MEDICAL POLICY	**Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)** **(Medicare Only)**
Effective Date: 7/1/2022  7/1/2022 Medical Officer Date	Medical Policy Number: 302 Medical Policy Committee Approved Date: 4/2021; 10/2021; 6/2022

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

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

APPLIES TO:

Medicare Only

DOCUMENTATION REQUIREMENTS

See Policy Guidelines for detailed documentation requirements.

MEDICARE POLICY CRITERIA

The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

NOTES:

- This Company Medicare medical policy is based on various references published by the Centers of Medicare and Medicaid Services (CMS).
- See "Policy Guidelines" below for Medicare-based definitions of terms used in this medical policy.

Service	Medicare Guidelines
General	I. The Company may have specific medical policies for various types of durable medical equipment, prosthetics, orthotics, or supplies (DMEPOS). When a specific Company medical policy is available for a particular DMEPOS item, that policy will apply. II. In the absence of a specific Company medical policy, this policy based on Medicare guidance, is applicable. **NOTE:** Some items may be medically indicated, but may still be non-covered based on Medicare regulatory guidelines. DMEPOS items and services considered ineligible for coverage by Medicare are not covered by the health plan unless allowed under a Medicare Advantage provider contract exception or specific member benefit. Some Medicare Advantage member contracts may provide **limited supplemental benefits** for select items or equipment. When there is conflict between this medical policy and the Evidence of Coverage (EOC), member EOC language takes precedence. In the event EOC language does not specifically address an item, Medicare guidance in this medical policy should be applied.
Durable Medical Equipment (DME)	Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §110.1 – Definition of Durable Medical Equipment *"Policy Guidelines" below provide detailed DME requirements, as well as sources of coverage criteria when NCDs, LCDs, and other resources are available.*

Prosthetics	Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services, §120 - Prosthetic Devices, A. General *"Policy Guidelines" below provide detailed information regarding prosthetics.*
Orthotics (aka, Braces)	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 *"Policy Guidelines" below provide detailed information regarding orthotics.*
Supplies and Accessories	Supplies and accessories may be eligible for coverage. However, supplies or components may have quantity limits established by Medicare. *"Policy Guidelines" below provide detailed information regarding covered and non-covered supplies and accessories. See Table 1 below for guidance regarding quantity limits for supplies.*
DMEPOS and Medical Supply List	The policy Appendix provides a list of miscellaneous items that may or may not be considered DMEPOS item. This is not an all-inclusive list and general Medicare medical necessity requirements remain the responsibility of providers and suppliers at all times.
DME, Orthotics, and Non-Prosthetic Limb Replacement	Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services, §110.2 - Repairs, Maintenance, Replacement, and Delivery, C. Replacement *"Policy Guidelines" below provide detailed information regarding covered and non-covered DME, orthotic, and non-prosthetic limb replacements.*
Prosthetic Limb Replacement	Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services, §120 - Prosthetic Devices, A. General *"Policy Guidelines" below provide detailed information regarding covered and non-covered prosthetic limb replacement.*
Warranties	Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §40.4 - Items Covered Under Warranty

	"Policy Guidelines" below provide detailed information regarding coverage or non-coverage of the repair or replacement of items or equipment under manufacturer warranty.
Repairs and Maintenance Services	• Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services, §110.2 - Repairs, Maintenance, Replacement, and Delivery, A. Repairs • Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services, §110.2 - Repairs, Maintenance, Replacement, and Delivery, B. Maintenance *"Policy Guidelines" below provide additional information regarding covered and non-covered repairs and maintenance.*
Upgrades	Upgrades to equipment (i.e., an item, component, or feature) when beyond what is medically necessary under Medicare's coverage requirements) are **not covered** *"Policy Guidelines" below provide additional information regarding upgrades.*
Duplicate Items, Including but Not Limited to Back-Up Equipment	Back-up equipment is not eligible for additional or separate reimbursement and is **not covered**. *"Policy Guidelines" below provide additional information regarding back-up equipment and duplicate items, including the DMEMAC "Same or Similar Chart."*
Additional Considerations	All claims are subject to member benefits and eligibility, provider contracts, and Medicare payment and bundling methodologies. Thus, payment is not guaranteed, even for items considered to be medically necessary.

