

Medical Policy

Durable Medical Equipment Prosthetics Orthotics and Supplies (DMEPOS)

MEDICAL POLICY NUMBER: 142

| | | |
|-----------------------------------|-------------------------------------|----|
| Effective Date: 7/1/2023 | COVERAGE CRITERIA | 2 |
| Last Review Date: 6/2023 | POLICY CROSS REFERENCES | 7 |
| Next Annual Review: 6/2024 | POLICY GUIDELINES..... | 7 |
| | REGULATORY STATUS..... | 19 |
| | BILLING GUIDELINES AND CODING | 19 |
| | REFERENCES | 21 |
| | POLICY REVISION HISTORY | 24 |
| | APPENDICES | 25 |

INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

Commercial

Medicaid/OHP*

Medicare**

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered “**not medically necessary**” for Medicare members.

COVERAGE CRITERIA

Notes:

- This policy is based on the Centers of Medicare and Medicaid Services (CMS) guidance found in references including, but not limited to, the National Coverage Determination (NCD) for Durable Medical Equipment Reference List ([280.1](#)) and the Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, 110.1 Definition of Durable Medical Equipment.
- Collectively, these benefit categories are known by Medicare as “DMEPOS” and the relevant Medicare guidelines have been translated to the criteria listed below.
- Claims are subject to applicable claim processing guidelines, provider contracts, and member benefits and eligibility. Therefore, items which meet medical necessity criteria or may appear to be medically indicated are not guaranteed reimbursement or payment.
- Member contracts may have specific language regarding medical equipment and devices. Member contract language takes precedence over medical policy.
- Not all equipment described in this medical policy are subject to routine medical necessity review. Some devices or equipment may be addressed by a separate medical policy, with prior authorization requirements. However, utilization of any DMEPOS may be subject to audit.

Medical Policy Criteria and Policy Guideline Quick Links

- ❖ Appendices:
 - [Appendix I](#) - Examples of DMEPOS items which may be **medically necessary**
 - [Appendix II](#) - Examples of **non-covered** DMEPOS items
- ❖ [Documentation requirements](#)
- ❖ General Medicare rules and regulatory guidance regarding the following:

- [Durable medical equipment \(DME\)](#), [prosthetics/orthotics](#), and [supply and accessory](#) definitions and coverage guidance.
- [Medicare Coverage Guidance Policies](#)
- [Replacement](#) of DMEPOS items.
- [Upgrades](#) or deluxe items.
- [Repairs, servicing and maintenance](#) of DMEPOS.
- ❖ [Regulatory Oversight](#) (e.g., how items are approved for marketing by the U.S. Food and Drug Administration [FDA] when used for their indicated purpose, etc.).

General Coverage – Initial Provision

- I. Durable medical equipment (DME), prosthesis, or orthosis may be considered **medically necessary** when the item meets all of the following criteria:
 - A. Not directly excluded from the patient’s coverage agreement or benefit contract.
 - B. Meets the Medicare definition of DME, prosthetic, or orthosis.
 - C. Considered safe and effective for the intended purpose.
 - D. Is considered medically reasonable and necessary for the patient, as determined by one of the following:
 1. Item meets coverage criteria found in a specific Company medical policy; or,
 2. Item meets Medicare coverage criteria.
 - E. The equipment provides the medically reasonable and appropriate level of performance and quality for the condition (i.e., item is not luxury or deluxe, the medical need for custom fabricated items is well documented, etc.); **and**
- II. Supplies and accessories may be considered **medically necessary** when both of the following are met:
 - A. The supply or accessory is required for the effective use of medically necessary DMEPOS (e.g., drugs/biologics used with nebulizer equipment for therapy, batteries required in order for DME to function, etc.); and,
 - B. The usual maximum quantity provided does not exceed the reasonable and necessary limits established by Medicare. (See [Table 1](#))
- III. Supplies and accessories are **not medically necessary and not covered** if any of the following apply:
 - A. The supply or accessory does not meet Criteria II.
 - B. The supply or accessory is considered a convenience item.
 - C. Supplies or accessories requested for non-covered DMEPOS.
 - D. The usual maximum quantity of supply provided exceeds the reasonable and necessary limits established by Medicare.*

* Exceptions may be made for Criterion III.D when the documentation warrants a unique clinical situation with a medical need to exceed established limits found in [Table 1](#).

- IV. DMEPOS items are considered **not medically necessary and not covered** if any of the following apply:
- A. The equipment does not meet Criteria I.
 - B. The equipment does not primarily serve a medical purpose (includes items or accessories intended to improve appearance or for aesthetic reasons).
 - C. The equipment is duplicative (e.g., back-up and spare equipment or equipment requested with functions that duplicate the function of existing home equipment [e.g., a floor sitter requested for a child with a wheelchair]).
 - D. The equipment serves comfort or convenience functions or is primarily for the convenience of a person caring for the patient.
 - E. The equipment is for first aid or other precautionary-type equipment.
 - F. The equipment is a self-help device or training equipment for the environmental setting or equipment not intended for use inside the home (e.g., DMEPOS items requested for recreational or leisure activities or DMEPOS items requested specifically for use outside the home, etc.).
 - G. Home or vehicle remodeling or modification to accommodate DME or patient condition (e.g., ramps, stair lifts, elevators, stair glides, wheelchair lifts, bathroom modifications, door modifications, etc.).
 - H. The equipment exceeds the appropriate level of performance (i.e., the item is considered “luxury,” an upgrade, or deluxe item, etc.).[†]
 - I. The equipment exceeds the total rent cost or purchase price, whichever is less; or,
 - J. The equipment is provided for a member who is a patient in an institution or facility that is considered a hospital or SNF.

