

P.O. Box 25610 Little Rock, AR 72221

Clinical Policy: Durable Medical Equipment and Orthotics Guidelines

Reference Number: AR.CP.MP.107

Date of Last Revision: 10/24

Revision Log

See <u>Important Reminder</u> at the end of this policy for important regulatory and legal information.

### 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. 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.

### Policy/Criteria

- I. It is the policy of QualChoice that durable medical equipment and orthotics 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.

#### **B. EQUIPMENT-SPECIFIC CRITERIA**

BURN GARMENTS	2
CARDIAC EQUIPMENT	
COMPRESSION THERAPY EQUIPMENT	
DIABETES CARE EQUIPMENT	
HEAT, COLD & LIGHT THERAPY EQUIPMENT	
NEWBORN CARE EQUIPMENT	4
OTHER EQUIPMENT	4
PROSTHETICS AND ORTHOTICS EQUIPMENT	
Pumps	10
RESPIRATORY EQUIPMENT	12
SURGICAL SUPPLIES	
Walkers	13
WHEELCHAIRS	13
Wound Care	14

BURN GARMENTS	CRITERIA	HCPCS
Burn garments <sup>3</sup>	Medically necessary with associated physical and/or occupational	A6501
	therapy when all of the following criteria are met:	A6502
	A. At risk of a post-burn contracture;	A6503
	B. The garment and physical and/or occupational therapies are being	A6504
	used with the intent of preventing the need for skin grafting or	A6505
	contractures as a result of hypertrophic scarring;	A6506
	C. Garment is requested by the PCP and/or the treating specialist.	A6507
		A6508
		A6509
		A6510
		A6511
		A6512
		A6513

CARDIAC EQUIPMENT	CRITERIA	HCPCS
Non-wearable	Considered not medically necessary as it is primarily considered a safety	E0617
external defibrillator	device.	
with integrated ECG		
analysis <sup>4</sup>		

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

DIABETES CARE EQUIPMENT	CRITERIA	HCPCS
Blood glucose monitor with integrated voice synthesizer <sup>7</sup>	Medically necessary for member/enrollee with diabetes who are legally blind (best corrected visual acuity less than 20/200).	E2100

DIABETIC SHOES & SHOE	Criteria	HCPCS
INSERTS		
	Most benefit plans exclude coverage of orthopedic shoes, foot	A5500
	orthotics or other supportive devices of the feet, except	A5507
	diabetics. (Please refer to your plan documents).	A5510
		A5513
	For diabetics who have the foot complications:	L3000
	a) Peripheral neuropathy involving the feet; or	L3003,
	b) History of pre-ulcerative calluses; or	L3010,
	c) History of previous ulceration; or	L3020
	d) Foot deformity; or e) Previous amputation of the foot or	L3030
	part of the foot.	L3031
	There is a limit on the number of foot orthotics that will be covered:  Shoes:  a) Two (2) pairs or a combined total of four (4) units per year if under 18 years of age; b) otherwise, one (1) pair or a combined total of two (2) units per year.  Shoe inserts: a. Two (2) pairs or a combined total of four (4) units of	
	<ul> <li>diabetic custom molded shoe inserts per year.</li> <li>b. In general, the following services will be covered for diabetics, when meeting above medical necessity criteria:</li> </ul>	
	c. Diabetic shoes Diabetic Custom Molded Foot Orthotics Custom Molded Orthotics	

HEAT, COLD & LIGHT	CRITERIA	HCPCS
THERAPY EQUIPMENT		
Ultraviolet panel	Medically necessary when meeting both of the following:	E0691
lights 8, 9	A. Refractory psoriasis;	E0692
	B. MD justifies treatment at home versus alternate sites (e.g.	E0693
	outpatient department at hospital). Panel lights should be	E0694
	considered, if several discrete body areas can be treated individually.	
	Note: Cabinet style lights should be reserved for extensive involvement	
	of body surface area.	

HEAT, COLD & LIGHT THERAPY EQUIPMENT	CRITERIA	HCPCS
Cold pad pump <sup>10</sup>	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	<ul> <li>Medically necessary for the following:</li> <li>A. Breast/chest feeding member if it is a covered benefit in the State</li> <li>B. Less than \$250.00 as a purchase</li> <li>C. If &gt;\$250 approve as rental up to purchase price then convert to purchase</li> <li>D. Limit one per member/enrollee.</li> </ul>	E0604