POLICY GUIDELINES

Documentation Requirements *Criteria*

While the following information is not required for every claim, all or part of this list 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;
  - 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) *Criteria*

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 which[6]:

- It 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 establish "durability," Medicare uses a minimum lifetime requirement (MLR) of at least 3 years. 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. While a piece of equipment may serve a useful medical purpose, that does not in itself mean it meets Medicare's definition of DME and may not be covered. Therefore, items with some remote medically related use may not be covered under Medicare rules.[8]

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.

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 *Criteria*

Prosthetics are defined as items which replace all or part of either an internal body organ ***OR*** the function of a permanently inoperative or malfunctioning internal body organ (Medicare defines "permanence" in the relevant manual). Coverage under this benefit includes, but is not limited to, prosthetic hands, arms, and legs, breast prostheses, and eye prostheses, to name a few.[9,10]

Note that dental devices, such as dentures, do not fall under the Prosthetic benefit for Medicare. Member EOCs should be reviewed to determine if these are excluded dental services or if they may be eligible for coverage.[11]

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.[10,12]

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.

Orthotics *Criteria*

An orthotic, also known as a brace, is a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body.[13,14] Note that items which do not meet the rigidity requirement are **not covered** because they do not meet the Medicare definition of orthotic or brace.

While it includes the phrase "orthotic" or "orthosis," oral orthotics and oral appliances are not included within the "DMEPOS" category. Under Medicare, these items are usually considered dental in nature and may not be covered.[15] Member EOCs should be reviewed to determine if these are excluded dental services or if they may be eligible for coverage.

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.[12,16]

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.

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	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. 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.
Surgical (Wound) Dressings	L33831	A54563	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. 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
Tracheostomy Care Supplies	L33832	A52492	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. 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.
Urological Supplies	230.17 / L33803	A52521	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 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). 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.

Regulatory Oversight

According to Medicare NCD 280.1, coverage decisions for DMEPOS take into account many factors, including but not limited to, relevant product approvals for marketing 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.[17] 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.[18] 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.[19]

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.[20] 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.[20]

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.

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, DMEMACs may determine the RUL of equipment, but in no case can it be less than 5-years. It is important to note that the determination of RUL is based on *when the equipment is delivered to the patient* – it is **not** based on the actual age of the equipment.[21-24]

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 following[26]:

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, which are addressed in a separate medical policy.)

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 necessary[10]:

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."[26] 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.[7,26,27]

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.[28] In addition, coverage of repairs or replacement part charges is not allowed for supplier-owned (rented) equipment and are the responsibility of the DME supplier.[28-31] 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.[27] 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 still 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.[32,33]

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.[34]

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.[35,36]

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

Since Advance Beneficiary Notice of Noncoverage (ABN) are not valid for use for Medicare Advantage Organizations (MAOs), if there is question regarding the medical reasonableness or necessity of an item, members or providers may submit an Advance Benefit Determination request to the plan to determine coverage.[37,38]

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.[39,40]

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.[41]

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 be[42]:

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.[43]

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.[44]

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).[45]

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]

BILLING GUIDELINES

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.

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.

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.

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 Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

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.

REGULATORY STATUS

Mental Health Parity Statement

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.

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 3/11/2022.
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 3/11/2022.

3. PDAC Advisory Article, *Coding Guideline – K0900 (Custom Durable Medical Equipment, Other Than Wheelchairs)*; https://dmepdac.com/palmetto/PDACv2.nsf/DIDC/U2F9VMG152~Articles%20and%20Publications~Advisory%20Articles. Published 2014. Accessed 3/11/2022.
4. Noridian web page for *Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)*; https://med.noridianmedicare.com/web/jfb/topics/dme. Accessed 3/11/2022.
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 3/11/2022.
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 3/11/2022.
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 3/11/2022.
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 3/11/2022.
9. Social Security Act (SSA) §1861(s)(8); https://www.ssa.gov/OP_Home/ssact/title18/1861.htm. Accessed 3/11/2022.
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 3/11/2022.
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 3/11/2022.
12. 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 3/11/2022.
13. Social Security Act (SSA) §1861(s)(9); https://www.ssa.gov/OP_Home/ssact/title18/1861.htm. Accessed 3/11/2022.
14. 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 3/11/2022.
15. DMEMAC Local Coverage Article (LCA) for *Oral Appliances for Obstructive Sleep Apnea – Policy Article* (A52512); https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=52512. Accessed 3/11/2022.

