



Policy Key: Durable Equipment/Durable Medical Equipment

TriWest Clinical Operations – TRICARE West

SCOPE

This Policy Key provides criteria to use during medical necessity review for Durable Equipment (DE)/Durable Medical Equipment (DME).

There are separate Policy Keys (PKs) for the following DE/DME items:

- Hospital Beds and Pressure Reducing Support Surfaces
- Wheeled Mobility (Wheelchairs and Scooters)
- Orthotic Devices and Therapeutic Shoes

This does not include DE/DME covered under the Extended Health Care Option (ECHO) benefit.

For Active-Duty Service Members (ADSM) and TRICARE Prime Remote (TPR) beneficiaries, reviewers must first apply guidance outlined in TRICARE Operations Manual Chapter 17, Section 3, Supplemental Health Care Program (SHCP). If a service is excluded under ADSM/TPR provisions, no further policy review is required under this or any other Policy Key. [29]

NOT COVERED [1,2,3,4,5,6,8,9]

- Luxury, deluxe, immaterial, or non-essential features, which increase the item's cost of the relative to a similar item without those features, based on industry standards for a particular item at the time the equipment is prescribed or replaced for a beneficiary
- Duplicate DE/DME that serves the same purpose as another item of DE/DME.
Note: Items that are essential to provide a fail-safe, in-home, life-support system are NOT considered duplicative, e.g., a portable oxygen concentrator as a back up to a stationary oxygen concentrator
- Elevator or Chair Lift
- Alterations to living spaces or permanent features attached thereto, even when it is necessary to accommodate the installation of covered DME or to facilitate entrance or exit
- Non-medical equipment (e.g., humidifier, electric air cleaners, exercycle, safety grab bars, training equipment)
- Replacement or repairs of DE/DME damaged while using the equipment in a manner inconsistent with its common use
- A DE/DME item that has been lost or stolen except as described in the coverage criteria.
- An item under warranty
- Repairs of deluxe, luxury, or immaterial features of DE/DME unless previously approved as medically necessary

- Excluded breast pump supplies
 - Breast pump batteries, battery-powered adapters, and battery packs
 - Regular “baby bottles” (Bottles not specific to pump operation), including associated nipples, caps, and lids
 - Breast pump cleaning supplies
 - Garments and other products that allow hands-free pump operation
 - Ice packs, labels, labeling lids, and other similar products
 - Nursing bras, bra pads, and other similar products
 - Over the counter (OTC) creams and ointment
- Non-pneumatic compression devices (e.g., Koya Dayspring) are unproven for the treatment of lymphedema. [36]
- Negative Pressure Wound Therapy (NPWT) Exclusions
 - Patients whose wounds respond to standard therapeutic measures
 - Patients who cannot tolerate NPWT use
 - Patients with the following contraindications:
 - Active bleeding
 - Difficult wound hemostasis
 - Exposed organs, vasculature, nerves, or anastomotic site
 - Inadequately debrided wounds
 - Untreated osteomyelitis
 - Necrotic tissue with eschar present
 - Wound infection
 - Malignancy in the wound
 - Non-enteric and unexplored fistulas
 - Uniform granulation tissue has been obtained.
 - The wound depth is less than one millimeter, as wounds of this depth cannot accommodate the sponge.
- Seat lifts for any indication not listed under the coverage criteria [8]
- Seat lifts that operate by spring release mechanism with a sudden, catapult-type motion that jolts the member from a seated to a standing position [8]
- Patient lifts for all other indications not listed under the coverage criteria [8]
- Electric powered recliner and elevating seat that are not considered medical in nature [8]
- Standing frame systems/standers are considered not medically necessary for members with complete paralysis of the hips and legs, whereby there is no improvement in the lower body strength following maintenance of standing position [9]
- Powered, electronic, or motorized standing frame systems / standers [9]
- Mobile Medical Applications (MMAs), Digital Therapeutics, and Sensors unless covered under the basic TRICARE benefit. Currently, no MMAs meet TRICARE coverage criteria. [1]
- <https://tricare.mil/CoveredServices/IsItCovered/SafetyMedicalSupplies>
- Safety Medical Supplies - TRICARE doesn't cover safety medical supplies, such as bath or toilet rails, safety beds, helmets, and childproof locks.
- Wearable seizure monitoring and detection devices. [5]