CRITERIA	HCPCS
Requests will be reviewed by a medical director and/or therapy advisor to determine medical necessity, based on all of the following:	E0316 E1399
<ul> <li>A. Standard bed or standard hospital bed must be unable to meet the positioning needs due to disability;</li> <li>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: <ol> <li>Bed rails;</li> <li>Mattress placed on the floor;</li> <li>Removal of all safety hazards;</li> <li>Bed alarms;</li> <li>Video/audio monitors;</li> <li>Child protection devices such as locks on doors, windows, cabinets, furniture anchors, gates at steps and doors;</li> <li>Physician-directed medication to address seizures, behaviors and sleep;</li> <li>Environmental modification to encourage calming behaviors and sleep;</li> <li>Established routines addressing sensory needs and/or behavior modification to assist with improved naptime or night time behaviors and sleep;</li> </ol> </li> <li>Medical diagnosis to include, but not limited to: <ol> <li>Cerebral palsy;</li> <li>Developmental delay;</li> <li>Genetic or neurological disorder that would cause vertigo, disorientation, or uncontrolled movement of the body or</li> </ol> </li> </ul>	E0328 or E0329 (when combined with E0316 or E1399)
	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;  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:  1. Bed rails;  2. Mattress placed on the floor;  3. Removal of all safety hazards;  4. Bed alarms;  5. Video/audio monitors;  6. Child protection devices such as locks on doors, windows, cabinets, furniture anchors, gates at steps and doors;  7. Physician-directed medication to address seizures, behaviors and sleep;  8. Environmental modification to encourage calming behaviors and sleep;  9. Established routines addressing sensory needs and/or behavior modification to assist with improved naptime or night time behaviors and sleep;  C. Medical diagnosis to include, but not limited to:  1. Cerebral palsy;  2. Developmental delay;  3. Genetic or neurological disorder that would cause vertigo,

OTHER EQUIPMENT	CRITERIA	HCPCS
	<ol> <li>Uncontrolled seizure disorder;</li> <li>Severe behavior disorder;</li> <li>Healthcare provider evaluation (typically from an occupational or physical therapist) to include:         <ol> <li>Specific information on functional status;</li> <li>Documentation of home evaluation;</li> <li>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> </li> <li>Name of and invoice for the bed or enclosure being requested.</li> <li>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.</li> </ol>	
Positioning seat	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:  A. Commercial device must be unable to meet the positioning needs due to height, weight, or disability;  B. Other positioning devices in the home must be reviewed to ensure a duplication of devices is not already in place.	T5001 E1399
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 17	Not medically necessary, as there is insufficient evidence in published peer-reviewed literature to support the use of this technology over currently available alternatives.	E1399, A9900

ORTHOTICS	Criteria	HCPCS
EQUIPMENT		
Back Braces	The following back braces are covered without	L0220, L0450
	preauthorization as outlined below:	L0454, L0626
	A) Rib belt with diagnosis of rib fracture(s)	L0627,L0630
	(S22.000A S22.9XXS)	

ORTHOTICS	CRITERIA	HCPCS
EQUIPMENT		
	B) Sacral and Thoracic/Lumbar/Sacral Orthotics with a diagnosis of: • Spinal stenosis (M48.04, M48.05, M48.06, M48.061, M48.062, M48.07, M48.08); • Thoracic vertebral fractures (S22.000A – S22.089S); • Lumbar vertebral fractures (S32.000A – S32.059S); • Sacral fractures (S32.10XA – S32.19XS); • Lumbar spondylolisthesis (M43.16); • Osteomyelitis of lumbar vertebra (M46.26); • Lumbar discitis (M46.46); • Lumbar spine instability (M53.2X6); • Subluxation lumbar spine (M99.13); • Lumbar surgeries: fusion of spine thoracolumbar region (M43.25), lumbar spinal fusion (M43.26), post laminectomy syndrome (M96.3), post-laminectomy lordosis (M96.4) with any diagnosis, and other post-procedural state, lumbar discectomy, lumbar laminectomy (Z98.89); • Any diagnosis code if requested within 10 days post-op for a thoracic and/or lumbar spinal surgery: 63003 – 63012, 63016 – 63017, 63030 – 63035, 63042, 63044, 63046 – 63048, 63085 – 63091, 63101 – 63103, 63170 – 63173, 63185 – 63191, 63197, 63200, 63251 – 63252, 63266 – 63268, 63271 – 63273, 63276 – 63278, 63281 – 63283, 63286 – 63295, 63301 – 63303, 63305 – 63308.  C) Scoliosis Orthotics (L1000 – L1290) with a diagnosis of: • Infantile idiopathic scoliosis, cervicothoracic-lumbosacral (M41.03 – M41.07); • Juvenile scoliosis, cervicothoracic-lumbosacral (M41.113 – M41.117); • Adolescent scoliosis, cervicothoracic-lumbosacral (M41.23 – M41.27); • Thoracogenic scoliosis (M41.34 – M41.35); • Neuromuscular cervicothoracic-lumbosacral (M41.35 – M41.37); • Other secondary scoliosis, cervicothoracic-lumbosacral (M41.43 – M41.47); • Other secondary scoliosis, cervicothoracic-lumbosacral (M41.53 – M41.57); • Other forms of scoliosis, cervicothoracic-lumbosacral (M41.83 – M41.87);	L1000, L1001, L1005, L1010, L1020, L1025, L1030, L1040, L1050, L1060, L1070, L1080, L1085, L1090, L1100, L1110, L1120, L1220, L1230, L1240, L1250, L1260, L1270, L1280, L1290
Cervical traction equipment <sup>11</sup>	<ul> <li>Medically necessary when all of the following are met:</li> <li>A. The appropriate use of the selected home cervical traction device has been demonstrated and was tolerated;</li> <li>B. One of the following: <ol> <li>Diagnosis of temporomandibular joint (TMJ) dysfunction and has received treatment for TMJ condition;</li> <li>Distortion of the lower jaw and neck anatomy (e.g. radical neck dissection) such that a chin halter is unable to be utilized;</li> </ol> </li> </ul>	E0849