16. 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 3/11/2022.
17. U.S. Food & Drug Administration (FDA) Premarket Notification 510(k). Content current as of 03/13/2020. Available from: 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: https://www.fda.gov/about-fda/cdrh-transparency/overview-medical-device-classification-and-reclassification.
19. 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.
20. 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.
21. 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 3/11/2022.
22. Noridian web page for *Replacement*; Last Updated: 02/25/2022; https://med.noridianmedicare.com/web/jddme/topics/repairs/replacement. Accessed 3/11/2022.
23. 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.
24. Noridian web page for *Items Requiring Frequent and Substantial Servicing*; https://med.noridianmedicare.com/web/jddme/topics/payment-categories/frequent-servicing. Accessed 3/11/2022.
25. 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 3/11/2022
26. Social Security Act (SSA) §1862(a)(2); https://www.ssa.gov/OP_Home/ssact/title18/1862.htm. Accessed 3/11/2022.
27. Noridian web page for *Warranties*; https://med.noridianmedicare.com/web/jddme/topics/repairs/warranties. Accessed 3/11/2022.
28. Noridian web page for *Repairs, Maintenance and Replacement*; Available at: https://med.noridianmedicare.com/web/jddme/topics/repairs. Accessed 3/11/2022.
29. Noridian web page for *Repairs*; Available at: https://med.noridianmedicare.com/web/jddme/topics/repairs/repairs. Accessed 3/11/2022.
30. 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 3/11/2022.

31. 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 3/11/2022.
32. 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 3/11/2022.
33. 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 3/11/2022.
34. 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 3/11/2022.
35. 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 3/11/2022.
36. Noridian web page for *Upgrades*; Available at: https://med.noridianmedicare.com/web/jddme/topics/upgrades. Accessed 3/11/2022.
37. Medicare Booklet MLN006266 May 2021 for *Medicare Advance Written Notices of Non-coverage*; https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/abn_booklet_icn006266.pdf. Accessed 3/11/2022.
38. Medicare Managed Care Manual, Chapter 4 – Benefits and Beneficiary Protections, §160 – Beneficiary Protections Related to Plan-Directed Care; https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf. Accessed 3/11/2022.
39. Noridian web page for *Back-Up Equipment*; https://med.noridianmedicare.com/web/jddme/search-result/-/view/2230703/back-up-equipment. Accessed 3/11/2022.
40. Noridian web page for *Back-Up Equipment*; Available at: https://med.noridianmedicare.com/web/jddme/claims-appeals/billing-situations/back-up-equipment. Accessed 3/11/2022.
41. Medicare Glossary Web page; Available at: https://www.cms.gov/apps/glossary/.
42. 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 3/11/2022.
43. 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 3/11/2022.
44. Noridian web page for *Who Can Order?*; https://med.noridianmedicare.com/web/jddme/topics/documentation/orders. Accessed 3/11/2022.

45. 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 3/11/2022.

APPENDIX

Criteria

The following list is primarily based on the Medicare NCD 280.1 and is not an all-inclusive list. Several items not included below may be addressed in separate Company medical policies. Not all items listed are subject to routine review by the health plan. Please see our "Prior-authorization List" for DMEPOS items and services which require prior authorization. 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. As a Medicare Advantage Organization (MAO), the health plan may offer benefits in excess of what Medicare covers in the form of a Supplemental Benefit. Some items below may be eligible for coverage under the supplemental benefit and within any noted benefit limits (e.g., annual maximums) set by the plan. EOC language has precedence where applicable. In the event EOC language does not address a specific request, the following Medicare references should be used and applied. Items or equipment not included in the EOC, or items provided in excess of the benefit limits, are considered non-covered.