COVERAGE CRITERIA

General Information [1]

- DE must be prescribed for a use consistent with required **U.S. Food and Drug Administration (FDA) approved labeling for the item**. When the prescribed use of an item appears to be extraordinary, a signed statement from the manufacturer that a specific medical device is FDA approved for such a use is adequate evidence that the FDA approval requirement is met.
- DE must be ordered by a physician, dentist, or allied health care professional
- DE can stand repeated use, is primarily and customarily to serve a medical purpose, and is generally not useful to an individual in the absence of an illness or injury
- DE includes the following:
 - Hospital Beds
 - Iron Lungs
 - DME
 - Wheelchairs
 - Cardiorespiratory monitor under specific conditions
- DE can be provided on a rental or purchase basis, based on the price most advantageous to the Government taking into consideration the anticipated duration of the medically necessary need and the current price information for the DE
- DME is DE that meets the following additional coverage criteria:
 - The item is medically appropriate to:
 - Improve, restore, or maintain the function of a malformed, diseased, or injured body part, or can otherwise minimize or prevent the deterioration of the beneficiary's function or condition
 - Maximize the beneficiary's function consistent with the beneficiary's physiological or medical needs

Initial Level of Review may approve any of the following conditions:

- **Customization** of DME owned by a beneficiary along with any accessory or item of supply if documentation provides the reason, it is essential for one of the following conditions:
 - To achieve therapeutic benefit for the patient
 - Make the equipment serviceable
 - Otherwise assuring the proper functioning of the equipment
- **Repairs** of beneficiary-owned DE
 - Repairs are necessary to make the equipment functional because of reasonable wear and usage and the manufacturer's warranty has expired, AND the repair cost is less than the replacement cost. Coverage includes using a temporary replacement item provided during a reasonable period of repair.

- **Replacement** of beneficiary-owned DE with a new order or prescription with an explanation of the medical need AND one of the following criteria:
 - Documentation that the DE is not functional due to normal wear, accidental damage, a change in the beneficiary's condition, or the device has been declared adulterated by the FDA.
 - Documentation that the DE is lost or stolen and not otherwise covered by another insurance (such as a homeowner's or automobile policy).
- **Supplies for Approved Devices** such as suction catheters, canisters, tubing, filters, etc. [1, 14]

***NOTE:** Consult a supervisor and then pend for SLR if there are any coding or cost concerns.*
- **Medically necessary upgrade** when the prescription specifically states the medical reason that the upgrade is necessary. For example, the beneficiary does not have the physical strength or balance required to lift a standard walker and, therefore, one with wheels is required.

Note: Request for DE lacking documentation of medical necessity for the deluxe, luxury, or immaterial feature device may have the TRICARE allowed amount for the base model applied to the upgraded equipment, with the beneficiary responsible for the difference between the allowed amount for the base model and the provider's billed charges.

Automatic Blood Pressure Monitors [12]

Initial level of review may approve for the following:

- A patient who is **also** receiving covered Remote Physiologic Monitoring (RPM) services for medically necessary blood pressure monitoring.

Automated External Defibrillators (AED) [3]

Note: Coverage is for **either** a wearable or non-wearable AED if a beneficiary meets the coverage criteria for both.

- **Wearable AED**
 - **Initial level of review** may approve if meets **ANY** of the following conditions:
 - An episode of ventricular fibrillation or a sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia (NOT occurring during the first 48 hours after an acute Myocardial Infarction (MI))
 - A familial or inherited condition with a high risk of life-threatening ventricular tachyarrhythmia, such as long QT syndrome, Brugada syndrome, catecholaminergic polymorphic ventricular tachycardia (CPVT), short QT syndrome, or hypertrophic cardiomyopathy.
 - Either a prior MI or dilated cardiomyopathy with a measured left ventricular ejection fraction less than or equal to 0.35
 - A previously implanted defibrillator requires explanation (removal).
- **Non-Wearable AED**

