

# Clinical Policy: Durable Medical Equipment and Orthotics and Prosthetics Guidelines

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## Description

DME is defined as equipment that can stand repeated use, is primarily and customarily used to serve a medical purpose, and is generally not useful to a person in the absence of an illness or injury.<sup>1</sup> Orthotic devices are rigid and semi-rigid devices used for the purpose of supporting a weak or deformed body part or restricting or eliminating motion in a disease or injured body part.<sup>2</sup> Prosthetic devices are custom-made artificial limbs or other assistive devices that replace a body part or function as a result of traumatic injuries, vascular disease, diabetes, cancer or congenital disorders.

## Policy/Criteria

- I. It is the policy of PA Health & Wellness (PHW)<sup>®</sup> that durable medical equipment, orthotics, and prosthetics are **medically necessary** when the general and applicable equipment-specific criteria in A and B are met:
  - A. **General criteria:** Both of the following have been provided to the member/enrollee and/or caregiver, as applicable:
    1. Education regarding use of the device, with demonstrated understanding;
    2. A trial of the requested device, with demonstrated ability to use it safely and effectively.

*Note: If a medically necessary, lesser cost item exists and will suit the member/enrollee's medical needs, a higher cost item will be denied.*

## EQUIPMENT-SPECIFIC CRITERIA

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AMBULATORY ASSIST PRODUCTS	CRITERIA	HCPCS
Gait trainers	<p>Medically necessary with therapist evaluation and ongoing treatment when <i>all</i> of the following criteria are met:</p> <ul style="list-style-type: none"> <li>A. Moderate to maximum support for walking is required;</li> <li>B. Cleared medically for weight bearing and can physiologically tolerate upright positioning;</li> <li>C. Evaluated with the requested gait trainer, can tolerate the positioning in the device, and has successfully demonstrated proper use;</li> <li>D. The member/enrollee and caregivers have been trained on the gait trainer and are motivated to continue ongoing use.</li> </ul> <p>**Codes E8000-E8002 indicate, “includes all accessories and components” as part of the definition of the code. Additional line items under E1399 should not be included with requests for gait trainers.</p>	E8000 E8001 E8002
Standing Frames	<p>Dynamic standing frames are medically necessary when meeting one of the following:</p> <ul style="list-style-type: none"> <li>A. Initial request, or replacement request due to physiological changes* and all of the following: <ul style="list-style-type: none"> <li>1. Age and ambulatory status, one of the following: <ul style="list-style-type: none"> <li>a. Age <math>\geq</math> 18 years and nonambulatory or losing the ability to ambulate;</li> <li>b. Age <math>&lt;</math>18 years and preambulatory, nonambulatory, or losing the ability to ambulate, and one of the following: <ul style="list-style-type: none"> <li>i. Developmental delay in ambulation and <math>\geq</math> 18 months of age;</li> <li>ii. Documented neurological or neuromuscular impairment and <math>\geq</math> 1 year of age;</li> </ul> </li> </ul> </li> <li>2. Documentation supports all of the following: <ul style="list-style-type: none"> <li>a. Patient meets height and weight requirements for requested standing frame;</li> <li>b. Alert and responsive to stimuli;</li> <li>c. No contraindications to supported standing program;</li> <li>d. Caregiver trained, available, and able to safely assist patient with use of standing frame;</li> </ul> </li> <li>3. Unable to stand without support due to decreased motor control or abnormal muscle tone;</li> <li>4. Care managed by a rehabilitation-related specialist or physician;</li> <li>5. Prescribed for daily use;</li> <li>6. Expected use for <math>\geq</math> 12 months;</li> <li>7. Demonstrated ability (through a direct trial) to mobilize in and/or operate the dynamic component;</li> </ul> </li> </ul>	E0642 **E1399

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AMBULATORY ASSIST PRODUCTS	CRITERIA	HCPCS
	<p>8. Documented functional need for or benefit from the dynamic component of the stander (not for use as exercise equipment or for exercise benefit).</p> <p>B. Replacement request (not due to physiological changes), all of the following:</p> <ol style="list-style-type: none"> <li>1. Documentation supports replacement device necessary due to irreparable damage or device exceeds reasonable useful lifetime <math>\geq 5</math> years;</li> <li>2. Physician documentation of proper use and continued benefit;</li> <li>3. Replacement with identical or nearly identical device;</li> </ol> <p>*Changes in physiological condition, such as strength, muscle tone, growth, or weight change, may potentially impact the appropriateness of the standing device currently in use.</p> <p>**Line item justification is required for any additional components submitted under the E1399 code.</p>	

BURN GARMENTS	CRITERIA	HCPCS
Burn garments <sup>11</sup>	<p>Medically necessary with associated physical and/or occupational therapy when <i>all</i> of the following criteria are met:</p> <ol style="list-style-type: none"> <li>A. At risk of a post-burn contracture;</li> <li>B. The garment and physical and/or occupational therapies are being used with the intent of preventing the need for skin grafting or contractures as a result of hypertrophic scarring;</li> <li>C. Garment is requested by the PCP and/or the treating specialist.</li> </ol>	<p>A6501 A6502 A6503 A6504 A6505 A6506 A6507 A6508 A6509 A6510 A6511 A6512 A6513</p>

