pays for reasonable and necessary labor and parts not otherwise covered under the manufacturer's or supplier's warranty. Otherwise, when a warranty is in place, neither the member nor the plan may be charged.[3,4] • Routine maintenance services (e.g., routine periodic servicing, testing, cleaning, regulating, and checking of the member's equipment) are not covered. However, more extensive (non-routine) maintenance services which are expected to be performed by authorized technicians

	based on the manufacturer' recommendations (e.g., breaking down sealed components and performing tests which require specialized testing equipment not available to the beneficiary) may be covered as repairs for member-owned, medically necessary equipment.[2] • A supplier that transfers to the beneficiary the title to a capped rental item is responsible for furnishing replacement equipment at no cost to the beneficiary or to the Medicare program if the carrier determines that the item furnished by the supplier will not last for the entire reasonable useful lifetime established for the equipment. In making this determination, the carrier may consider whether the accumulated costs of repair exceed 60 percent of the cost to replace the item.
Upgrades	**Important Notes:** • An upgrade is defined by Medicare as an item with features that go beyond what is medically necessary.[5] An item can be considered an upgrade even if the physician has signed an order for it. Not all replacements with additional features would be considered upgrades by this definition, and requests for supplies that may be upgrades should be reviewed according to the relevant Medicare guidance. • An upgrade may be an *entire item or device* or it may be an excess *component*, such as a special feature or service provided in addition to, or is more extensive and/or more expensive than, the item that would be considered reasonable and necessary under Medicare's coverage requirements. • Requests for the replacement of properly functioning equipment for the sole purpose of allowing the member to obtain an upgrade to newer technology may be denied as not medically necessary.
Duplicate Items, including but not limited to Back-Up Equipment	**Important Notes:** • Back-up medical equipment is defined as an identical or similar device that is used to meet the ***same*** medical need for a beneficiary but is provided for precautionary reasons to deal with an emergency when the primary piece of equipment malfunctions.[6] • Medicare does not pay separately or make an additional payment for back-up equipment. • Backup equipment must be distinguished from multiple medically necessary items that are defined as identical or similar devices, each meeting a ***different*** medical need for the beneficiary, which may be eligible for reimbursement if required to serve a different purpose.[6]

	• Examples of non-covered duplicate or back-up equipment include, but are not limited to, spare tanks of oxygen, extra wheelchairs for designated use only in certain settings (e.g., outdoor only use), etc.
Supplies and Accessories	• Supplies and accessories necessary for the effective use of durable medical equipment DME, prosthetics, or orthotics (e.g., batteries, tubing, tape, etc.) may be covered if the primary DME, prosthetic or orthotic item itself is medically necessary, but are not generally subject to the requirements above for replacement. • While the replacement of such supplies is not routinely reviewed for medical necessity, utilization may be subject to audit. • Some items may have specific utilization guidelines in local coverage determinations (LCDs) or articles (LCAs) and the health plan may defer to current policies, guidelines, and/or interpretations established by CMS to determine appropriateness of the replacement frequency of such supplies and accessories.
Additional considerations	• For all services, claim adjudication is subject to claim processing guidelines and provider contracts and therefore, an item that meets medically necessary criteria is not guaranteed reimbursement.

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- All requests will require documentation to indicate the continued medical need of the device/equipment in question prior to replacement and how long the member has had the current item/equipment.
- In addition, the following is also necessary for an accurate and efficient review:
    - 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 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 patient'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).

DEFINITIONS

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.

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.

Minimum Lifetime Requirement (MLR): The MLR is used to refer to the specified 3-year duration for repeated use (durability). Repeated rental requires full functionality over the entire MLR. Items with an MLR of less than 3-years are not eligible to be classified as DME.

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.

Replacement: Replacement 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.

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.

Warranty: A warranty is commonly considered to be a guarantee by a manufacturer promising to repair or replace an item, if necessary, within a specified period.

CROSS REFERENCES

Durable Medical Equipment Policies, Medicare Advantage Medical Policy Manual Index

REFERENCES

1. Noridian. *Items Requiring Frequent and Substantial Servicing*; https://med.noridianmedicare.com/web/jddme/topics/payment-categories/frequent-servicing [Last Accessed 08/10/2023]
2. Medicare Benefit Policy Manual Chapter 15; 110.2 - Repairs, Maintenance, Replacement, and Delivery [Last Accessed 08/10/2023]
3. Medicare Claims Processing Manual, Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), §40.4 - Items Covered Under Warranty [Last Accessed 08/10/2023]
4. Noridian. https://med.noridianmedicare.com/web/jddme/topics/repairs/warranties [Last Accessed 08/10/2023]
5. Medicare Claims Processing Manual, Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), §120 - DME MACs - Billing Procedures Related To Advanced Beneficiary Notice (ABN) Upgrades [Last Accessed 08/10/2023]
6. Noridian. *Back-Up Equipment*; https://med.noridianmedicare.com/web/jddme/search-result/-/view/2230703/back-up-equipment [Last Accessed 08/10/2023]
7. Noridian. *Replacement*; https://med.noridianmedicare.com/web/jddme/topics/repairs/replacement [Last Accessed 08/10/2023]
8. Noridian. *Replacement of Durable Medical Equipment*; https://med.noridianmedicare.com/web/jddme/search-result/-/view/2230703/replacement-of-durable-medical-equipment [Last Accessed 08/10/2023]
9. Noridian. *Reasonable Useful Lifetime - Clarification*; https://med.noridianmedicare.com/web/jddme/search-result/-/view/2230703/reasonable-useful-lifetime-clarification [Last Accessed 08/10/2023]
10. Noridian. *Correct Coding - Warranty, Reasonable Useful Lifetime (RUL), and the Minimum Lifetime Requirement (MLR) for Durable Medical Equipment*; https://med.noridianmedicare.com/web/jddme/policies/dmd-articles/2021/warranty-reasonable-useful-lifetime [Last Accessed 08/10/2023]
11. Noridian. *Repairs, Maintenance and Replacement*; https://med.noridianmedicare.com/web/jddme/topics/repairs [Last Accessed 08/10/2023]
12. Noridian. *Upgrades*; https://med.noridianmedicare.com/web/jddme/topics/upgrades [Last Accessed 08/10/2023]
13. General Payment Rules 42 CFR § 414.229(f)(2); 414.210(f)(1) and 414.210(e)(4). 42 CFR [Last Accessed 08/10/2023]

CODING

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	

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*