Replacements

- V. Replacement of supplies and accessories required for the effective use of DME, prosthetics, or orthotics (e.g., batteries, tubing, tape, etc.) may be considered **medically necessary** if the primary DME, prosthetic, or orthotic item itself was determined to be medically necessary. *(Supplies and accessories are not subject to the 5-year reasonable useful lifetime [RUL] requirement for replacement.)*
- VI. Replacement of all or part of a member-owned DME *(see Criteria VIII and IX below for replacement of prosthetics or components/accessories of prosthetics)* may be considered **medically necessary** when both of the following are met:
- A. The DME item(s) continues to be medically necessary for the member; and
 - B. One or more of the following applies:
 - i. The current DME item(s) has been lost, stolen or irreparably damaged; or

[†] Criterion IV.H does not apply to the provision of medically necessary items in the absence of an upgrade request when general criteria are met. The need for a DMEPOS item may be considered medically necessary, even if the upgraded or deluxe feature/component is not medically necessary. In these situations, the Company may choose to allow the item at the allowable rate of the standard model and any difference for the upgraded or deluxe features will be denied

- ii. The current DME item(s) is irreparably worn and has exceeded the minimum 5-year RUL expectancy[‡]; or
- iii. There is clinical evidence demonstrating a significant change in the patient's medical condition and both of the following are met:
 - 1. The current DME item(s) no longer meets the patient's medical needs; and
 - 2. It is the least costly option to replace the equipment in order to meet the patient's medical needs.
- iv. A component or accessory required for the effective use of a DME item is irreparably worn and the replacement part is no longer available and cannot be substituted with another manufacturer's part. *(The primary DME item is considered effectively nonfunctional and must be replaced.)*

VII. Replacement of DME is **not medically necessary and not covered** for any of the following:

- A. Criterion VI above is not met.
- B. Equipment is being rented.
- C. The current DME item(s) is irreparably worn and has **not** exceeded the minimum 5-year RUL expectancy.
- D. Oxygen equipment replacement requests during the reasonable useful lifetime (RUL) of the equipment.
- E. Replacement of equipment due to member abuse, neglect or intentional damage.
- F. Items that are being or have been recalled (recalled items must be replaced at no charge to the member or health plans); and
- G. Items still covered under manufacturer warranty and maintenance services.

VIII. In the absence of a medical policy with more specific coverage criteria, replacement of a prosthetic or component of a prosthetic may be considered **medically necessary** when one or more of the following conditions are met:

- A. There is a significant change in the physiological condition of the patient and the current prosthetic no longer meets the patient's medical needs; or
- B. There is a change in the condition of the prosthetic or component of the prosthetic that cannot be repaired; or
- C. The condition of the prosthetic or component is repairable, but the cost of repairs would be more than 60 percent of the cost of a replacement prosthetic or component.

IX. Replacement of a prosthetic or component of a prosthetic is considered **not medically necessary** when any of the following conditions are met:

- A. There is no documented significant change in the physiological condition of the patient that results in the current prosthetic to no longer meet their medical needs; or

[‡] Criterion VI.B.ii does have exceptions to the 5-year RUL. These include prosthetics (see Criterion VIII.), supplies (see Criterion V.), and some knee orthoses (see Policy Guidelines)

- B. The current prosthetic is functional and continues to meet the patient's medical needs; or
- C. Required repairs to bring the prosthetic back to good condition cost less than 60 percent of the cost of a replacement device or replacement component.

Upgrades

The criteria below are for replacement items which include upgrade or deluxe requests. See Criterion IV above for upgrade or deluxe requests for initial issue of DMEPOS.

- X. Requests for replacement items with upgraded features or components (additional or deluxe features which exceed the medical need) are **not medically necessary and not covered**.[§]
- XI. Upgrade requests to DME, prosthetics, or orthotics already in use by the patient are **not medically necessary and not covered**.

Repairs and Maintenance

- XII. Repair (labor and parts) of DMEPOS may be considered **medically necessary** when all of the following are met:
 - A. Member-owned (purchased) medically necessary equipment; and
 - B. The repairs are necessary to make the equipment serviceable (bring back to good condition and working order); and
 - C. The item is not under manufacturer or supplier warranty, unless a warranty specifically excludes a specific service or part (the Company may provide coverage for reasonable and necessary labor and parts which are excluded from the warranty); and
 - D. 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).
- XIII. Non-routine maintenance service or more extensive service which are required to be performed by authorized technicians (determined by manufacturer recommendations) may be considered **medically necessary** for member-owned, medically necessary equipment. *(Example: Breaking down sealed components and performing tests which require specialized testing equipment not available to the patient.)*
- XIV. Repair (labor and/or parts parts) or maintenance servicing of DME, prosthetics or orthotics are considered **not medically necessary and not covered** for any of the following:
 - A. Any equipment covered under manufacturer or supplier warranty (A DMEPOS supplier must notify 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).

[§] Criterion X does not apply to the medically necessary replacement of items in the absence of an upgrade request when criteria are met. The need for a replacement DMEPOS item may be considered medically necessary, even if the upgraded or deluxe feature/component is not medically necessary.

- B. Equipment which was previously denied.
- C. Supplier-owned (rented) equipment, including oxygen.
- D. Request for the repair of an integrated component on beneficiary-owned equipment (with or without replacement parts) of a multi-function ventilator (HCPCS E0467).^{**}
- E. Routine periodic servicing, testing, cleaning, regulating, and checking of the member's equipment among other services.
- F. Maintenance service for supplier owned (rented) equipment.

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be [accessed here](#).

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

[Criteria](#)

While the following information is not required with every claim submission, all or part of it may be requested for auditing purposes. Documentation should include medical records and/or chart notes to support the medical need for the item in question. Other documentation for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) includes, but may not be limited to, the following:^{1,2}

- All requests:
 - Make, model and/or manufacturer name of equipment/device;
 - Indication of whether request is for *initial provision* of item or if request is for the *replacement* of an item;
 - For items noted to be “custom” or “custom made,” documentation must include how the item is uniquely constructed or substantially modified for a specific individual according to a physician’s description and orders (i.e., what makes the item a one-of-a-kind item).
 - This does not apply to custom-*fitted* items, only to custom *fabricated* items. In addition, the use of customized *options or accessories* or custom fitting of *certain parts* does **not** result in equipment being considered “customized.”³
- Initial Provision of an item/equipment:
 - Written and signed order or prescription (also referred to as Standard Written Order, or SWO) or certificate of medical necessity (CMN) from the treating provider;

^{**} The devices referenced in Criterion XIV.D integrate the function of multiple types of equipment into a single device, and thus, it is considered as unbundling if the date(s) of service for the repair overlaps any date(s) of service for code E0467