CARDIAC EQUIPMENT	CRITERIA	HCPCS
Non-wearable external defibrillator with integrated ECG analysis	Considered not medically necessary as it is primarily considered a safety device.	E0617

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COMPRESSION THERAPY EQUIPMENT	CRITERIA	HCPCS
Non-pneumatic compression devices <sup>6</sup>	There is insufficient clinical evidence to support the safety and effectiveness of non-pneumatic compression devices over the use of standard pneumatic compression devices.	K1032 K1033

DIABETES CARE EQUIPMENT	CRITERIA	HCPCS
Blood glucose monitor with integrated voice synthesizer <sup>13</sup>	Medically necessary for member/enrollee with diabetes who are legally blind (best corrected visual acuity less than 20/200).	E2100

HEAT, COLD & LIGHT THERAPY EQUIPMENT	CRITERIA	HCPCS
Ultraviolet panel lights	Medically necessary for both of the following: A. Refractory psoriasis; B. MD justifies treatment at home versus alternate sites (e.g. outpatient department at hospital). Panel lights should be considered, if several discrete body areas can be treated individually. Cabinet style should be reserved for extensive involvement > 54% of body surface area.	E0691 E0692 E0693 E0694
Cold pad pump	Considered not medically necessary for post-operative management as research does not indicate improved outcomes in pain or edema management with the use of cold compression therapy over the use of other treatments to include conservative treatment, cold therapy alone, compression therapy alone, etc.	E0236

NEWBORN CARE EQUIPMENT	CRITERIA	HCPCS
Breast pumps	Medically necessary for the following: A. Breast feeding mother if it is a covered benefit in the State B. Less than \$250.00 as a purchase C. If >\$250 approve as rental up to purchase price then convert to purchase D. Limit one per member/enrollee.	E0604

OTHER EQUIPMENT	CRITERIA	HCPCS
Enclosed Beds <sup>13, 14, 15, 16</sup>	Requests will be reviewed by a medical director and/or therapy advisor to determine medical necessity, based on all of the following:  A. Standard bed or standard hospital bed must be unable to meet the positioning needs due to disability;	E0316 E1399 E0328 or E0329 (when combined)

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OTHER EQUIPMENT	CRITERIA	HCPCS
	<p>B. Less intensive alternatives to improve the member's/enrollee's safety have been tried and ruled out (to include documentation of why they could not meet medical needs). Considerations include, but are not limited to:</p> <ol style="list-style-type: none"> <li>1. Bed rails;</li> <li>2. Mattress placed on the floor;</li> <li>3. Removal of all safety hazards;</li> <li>4. Bed alarms;</li> <li>5. Video/audio monitors;</li> <li>6. Child protection devices such as locks on doors, windows, cabinets, furniture anchors, gates at steps and doors;</li> <li>7. Physician-directed medication to address seizures, behaviors and sleep;</li> <li>8. Environmental modification to encourage calming behaviors and sleep;</li> <li>9. Established routines addressing sensory needs and/or behavior modification to assist with improved naptime or night time behaviors and sleep;</li> </ol> <p>C. Medical diagnosis to include, but not limited to:</p> <ol style="list-style-type: none"> <li>1. Cerebral palsy;</li> <li>2. Developmental delay;</li> <li>3. Genetic or neurological disorder that would cause vertigo, disorientation, or uncontrolled movement of the body or extremities;</li> <li>4. Uncontrolled seizure disorder;</li> <li>5. Severe behavior disorder;</li> </ol> <p>D. Healthcare provider evaluation (typically from an occupational or physical therapist) to include:</p> <ol style="list-style-type: none"> <li>1. Specific information on functional status;</li> <li>2. Documentation of home evaluation;</li> <li>3. Documentation of education provided to caregivers on proper use of a bed enclosure, noting: they are to be used for medical support, improved safety transitioning in and out of the bed, and improved safety while sleeping;</li> </ol> <p>E. Name of and invoice for the bed or enclosure being requested.</p> <p>Note: Enclosed beds should not be used as a discipline measure or as a restraint during times of high agitation or aggression. To limit sensory deprivation, enclosed beds should be used at night for sleeping and only for short rests or naps during the day.</p>	<p>with E0316 or E1399)</p>
Positioning seat	<p>Requests should have a physician or therapy advisor review to determine medical necessity. Medically necessary with therapist evaluation and ongoing treatment and <i>all</i> of the following criteria are met:</p> <ol style="list-style-type: none"> <li>A. Commercial device must be unable to meet the positioning needs due to height, weight, or disability;</li> <li>B. Other positioning devices in the home must be reviewed to ensure a duplication of devices is not already in place.</li> </ol>	<p>T5001 E1399</p>

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OTHER EQUIPMENT	CRITERIA	HCPCS
Specialized supply or equipment	Requests for not otherwise specified supplies or miscellaneous equipment codes will have a physician or therapy advisor review to determine medical necessity.	E0240 T2028 T2029 K0108 K0739 E1399 (For wheelchair seating refer to CP.MP.99)
ROMTech® PortableConnect® Device <sup>17</sup>	Not medically necessary, as there is insufficient evidence in published peer-reviewed literature to support the use of this technology and currently available alternatives.	E1399, A9900