- **Initial level of review** may approve if a previously implanted defibrillator requires explanation
- **Medical Director** may approve if meets **ANY** of the following conditions:
 - An implanted AED is contraindicated and **ONE** of the following conditions is documented:
 1. An episode of cardiac arrest due to ventricular fibrillation, not from a transient or reversible cause
 2. An episode of ventricular fibrillation or a sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia not associated with acute MI and not from a transient or reversible cause
 3. A familial or inherited condition with a high risk of life-threatening ventricular tachyarrhythmia, such as long QT syndrome, Brugada syndrome, catecholaminergic polymorphic ventricular tachycardia (CPVT), short QT syndrome, or hypertrophic cardiomyopathy
 4. Coronary artery disease with a prior MI with a measured left ventricular ejection fraction less than or equal to 0.35 and inducible, sustained ventricular tachycardia or ventricular fibrillation during an electrophysiologic (EP) study **AND BOTH** of the following conditions:
 - The MI occurred more than 4 weeks before prescribing the AED.
 - The EP test was performed more than 4 weeks after the qualifying MI.
 - A prior MI and measured left ventricular ejection fraction less than or equal to 0.30, **AND ALL** the following conditions apply:
 1. Does not have cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm.
 2. Has not had a coronary artery bypass graft or percutaneous transluminal coronary angioplasty within the past three months
 3. Has not had an enzyme-positive MI within the past month
 4. Does not have clinical symptoms or findings that would make them a candidate for coronary revascularization
 5. Does not have irreversible brain damage from preexisting cerebral disease
 6. Does not have any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than one year.
 - Meets one of the previous non-wearable AED coverage criteria **AND** has NYHA Class IV heart failure.
 - Has ischemic dilated cardiomyopathy, documented prior MI, New York Heart Association (NYHA) Class II and III heart failure, and measured left ventricular ejection fraction less than or equal to 35%
 - Has non-ischemic dilated cardiomyopathy greater than three months, NYHA Class II and III heart failure, and measured left ventricular ejection fraction less than or equal to 35%

Continuous Passive Motion (CPM) Devices (E0935, E0936) [30,31]

Initial Level of Review may approve for **ANY** of the following conditions when the device is **FDA-**approved:

Post-Surgical Joint Therapy

CPM for joints that are replaced, traumatized, infected, operated upon, or when used following extensive burns involving one or more kinetic areas, **AND ALL** the following criteria are met:

- Use in the patient's home begins within **two** calendar days following surgery (assuming discharge within that timeframe)
- If CPM was being used in the hospital immediately prior to discharge, continuity may be maintained at home not to exceed a combined total of **three** continuous weeks (hospital and home)
- Documentation from the TRICARE-authorized provider includes:
 - Surgical procedure date and type (joint replacement, trauma repair, infection treatment, burn care)
 - Medical justification for home CPM continuation
 - Expected duration of therapy (not to exceed three weeks total)

Post-Cast/Splint Removal Therapy

CPM following removal of an orthopedic cast or splint that was applied following surgery, **AND ALL** the following criteria are met:

- Cast or splint was applied following a surgical procedure on the joint
- CPM begins within **two** calendar days of removal of the cast or splint
- Reimbursement will not exceed **three** continuous weeks from the date of cast/splint removal
- Documentation includes:
 - Original surgical procedure date and type
 - Cast/splint removal date
 - Medical justification for CPM therapy

NOTE: Evidence has shown that maximum benefits from CPM are derived within the three-week time limits specified above.

Continuous Positive Airway Pressure (CPAP) Batteries And Portable Devices for ADSM [27]

CPAP

- **Initial level of review** may approve portable CPAP devices for ADSM when **ALL** the following conditions are met **and** documented on the referral:
 - The ADSM has a diagnosis of Obstructive Sleep Apnea (OSA); and
 - The ADSM travels on official business at least three days per month or is being deployed.

- The device shall have humidification and battery capability.
- If the ADSM already has a standard CPAP device, the contractor shall authorize a portable device if criteria are met.
- Upon initial referral for a CPAP device, the contractor shall authorize a portable device if criteria are met. The contractor shall not authorize a standard CPAP device in addition to a portable device.
- The contractor shall code portable CPAP devices using Healthcare Common Procedure Coding System (HCPCS) code **E1399** and shall reimburse based upon the billed charge.