- Medical records and chart notes relevant to the item or equipment requested, which should include **at least all of** these elements:
 - Diagnosis, medical history, including duration and prognosis of condition, clinical course of the condition (worsening or improving), other attempted interventions with associated outcomes, nature and extent of functional limitations (especially impact to activities of daily living or ADLs, whether or not the individual has used the item before or if the member has received instruction on proper use.
 - Documentation as appropriate for the specific item or equipment under review to support all of the following (this list may not be all-inclusive):
 - Quantity(ies) ordered, frequency of use, and duration of use or length of need.
- Replacement Requests: Documentation in the medical records and/or chart notes must support the **continued** medical need for the item in question, as well as the reasonable and necessary nature of the replacement request.
 - Replacement due to Irreparable Damage: Verification of how the equipment was damaged (i.e., description of incident which caused the damage) and a physician's order and/or new Certificate of Medical Necessity (CMN) to confirm the continued medical necessity of the item.
 - Replacement due to Irreparable Wear: Documentation that a comprehensive repair evaluation has been conducted which documents specifically what is wrong with the equipment down to the part level. This should also include, when applicable, 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 confirm the continued medical necessity of the item. (Note, if a replacement is requested due to irreparable wear of an *accessory*, but the replacement accessory is no longer available and cannot be substituted with another available item, a current detailed written physician's order with an explanation of why the item must be replaced is needed [items which require a CMN may use a current CMN if a sufficient narrative description is included]).
 - Replacement due to Change in the Medical Condition: Documentation detailing what has changed for the member, specifically why the existing equipment is inadequate, and physician's order and/or new CMN to confirm the continued medical necessity of the item.
 - Repair: A repair evaluation is needed and documentation must demonstrate the item/part requested is medically or reasonably necessary to restore the equipment to a serviceable condition. There must also be an attestation that the item or part is not covered under manufacturer warranty.
 - Note: Parts that are not reasonable or medically necessary to make a piece of equipment serviceable should **not** be included with the estimate for the replacement or repair request (e.g., parts used for patient convenience or those which only have aesthetic value do not make the primary DME item serviceable and should not be included in an estimate).
 - Lost DME: Written explanation regarding the circumstances of the loss.
 - Stolen DME: A police report should be provided.

Note: According to the local durable medical equipment Medicare contractor (DMEMAC), Noridian, "Suppliers are trained on coverage criteria for equipment; however, the documentation to support such

criteria must be present in the patient's medical record and cannot come from the supplier." Clinical documentation may include records from hospitals, nursing facilities, home health agencies, and other health care professionals.⁴

DURABLE MEDICAL EQUIPMENT (DME), PROSTHETICS AND ORTHOTICS

[Criteria](#)

Durable Medical Equipment

Medicare requires that all items and services be both medically reasonable **and** necessary.⁵ If an inquiry or claim is received for an item which does not appear to fall logically into a generic category listed in NCD 280.1, the Company must determine whether the item may be covered under the Medicare DME benefit. These coverage decisions are made using various Medicare references, as well as consideration of approval by the U.S. Food and Drug Administration (FDA) and if the item is generally considered safe and effective for the intended purpose. (*NCD 280.1*)

The Durable Medical Equipment, Prosthetic, and Orthotic Services (DMEPOS) benefit originated with the Medicare program as part of the home health benefit under the *Social Security Act*. Thus, DMEPOS items are intended to assist with medical needs within the *home* environment.⁴ The term *DME* is defined by Medicare as equipment which⁶:

- Is considered "durable," in that it can withstand repeated use (i.e., is not disposable or could normally be rented and used by successive patients);
 - To determine "durability," Medicare uses a minimum lifetime requirement (MLR) of at least 3 years. The 3-year MLR is a Medicare requirement for an item to meet the "durability" requirement in order 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."⁷ However, the MLR is **not** the reasonable useful lifetime (RUL) requirement for DME items, which is used to determine how often it is reasonable to pay for the replacement of an item or component.
- Is primarily and customarily used to serve a medical purpose;
- Generally is not useful to a person in the absence of illness or injury; and,
- Is appropriate for use in a patient's home.

Items which do not have specific coverage criteria provided are still required to satisfy Medicare's general coverage requirements for DME. Specifically, items must first fully meet the definition of DME. The fact an item was or can be dispensed by a DME supplier or professional provider does not mean the item is classified as "durable medical equipment" or is eligible for coverage. In addition, while a device or piece of equipment may serve a useful medical purpose, that does not in itself mean it meets Medicare's definition of DME and thus, may not be covered.⁸

Implanted DME with related replacement parts, accessories, and supplies are not always included within the "DMEPOS" category, and therefore, they may not be subject to some DME/prosthetic rules.

In addition to prosthetics, orthotics, and supplies addressed below, other Medicare benefit categories do exist for various DME items. The omission of those benefit categories from this medical policy does **not** imply coverage requirements for those items are not valid.

Prosthetics and Orthotics

Prosthetic devices are items which replace all or part of a body organ or limb. Examples include, but are not limited to, artificial limbs, parenteral and enteral (PEN) nutrition, cardiac pacemakers, prosthetic lenses, breast prostheses (including a surgical brassiere) for postmastectomy patients, maxillofacial devices, and devices which replace all or part of the ear or nose.^{9,10} However, dental items, such as dentures, are not considered prosthetic devices, but may be eligible for coverage if a Plan member has dental benefits which provide coverage for dentures.¹¹

Orthoses are rigid or semi-rigid devices used for supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. Items that are not sufficiently rigid to be capable of providing the necessary immobilization or support to the body part for which it is designed would not meet this definition and therefore, would be noncovered.^{12,13}

Supplies necessary to achieve the therapeutic benefit of the prosthesis or to assure the proper functioning of a medically necessary prosthetic device are also covered.¹⁴

Many implanted devices are not included within the “DMEPOS” category. Examples include, but may not be limited to, internal fixation supplies such as spinal surgery hardware (spinal cages, screws, rods, etc.) and implanted retinal prostheses, with their related replacement parts, accessories, and supplies. These items are not subject to certain DMEPOS rules, such as some replacement requirements.

SUPPLIES AND ACCESSORIES

[Criteria](#)

Supplies and accessories (including drugs or biologicals) that are necessary to achieve the therapeutic benefit of the prosthesis or to assure the proper functioning for the effective use of the equipment (e.g., batteries, tubing, tape, etc.) may be covered if the primary item itself is medically necessary.¹⁵

For DMEPOS items which do not meet Medicare’s coverage requirements, any associated supplies and accessories are also non-covered. In addition, some accessories may be considered an “upgrade” that may not be medically reasonable or necessary. These items would also be non-covered. Upgrades are addressed later in this medical policy.