PROSTHETICS AND ORTHOTICS EQUIPMENT	CRITERIA	HCPCS
Cervical traction equipment <sup>11</sup>	Medically necessary when all of the following are met: A. The appropriate use of the selected home cervical traction device has been demonstrated and was tolerated; B. One of the following: 1. Diagnosis of temporomandibular joint (TMJ) dysfunction and has received treatment for TMJ condition; 2. Distortion of the lower jaw and neck anatomy (e.g. radical neck dissection) such that a chin halter is unable to be utilized; 3. The treating physician orders and/or documents the medical necessity for greater than 20 pounds of cervical traction in the home setting.	E0849
Halo procedure equipment & Fracture Frames	Halo and fracture frame placement is generally performed on an emergent or inpatient basis and will be reviewed at the appropriate level of care using nationally recognized decision support tools.	E0947 E0948 L0810 L0820 L0830 L0859
Cervical collar, custom molded	Requests for custom molded cervical collar will be reviewed by a licensed physical or occupational therapist. Documentation accompanying the request must state reason why pre-fabricated collar not adequate.	L0170 L0190 L0200
Spinal orthotics	Requests for spinal orthotics will be reviewed using relevant nationally recognized decision support tool criteria for similar codes.	L0700 L0710 L0999 L1000 L1001 L1005

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PROSTHETICS AND ORTHOTICS EQUIPMENT	CRITERIA	HCPCS
Hip orthotics	<p>Medically necessary when ordered by an orthopedist for treatment of, or postoperatively for any of the following:</p> <ul style="list-style-type: none"> <li>• Total hip arthroplasty;</li> <li>• Slipped capital femoral epiphysis;</li> <li>• Legg-Calvé-Perthes disease;</li> <li>• Hip labral tear;</li> <li>• Hip dysplasia for Charcot-Marie-Tooth disease.</li> </ul> <p>Lateral replacements due to growth are considered medically necessary in pediatrics for diagnoses such as hip dysplasia with Charcot-Marie-Tooth disease.</p>	<p>L1640 L1680 L1685 L1686 L1690</p>
Legg Perthes orthotics	<p>Medically necessary when ordered by an orthopedist for use in the treatment for Legg-Calvé-Perthes disease in children.</p>	<p>L1700 L1710 L1720 L1730 L1755</p>
Hip-knee-ankle-foot orthotics (HKAFO)	<p>Requests for orthotics will be reviewed on a case by case basis.</p>	<p>L2050 L2060 L2090</p>
Orthotic components	<p>Requests for orthotic components listed will be reviewed using relevant nationally recognized decision support tool criteria for similar codes.</p>	<p>L2570 L2580 L2627 L2628</p>
Foot orthotics, custom	<p>Medically necessary for arch, heel, or other foot pain when indicated by both of the following:</p> <ol style="list-style-type: none"> <li>1. Presence of at least one of the following conditions: <ul style="list-style-type: none"> <li>A. Diplegic cerebral palsy;</li> <li>B. Juvenile idiopathic arthritis;</li> <li>C. Pes cavus (high arch);</li> <li>D. Rheumatoid arthritis;</li> <li>E. Plantar fasciitis when symptoms have been present for 3 months or more and;</li> <li>F. Posterior tibial tendon dysfunction in adult, as indicated by one or more of the following: <ol style="list-style-type: none"> <li>1. Stage I disease (tenosynovitis without deformity);</li> <li>2. Stage II disease (flexible and passively correctable deformity);</li> </ol> </li> </ul> </li> <li>2. Documentation that adjustment of activities, anti-inflammatory medications, prefabricated orthotics, physical therapy intervention and stretching of calf muscles and plantar surface have failed to improve symptoms.</li> </ol>	<p>L3000 L3001 L3002 L3003 L3010 L3020 L3030 L3031 L3070 L3080</p>
Orthopedic footwear, custom	<p>Requests for custom orthotic components will be reviewed using relevant nationally recognized decision support tool criteria for similar codes.</p>	<p>L3230</p>

