

Clinical Policy: Durable Medical Equipment and Orthotics and Prosthetics Guidelines
Reference Number: CP.MP.107

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Revision Log

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

#### **Description**

Durable medical equipment (DME) is defined as equipment that can withstand repeated use, is primarily and customarily used to serve a medical purpose, is appropriate for use in the home, 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. 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 health plans affiliated with Centene Corporation<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: All of the following:
    - 1. Equipment is necessary and reasonable for the treatment of an illness or injury or to improve the functioning of a physical deficit;\*
    - 2. Both of the following have been provided to the member/enrollee and/or caregiver, as applicable:
      - a. Education regarding use of the device, with demonstrated understanding;
      - b. A trial of the requested device, with demonstrated ability to use it safely and effectively.

#### \*Note:3,4

- Equipment is necessary when it can be expected to make a meaningful contribution to the treatment of the patient's illness or injury or to the improvement of his or her malformed body member.
- Although an item of DME may serve a useful medical purpose, additional considerations should be made to whether the item is reasonable, such as, whether the expense of the item is disproportionate to the therapeutic benefits, whether it is substantially more costly than a medically appropriate and realistically feasible alternative plan of care, and/or whether the item will serve essentially the same purpose as equipment already available.
- Additional "deluxe" features or items that are rented or purchased for aesthetic reasons or added convenience, do not meet the reasonableness test.
- 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

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BURN GARMENTS	Criteria	HCPCS
Burn garments <sup>5</sup>	Medically necessary with associated physical and/or occupational	A6501
	therapy when both of the following 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
		A6507
		A6508
		A6509
		A6510
		A6511
		A6512
		A6513

CARDIAC	CRITERIA	HCPCS
EQUIPMENT  Non-wearable external defibrillator with integrated ECG analysis <sup>6</sup>	Not medically necessary, as it is primarily considered a safety device.	E0617
Wearable Cardioverter Defibrillator (WCD) <sup>7,8</sup>	<ul> <li>Initial requests for wearable cardioverter defibrillators (WCD) are considered medically necessary for 30 days when meeting all of the following:</li> <li>A. Member/enrollee is ≥ 18 years of age with increased risk of sudden cardiac death;</li> <li>B. One of the following: <ol> <li>Awaiting cardiac transplant;</li> <li>Previously implanted cardioverter defibrillator (ICD) must be removed due to infection and awaiting re-implantation;</li> <li>Newly indicated ICD delayed due to one of the following;</li> <li>Systemic infection;</li> <li>Left ventricular ejection fraction (LVEF) ≤ 35% and any of the following: <ol> <li>Myocardial infarction (MI) within the past 40 days;</li> </ol> </li> </ol></li></ul>	K0606



CARDIAC	Criteria	HCPCS
EQUIPMENT		
	ii. Coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI) within the past 90 days; iii. Newly diagnosed nonischemic cardiomyopathy that is potentially reversible and undergoing a trial of optimal medical therapy; C. Device is FDA approved and used according to FDA indications.	
	Ongoing requests for WCDs are considered medically necessary for 30-days (up to a total of 90 days) when meeting all of the following:  A. Initial request criteria continues to be met;  B. Adherence is confirmed by device reports and attestation from the ordering provider;  C. Plan of care has been updated with progression towards a definitive treatment pathway.	

COMPRESSION THERAPY EQUIPMENT	CRITERIA	HCPCS
Non-pneumatic compression devices <sup>9,10</sup>	Not medically necessary, as there is insufficient clinical evidence to support the safety and effectiveness of non-pneumatic compression devices over the use of standard pneumatic compression devices.	E0678 E0679 E0680 E0681

DIABETES CARE	Criteria	HCPCS
EQUIPMENT		
Blood glucose monitor with integrated voice synthesizer <sup>11,12</sup>	Medically necessary for member/enrollees with diabetes who are legally blind (best corrected visual acuity of 20/200 or worse in both eyes).	E2100

HEAT, COLD &	Criteria	HCPCS
LIGHT THERAPY EQUIPMENT		
Ultraviolet panel lights <sup>13,14</sup>	<ul> <li>Medically necessary when meeting both of the following:</li> <li>A. Refractory psoriasis;</li> <li>B. Documentation supports 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.</li> <li>Note: Cabinet-style lights should be reserved for extensive involvement of body surface area.</li> </ul>	E0691 E0692 E0693 E0694
Cold pad pump 15	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 when breast pumps are a covered benefit for the member/enrollee.	E0604