Because these items generally require replacement on a more frequent basis, they are not usually subject to the requirements for DME replacement (i.e., the 5-year RUL rule may not apply).

While the provision of supplies is not routinely reviewed for medical necessity, utilization may be subject to audit and quantity limits may apply, as found in local coverage determinations (LCDs) or articles (LCAs). The Company may defer to current policies, guidelines, and/or interpretations

established by CMS to determine appropriateness of the provision and replacement frequency of such supplies and accessories.

Table 1: Sources of quantity limit guidance

Note: This list is not all-inclusive. If a supply category is not listed, see the DMEMAC's [list of active LCDs and LCAs](#) or Medicare-established [medically unlikely edits \(MUEs\)](#) for the appropriate resource.

| Supply Quantity Limits References | | | |
|-----------------------------------|---------------------------------|------------------------|--|
| Supply Category | NCD / LCD | LCA | Notes |
| Ostomy Supplies | L33828 | A52487 | <p>The table provided in the LCD list the maximum number of items/units of supply quantities that are usually reasonable and necessary; however, the actual quantity needed for an individual patient may be more or less than the amount listed, based on unique clinical factors that affect the frequency of supply changes. Quantities in excess of these amounts will be denied as not medically necessary unless an explanation is clearly documented in the patient's medical record to support the medical need for extra quantities.</p> <p>A table in the LCA provides information regarding what is included in various ostomy supply kits, and thus, what should not be unbundled and reported separately.</p> |
| Surgical (Wound) Dressings | L33831 | A54563 | <p>The Surgical Dressings Reference chart provides a quick look at what surgical dressings are covered for various wound depths and exudates, along with Medicare's recommended frequency of change coverage information.</p> <p>No more than a one month's supply of dressings may be provided at one time, unless there is documentation to support necessity of greater quantities in home setting in an individual case</p> |
| Tracheostomy Care Supplies | L33832 | A52492 | <p>The table provided in the LCD lists the maximum number of items/units of supply quantities that are usually reasonable and necessary; however, an individual patient medical need may be more or less than the amount listed, based on individual and unique clinical factors that affect the frequency of supply changes. Quantities in excess of these amounts will be denied as not medically necessary unless an explanation is clearly documented in the patient's medical record to support the medical need for extra quantities.</p> <p>Multiple tables in the LCA provide information regarding what is included in various tracheostomy kits, and thus, what should not be unbundled and reported separately.</p> |
| Urological Supplies | 230.17 / L33803 | A52521 | <p>Multiple tables provided in the LCD list the maximum number of items/units of supply quantities that are usually reasonable and necessary; however, an individual</p> |

| | | | |
|--|--|--|---|
| | | | <p>patient medical need may be more or less than the amount listed, based on individual and unique clinical factors that affect the frequency of supply changes. Quantities in excess of these amounts will be denied as not medically necessary unless an explanation is clearly documented in the patient's medical record to support the medical need for extra quantities (e.g., obstruction, sludging, clotting of blood, or chronic, recurrent urinary tract infection).</p> <p>A table in the LCA provides information regarding what is included in various urological supply kits, and thus, what should not be unbundled and reported separately.</p> |
|--|--|--|---|

REGULATORY OVERSIGHT

[Criteria](#)

According to Medicare NCD 280.1, coverage decisions for DMEPOS take into account many factors, including but not limited to, relevant product approvals by the Food and Drug Administration (FDA). Devices intended for human use require some level of government regulatory oversight to demonstrate they are safe and effective, but not all devices and accessories require the same level of FDA oversight.¹⁶ Medical devices are categorized into one of three classes based on the risks they pose and the regulatory controls necessary to provide a reasonable assurance of their safety and effectiveness. The amount of oversight and approval required is determined by which class an item or device is assigned to. Class I devices generally pose the lowest risk to the patient or user, while Class III devices pose the highest risk.¹⁷ Most Class I and some Class II devices are exempt from 510(k) requirements if it is determined that a 510(k) is not required to provide reasonable assurance of safety and effectiveness for the device; however, these devices may still be subject to certain rules set by the FDA.¹⁸

This regulation also applies to device *accessories*, which are defined as “a finished device that is intended to support, supplement, and/or augment the performance of one or more parent devices.” It is worth noting the FDA specifically states that while an item *can* be used in conjunction with a parent device, this does not in itself imply the item is qualified to be defined as an “accessory.” For example, a mobile smart phone would not be considered an accessory, even if it is used for the purpose of downloading a medical application (app) because while the mobile smart phone may be compatible with medical devices, the mobile smart phone was not specifically intended for use with any single medical device.¹⁹ Accessories are also reviewed to evaluate any risk they may pose when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness of the accessory component. The review of accessories only considers the safety and effectiveness of the accessory. This means decisions are not based on the classification of the parent device for which the accessory is intended to be used with.¹⁹

Routine review for FDA approval will not likely be performed for most items, especially common devices, components or accessories, assuming the item requested will be used in a manner consistent with the intended purpose; however, all items or devices are subject to audit as deemed necessary by the Plan.

MEDICARE COVERAGE GUIDANCE POLICIES

[Criteria](#)

Items classified as DME may not be covered if Medicare's coverage criteria are not met. Several DMEPOS items and equipment have coverage requirements detailed in either a national coverage determination (NCD), related local coverage determination (LCD), or local coverage article (LCA). Some helpful resources may include the following:

- [NCDs related to DMEPOS](#) (Chapters §280.1-280.15 addresses many DMEPOS items, but other sections of the NCD manual may also be used, including but not limited to, §10.2, §40.2-40.4, §50.1-50.4, §80.1, §80.4, §80.5, §80.12, §150.2, electrical stimulators in §160, home oxygen in §240, and wound treatment devices in §270).
- [Active Noridian LCDs and LCAs related to DMEPOS](#) (Many items addressed in NCDs also have applicable LCDs and LCAs).
- The Noridian web page for [Noncovered Items](#)

In addition, the [Medicare DMEPOS Fee Schedule](#) may also be useful since some items are not included in the Medicare DMEPOS Fee Schedule because they are not eligible for coverage under Medicare. However, while the absence of an item from the DMEPOS Fee Schedule *may* be an indicator of non-coverage, it is not a *definitive* indicator, and thus, shouldn't be the sole rationale for such decision-making.