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PROSTHETICS AND ORTHOTICS EQUIPMENT	CRITERIA	HCPCS
	In addition to supporting the medical necessity of foot orthotics, information must be provided to indicate why prefabricated devices cannot meet the need/why custom devices are necessary.	
Shoulder, elbow, wrist, hand, finger orthotics	<p>Medically necessary when ordered immediately post-operative for orthopedic surgeries such as rotator cuff repair, tendon repair, or ORIF.</p> <p>Replacement due to normal wear and tear is considered medically necessary when the item is a lateral purchase and the orthotic is still needed; Coverage is based on contract guidelines for replacement DME.</p>	L3904 L4000 L4010 L4020 L4030 L4130 L4205
Prosthetics and additions: Upper Extremity and Myoelectric	<p>Requests for upper extremity and myoelectric prosthetics will be reviewed by a medical director and/or therapy advisor when the request specific criteria in A. or B. is met:</p> <p>A. Initial request meets all of the following:</p> <ol style="list-style-type: none"> <li>1. Medical record documentation supports all of the following:               <ol style="list-style-type: none"> <li>a. Functional needs cannot be met with activity modification and compensatory techniques;</li> <li>b. Requested prosthesis is anticipated to meet functional needs;</li> </ol> </li> <li>2. Clinical examination findings include all of the following:               <ol style="list-style-type: none"> <li>a. Appropriate residual limb length;</li> <li>b. Limb volume stable;</li> <li>c. Ability to tolerate weight of prosthetic device;</li> <li>d. Environmental exposures appropriate for requested prosthesis;</li> <li>e. Ability to access specialized service and care as necessary;</li> <li>f. Stable condition of extremity to include skin integrity, strength, and ROM sufficient to use requested device;</li> <li>g. Cognitive function necessary to master prosthetic use;</li> </ol> </li> <li>3. Comprehensive prosthetic rehabilitation plan includes all of the following:               <ol style="list-style-type: none"> <li>a. Successful participation in pre-prosthetic training and therapy;</li> <li>b. Method of prosthetic control discussed;</li> <li>c. Functional task training with occupational or physical therapy;</li> <li>d. Concurrent home exercise program;</li> <li>e. Follow-up care schedule planned.</li> </ol> </li> </ol> <p>B. Replacement request, all of the following:</p> <ol style="list-style-type: none"> <li>1. Replacement is requested due to one of the following:               <ol style="list-style-type: none"> <li>a. Current prosthesis no longer functions properly or physiological or surgical changes to residual limb no longer accommodate current prosthesis;</li> </ol> </li> </ol>	L6000, L6010, L6020, L6026, L6050, L6055, L6100, L6110, L6120, L6130, L6200, L6205, L6250, L6300, L6310, L6320, L6350, L6360, L6370, L6380, L6382, L6384, L6386, L6388, L6400, L6450, L6500, L6550, L6570, L6580, L6582, L6584, L6586, L6588, L6590, L6623, L6624, L6625, L6628, L6638, L6646, L6647, L6648, L6689, L6690, L6692, L6693, L6704, L6707, L6708, L6709, L6711, L6712, L6713, L6714, L6715, L6721, L6722, L6885, L6895, L6900, L6905, L6910, L6915, L6920, L6930, L6940, L6950, L6960, L6965,



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PROSTHETICS AND ORTHOTICS EQUIPMENT	CRITERIA	HCPCS
	<ul style="list-style-type: none"> <li>b. Irreparable wear to prosthesis or prosthetic components;</li> <li>c. Significant change in member/enrollee condition resulting in poor fit or function of prosthesis or prosthetic components;</li> </ul> <ol style="list-style-type: none"> <li>2. Irreparable damage to prosthesis or prosthetic components or repair cost &gt; 60% of replacement cost;</li> <li>3. Prosthesis has been properly cared for following manufacturer's recommendations;</li> <li>4. Medical documentation includes all of the following:               <ul style="list-style-type: none"> <li>a. Supports continued use and medical need;</li> <li>b. Continued motivation to use the device for functional benefit;</li> <li>c. Functional level continues to be appropriate for prosthesis and components in use;</li> <li>d. Replacement with same or similar prosthesis and/or components;</li> <li>e. Updated practitioner's order on file or order not required (for loss or irreparable damage).</li> </ul> </li> </ol>	L6970, L6975, L7040, L7170, L7185, L7186, L7405, L7499
Prosthetics and additions: Lower Extremity	Requests for these prosthetics and additions will be reviewed by a licensed physical or occupational therapist.	L5990
Breast Prosthetics	Medically necessary post-masectomy or for treatment of gender dysphoria and documentation supports that prefabricated prosthetics will not suffice.	L8030 L8035
MyoPro® Orthosis <sup>33</sup>	Not medically necessary, as there is insufficient evidence in published peer-reviewed literature to support the use of this technology over other technologies and currently available alternatives.	L8701 L8702

PUMPS	CRITERIA	HCPCS
Ambulatory infusion pump <sup>18</sup>	Medically necessary when used for one of the following indications: <ol style="list-style-type: none"> <li>A. Iron Poisoning: administration of deferoxamine for the treatment of acute iron poisoning and iron overload;</li> <li>B. Chemotherapy for liver cancer: treatment of primary hepatocellular carcinoma or colorectal cancer where this disease is unresectable; OR, where the patient refuses surgical excision of the tumor;</li> <li>C. With opioid drugs when used for intractable pain caused by cancer.</li> <li>D. To administer a drug considered reasonable and necessary by either:               <ol style="list-style-type: none"> <li>1. Prolonged infusion of at least 8 hours because of proven improved clinical efficacy (i.e., proven or generally accepted to have significant advantages over intermittent bolus</li> </ol> </li> </ol>	E0780 E0781