ORTHOTICS	Criteria	HCPCS
EQUIPMENT		
	<ol> <li>The treating physician orders and/or documents the medical necessity for greater than 20 pounds of cervical traction in the home setting.</li> </ol>	
Halo procedure	Halo and fracture frame placement is generally performed on an	E0947
equipment &	emergent or inpatient basis and will be reviewed at the	E0948
Fracture Frames	appropriate level of care using nationally recognized decision	L0810
	support tools.	L0820
		L0830
		L0859
Cervical collar,	Requests for custom molded cervical collar will be reviewed by a	L0170
custom molded	licensed physical or occupational therapist. Documentation	L0190
	accompanying the request must state reason why pre-fabricated collar not adequate.	L0200
Hip orthotics	Medically necessary when ordered by an orthopedist for	L1640
	treatment of, or postoperatively for any of the following:	L1680
	A. Total hip arthroplasty;	L1685
	B. Slipped capital femoral epiphysis;	L1686
	C. Legg-Calvé-Perthes disease;	L1690
	D. Hip labral tear;	
	E. Hip dysplasia for Charcot-Marie-Tooth disease.	
	Lateral replacements due to growth are considered medically	
	necessary in pediatrics for diagnoses such as hip dysplasia with Charcot-Marie-Tooth disease.	
Legg Perthes	Medically necessary when ordered by an orthopedist for use in the	L1700
orthotics	treatment for Legg-Calvé-Perthes disease in children.	L1710
		L1720
		L1730
		L1755
Hip-knee-ankle-	Requests for orthotics will be reviewed on a case by case basis.	L2050
foot orthotics		L2060
(HKAFO)		L2090
Orthotic	Requests for orthotic components listed will be reviewed usinLg	L2570
components	relevant nationally recognized decision support tool criteria for	L2580
, , , , , , , , , , , , , , , , , , , ,	similar codes.	L2627
		L2628
Knee Braces	Only specific types of knee braces are covered by QualChoice	K0672,
	Requests for custom fabricated knee orthotics require prior	L1810, L1812
	authorization and as outlined below: a) Must be submitted	L1820,L1831
	by the ordering provider's office (not by the vendor), along	L1834,L1836
		L1830,L1832,
	with the member's medical records, such as clinic progress	L1833,L1840
	notes. Information submitted on a vendor request form will	L1843,L1844,
	not be accepted.	L1845, L1846,
	The following knee braces are covered by QualChoice as	L1847,L1848,
	outlined below:	L1850, L1851,

ORTHOTICS
EQUIPMENT

ORTHOTICS CRITERIA	HCPCS
EQUIPMENT	
Custom–fabricated knee braces require prior authorization and are covered as outlined below:  Member is ambulatory AND - There is deformity of the leg or knee such that a prefabricated brace cannot be used, AND - Member's exact measurements of thigh and calf are submitted.  7) Additions to the knee braces–straight knee joint, heavy—duty, each joint is considered medically necessary when: - The coverage criteria for the base orthosis code is met AND - The member weighs more than 300lbs.  8) Additions to the custom fabricated knee braces are considered medically necessary when:  The member meets the criteria for a custom-fabricated knee brace AND - Either daily activity level requires a brace designed for high impact/high stress activities, OR - The member weighs greater than 250 pounds.  9) The following are examples of non-covered knee orthotics: Knee orthosis, double upright with adjustable joint, with inflatable air support chamber, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise; Knee orthosis, double upright with adjustable joint, with inflatable air support chamber(s), prefabricated, off-the-shelf;  10) The following additions to knee braces are considered part of base orthotic and therefore are not separately payable Addition to lower extremity orthotic, removable soft interface, all components, replacement only, each; - Addition to lower extremity orthotic, soft interface for molded plastic, above knee section: - Addn to lower extremity orthotic, the finite for molded plastic, above knee section: - Addn to lower extremity orthotic, femoral length sock, fracture or equal, ea - Addn to lower extremity orthotic, femoral length sock, fracture or equal, ea - Limits  QualChoice does not cover ANY knee brace and associated accessories are considered not medically necessary and are	HCPCS