The Company will defer to current policies, guidelines, and/or interpretations established by Medicare to determine appropriateness of the DMEPOS item when available. In the absence of a specific Medicare policy reference, the health plan may choose to develop a separate medical policy.

Note: Not all items may have specific coverage criteria, but all items are still required to be medically reasonable and necessary according to the policy guidelines above, including meeting the definition of DMEPOS.

DME, ORTHOTICS, AND NON-PROSTHETIC LIMB REPLACEMENT

[Criteria](#)

Medicare defines "replacement" of DME as the provision of an entire identical or nearly identical item when it is lost, stolen or irreparably damaged. Irreparable wear is defined by Medicare as "deterioration sustained from day-to-day usage over time and a specific event cannot be identified." Replacement of equipment which is required due to irreparable wear does take into consideration the reasonable useful lifetime (RUL) of the equipment. The RUL of durable medical equipment is determined by Medicare and in the absence of specific program instructions, DMEPOS may determine the RUL of equipment, but in no case can it be less than 5-years.²²⁻²⁴

The following scenarios for replacement are **not covered**:

- Replacement of rented equipment (including equipment in the frequent and substantial servicing or oxygen equipment payment categories because items in these categories are

meant to be rented and suppliers are responsible for supplying needed replacement equipment)²⁵;

- Replacement required due to member abuse, neglect or intentional damage. Cases suggesting malicious damage, culpable neglect, or wrongful disposition of equipment may be investigated and denied if the Company determines it is unreasonable to make plan payment under the circumstances;
- Recalled items (recalled items must be replaced at no charge to the member or health plan);
- Items still under manufacturer warranty (see below).
- Replacement required due to irreparable wear *during* the 5-year reasonable useful lifetime (RUL) period. (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.

Considerations to the replacement of any item include all of the following²⁶:

1. Would the expense of the item be clearly disproportionate to the therapeutic benefits which could ordinarily be derived from use of the equipment?
2. Is the item substantially more costly than a medically appropriate and realistically feasible alternative of care?
3. Does the item service essentially the same purpose as equipment already available to the patient?

The Noridian "[Same or Similar Chart](#)" can be useful in determining if two items are identical or nearly identical. However, same or similar equipment rules may not apply to situations where a new device with additional technological features becomes available. Review must be performed to determine whether the new feature(s) meets the patient's medical need that is not met by their current equipment.

- If the new feature or device meets a current medical need that is not met by the current equipment because the appropriate technology was not available at the time the patient purchased the item, even if there has been no change in the patient's condition, the 5-year RUL rules do not apply and the replacement item **may be medically necessary**.
- If the new item is meeting the same medical need as the old item, but in a more efficient manner or is more convenient, with no documented change in the patient's condition, the replacement item is **not covered**.

The item must be lost, stolen, **irreparably** worn or damaged - if repairs can be made reasonably to the item, it should not be replaced. For irreparably worn items, the equipment must also have exceeded the minimum 5-year RUL expectancy. (Exceptions may apply to some knee orthotics.)

In rare situations, an accessory required for the effective use of a DME item is irreparably worn or damaged and the replacement part needed is no longer available and cannot be substituted with another manufacturer's part. For example, if an individual has an electrical nerve stimulator which

needs replacement lead wires, but the lead wires for that model of stimulator are no longer manufactured and cannot be substituted with another brand, then the nerve stimulator unit itself is considered effectively nonfunctional and the entire stimulator unit must be replaced.

PROSTHETIC LIMB REPLACEMENT

[Criteria](#)

Payment may be made for the replacement of a prosthetic device or for part of a device if it is determined that the replacement device or part is necessary due of any of the following reasons as long as the required use of the prosthetic is otherwise medically reasonable and necessary¹⁰:

1. A change in the physiological condition of the patient;
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.

Note that for prosthetics, the 5-year replacement rule does not apply.¹⁰

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.”

If the existing equipment is functioning and is adequate for the member’s needs, but a prosthetic replacement is requested as an upgrade, see the “Upgrades” information in the policy.

WARRANTIES

[Criteria](#)

Medicare does not provide program payment “for which the individual furnished such items or services has no legal obligation to pay, and which no other person (by reason of such individual’s membership in a prepayment plan or otherwise) has a legal obligation to provide or pay for.”²⁷ This includes repairs, replacements or other services which may be covered under a manufacturer warranty. A DMEPOS supplier must notify all parties 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. Since there was no charge involved, no payment is made for equipment replaced free of charge by the warrantor.^{7,27,28}

REPAIRS AND MAINTENANCE

[Criteria](#)

Repair or maintenance of equipment in the frequent and substantial servicing or oxygen equipment payment categories are not eligible for coverage under Medicare because equipment in these categories is paid on a rental basis only.²⁹ In addition, coverage of repairs or replacement part charges is not allowed for supplier-owned (rented) equipment.³⁰⁻³² Note the definition is to “put the equipment back in good condition.” This does not mean the equipment is brought back to a “like new” condition. 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 non-covered equipment. Non-coverage can be due to any reason, including but not limited to, the item not meeting the definition of DME or the member not meeting established medical necessity criteria.

Some warranties may specifically exclude an item or service from being covered under the warranty. The Company may allow for reasonable and necessary labor and parts not otherwise covered under the manufacturer or supplier's warranty. Otherwise, when a warranty is in place, neither the member nor the plan may be charged.²⁸ Note that if a part or component is eligible for coverage under warranty, but the manufacturer *chooses* to not cover the cost to repair that item (e.g., member abuse of the item), then because the item is part of the warranty coverage provision, the health plan may also deny such repairs.

The DMEMAC provides a table with table with the number of units of service allowed for commonly repaired items. See the "[Repair Labor Billing and Repair Payment Policy \(K0739\)](#)" table on the Noridian website. Note that this table applies to items not being rented and out-of-warranty items. Time is determined to establish "units of service" and this includes basic troubleshooting and diagnosing the problem, but no payment is made for travel time or equipment pick-up and/or delivery.

Routine maintenance services (e.g., routine periodic servicing, testing, cleaning, regulating, and checking of the member's equipment) are not covered. However, more extensive (nonroutine) maintenance services which are expected to be performed by authorized technicians based on the manufacturer's 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.^{33,34}

According to Medicare, "renters of equipment recover from the rental charge the expenses they incur in maintaining in working order the equipment they rent out, separately itemized charges for repair" and "maintenance of rented equipment" are not covered. Therefore, repair and maintenance charges for equipment being rented are not covered and are the responsibility of the DME supplier.