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PUMPS	CRITERIA	HCPCS
	<p>administration regimens or infusions lasting less than 8 hours) or</p> <p>2. Intermittent infusion, each episode of infusion lasting less than 8 hours, and both of the following criteria:</p> <p>a. Does not require the return to the physician's office prior to the beginning of each infusion.</p> <p>b. Strictly controlled rate of infusion is necessary because systemic toxicity or adverse effects of the drug are unavoidable without infusing it at a controlled rate as indicated in the Physician's Desk Reference, or the U.S. Pharmacopeia Drug Information</p>	
Gastric suction pump, home model <sup>19</sup>	Medically necessary for home use for gastric suction due to inability to empty gastric secretions through normal gastrointestinal functions.	E2000
Implantable infusion pumps <sup>18</sup>	<p>Medically necessary when meeting both of the following:</p> <p>A. One of the following indications:</p> <p>1. Chemotherapy for liver cancer: primary hepatocellular carcinoma or Duke's Class D colorectal cancer, in which the metastases are limited to the liver and where either the disease is unresectable, or the patient refuses excision of the tumor;</p> <p>2. Anti-spasmodic drugs for severe spasticity: administered intrathecal to treat chronic intractable spasticity in patients unresponsive to less invasive medical therapy including both of the following:</p> <p>1. A 6-week trial of noninvasive methods, such as oral anti-spasmodic drugs, that failed to adequately control the spasticity or produced intolerable side effects;</p> <p>2. Prior to pump implantation, there has been a favorable response to a trial of intrathecal dose of the anti-spasmodic drug;</p> <p>3. Opioid drugs for treatment of chronic intractable pain- see CP.MP.173 Implantable Intrathecal Pain Pumps;</p> <p>4. Other uses when all of the following are met:</p> <p>a. The drug is reasonable and necessary for the treatment of the individual;</p> <p>b. It is medically necessary that the drug be administered by an implanted infusion pump. The infusion pump has been FDA-approved for the drug being administered and the purpose for which it is being administered;</p> <p>B. None of the following contraindications to implantation of an infusion pump:</p> <p>1. Known allergy or hypersensitivity to the drug being used (e.g., oral baclofen, morphine, etc.);</p> <p>2. Active infection;</p> <p>3. Body size insufficient to support the weight and bulk of the device;</p> <p>4. Presence of another implanted programmable device;</p> <p>5. Heparin or insulin is the drug intended for administration.</p>	E0782 E0783 E0785 E0786

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<b>PUMPS</b>	<b>CRITERIA</b>	<b>HCPCS</b>
Parenteral pump for medication administration <sup>20</sup>	Medically necessary for uninterrupted parenteral administration of medication via pump.	K0455

<b>RESPIRATORY EQUIPMENT</b>	<b>CRITERIA</b>	<b>HCPCS</b>
Nebulizer, ultrasonic	Not medically necessary, as it provides no clinical advantage over use of a small-volume nebulizer (E0574) and compressor.	E0575
IPPB & supplies	Medically necessary for member/enrollee with respiratory disease when an incentive spirometer is ineffective.	E0500 E0550
Oximeter <sup>16</sup>	<p>Medically necessary when used as a monitoring and alarm device for any of the following:</p> <ul style="list-style-type: none"> <li>A. To monitor individuals on a home ventilator or with a tracheostomy</li> <li>B. To determine appropriate home oxygen requirements</li> <li>C. To wean an individual from home oxygen</li> <li>D. To monitor an unstable respiratory condition</li> </ul> <p>Not medically necessary when used for any of the following:</p> <ul style="list-style-type: none"> <li>A. Oximetry when used as a diagnostic procedure</li> <li>B. Monitoring of a stable respiratory condition</li> <li>C. Asthma management</li> <li>D. Other conditions not listed above</li> </ul>	E0445
Oxygen tent	Medically necessary when the ability to breathe is impaired and for whom supplemental oxygen is required.	E0455
Intrapulmonary percussive ventilation devices (Volara™, Percussionaire-TRUE-IPV®) <sup>22-24</sup>	Current evidence does not support the effectiveness of intrapulmonary percussive ventilation (IPV).	E1399

<b>SURGICAL SUPPLIES</b>	<b>CRITERIA</b>	<b>HCPCS</b>
Other surgical supplies	These items are used as part of a surgical procedure and will be reviewed according to the relevant surgical procedure or level of care.	L8035, L8040, L8041, L8042, L8043, L8044, L8045, L8046, L8047, L8499, L8600, L8609, L8610, L8612, L8615, L8631, L8659

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<b>WALKERS</b>	<b>CRITERIA</b>	<b>HCPCS</b>
Walker, standard <sup>29</sup>	Requests for standard walkers are considered medically necessary when meeting all of the following: A. Mobility-related activities of daily living (MRADLs) in the home cannot be met due to mobility limitation; B. Walker is able to be safely used by member/enrollee; C. Functional mobility deficit will be sufficiently resolved with the use of a walker.	E0130 E0135 E0141 E0143
Walker, heavy duty <sup>29</sup>	Requests for heavy duty walkers (E0148, E0149) are considered medically necessary when meeting the above standard walker criteria and the member/enrollee weighs more than 300 pounds.  Requests for heavy duty, multiple braking system, variable wheel resistance walkers (E0147) are considered medically necessary when meeting the above standard walker criteria and the member/enrollee is unable to use a standard walker due to a severe neurologic disorder or other condition causing the restricted use of one hand.	E0148 E0149  E0147