ORTHOTICS	Criteria	HCPCS
EQUIPMENT		
	2) Functional knee braces utilized solely for participation in	
	sports or to improve athletic performance;	
	3) Patellofemoral knee braces/sleeves for the treatment of	
	postoperative knee effusion or patellofemoral syndrome	
	without subluxation or dislocation;	
	4) Functional knee braces after successful reconstructive	
	ligament surgery;	
	5) Socks and brace sleeves used in conjunction with the orthotic device;	
	6) Additional removable or non-removable interface	
	dispensed with the initial device are not separately	
	reimbursable;	
	7) Inflatable air bladder incorporated into the design, as it	
	has no proven clinical benefit.	
Shoulder, elbow,	Medically necessary when ordered immediately post-operative	L3904
wrist, hand, finger	for orthopedic surgeries such as rotator cuff repair, tendon repair,	L4000
orthotics	or ORIF.	L4010
		L4020
	Replacement due to normal wear and tear is considered medically	L4030
	necessary when the item is a lateral purchase and the orthotic is	L4130
	still needed; Coverage is based on contract guidelines for replacement DME.	L4205
Breast Prosthetics	Medically necessary post-masectomy or for treatment of gender	L8030
	dysphoria and documentation supports that prefabricated	L8035
	prosthetics will not suffice.	
MyoPro <sup>®</sup>	Not medically necessary, as there is insufficient evidence in	L8701
Orthosis <sup>33</sup>	published peer-reviewed literature to support the use of this	L8702
	technology over other technologies and currently available	
	alternatives.	

Pumps	CRITERIA	HCPCS
Ambulatory infusion	Medically necessary when used for one of the following indications:	E0780
pump <sup>18</sup>	A. Iron Poisoning: administration of deferoxamine for the	E0781
	treatment of acute iron poisoning and iron overload;	
	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;	
	C. With opioid drugs when used for intractable pain caused by	
	cancer.	

Pumps	Criteria	HCPCS
	<ul> <li>D. To administer a drug considered reasonable and necessary by either:</li> <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 administration regimens or infusions lasting less than 8 hours) or</li> <li>2. Intermittent infusion, each episode of infusion lasting less than 8 hours, and both of the following criteria: <ul> <li>a. Does not require the return to the physician's office prior to the beginning of each infusion.</li> <li>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</li> </ul> </li> </ul>	
Gastric suction pump,	Medically necessary for home use for gastric suction due to inability	E2000
home model 19	to empty gastric secretions through normal gastrointestinal	
Local catalata Cafe at a	functions.	50702
Implantable infusion	Medically necessary when meeting both of the following:	E0782
pumps 18	<ul><li>A. One of the following indications:</li><li>1. Chemotherapy for liver cancer: primary hepatocellular</li></ul>	E0783 E0785
	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;  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:  a. A 6-week trial of noninvasive methods, such as oral antispasmodic drugs, that failed to adequately control the spasticity or produced intolerable side effects;  b. Prior to pump implantation, there has been a favorable response to a trial of intrathecal dose of the antispasmodic drug;  3. Opioid drugs for treatment of chronic intractable pain-see CP.MP.173 Implantable Intrathecal Pain Pumps;  4. Other uses when all of the following are met:  a. The drug is reasonable and necessary for the treatment of the individual;  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	E0786

Pumps	Criteria	HCPCS
	<ul> <li>B. None of the following contraindications to implantation of an infusion pump:</li> <li>1. Known allergy or hypersensitivity to the drug being used (e.g., oral baclofen, morphine, etc.);</li> <li>2. Active infection;</li> <li>3. Body size insufficient to support the weight and bulk of the device;</li> <li>4. Presence of another implanted programmable device;</li> <li>5. Heparin or insulin is the drug intended for administration.</li> </ul>	
Parenteral pump for medication administration <sup>20</sup>	Medically necessary for uninterrupted parenteral administration of medication via pump.	K0455
Vacuum erection device <sup>21, 22</sup>	A vacuum erection device (VED) and tension ring are medically necessary for the treatment of erectile dysfunction when prescribed by a physician.	L7900 L7902