A supplier that transfers the title of a capped rental item to a member 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.³⁵

UPGRADES

[Criteria](#)

Upgraded items may be the base item, a component, or a special feature of an item which goes beyond what is medically necessary under Medicare's coverage requirements. Upgraded equipment are **not covered**, even if a physician has signed an order for it.^{36,37}

Requests for the replacement of properly functioning equipment for the sole purpose of upgrading to newer technology is **not medically necessary**.

BACK-UP EQUIPMENT AND DUPLICATE ITEMS

[Criteria](#)

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 provided for precautionary reasons in the event the primary piece of equipment malfunctions. 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.^{38,39}

Examples 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.

DEFINITIONS

Activities of Daily Living (ADLs): Activities performed during a normal day, including but are not limited to, tasks such as eating, toileting, grooming, dressing, and bathing that are necessary to maintain or improve the client's health.⁴⁰

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.

Custom DME: In order to be considered a customized DME item, the item (including a wheelchair) must be⁴¹:

1. Uniquely constructed or substantially modified for a specific beneficiary according to a physician's description and orders (e.g., one-of-a-kind item, fabricated to meet unusual specific needs) and
2. So different from another item used for the same purpose that the two items cannot be grouped together for pricing purposes.

Items which are measured, assembled, fitted, or adapted to accommodate body size, weight, disability, period of need, or intended use (i.e., custom *fitted* items) or items which have been assembled by a supplier, or ordered from a manufacturer, using available customized features, modifications or components do not meet the definition of "customized" because these items are not uniquely constructed or substantially modified and can be grouped with other items for pricing purposes. The use of "customized" options, custom ordered options/accessories or custom fitting of certain parts does **not** result in the equipment being considered as custom DME.

Home Setting: For rental and purchase of DME, a "home" is defined as the member's place of permanent residence, which can include an individual's own dwelling (e.g., home or apartment), a relative's home, a home for the aged, or some other type of institution (such as an assisted living facility,

or an intermediate care facility for individuals with intellectual disabilities (ICF/IID)). Note: Hospitals, skilled nursing facilities (SNFs), or any setting that exists primarily for the purpose of providing medical/nursing care are **not** considered a “home” for purposes of DME rental or purchase. IMPORTANT: Medicare place of service (POS) rules with respect to DMEPOS claims will be applied during the claim adjudication process.⁴²

Identical, Same, or Similar Devices: Refers to an identical or similar device that is already in the member’s possession, that is still within the RUL 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: A specific accident or incident (wheelchair falling out of a moving vehicle) or to a natural disaster (e.g., fire, flood). While the term “irreparable” means the item is not repairable, in the context of this policy, irreparable damage also refers to situations where it may not be cost effective to repair the equipment and thus replacement may be a better option.

Irreparable Wear: Deterioration sustained from day-to-day usage over time. A specific event cannot be identified. While “irreparable” means the item is not repairable, in the context of this policy, irreparable also means it may not be cost effective to repair equipment. However, replacement of equipment due to irreparable wear does take into consideration the RUL of the equipment.

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

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 under Medicare.

Orthotics (Orthoses): Rigid or semi-rigid devices used for supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. Items that are not sufficiently rigid to be capable of providing the necessary immobilization or support to the body part for which it is designed would not meet this definition and therefore, would be noncovered.

Practitioner/Clinician: An individual licensed pursuant to federal and state law to engage in the provision of health care services within the scope of the practitioner's license and certification. Note: Medicare rules regarding ordering providers applies. While Medicare and member benefits within EOCs may allow coverage to see certain provider types (e.g., chiropractors, naturopaths, etc.), these providers may not be eligible to order or supply DMEPOS items under Medicare federal payment rules.⁴³

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.

Used equipment (DME): Any equipment that has been previously purchased or rented by someone before the current purchase transaction and equipment (e.g. equipment used for trial periods or as a demonstrator).⁴⁴

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.⁷

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. See the “Regulatory Oversight” information above.

BILLING GUIDELINES AND CODING

GENERAL

The Company may defer to the Medicare Pricing, Data Analysis, and Coding (PDAC) contractor (Palmetto GBA) for proper code assignment of most items. For products which have been reviewed by the PDAC and assigned HCPCS code A9270 *Noncovered item or service*, these items will be considered non-covered by Medicare or the Medicare Advantage health plan, even if another HCPCS code is submitted for consideration.

Only CMS and the Durable Medical Equipment Medicare Administrative Contractors (DME MAC) have the authority to establish HCPCS Level II Coding Guidelines. The PDAC contractor with input from the

DME MACs are responsible for assigning individual DMEPOS products to HCPCS code categories for billing Medicare. In addition, the PDAC contract states the following⁴⁶:

“Manufacturers and other entities do not have similar authority to assign their own code determinations to specific products. Often these unofficial and unauthorized coding assignments are described as "recommendations." DMEPOS suppliers are cautioned that such recommendations have no official status and, in the event of a claim review, may result in an incorrect coding claim denial. In addition, these unofficial coding recommendations are not helpful in defense of an incorrect coding claim denial during the appeals process.”

Many specific HCPCS codes are available for a variety of DME, prosthetic, orthotic, and supply or accessory items. When specific code(s) are available, these must be used to represent the item or device provided. Only when there is no appropriate code available may an “unlisted code” or “not otherwise classified” (NOC) code (e.g., HCPCS codes E1399, L2999, K0108, etc.) be reported. Incorrect use of unlisted codes or failure to use specific codes when available may result in inaccurate reimbursement, incorrect review outcomes, incorrect or unnecessary denials and/or recovery of any monetary funds paid.

This includes appropriate coding for customized equipment or components. Items that are measured, assembled, fitted, or adapted in consideration of a patient’s body size, weight, disability, period of need, or intended use (i.e., custom fitted items) or which been assembled by a supplier, or ordered from a manufacturer using available customized feature, modification or component options do not meet the definition of customized items and the HCPCS code(s) for the standard version of the item should be used.³

Of note, HCPCS code E1399 is defined as, *Durable medical equipment, miscellaneous*. Thus, if an item or device does **not** meet the definition of DME, the use of this code is inappropriate and another code (e.g., A9270) should be used.

Appropriate Coding for Replacement DMEPOS

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.