<b>WHEELCHAIRS</b>	<b>CRITERIA</b>	<b>HCPCS</b>
Manual wheelchair <sup>30</sup>	Initial request is medically necessary when meeting all of the following: A. Mobility-related activities of daily living (MRADLs) in the home cannot be met due to mobility limitation, all of the following: 1. Mobility limitation cannot be met with a cane or walker; 2. Mobility limitation can be met with a manual wheelchair; 3. Home provides adequate access and maneuvering space for requested manual wheelchair; 4. Willingness to use a manual wheelchair in the home; B. One of the following: 1. Caregiver is available and willing to assist with wheelchair use; 2. Manual wheelchair can be safely and efficiently propelled by user; C. Wheelchair use will significantly improve MRADLs.  Replacement is medically necessary when meeting all of the following: A. Documentation supports at least one of the following: 1. Growth features of current wheelchair have been maximized; 2. Repair or replacement of parts no longer effective; 3. Current wheelchair in use $\geq$ 5 years; 4. Change in functional status of member/enrollee documented; B. Mobility-related activities of daily living (MRADLs) in the home cannot be met due to mobility limitation, all of the following: 1. Mobility limitation cannot be met with a cane or walker; 2. Mobility limitation can be met with a manual wheelchair; 3. Home provides adequate access and maneuvering space for requested manual wheelchair; 4. Willingness to use a manual wheelchair in the home;	E1050, E1060, E1070, E1083, E1084, E1085, E1086, E1087, E1088, E1089, E1090, E1091, E1092, E1093, E1100, E1110, E1130, E1140, E1150, E1160, E1170, E1171, E1172, E1180, E1190, E1195, E1200, E1221, E1222, E1223, E1224, E1240, E1250, E1260, E1270, E1280, E1285, E1290, E1295, K0009

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WHEELCHAIRS	CRITERIA	HCPCS
	<p>C. One of the following:</p> <ol style="list-style-type: none"> <li>1. Caregiver is available and willing to assist with wheelchair use;</li> <li>2. Manual wheelchair can be safely and efficiently propelled by user;</li> </ol> <p>D. Wheelchair use will significantly improve MRADLs.</p>	
Power seat elevator on power wheelchair <sup>31</sup>	<p>Medically necessary as a component on a power wheelchair when all of the following are met:</p> <ol style="list-style-type: none"> <li>A. A licensed, certified medical professional (i.e. physical or occupational therapist) is involved with the assessment, prescription, trials and training of equipment;</li> <li>B. Adequate cognitive function to safely use the seat elevating feature;</li> <li>C. A clear functional need for the feature is indicated;</li> <li>D. Provision of the feature will improve functional independence with an activity, such as but not limited to: facilitating reach for the completion of ADLs or IADLs or improving transfer biomechanics and safety.</li> </ol>	E2300
Robotic Arm, Wheelchair-mounted (JACO) <sup>32</sup>	There is insufficient clinical evidence to support safety and improved health outcomes of the JACO Assistive Robotic Arm (Kinova, Inc.) over other technologies.	E1399
Rollabout chair	Medically necessary when used in lieu of a wheelchair for those who would qualify for a wheelchair (except for the ability to self-propel a manual wheelchair).	E1031
Wheelchair repair	<p>Requests for wheelchair repairs specifically using codes K0108, K0739, or E1399, are medically necessary when reviewed by a physician or therapy advisor and when meeting the following criteria:</p> <ol style="list-style-type: none"> <li>A. Wheelchair is less than 5 years old (as evident by the age/date of purchase information provided);</li> <li>B. Cost of repairs is less than the cost of replacement;</li> <li>C. Information is provided to support the need for repairs due to normal wear and tear, as opposed to abuse/misuse or overutilization (as based on review of previous repair history, age and overall condition).</li> </ol> <p>One month's rental for a standard manual wheelchair is considered medically necessary if a member/enrollee owned wheelchair is being repaired.<sup>30</sup></p>	K0108 K0739 E1399

WOUND CARE	CRITERIA	HCPCS
Whirlpool tub	Considered not medically necessary.	E1310

\*\* It is the policy of PA Health & Wellness<sup>®</sup> (PHW) that determinations for services that are considered **not medically necessary** must be considered on a case-by-case basis by a physician or ad hoc committee and must be made in accordance with the Benefit Plan Contract provisions and applicable state and federal requirements. Denials will require medical director review.

### **Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

### **Background**

DME items have the following characteristics:

- The equipment is prescribed by a physician;
- The equipment meets the definition of DME;
- The equipment is necessary and reasonable for the treatment of an illness or injury;
- The equipment is manufactured primarily for use in the home environment, but is not limited to use in the home.

#### *Member/Enrollee's Home*

For purposes of rental and purchase of DME, a member/enrollee's home may be their own dwelling, an apartment, a relative's home, a home for the aged or some other type of institution. However, an institution may not be considered a member/enrollee's home if the following are met:

- Meets at least the basic requirement in the definition of a hospital, i.e., it is primarily engaged in providing by or under the supervision of physicians, inpatient, diagnostic and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, and sick persons, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons; or
- Meets at least the basic requirement in the definition of a skilled nursing facility, i.e., it is primarily engaged in providing to inpatients skilled nursing care and related services for members/enrollees who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.

Members/enrollees who have been permanently admitted to an inpatient skilled nursing facility or inpatient hospice and who have changed their home address to that of the SNF or hospice will have the SNF or hospice defined as their home.