Item	Description/Coverage
Air Cleaners	Environmental control equipment; not primarily medical in nature (§1861(n) of the Act). (NCD 280.1)
Air Conditioners	Environmental control equipment; not primarily medical in nature (§1861(n) of the Act). (NCD 280.1)
Air Purifiers	Environmental control equipment; not primarily medical in nature (§1861(n) of the Act).
Air Splint	Medical supply (included in the Physician's claim at the time of application).
Air-Fluidized Bed	Potentially covered; coverage criteria are available.
Alternating Pressure Pads, Mattresses and Lamb's Wool Pads	Potentially covered; coverage criteria are available.
Audible/Visible Signal/Pacemaker Monitors	See Self-Contained Pacemaker Monitors
Augmentative Communication Devices	Potentially covered; coverage criteria are available
Bathtub Lifts and Seats	Not primarily medical in nature (§1861(n) of the Act). (NCD 280.1) (See EOC for possible bathroom safety devices Supplemental Benefit)
Bead Beds	See Air-Fluidized Beds.
Bed Baths (home type)	Not primarily medical in nature (§1861(n) of the Act). (NCD 280.1)
Bed Lifters (bed elevators)	Not primarily medical in nature (§1861(n) of the Act). (NCD 280.1)

Bedboards	Not primarily medical in nature (§1861(n) of the Act). (NCD 280.1)
Bed Pans (autoclavable hospital type)	Potentially covered; coverage criteria are available.
Bed Side Rails	Potentially covered; coverage criteria are available.
Beds-Lounges (power or manual)	Not a hospital bed; comfort or convenience item; not primarily medical in nature (§1861(n) of the Act). (NCD 280.1)
Beds (Oscillating)	Institutional equipment; inappropriate for home use. (NCD 280.1)
Bidet Toilet	Seats See Toilet Seats
Blood Glucose Analyzers (Reflectance Colorimeter)	Unsuitable for home use. (NCD 280.1)
Blood Glucose Monitors	Potentially covered; coverage criteria are available.
Blood Pressure Monitor / Sphygmomanometer	Automatic blood pressure monitors: Non-covered (CMS Status "N" code and convenience item); exceptions may be considered for patients on home dialysis. (Retired Noridian LCA A33674 and Noridian web page) Note: Ambulatory blood pressure monitoring (ABPM) services described in NCD 20.19 are reported using procedure codes (93784, 93786, 93788, 93790) and are not considered DME.
Braille Teaching Texts	Educational equipment; not primarily medical in nature (§1861(n) of the Act). (NCD 280.1)
Canes	NCD 280.3
Carafes	Convenience item; not primarily medical in nature (§1861(n) of the Act). (NCD 280.1)
Casts (plaster, fiberglass)	Medical supply (included in the Physician's claim at the time of application).
Catheters	Nonreusable disposable supply (§1861(n) of the Act). (NCD 280.1 and the Medicare Claims Processing Manual, Chapter 20, DMEPOS; however, coverage may be provided).
Commodes	Potentially covered; coverage criteria are available.
Communicators	Potentially covered; coverage criteria are available.
Crutches	Potentially covered; coverage criteria are available.
Cushion Lift Power Seats	See Seat Lifts
Dehumidifiers (room or central heating system type)	Environmental control equipment; not primarily medical in nature (§1861(n) of the Act). (NCD 280.1)

Diathermy Machines (standard pulses wave types)	Inappropriate for home use (NCD 280.1 and 150.5)
Digital Electronic Pacemaker Monitors	See Self-Contained Pacemaker Monitors.
Disposable Sheets and Bags	Non-reusable disposable supplies (§1861(n) of the Act). (NCD 280.1)
Non-surgical Dressings/Bandages (e.g., Ace bandages)	Medical supply when provided in a provider's office (included in the Physician's claim at the time item is provided). Otherwise considered "over the counter" and not eligible for coverage.
Elastic Stockings	Non-reusable supply; not rental-type items (§1861(n) of the Act). (NCD 280.1 and 270.5)
Electric Air Cleaners	See Air Cleaners
Electric Hospital Beds	Potentially covered; coverage criteria are available.
Electrical Stimulation for Wounds	Inappropriate for home use. (NCD 280.1 and 270.1)
Electrostatic Machines	See Air Cleaners and Air Conditioners
Elevators	Convenience item; not primarily medical in nature (§1861(n) of the Act). (NCD 280.1)
Emesis Basins	Convenience item; not primarily medical in nature (§1861(n) of the Act). (NCD 280.1)
Esophageal Dilators	Physician instrument; inappropriate for patient use. (NCD 280.1)
Exercise Equipment	Not primarily medical in nature (§1861(n) of the Act). (NCD 280.1)
Fabric Supports (Support Hose)	Nonreusable supplies; not rental-type items (§1861(n) of the Act). (NCD 280.1)
Face Masks (oxygen)	Potentially covered; coverage criteria are available.
Face Masks (surgical)	Nonreusable disposable items (§1861(n) of the Act).
Flow Meters	See Medical Oxygen Regulators
Fluidic Breathing Assisters	See Intermittent Positive Pressure Breathing Machines
Fomentation Devices	See Heating Pads
Gel Flotation Pads and Mattresses	See Alternating Pressure Pads and Mattresses
Grab Bars	Self-help device; not primarily medical in nature (§1861(n) of the Act). (NCD 280.1) (See EOC for possible bathroom safety devices Supplemental Benefit)
Heat and Massage Foam Cushion Pads	Not primarily medical in nature; personal comfort item (§1861(n) and 1862(a)(6) of the Act). (NCD 280.1)
Heating and Cooling Plants	Environmental control equipment not primarily medical in nature (§1861(n) of the Act). (NCD 280.1)