RESPIRATORY	Criteria	HCPCS
EQUIPMENT		
Nebulizer, ultrasonic <sup>23</sup>	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>24</sup>	Medically necessary when used as a monitoring and alarm device for any of the following:  A. To monitor individuals on a home ventilator or with a tracheostomy  B. To determine appropriate home oxygen requirements  C. To wean an individual from home oxygen  D. To monitor an unstable respiratory condition  Not medically necessary when used for any of the following:  A. Oximetry when used as a diagnostic procedure  B. Monitoring of a stable respiratory condition  C. Asthma management  D. Other conditions not listed above	E0445
Oxygen tent <sup>24</sup>	Medically necessary when the ability to breathe is impaired and for whom supplemental oxygen is required.	E0455
Intrapulmonary percussive ventilation devices (Volara <sup>™</sup> , Percussionaire-TRUE-IPV <sup>®</sup> ) <sup>25, 26, 27, 28</sup>	Current evidence does not support the effectiveness of intrapulmonary percussive ventilation (IPV).	E1399



### P.O. Box 25610 Little Rock, AR 72221

Eretic Hook)			
SURGICAL	CRITERIA		HCPCS
SUPPLIES			
Other	These items are used as part of a surgical procedure and will be	L8040, L8041	L, L8042,
surgical	reviewed according to the relevant surgical procedure or level of	L8043, L8044	1, L8045,
supplies	care.	L8046, L8047	7, L8499,
		L8600, L8609	9, L8610,
		L8612, L8615	5, L8631,
		L8659	

WALKERS	Criteria	HCPCS
Walker,	Requests for standard walkers are considered medically necessary when	E0130
standard <sup>29</sup>	meeting all of the following:	E0135
	A. Mobility-related activities of daily living (MRADLs) in the home cannot	E0141
	be met due to mobility limitation;	E0143
	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.	
Walker, heavy	Requests for heavy duty walkers (E0148, E0149) are considered medically	E0148
duty <sup>29</sup>	necessary when meeting the above standard walker criteria and the	E0149
	member/enrollee weighs more than 300 pounds.	
	Requests for heavy duty, multiple braking system, variable wheel resistance	E0147
	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.	

WHEELCHAIRS	CRITERIA	HCPCS
Power seat	Medically necessary as a component on a power wheelchair when	E2300
elevator on	all of the following are met:	
power	A. A licensed, certified medical professional (i.e. physical or	
wheelchair 31	occupational therapist) is involved with the assessment,	
	prescription, trials and training of equipment;	
	B. Adequate cognitive function to safely use the seat elevating	
	feature;	
	C. A clear functional need for the feature is indicated;	
	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.	

WHEELCHAIRS	CRITERIA	HCPCS
Robotic Arm, Wheelchair- mounted (JACO)	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

Wound Care	CRITERIA	HCPCS
Whirlpool tub	Considered not medically necessary.	E1310

#### **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 upto-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.

# CLINICAL POLICY DME and Orthotics Criteria

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.

#### 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
Policy created	06/09	06/09

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Modified corporate policy. Changes for initial approval incorporating policies		10/24

#### References

- National coverage determination: Durable medical equipment (DME) reference list (280.1). Centers for Medicare and Medicaid Services w, ebsite. <a href="https://www.cms.gov/medicare-coverage-database/search.aspx">https://www.cms.gov/medicare-coverage-database/search.aspx</a>. Published May 16, 2023. Accessed September 27, 2023.
- Local coverage article. Knee orthoses policy article (A52465). Centers for Medicare & Medicaid Services website. <a href="http://www.cms.hhs.gov/mcd/search.asp">http://www.cms.hhs.gov/mcd/search.asp</a>. Published October 1, 2015 (revised July 20, 2023). Accessed September 29, 2023.
- 3. Local coverage article. Surgical dressings (A54563). Centers for Medicare & Medicaid Services website. <a href="http://www.cms.hhs.gov/mcd/search.asp">http://www.cms.hhs.gov/mcd/search.asp</a>. Published October 1, 2015 (revised September 7, 2023). Accessed September 19, 2023.
- 4. Rea TD, Eisenberg MS. Automated external defibrillators. UpToDate. <a href="http://www.utdol.com">http://www.utdol.com</a>. Published September 7, 2021. Accessed September 29, 2023.
- 5. National coverage determination. Pneumatic compression devices (280.6). Centers for Medicare & Medicaid Services website. <a href="http://www.cms.hhs.gov/mcd/search.asp">http://www.cms.hhs.gov/mcd/search.asp</a>. Published January 14, 2002. Accessed September 24, 2023.
- Evidence analysis research brief: Dayspring (Koya Medical Inc.) for treatment of lymphedema. Hayes. <a href="www.hayesinc.com">www.hayesinc.com</a>. Published March 27, 2023. Accessed September 20, 2023.
- National coverage determination. Home blood glucose monitors (40.2). Centers for Medicare & Medicaid Services website. <a href="http://www.cms.hhs.gov/mcd/search.asp">http://www.cms.hhs.gov/mcd/search.asp</a>.
   Published June 19, 2006. Accessed September 24, 2023.
- National coverage determination. Treatment of psoriasis (250.1). <a href="http://www.cms.hhs.gov/mcd/search.asp">http://www.cms.hhs.gov/mcd/search.asp</a>. Published January 1, 1966. Accessed September 29, 2023.
- 9. Elmets CA, Lim HW, Stoff B, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy. J Am Acad Dermatol. 2019; 81(3):775-804.
- Local coverage determination: Heating pads and heat lamps (L33784). Centers for Medicare and Medicaid Services website. <a href="https://www.cms.gov/medicare-coverage-database/search.aspx">https://www.cms.gov/medicare-coverage-database/search.aspx</a>. Published October 1, 2015 (updated January 1, 2020). Accessed September 29, 2023.
- 11. Local coverage determination. Cervical traction devices (L33823). Centers for Medicare & Medicaid Services website. <a href="http://www.cms.hhs.gov/mcd/search.asp">http://www.cms.hhs.gov/mcd/search.asp</a>. Published October 1, 2015 (revised January 1, 2020). Accessed September 24, 2023.