#### *Products*

Products is defined as a listing of the most common items, or group of items, that are or may be perceived as home medical equipment. This listing, while reasonably complete, is not intended to quantify the entire spectrum of products that may be considered DME either now or in the future.

#### *Durability*

An item is considered durable if it can withstand repeated use, i.e., the type of item that could normally be rented. Medical supplies of an expendable nature, such as incontinence pads, lamb's wool pads, catheters, ace bandages, elastic stockings, surgical facemasks, sheets and bags are not considered "durable" within the meaning of the definition. There are other items that although durable in nature, may fall into other coverage categories such as supplies and orthotics and prosthetics. Orthotics and Prosthetics items include, but are not limited to, braces, artificial limbs and eyes.

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*Medical Equipment*

Medical equipment is defined as equipment primarily and customarily used for medical purposes and is not generally useful in the absence of illness or injury. In most instances, no documentation will be needed to support whether a specific item of equipment is medical in nature. However, some cases will require documentation to determine whether the item constitutes medical equipment. This documentation would include the advice of local medical organizations and facilities and specialists in the field of physical medicine and rehabilitation. If the equipment is new on the market, it may be necessary, prior to seeking professional advice, to obtain information from the supplier or manufacturer explaining the design, purpose, effectiveness and method of using the equipment in the home as well as the results of any tests or clinical studies that have been conducted.

Personal computers or mobile technology such as iPads, smart phones, iPods, personal digital assistants, etc., may be considered as medical equipment when used for the purpose of speech generating equipment when other non-medical functions are limited or disabled and that device is used as the primary source of communication for those qualifying for a speech generating device.

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Revised section on Orthotic Care Equipment, Hip/Knee/Ankle/Foot Orthotics (L2050, L2060, L2090) noting that when requested, they would be reviewed on a case-by-case basis. Added E0770, Peroneal Nerve Stimulation as investigational and not medically necessary to section on Stimulator Equipment.	09/18	10/18
Added A6511 to section on Burn garments. Deleted section for enteral pumps and supplies because other criteria exists. Added reference to CP.MP.117, Spinal Cord Stimulation in section on Implantable neurostimulator.	12/18	
Changed section “Parenteral pumps and supplies” to “Parenteral pumps for medication administration”, changed criteria from TPN use only to uninterrupted medication administration, per code description. In implantable infusion pump, replaced chronic non-malignant pain criteria with a reference to PA.CP.MP.173 intrathecal pain pumps. Other minor rewording for clarity with no clinical significance. Updated flexion/extension devices according to current InterQual availability: removed E1801 and added E1802 & E1812	12/19	
Added E1399 miscellaneous component code criteria under Gait Trainers; Added E1399, K0108, and K0739 as miscellaneous equipment codes requiring physician or therapy advisor review under Specialized Supply or Equipment. Removed E1811, E1815, and E1818 for flexion/extension devices, as they are	12/19	

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included in PA.CP.MP.144 Mechanical Stretching Devices for Joint Stiffness and Contracture.		
Gait trainers: Removed code E1399 and replaced it with a note stating E1399 is not necessary. Under Ambulatory Assist Products: Added criteria for standing frames for codes E1399 and E0642; Under Heat, Cold & Light Therapy Equipment: Changed coverage recommendation for Cold Pad Pump to “Not medically necessary; Under Orthopedic Care Equipment: Added criteria for traction equipment for E0849 that targets Temporomandibular Joint Dysfunction; Moved Fracture Frames with codes E0947 and E0948 to the section with Halo Procedure Equipment as criteria and indications are the same; Changed male vacuum erection devices from not medically necessary to medically necessary; Added hip labral tears as an indication for a Hip Orthotic; Added clarification to prosthetics and additions section to avoid inappropriate application; For positioning seat, added a requirement for review by therapist or MD; Under Other Equipment: Added criteria for E1399, K0108 and K0739 when they are used for wheelchair repairs; Added criteria for E2300 Seat Elevators; Under Stimulator Equipment: Added E0770 when the diagnosis is spinal cord injury to the coverage criteria detailed under Neuromuscular stimulator.	04/21	
Clarified that E0617 is a non-wearable external defibrillator. Stylist changes in several sections moving from bullet points to Letters & Numbers. Remove references to InterQual to make the policy more timeless. Insert “independent” to indicate the type of therapist review required.	04/21	
Removed criteria for flexion/extension devices, and associated codes E1802, E1810, and E1812 as they are now in CP.MP.144 Mechanical Stretch Devices. Removed criteria for E0466, non-invasive ventilators, and second non-invasive ventilators, as this is now included in CP.MP.184 Non-invasive home ventilators. Clarified that back up ventilator is necessary in the case of a wheelchair mounted ventilator if the ventilator could not reach from the wheelchair to the bed. Restructured second/backup ventilator criteria, and removed “may be considered” from the remote geographic access indication.	04/21	
Code E0780 added to criteria for ambulatory infusion pump. Moved ambulatory and implantable infusion pump criteria into pumps section. Updated table of contents.	04/21	
Under Wound Care, removed HCPC’s code Q4111, GammaGraft, as code is included in CP.MP.185 Skin Substitutes for Chronic Wounds. Removed “member” from criteria and reworded, without impact on criteria. When not possible to	04/21	