Batteries for CPAP Machine

- **Initial level of review** may approve batteries for both standard and portable devices and adaptive equipment when **ALL** the following criteria are met:
 - The request shall document that the eligible Active Duty Service Member (ADSM) is on deployment status and is not within one year of retirement or separation.
 - The contractor shall provide a replacement battery if the current battery is no longer functional after normal use or damaged during deployment at no fault of the eligible ADSM. The ADSM will document so in the request.
 - If the battery is lost or damaged because of the ADSM personal negligence, the contractor shall not use SHCP funds to replace the battery.

External lower extremity nerve stimulator for restless legs syndrome, each (E0743) [28]

Initial level of review may approve for the following indication:

- Restless legs syndrome (RLS)
Note: Refer to First Level Review Denial Auto-Text for if request does not meet above criteria.

External upper limb tremor stimulator of the peripheral nerves of the wrist, Supplies and Accessories (A4542) [28]

Initial level of review may approve for the following indication:

- Essential tremor by stimulating the peripheral nerves in the upper extremity
Note: Refer to First Level Review Denial Auto-Text for if request does not meet above criteria.

Gait Trainers [10] such as Rifton Gait Trainer/Pacer Gait Trainer, KidWalk Gait Mobility System, Therapeutic Ambulatory Orthotic System

- **Medical Director** may approve when meets **ALL** the following conditions:
 - Beneficiary with Cerebral Palsy or other neurological disorder
 - Requires moderate to maximum support for walking
 - Demonstrated ability to walk using the device

Heavy-Duty Hospital Grade Breast Pump [2]



Initial level of review may approve for **ANY** of the following for an infant less than 36 weeks gestation (premature) at birth:

- Infant remains in the hospital during the immediate post-partum period
- If, after the infant's discharge, the provider documents the medically necessary reason for continued use of the medical grade breast pump
- Pump and associated supplies to support initiation of lactation for mothers and infants who are separated due to illness or who are unable to feed directly from the breast due to maternal or infant medical complications, congenital anomalies, induced lactation, relactation, adoption, or other medical conditions for mother or infant which preclude effective feeding at the breast

Home Prothrombin (PT) International Normalized Ratio (INR) Monitor and Supplies [13]

Monitor

Device must be FDA Approved

- **Initial level of review** may approve the **monitor** for the following criteria:
 - Must have a condition requiring lifetime warfarin therapy and monitoring of PT activity.
 - Requires frequent PT testing once a week or multiple times per month.
 - Must have the ability to use the PT monitoring device (caregiver or patient) after obtaining education on its proper use from an appropriate healthcare professional.
 - Monitor must be prescribed by a physician.
 - Related services and **supplies**, such as PT/INR test strips and office visits, are covered.

Supplies

- **Initial level of review** may approve INR home test supplies (G0249) for the following criteria:
 - Requires a signed order form from the provider.

Home Ventilator with Dual Function (E0468) [25, 26]

Initial Level of Review may approve for **ventilation and cough stimulation** when meets **ANY** the following conditions:

- Awake arterial blood gas (ABG) $\text{PaCO}_2 \geq 52$ mm Hg while on supplemental oxygen (if prescribed)
- Obstructive sleep apnea (OSA) and CPAP treatment have been considered and ruled out (clinical documentation suffices)
- Need for advanced ventilatory support with **any** of the following:
 - Higher inspiratory pressures than those deliverable by standard bilevel devices (E0471)
 - $\text{FiO}_2 > 40\%$ or > 5 L/min nasal oxygen
 - Ventilator support for ≥ 10 hours/day (including daytime use)
 - Sophisticated alarms and internal battery (for high-dependency patients)
 - Mouthpiece ventilation during the day
 - Persistence of hypercapnia ($\text{PaCO}_2 \geq 52$ mm Hg) despite adequate adherence to BPAP therapy

Intermittent Pneumatic Compression and Sequential Pneumatic Compression [31,32]

Initial Level of Review may approve purchase and rental when meeting the criteria for the following conditions:

- **Thromboprophylaxis (Prevention of Venous Thromboembolism, Pulmonary Embolism, and Deep Vein Thrombosis)**
 - **Documentation** must include:
 - Specific patient indications for use
 - Clinical evaluation supporting medical necessity
 - *Notes to include contraindication to pharmacologic thromboprophylaxis methods, high bleeding risk, and severely limited mobility and others*
 - Anticipated length of need
 - **Authorization**
 - Initial authorization not to exceed **30 days**
- **Chronic Venous Insufficiency and Post-Thrombotic Syndrome**
 - ≥ 6 months of documented failure of standard conservative therapy
 - **Authorization:**
 - Initial authorization not to exceed 180 days

Continued coverage may be approved with adequate documentation from the prescribing physician. Documentation must include:

- Clinical evaluation supporting medical necessity
- Anticipated length of need

NOTE: Prior authorization is not required for inpatient use of pneumatic compression or at an outpatient facility as part of standard medical treatment.

Lymphedema Pumps (Segmental and Non-segmental) [33,34]

Initial Level of Review may approve purchase and rental when meeting the criteria for both institutional and home use when **ALL** the following conditions are met:

- Physician's prescription to include:
 - Segmental type pump
 - With or without a calibrated pressure gradient
- Documented diagnosis of **lymphedema:**
 - Primary or secondary lymphedema, or
 - Other conditions associated with lymphedema such as:
 - Cancer-related therapy,
 - Infection,
 - Chronic venous disease, OR
 - Surgery.
- Documentation must include:

- Specific patient indications for use
- Clinical evaluation supporting medical necessity
- Anticipated length of need
- Authorization shall not exceed 180 days

Continued coverage may be approved upon adequate documentation from the prescribing physician. Documentation must include:

- Clinical evaluation supporting medical necessity
- Anticipated length of need

Lifts [8]

Seat Lift Mechanism

- **Initial level of review** may approve when **ALL** the following conditions are met:
 - Incapable of standing up from a regular armchair at home
 - Severe hip or knee arthritis, or severe neuromuscular disease
 - The seat lift mechanism must be prescribed to effect improvement, or arrest or retard deterioration in the member's condition
 - Once standing, the member must have the ability to ambulate

Patient Lift (e.g., electric, Hoyer, hydraulic)

- **Initial level of review** may approve when meets the following:
 - Transferring between bed and chair, wheelchair, or commode requires the assistance of more than one person and without the lift the beneficiary would be bed bound

Mucus Clearance Devices [4]

Device must be FDA approved

- **Initial Level of Review** may approve for **ANY** of the following conditions:
 - Beneficiaries with mucus producing lung diseases, including, but not limited to Cystic Fibrosis (CF) and Chronic Obstructive Pulmonary Disease (COPD) (which encompasses both chronic bronchitis and emphysema)
 - Beneficiaries with secretory impairment that requires mucus clearance
 - Intrapulmonary Percussive Ventilation (IPV) when the diagnosis is CF

Negative Pressure Wound Therapy (NPWT) [6]

Pump and supplies are covered for the following conditions when meets the medical necessity criteria and careful consideration of the risk factors below.

- **Conditions:**
 - Complications of surgically created wound (e.g., dehiscence, post-sternotomy disunion with exposed sternal bone, post-sternotomy mediastinitis, or postoperative disunion of the abdominal wall)
 - Traumatic wound (e.g., preoperative flap or graft, exposed bones, tendons, or vessels) and a need for accelerated formation of granulation tissue not achievable by other

topical wound treatments (e.g., the individual has comorbidities that will not allow for healing times usually achievable with other available topical wound treatments)

- Chronic nonhealing Stage III or IV pressure ulcer, diabetic neuropathic ulcer or chronic venous ulcer with lack of improvement for at least the previous 30 calendar days despite standard wound therapy, including the application of moist topical dressings, debridement of necrotic tissue (if present), maintenance of an adequate nutritional status, and weekly evaluations with documentation of wound measurements (i.e., length, width, and depth)

- **Risk Factors:**

- Patients on anticoagulation therapy
- Patients with friable vessels and infected blood vessels, sharp edges in the wound (i.e., bone fragments), or Spinal Cord Injury (SCI) (stimulation of sympathetic nervous system)
- Patients requiring Magnetic Resonance Imaging (MRI), hyperbaric chamber, defibrillation
- Patient size and weight
- Use near vagus nerve (bradycardia)
- Circumferential dressing application
- Mode of therapy-intermittent versus continuous negative pressure

- **Initial Level of Review** may approve the initial 30 days for **ANY** of the conditions listed above.