Rental vs. Purchase

DME benefits are limited to either the total rental cost or the purchase price, whichever is less.

| CODES* | | |
|--------|------|--|
| CPT | None | |
| HCPCS | None | |

*Coding Notes:

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- See the non-covered and prior authorization lists on the Company [Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website](#) for additional information.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. DMEMAC Local Coverage Article (LCA) for Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426); <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55426>. Accessed 4/2023.
2. Medicare Program Integrity Manual, Chapter 5 – Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items and Services Having Special DME Review Considerations, §5.9 – Documentation in the Patient’s Medical Record. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c05.pdf>. Last updated 2021. Accessed 4/2023.
3. PDAC Advisory Article, *Coding Guideline – K0900 (Custom Durable Medical Equipment, Other Than Wheelchairs)*; Available at: <https://dmepdac.com/palmetto/PDACv2.nsf/DIDC/U2F9VMG152~Articles%20and%20Publications~Advisory%20Articles>. Published 2014. Accessed 4/2023.
4. Noridian web page for *Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)*; <https://med.noridianmedicare.com/web/jfb/topics/dme>. Accessed 4/2023.
5. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §110 – Durable Medical Equipment – General; <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf>. Accessed 4/2023.
6. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §110.1 – Definition of Durable Medical Equipment; <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf>. Accessed 4/2023.
7. Noridian web page for *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>. Accessed 4/2023.
8. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §110.1 – Definition of Durable Medical Equipment; B. Medical Equipment, 2. Equipment Presumptively Nonmedical; <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf>. Accessed 4/2023.
9. Social Security Act (SSA) §1861(s)(8); https://www.ssa.gov/OP_Home/ssact/title18/1861.htm. Accessed 4/2023.
10. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §120 – Prosthetic Devices, A. General; <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf>. Accessed 4/2022.

11. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §120 – Prosthetic Devices, C. Dentures; <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf>. Accessed 4/2023.
12. Social Security Act (SSA) §1861(s)(9); https://www.ssa.gov/OP_Home/ssact/title18/1861.htm. Accessed 4/2023.
13. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §130 – Leg, Arm, Back, and Neck Braces, Trusses, and Artificial Legs, Arms, and Eyes; <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf>. Accessed 4/2023.
14. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §120 – Prosthetic Devices, D. Supplies, Repairs, Adjustments, and Replacement; <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf>. Accessed 4/2023.
15. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §110.3 – Coverage of Supplies and Accessories; <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf>. Accessed 4/2023.
16. U.S. Food & Drug Administration (FDA) Premarket Notification 510(k). Content current as of 03/13/2020. Available from:
17. <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k>.
18. U.S. Food & Drug Administration (FDA) Overview of Medical Device Classification and Reclassification. Content current as of 12/19/2017. Available from:
19. <https://www.fda.gov/about-fda/cdrh-transparency/overview-medical-device-classification-and-reclassification>.
20. U.S. Food & Drug Administration (FDA) Class I and Class II Device Exemptions. Content current as of 02/23/2022. Available from: <https://www.fda.gov/medical-devices/classify-your-medical-device/class-i-and-class-ii-device-exemptions>.
21. U.S. Food & Drug Administration (FDA) Medical Device Accessories. Content current as of 08/14/2020. Available from: <https://www.fda.gov/medical-devices/classify-your-medical-device/medical-device-accessories>.
22. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §110.2 – Repairs, Maintenance, Replacement, and Delivery, C. Replacement; <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf>. Accessed 4/2023.
23. Noridian web page for *Replacement*; Last Updated: 02/25/2022; <https://med.noridianmedicare.com/web/jddme/topics/repairs/replacement>. Accessed 4/2023.
24. Noridian web page for *Replacement of Durable Medical Equipment*; <https://med.noridianmedicare.com/web/jddme/search-result/-/view/2230703/replacement-of-durable-medical-equipment>. Accessed 3/11/2022.
25. Noridian web page for *Items Requiring Frequent and Substantial Servicing*; <https://med.noridianmedicare.com/web/jddme/topics/payment-categories/frequent-servicing>. Accessed 4/2023.
26. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §110.1 – Definition of Durable Medical Equipment, C. Necessary and Reasonable, 2. Reasonableness of the Equipment; <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf>. Accessed 4/2023

27. Social Security Act (SSA) §1862(a)(2); https://www.ssa.gov/OP_Home/ssact/title18/1862.htm. Accessed 4/2023.
28. Noridian web page for *Warranties*; <https://med.noridianmedicare.com/web/jddme/topics/repairs/warranties>. Accessed 4/2023.
29. Noridian web page for *Repairs, Maintenance and Replacement*; Available at: <https://med.noridianmedicare.com/web/jddme/topics/repairs>. Accessed 4/2023.
30. Noridian web page for *Repairs*; Available at: <https://med.noridianmedicare.com/web/jddme/topics/repairs/repairs>. Accessed 4/2023.
31. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §110.2 – Repairs, Maintenance, Replacement, and Delivery, A. Repairs and B. Maintenance; <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf>. Accessed 4/2023.
32. Medicare Claims Processing Manual, Chapter 20 – Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), §40 – Payment for Maintenance and Service of Equipment; <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf>. Accessed 4/2023.
33. Medicare Benefit Policy Manual, Chapter 20 – Medicare Claims Processing Manual, Chapter 20 – Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), §10.2 – Coverage Table for DME Claims; <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf>. Accessed 4/2023.
34. Medicare Claims Processing Manual, Chapter 20 – Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), §40 – Payment for Maintenance and Service of Equipment; <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf>. Accessed 4/2023.
35. 42 CFR § 414.229(f)(2); 414.210(f)(1) and 414.210I(4); Available at: https://www.govregs.com/regulations/title42_chapterIV-i1_part414_subpartD_section414.210. Accessed 4/2023.
36. 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; Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf>. Accessed 4/2023.
37. Noridian web page for *Upgrades*; Available at: <https://med.noridianmedicare.com/web/jddme/topics/upgrades>. Accessed 4/2023.
38. Noridian web page for *Back-Up Equipment*; <https://med.noridianmedicare.com/web/jddme/search-result/-/view/2230703/back-up-equipment>. Accessed 4/2023.
39. Noridian web page for *Back-Up Equipment*; Available at: <https://med.noridianmedicare.com/web/jddme/claims-appeals/billing-situations/back-up-equipment>. Accessed 4/2023.
40. Medicare Glossary Web page; Available at: <https://www.cms.gov/apps/glossary/>.
41. 42 CFR §414.224(a) for *Customized items*; <https://www.govinfo.gov/content/pkg/CFR-2012-title42-vol3/pdf/CFR-2012-title42-vol3-sec414-224.pdf>. Accessed 4/2023.
42. Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services, §110.1 - Definition of Durable Medical Equipment, D. Definition of a Beneficiary's Home; <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf>. Accessed 4/2023.
43. Noridian web page for *Who Can Order?*; <https://med.noridianmedicare.com/web/jddme/topics/documentation/orders>. Accessed 4/2023.