Heating Pads	Potentially covered; coverage criteria are available.
Heat Lamps	Potentially covered; coverage criteria are available.
Helmets (cranial orthosis or protective safety equipment)	Potentially covered; cranial orthoses may be eligible for coverage when used for individuals with head injuries, but these are not meant for recreational purposes; helmets used for protective or safety purposes are not primarily medical in nature (§1861(n) of the Act).
Holter Monitor (cardiac event monitor)	Medical supply (included in the Physician's claim at the time of application).
Hospital Beds	Potentially covered; coverage criteria are available.
Hot Packs	See Heating Pads
Humidifiers (oxygen)	See Oxygen Humidifiers
Humidifiers (room or central heating system types)	Environmental control equipment; not medical in nature (§1861(n) of the Act). (NCD 280.1)
Hydraulic Lifts	See Patient Lifts
Incontinent Pads	Nonreusable supply; hygienic item (§1861(n) of the Act). (NCD 280.1)
Infusion Pumps	Potentially covered; coverage criteria are available.
Injectors (hypodermic jet)	Not covered self-administered drug supply; pressure powered devices (§1861(s)(2)(A) of the Act) for injection of insulin.
Intermittent Positive Pressure Breathing Machines	Potentially covered; coverage criteria are available.
Internal Fixation Devices (e.g., cages, rods, screws, etc.)	Medical supply; not considered DMEPOS; usually part of a surgical procedure, implanted into the body; not reported by the physician, but may be reported on the facility claim as a facility expense.
Iron Lungs	See Ventilators
Irrigating Kits	Nonreusable supply; hygienic equipment (§1861(n) of the Act). (NCD 280.1)
Lamb's Wool Pads	See Alternating Pressure Pads, Mattresses, and Lamb's Wool Pads
Leotards and Pressure Leotards	Non-reusable supply, not rental-type item (§1861(n) of the Act). (NCD 280.1)

Massage Devices	Deny - personal comfort items; not primarily medical in nature (§1861(n) and 1862(a)(6) of the Act). (NCD 280.1)
Mattresses	Potentially covered; coverage criteria are available.
Mobile Geriatric Chairs	Potentially covered; coverage criteria are available. (NCD 280.1) See also Rolling Chairs.
Modifications to home, vehicle, etc. (e.g., ramps, patient lifts, car lift rack/platform) and related expenses and equipment	Deny - not primarily medical in nature (§1861(n) and 1862(a)(6) of the Act). (NCD 280.1) and the Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §80 - Personal Comfort Items
Monitoring Technology; Fitness (e.g., FitBit®, WeGo®, Fuelband®, pedometers, heart rate monitors, and GPS watches)	Deny – Considered "exercise equipment" and "not primarily medical in nature (§1861(n) of the Act). (See also the Noridian web page for *Correct Coding - Fitness Monitoring Technologies*)
Monitoring Technology; RAD or PAP devices (tracking data downloaded for further analysis by a healthcare provider, DME supplier, or member)	Deny - Not primarily medical in nature (§1861(n) of the Act). (LCD L33718 and LCA A52467)
Motorized Wheelchairs	Potentially covered; coverage criteria are available.
Muscle Stimulators	Potentially covered; coverage criteria are available.
Nebulizers	Potentially covered; coverage criteria are available.
Oscillating Beds	Institutional equipment - inappropriate for home use. (NCD 280.1)
Over-bed Tables	Convenience item; not primarily medical in nature (§1861(n) of the Act). (NCD 280.1)
Paraffin Bath Units (Portable)	NCD 280.1 (states possibly covered, but unknown based on what NCD or LCD)
Paraffin Bath Units (Standard)	Institutional equipment; inappropriate for home use. (NCD 280.1)
Parallel Bars	Support exercise equipment; primarily for institutional use; in the home setting other devices satisfy patient's need. (NCD 280.1)
Patient Lifts	Potentially covered; coverage criteria are available.
Percussors	NCD 280.1
Portable Oxygen Systems	1. Regulated - Potentially covered; coverage criteria are available.