- **Initial Level of Review** may approve subsequent 30-day episodes for a total of 120 days with documentation of the following conditions:

- Evidence of wound healing by a licensed health care professional, e.g., decreased wound size, presence of new granulation tissue
- No evidence on contraindications, e.g., bleeding, infection, and eschar

Note: NWPT may have been initiated in an inpatient setting and those days should be included in the total of 120 days.

- **Medical Director** may approve continued NPWT beyond 120 days based on individual consideration when **ALL** the following documentation requirements are met:

- Documentation of the wound's healing progression on two successive dressing changes, as determined by quantitative measurements of wound characteristics including wound length and width (surface area), or depth, serially observed and documented
- Documentation of appropriate medical professional supervision or performance of weekly wound measurement and assessment functions as well as the negative pressure wound therapy dressing changes required
- No evidence on contraindications e.g., bleeding, infection, and eschar

Static Progressive Stretch Wrist Device, flexion and/or extension, with/without range of motion adjustment (E1806)

- **Initial Level of Review** may approve for **ANY** of the following indications:

- Maximum use of six (6) months, [15-17]

- Within six months of the course, [18]
- Loss of range of motion after: [19-22]
 - Trauma
 - Surgery
 - Neurological events: [21, 23]
 - Stroke
 - Cerebral Palsy
 - Neuromuscular Disorders
 - Muscular dystrophy
 - Traumatic brain injury
 - Other disorders causing stiffness and contractures

Standing Frame [9]

Medical Director may approve when meets ALL the following conditions:

- Standing frame is non-powered
- Documented neuromuscular condition, e.g., cerebral palsy, multiple sclerosis, spinal cord injury, stroke
- Impaired ability to stand, but once standing, can maintain this position due to residual strength in the hips, legs, and lower body
- Completed standing device training and has demonstrated an ability to safely use the device in a home setting

NOTE: A stander is considered a duplicate item when the beneficiary has a gait trainer; requests in these cases should be denied.

DEFINITIONS

Durable Equipment (DE) – Medically necessary item that can withstand repeated use, is primarily and customarily used to serve a medical purpose and is generally not useful to an individual in the absence of an illness or injury. [11]

Durable Medical Equipment (DME) – DE that meets the criteria for DE and is medically appropriate to improve, restore or maintain the function or a malformed, disease, or injured body part or can otherwise minimize or prevent the deterioration of the beneficiary's function or condition: or maximized the beneficiary's function consistent with their physiological or medical needs. [11]

Mucus Clearance Devices – are designed to clear mucus secretions from the lungs of patients with mucociliary clearance impairment. Some mucus clearance devices resemble a combination of a smoker's pipe and a referee's whistle. It consists of a hardened plastic mouthpiece at one end, a plastic perforated cover at the opposite end, and a valve on the inside created by a high-density stainless steel ball resting in a plastic circular cone. Other bronchial drainage systems include an air oscillator and an inflatable vest and uses high-frequency chest wall oscillations, which also clear



mucus from the airway wall. This type of system is a mechanical form of Chest Physical Therapy (CPT) used as an alternative to conventional CPT in patients with Cystic Fibrosis (CF)

Negative Pressure Wound Therapy (NPWT) – applies a localized vacuum to draw the edges of an open wound together while providing a moist environment conducive to rapid wound healing. NPWT is also known as Topical Negative Pressure (TNP) and Vacuum-Assisted Closure (VAC). The NPWT’s goal is to create a controlled, closed wound amenable to surgical closure, grafting, or healing by secondary intention. An evacuation tube is embedded in a dressing made of foam. After thorough wound debridement, the foam dressing is placed within the wound bed and covered by a dressing to form an airtight seal, and the tube is attached to a vacuum unit. Continuous or intermittent negative pressure is applied. The amount of pressure is determined by the wound type. [6]

CODES

HCPCS A4281-A4286, A7000, A7025-A7026, E0480-E0484, E0603-E0604, S8185, G0249, G0248, G0250, A4542

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