44. Medicare Benefit Policy Manual, Chapter 20 - Medicare Claims Processing Manual, Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), §30.1.1 - Used Equipment; <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf>. Accessed 4/2023.

POLICY REVISION HISTORY

| DATE | REVISION SUMMARY |
|-------------|---|
| 7/2022 | Annual review (converted to new format 2/2023) |
| 7/2023 | Annual review; no change to criteria, added "Billing Guideline" information about authority for HCPCS code assignment of products |

APPENDICES

APPENDIX I – Potentially Covered Equipment and Related Services

[Criteria](#)

The following list are examples of items or equipment which may potentially be considered medically necessary DMEPOS items. This is **not** an all-inclusive list. In addition, the inclusion of an item on this list does not guarantee payment or reimbursement. Some items listed below may be addressed in separate medical policies. While not all items are subject to routine review by the Company, utilization may be subject to audit. Providers remain responsible for correct coding, billing practices, and medical necessity whether or not there is a formal policy or prior authorization requirements in place.

Table 2: APPENDIX I

| Potentially Covered Equipment and Related Services | |
|--|---|
| Alternating pressure pad/mattress | Oxygen regulator |
| Bed pans | Percussor |
| Blood glucose monitor | Postural drainage boards (if chronic pulmonary condition) |
| Cane | Quad canes (if mobility assistive equipment [MAE] requirements are met) |
| Commode | Rolling chairs (if MAE requirements are met) |
| Continuous positive pressure airway device | Safety roller (if MAE requirements are met) |
| Crutches | Seat lift mechanism of seat lift chair |
| Face masks (oxygen) | Sitz bath |
| Gel flotation pad | Speech generating devices |
| Heat Lamp | Suction machine |
| Heating pad | Syringes |
| Infusion pump | Traction |
| Intermittent positive pressure breathing machines | Trapeze bars |
| IPPM machine | Ultraviolet cabinet |
| Lymphedema pump | Urinal |
| Mattress (if hospital bed covered) | Vaporizer |
| Muscle stimulator (for specific conditions) | Ventilator |

| | |
|---|--------------------------|
| Nebulizer | Walker |
| Oxygen humidifiers (if oxygen prescribed) | Wheelchair |
| Oxygen mask | Whirlpool bath equipment |

APPENDIX II – Non-Covered Equipment and Services

[Criteria](#)

The following list includes examples of items or equipment which are **not** considered covered DMEPOS items or are **not** medically reasonable or necessary. This is **not** an all-inclusive list.

Table 3: APPENDIX II

| Non-Covered Equipment and Services | |
|--|--|
| Ace bandages | Identification tags |
| Air cleaners | Incontinence pads or protective covers |
| Air conditioners | Irrigating kits |
| Baby scales | Jacuzzis |
| Bags | Leotards |
| Bathroom equipment (shower bench, raised toilet seat, tub lifts, etc.) | Low vision aids |
| Bed baths | Massage chair or devices |
| Bed lifters | Mobility monitors (e.g., bed exit monitors, alarms, or fall detection systems) |
| Bed boards | Oscillating Beds |
| Beds lounges (power or manual) | Over-bed table |
| Beds Oscillating | Paraffin bath units |
| Bed wetting prevention devices (e.g., enuresis alarms, etc.) | Parallel bars |
| Bladder stimulators (pacemakers) | Personal care items (e.g., girdles, belts, harnesses, etc.) |
| Blood glucose analyzers (reflectance colorimeter) | Physical fitness equipment |
| Bracelets (Medical alert) | Portable room or space heaters |
| Car seats or vehicular restraint systems (e.g., EZ-On Vest) | Portable whirlpool pumps |
| Carafes | Posture chair |

| | |
|--|--|
| Catheters [nonreusable disposable supply (§1861(n) of the Act). (See The Medicare Claims Processing Manual, Chapter 20, DMEPOS).] | Preset portable oxygen units |
| Cradles | Raised toilet seat |
| Dehumidifiers | Ramps and other home modifications (e.g., stair lifts, stair glides, wheelchair lifts, bathroom modifications, doorway restructuring, etc.) |
| Diathermy machines (standard or pulsed) | Restraints |
| Disposable sheets or bags | Safety bed systems (manual or electric; e.g., SleepSafe, Posey Bed Enclosure Safety System, Vail Enclosure beds; this exclusion does not apply to rails or enclosures used in conjunction with medically necessary hospital-grade beds) |
| Elastic stockings (TED hose, surgical stockings; see Compression Hose Stocking medical policies for criteria regarding compression hose) | Safety equipment, such as knee, elbow pads and wrist guards or other safety items to protect or assist performance in sports-related activities or protective helmets used to prevent injury to the head (cranial molding helmets or orthoses used to provide active treatment, such as avoid the need for surgery and/or to facilitate a successful post-surgical outcome, may be allowed as DME) |
| Electric air cleaner | Safety goggles |
| | Safety grab bars |
| Electrostatic machines | Sauna bath |
| Elevators | Sheets |
| Emesis basins | Smoke and carbon monoxide detectors |
| Environmental control devices or that enhance the environmental setting (ergonomic chairs, desks, etc.) | Spare oxygen tanks |
| Esophageal dilators | Speech teaching machine |
| Exercise equipment | Standing tables |
| Fabric supports | Strollers |
| Face masks, surgical | Telephone alert system |
| Feminine hygiene products | Telephone arm |
| Fire extinguishers | Thermometers |
| First aid kits | Toilet Seats |
| Generators | Training equipment (Braille texts) |

| | |
|--|--------------------------|
| Hand controls for vehicles | Vans or other automobile |
| Heat and massage foam cushions or pads | Washcloths |
| Heating and cooling plants | Whirlpool pumps |
| Hose, support | White cane |
| Hot tubs and spas | Service animal |
| Humidifier | |