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<p>remove, replaced “member” with “member/enrollee.” Replaced “members” with “members/enrollees” in the disclaimer of the policy.</p>		
<p>Added note to the description stating that if a lower cost, medically necessary item exists and will meet the member’s needs, the lower cost item will be approved. Updated policy to remove diaphragmatic nerve stimulation criteria, which was transferred to CP.MP.203 Diaphragmatic Phrenic Nerve Stimulation. Nebulizer, ultrasonic: changed to not medically necessary with supporting statement. Blood glucose monitor with integrated voice synthesizer: revised language from diabetics to member/enrollee with diabetes. Implantable infusion pumps: Added contraindications. Gastric suction pump: added requirement of inability to empty gastric secretions through normal gastrointestinal functions. Wheelchair criteria added to its own table. Criteria for manual added and coding updated. Direction added to use nationally recognized criteria for upper extremities and myoelectric prosthetics. Split lower extremity prosthetics into its own row. Removed codes from Shoulder, elbow, wrist, hand, finger orthotics that were duplicated in IQ, L3720, L3730, L3740, L3760, L3900, L3901, L3960, L3962 and L3999. Updated table of contents. References reviewed and updated.</p>	<p>04/21</p>	
<p>Annual Review Complete. Added criteria for enclosed beds to “Other Equipment” section of policy. Added references and codes E0316, E1399 and E0328 or E0329 (when combined with E0316 or E1399) for enclosed beds. Replaced “investigational” with “not proven safe and effective” in the following sections: Pneumatic compression devices, neuromuscular stimulator, and peroneal nerve stimulators. Updated policy to remove neuromuscular stimulator, functional neuromuscular stimulator, and peroneal nerve stimulator, which was transferred to PA.CP.MP.48 Neuromuscular Electrical Stimulation (NMES). Replaced existing Standing Frames criteria with new initial request and replacement request criteria. Revised section on pneumatic compression devices to state that they are not proven safe and effective for lymphedema of the abdomen, trunk, chest, genitals, or neck, and for arterial insufficiency. Added criteria for Wheelchair-mounted Assistive Robotic Arm (JACO). Changed “review date” in the header to “date of last revision” and “date” in the revision log header to “revision date.” Reorganized Standing Frame criteria and required that replacement requests also meet existing criteria for the initial request. For initial request under 18, added "and one of the following: Developmental delay in ambulation and <math>\geq</math> 18 months of age;</p>	<p>02/06/2023</p>	

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<p>Documented neurological or neuromuscular impairments and <math>\geq 1</math> year of age.” Required that documentation supports meeting height and weight requirements, alert and responsive to stimuli, no contraindications to standing program, and caregiver trained, available, and able to safely assist. Removed requirement for “able to tolerate upright position.” Added informational note. Removed requirement for replacement requests not due to physiological changes to meet existing criteria and reformatted criteria. Contents table renumbered. References reviewed and updated. Added burn garment HCPCS codes A6502, A6503, A6504, A6505, A6506, A6508, A6509, A6510, A6512 and A6513 to policy. Made note for HCPCS code K0108 to refer to PA.CP.MP.99 for wheelchair seating in Specialized supply or Equipment section. Removed cardiac event monitor (E0616) criteria from cardiac equipment section of policy and moved to PA.CP.MP.243 Implantable Loop Recorders. Removed invasive home ventilator criteria (E0465) and moved to PA.CP.MP.184 Home Ventilators. Added statement that current evidence does not support the effectiveness of intrapulmonary percussive ventilation (E1399). Updated references. Specialist reviewed.</p> <p>Manual Wheel Chair “Mobility limitation in the community”  <b>** It is the policy of PA Health &amp; Wellness<sup>®</sup> (PHW) that determinations for services that are considered <b>not medically necessary</b> must be considered on a case-by-case basis by a physician or ad hoc committee and must be made in accordance with the Benefit Plan Contract provisions and applicable state and federal requirements. Denials will require medical director review.</b></p>		
<p>Annual review. Updated description with no impact on criteria. Changed Orthopedic Care Equipment to Prosthetics and Orthotics Equipment. Table of contents updated. Retired pneumatic compression device criteria (E0675) for IQ. Updated "Cabinet style..." note under Ultraviolet panel lights. Under “Other Equipment” added code E0240 to “Specialized supply or equipment” section and added section, criteria, and coding (E1399, A9900) for “ROMTech device”. Reformatted Foot orthotics, custom criteria in “Prosthetics and Orthotics Equipment” section. Added criteria for Prosthetics and additions: Upper Extremity and Myoelectric in “Prosthetics and Orthotics Equipment” section. Added section, criteria, and coding (L8701, L8702) for “MyoPro Orthosis” under “Prosthetics and Orthotics Equipment”. Removed code L8035 from "other surgical supplies"</p>	10/2023	

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and added section and criteria for "Breast Prosthetics" (L8030, L8035). Removed pediatric wheelchair codes (E1229, E1231, E1232, E1233, E1234, E1235, E1236, E1237, E1238, E1037) from manual wheelchair section. References reviewed, updated, and reformatted. Internal specialist review.		

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