- 12. DMEPOS quality standards. Centers for Medicare & Medicaid Services website. <a href="https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/DMEPOSQuality/DMEPOSQualBooklet-905709.html">https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/DMEPOSQuality/DMEPOSQualBooklet-905709.html</a>. Published December 2022. Accessed September 12, 2023.
- 13. Restraint and seclusion Enclosure beds, side rails and mitts. The Joint Commission website. <a href="https://www.jointcommission.org/standards/standard-faqs/critical-access-hospital/provision-of-care-treatment-and-services-pc/000001668/">https://www.jointcommission.org/standards/standard-faqs/critical-access-hospital/provision-of-care-treatment-and-services-pc/000001668/</a>. Published April 11, 2016 (updated July 20, 2022). Accessed September 20, 2023.
- 14. Enclosure bed: A protective and calming restraint. American Nurse Association website. <a href="https://www.myamericannurse.com/use-enclosure-beds/">https://www.myamericannurse.com/use-enclosure-beds/</a>. Published January 13, 2015. Accessed September 24, 2023.
- 15. State Operations Manual Appendix A Survey Protocol, Regulations and Interpretive Guidelines for Hospitals. Centers for Medicare & Medicaid Services. <a href="https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap">https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap</a> a hospitals.pdf. Published May 21, 2004 (revised July 21, 2023). Accessed September 24, 2023.
- 16. National coverage determination: Hospital beds (280.7). Centers for Medicare and Medicaid Services website. <a href="http://www.cms.hhs.gov/mcd/search.asp">http://www.cms.hhs.gov/mcd/search.asp</a>. Published January 1, 1966. Accessed September 24, 2023.
- 17. Evolving evidence review: ROMTech/PortableConnect (ROM Technologies Inc.) for telerehabilitation following total knee arthroplasty. Hayes. <a href="https://www.hayesinc.com/">https://www.hayesinc.com/</a>. Published March 10, 2022 (annual review May 19, 2023). Accessed September 19, 2023.
- 18. National coverage determination. Infusion pumps (280.14). Centers for Medicare & Medicaid Services website. <a href="http://www.cms.hhs.gov/mcd/search.asp">http://www.cms.hhs.gov/mcd/search.asp</a>. Published December 17, 2004. Accessed September 12, 2023.
- 19. Local coverage determination. Suction pumps (L33612). Centers for Medicare & Medicaid Services website. <a href="http://www.cms.hhs.gov/mcd/search.asp">http://www.cms.hhs.gov/mcd/search.asp</a>. Published October 1, 2015 (revised April 1, 2023). Accessed September 24, 2023.
- Local coverage article. External infusion pumps policy article (A52507).
   <a href="http://www.cms.hhs.gov/mcd/search.asp">http://www.cms.hhs.gov/mcd/search.asp</a>. Published October 1, 2015 (revised October 1, 2023). Accessed September 29, 2023.
- 21. Local coverage determination. Vacuum erection devices (L34824). Centers for Medicare & Medicaid Services website. <a href="http://www.cms.hhs.gov/mcd/search.asp">http://www.cms.hhs.gov/mcd/search.asp</a>. Published October 1, 2015 (revised January 1, 2020). Accessed September 12, 2023.
- 22. Khera M. Treatment of male sexual dysfunction. UpToDate. <a href="www.uptodate.com">www.uptodate.com</a>. Published July 17, 2023. Accessed September 12, 2023.
- 23. Local coverage determination: Nebulizers (L33370). Centers or Medicare and Medicaid Services website. <a href="https://www.cms.gov/medicare-coverage-database/search.aspx">https://www.cms.gov/medicare-coverage-database/search.aspx</a>. Published October 15, 2015 (revised January 1, 2023). Accessed September 28, 2023.
- 24. Local coverage determination. Oxygen and oxygen equipment (L33797). <a href="http://www.cms.hhs.gov/mcd/search.asp">http://www.cms.hhs.gov/mcd/search.asp</a>. Published October 1, 2015 (revised April 1, 2023). Accessed September 29, 2023.
- 25. Evidence analysis research brief: Volara (Hillrom) for respiratory therapy. Hayes. <a href="https://www.hayesinc.com">www.hayesinc.com</a>. Published August 14, 2023. Accessed September 20, 2023.