	2. Preset Deny - (flow rate Deny - emergency, first-aid, or not adjustable) precautionary equipment; essentially not therapeutic in nature. (NCD 280.1)
Portable Room Heaters	Environmental control equipment; not primarily medical in nature (§1861(n) of the Act). (NCD 280.1)
Portable Whirlpool Pumps	Not primarily medical in nature; personal comfort items (§§1861(n) and 1862(a)(6) of the Act). (NCD 280.1)
Postural Drainage Boards	Potentially covered; coverage criteria are available. (NCD 280.1)
Precautionary equipment, not otherwise specified	Precautionary supplies are not covered. These are considered convenience items and they are not primarily medical in nature; members may already have the same or similar item used to treat the beneficiary or the precautionary equipment is not used to treat or diagnosis a medical condition, it is used for preventive measures. These are non-covered. (§1861(n) of the Act).
Pulse Tachometers	Not reasonable or necessary for monitoring pulse of homebound patient with/without a cardiac pacemaker. (NCD 280.1)
Quad-Canes	Potentially covered; coverage criteria are available.
Raised Toilet Seats	Convenience item; hygienic equipment; not primarily medical in nature (§1861(n) of the Act). (NCD 280.1) (See EOC for possible bathroom safety devices Supplemental Benefit)
Respirators	See Ventilators
Rolling Chairs	Potentially covered; coverage criteria are available. (NCD 280.1) See also Mobile Geriatric Chairs.
Safety Rollers	Potentially covered; coverage criteria are available.
Sauna Baths	Not primarily medical in nature; personal comfort items (§§1861(n) and 1862(a)(6) of the Act). (NCD 280.1)
Scale (digital or analog)	Not primarily medical in nature; exceptions may be considered for patients on home dialysis. (Retired Noridian LCA A33674 and Noridian web page)
Seat Lifts	Potentially covered; coverage criteria are available.
Self Contained Pacemaker Monitors	Potentially covered; coverage criteria are available.
Sitz Baths	Potentially covered; coverage criteria are available.

Speech Teaching Machines	Education equipment; not primarily medical in nature (§1861(n) of the Act). (NCD 280.1)
Stairway Elevators	See Elevators
Steam Packs	See Heating Pads
Suction Machine or Pump	Potentially covered; coverage criteria are available.
Surgical Dressings	Potentially covered; coverage criteria are available. Coverage depends on when provided and how/where used.
Surgical Leggings	Non-reusable supply; not rental-type item (§1861(n) of the Act). (NCD 280.1)
Telephone Alert Systems	These are emergency communications systems and do not serve a diagnostic or therapeutic purpose. (NCD 280.1)
Toilet Seats	Not medical equipment (§1861(n) of the Act). (NCD 280.1)
Traction Equipment	Potentially covered; coverage criteria are available.
Trapeze Bars	Potentially covered; coverage criteria are available
Treadmill Exercisers	Exercise equipment; not primarily medical in nature (§1861(n) of the Act). (NCD 280.1)
Ultraviolet Cabinets	Potentially covered; coverage criteria are available.; however, medical and other factors must justify treatment at home rather than at alternative sites, e.g., outpatient department of a hospital.
Urinals autoclavable	Potentially covered; coverage criteria are available.
Vaporizers	Potentially covered; coverage criteria are available.
Ventilators	Potentially covered; coverage criteria are available.
Water and Pressure Pads and Mattresses	See Alternating Pressure Pads, Mattresses and Lamb's Wool Pads
Whirlpool Bath Equipment	Potentially covered; coverage criteria are available.
Whirlpool Pumps	Not primarily medical in nature; personal comfort items (§§1861(n) and 1862(a)(6) of the Act). (NCD 280.1)
White Canes	Not considered Mobility Assistive Equipment. (NCD 280.1 and 280.2)