- 26. Lauwers E, Ides K, Van Hoorenbeeck K, Verhulst S. The effect of intrapulmonary percussive ventilation in pediatric patients: A systematic review. *Pediatr Pulmonol*. 2018;53(11):1463 to 1474. doi:10.1002/ppul.24135
- 27. Huynh TT, Liesching TN, Cereda M, et al. Efficacy of Oscillation and Lung Expansion in Reducing Postoperative Pulmonary Complication. *J Am Coll Surg*. 2019;229(5):458 to 466.e1. doi:10.1016/j.jamcollsurg.2019.06.004
- 28. Aboussouan LS. Role of mucoactive agents and secretion clearance techniques in COPD. UpToDate. <a href="https://www.uptodate.com">www.uptodate.com</a>. Updated May 22, 2023. Accessed September 27, 2023.
- 29. Local coverage determination: Walkers (L33791). Centers for Medicare and Medicaid Services website. <a href="https://www.cms.gov/medicare-coverage-database/search.aspx">https://www.cms.gov/medicare-coverage-database/search.aspx</a>. Published October 1, 2015 (revised January 1, 2020). Accessed November 18, 2022.
- 30. Local coverage determination: Manual wheelchair bases (L33788). Centers for Medicare and Medicaid Services website. <a href="https://www.cms.gov/medicare-coverage-database/search.aspx">https://www.cms.gov/medicare-coverage-database/search.aspx</a>. Published October 1, 2015 (revised January 1, 2020). Accessed September 28, 2023.
- 31. Schiappa V, Piriano J, Bernhardt L, et al. RESNA Position on the Application of Seat-Elevation Devices for Power Wheelchair Users Literature Update. Rehabilitation Engineering and Assistive Technology Society of North America.

  <a href="https://www.resna.org/Portals/0/Documents/Position%20Papers/RESNA App%20of%20Seat%20Elevation%20Devices%202019.pdf">https://www.resna.org/Portals/0/Documents/Position%20Papers/RESNA App%20of%20Seat%20Elevation%20Devices%202019.pdf</a>. Published September 25, 2019. Accessed September 24, 2023.
- 32. Beaudoin M, Lettre J, Routhier F, Archambault PS, Lemay M, Gélinas I. Long-term use of the JACO robotic arm: a case series. *Disabil Rehabil Assist Technol*. 2019;14(3):267 to 275. doi:10.1080/17483107.2018.1428692
- 33. Evolving evidence review: MyoPro Orthosis (Myomo Inc.) for Upper Extremity Paralysis/Paresis After Stroke. Hayes. <a href="www.hayesinc.com">www.hayesinc.com</a>. Published March 6, 2023. Accessed October 10, 2023.
- 34. Khoo B, Gonzalvo A, Kweh BTS. Spinal orthoses in osteoporotic vertebral fractures of the elderly. *Journal of Spine Surgery*. 2023;9(3):224-228. doi:https://doi.org/10.21037/jss-23-76
- 35. Muscular Dystrophy OrthoInfo AAOS. www.orthoinfo.org. Accessed April 9, 2024. <a href="https://orthoinfo.aaos.org/en/diseases--conditions/muscular-dystrophy/#:~:text=Your%20child">https://orthoinfo.aaos.org/en/diseases--conditions/muscular-dystrophy/#:~:text=Your%20child</a>
- 36. Osteoporosis and Spinal Fractures OrthoInfo AAOS. Aaos.org. Published 2016. https://orthoinfo.aaos.org/en/diseases--conditions/osteoporosis-and-spinal-fractures/
- 37. Nonsurgical Treatment Options for Scoliosis OrthoInfo AAOS. Aaos.org. Published 2015. https://orthoinfo.aaos.org/en/treatment/nonsurgical-treatment-options-for-scoliosis/
- 38. Annaswamy TM, Cunniff KJ, Kroll M, et al. Lumbar Bracing for Chronic Low Back Pain: A Randomized Controlled Trial. *Am J Phys Med Rehabil*. 2021;100(8):742-749. doi:10.1097/PHM.000000000001743
- 39. Qaseem A, Wilt TJ, McLean RM, Forciea MA. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians. *Annals of Internal Medicine*. 2017;166(7):514. doi:https://doi.org/10.7326/m16-2367

- 40. WHO. WHO releases guidelines on chronic low back pain. www.who.int. Published December 7, 2023. <a href="https://www.who.int/news/item/07-12-2023-who-releases-guidelines-on-chronic-low-back-pain">https://www.who.int/news/item/07-12-2023-who-releases-guidelines-on-chronic-low-back-pain</a>
- 41. VA/DoD CLINICAL PRACTICE GUIDELINE for DIAGNOSIS and TREATMENT of LOW BACK PAIN Department of Veterans Affairs Department of Defense QUALIFYING STATEMENTS. https://www.healthquality.va.gov/guidelines/Pain/lbp/VADoDLBPCPG092917.pdf
- 42. World Health Organization. Osteoarthritis. www.who.int. Published July 14, 2023. <a href="https://www.who.int/news-room/fact-sheets/detail/osteoarthritis">https://www.who.int/news-room/fact-sheets/detail/osteoarthritis</a>
- 43. Osteoarthritis OrthoInfo AAOS. www.orthoinfo.org. Accessed April 9, 2024. <a href="https://orthoinfo.aaos.org/en/diseases--conditions/osteoarthritis/#:~:text=A%20balanced%20fitness%20program%2C%20physical">https://orthoinfo.aaos.org/en/diseases--conditions/osteoarthritis/#:~:text=A%20balanced%20fitness%20program%2C%20physical</a>
- 44. American Association of Neurological Surgeons. Lumbar Spinal Stenosis Symptoms, Diagnosis and Treatments. Aans.org. Published 2019.

  <a href="https://www.aans.org/en/Patients/Neurosurgical-Conditions-and-Treatments/Lumbar-Spinal-Stenosis">https://www.aans.org/en/Patients/Neurosurgical-Conditions-and-Treatments/Lumbar-Spinal-Stenosis</a>
- 45. Lumbar Spinal Stenosis OrthoInfo AAOS. Aaos.org. Published 2013. https://orthoinfo.aaos.org/en/diseases--conditions/lumbar-spinal-stenosis/
- 46. Adult Spondylolisthesis in the Low Back OrthoInfo AAOS. www.orthoinfo.org. <a href="https://orthoinfo.aaos.org/en/diseases--conditions/adult-spondylolisthesis-in-the-low-back/">https://orthoinfo.aaos.org/en/diseases--conditions/adult-spondylolisthesis-in-the-low-back/</a>
- 47. Low Back Pain OrthoInfo AAOS. www.orthoinfo.org. <a href="https://orthoinfo.aaos.org/en/diseases--conditions/low-back-pain/">https://orthoinfo.aaos.org/en/diseases--conditions/low-back-pain/</a>
- 48. Weinstein SL, Dolan LA, Wright JG, Dobbs MB. Effects of Bracing in Adolescents with Idiopathic Scoliosis. *New England Journal of Medicine*. 2013;369(16):1512-1521. doi:https://doi.org/10.1056/nejmoa1307337
- 49. Kaelin AJ. Adolescent idiopathic scoliosis: indications for bracing and conservative treatments. *Ann Transl Med.* 2020;8(2):28. doi:10.21037/atm.2019.09.69
- 50. Kaelin AJ. Adolescent idiopathic scoliosis: indications for bracing and conservative treatments. *Annals of Translational Medicine*. 2020;8(2):28. doi:https://doi.org/10.21037/atm.2019.09.69
- 51. Weinstein SL, Dolan LA, Wright JG, Dobbs MB. Effects of bracing in adolescents with idiopathic scoliosis. *N Engl J Med*. 2013;369(16):1512-1521. doi:10.1056/NEJMoa1307337
- 52. Capek V, Baranto A, Brisby H, Westin O. Nighttime versus Fulltime Brace Treatment for Adolescent Idiopathic Scoliosis: Which Brace to Choose? A Retrospective Study on 358 Patients. *Journal of Clinical Medicine*. 2023;12(24):7684. doi:https://doi.org/10.3390/jcm12247684

#### **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical

# CLINICAL POLICY DME and Orthotics Criteria

policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

# CLINICAL POLICY DME and Orthotics Criteria

©2018 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene and Centene Corporation are registered trademarks exclusively owned by Centene Corporation.