OTHER EQUIPMENT	Criteria	HCPCS_
OTHER EQUIPMENT Enclosed Beds <sup>16</sup> , 17,18,19	Medically necessary when meeting all of the following:  A. Standard bed or standard hospital bed is unable to meet positioning needs due to disability;  B. Less intensive alternatives to improve the member/enrollee's safety have been tried and ruled out (to include documentation of why medical needs could not be met). 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. Diagnosis including but not limited to any of the following:  1. Cerebral palsy;  2. Developmental delay;  3. Genetic or neurological disorder that would cause vertigo, disorientation, or uncontrolled movement of the body or extremities;  4. Uncontrolled seizure disorder;  5. Severe behavior disorder;  D. Healthcare provider evaluation (typically from an occupational or physical therapist) to includes all of the following:  1. Specific information on functional status;  2. Documentation of home evaluation;  3. Documentation of education provided to caregivers on proper use of a bed enclosure, noting that they are to be used for medical support, improved safety transitioning in and out of the bed, and improved safety while sleeping;  E. Name of and invoice for the bed or enclosure being requested.  All requests for enclosed beds require mandatory secondary review by a medical director and/or therapy advisor.	E0316 E1399 E0328 or E0329 (when combined with E0316 or E1399)
	Note:	



OTHER EQUIPMENT	Criteria	HCPCS
Positioning cost	<ul> <li>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> <li>When the above criteria are met, only basic beds will be considered medically necessary. Upgrades for aesthetic purposes or upgrades that do not meet the rules for DME will not be covered as part of an enclosed bed purchase. This includes but is not limited to any of the following:</li> <li>Special lights, sounds, fans, cameras, two-way talk monitors, vibration pads weighted blankets;</li> <li>Custom wood types, finishes or engravings, special coverings on the outside of the bed;</li> <li>Custom upgrades where lower cost alternatives are readily available.</li> <li>Medically necessary when all of the following are met:</li> </ul>	T5001
Positioning seat	<ul> <li>A. Documentation of therapist evaluation and ongoing treatment plan;</li> <li>B. Commercial device must be unable to meet the positioning needs due to height, weight, or disability;</li> <li>C. Other positioning devices in the home must be reviewed to ensure duplication of devices are not already in place.</li> <li>All requests for positioning seats require mandatory secondary review by a medical director and/or therapy advisor.</li> </ul>	E1399
Specialized supply or equipment  Note: For requests related to wheelchair seating refer to CP.MP.99.	Requests for not otherwise specified supplies or miscellaneous equipment codes require mandatory secondary review by a medical director and/or therapy advisor to determine medical necessity.	E0240 T2028 T2029 K0108 K0739 E1399
ROMTech® PortableConnect® Device <sup>20</sup>	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

PROSTHETICS AND ORTHOTICS EQUIPMENT	CRITERIA	HCPCS
Cervical traction equipment <sup>21</sup>	<ul> <li>Medically necessary when all of the following are met:</li> <li>A. Musculoskeletal or neurologic impairment requiring traction equipment;</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



PROSTHETICS	CRITERIA	HCPCS
AND ORTHOTICS EQUIPMENT		
Equit MENT	3. The treating physician orders and/or documents the medical necessity for greater than 20 pounds of cervical traction in the home setting.	
Cervical collar, custom molded	Requests for custom molded cervical collars require mandatory secondary review by a medical director and/or therapy advisor to determine medical necessity.	L0170 L0190 L0200
	Documentation accompanying the request must state the reason why a prefabricated collar is not adequate.	
Spinal Orthotics	Requests for spinal orthotics will be reviewed using relevant nationally recognized decision support tool criteria for similar codes.	L0700, L0710, L0720, L0999, L1000, L1001, L1005, L1006
Hip orthotics <sup>22</sup>	Medically necessary when ordered by an orthopedic surgeon for treatment of, or postoperatively for any of the following:  A. Total hip arthroplasty; B. Hip labral tear; C. Hip disorders in children when used to stabilize the hip and/or to correct and maintain hip abduction.  Lateral replacements due to growth are considered medically necessary in pediatrics for diagnoses such as hip dysplasia with Charcot-Marie-Tooth disease.	L1640 L1680 L1685 L1686 L1690
	Requests for hip orthotics for hip osteoarthritis in patients who are not surgical candidates will be reviewed on a case-by-case basis by a medical director and/or therapy advisor.	
Legg Perthes orthotics	Medically necessary when ordered by an orthopedic surgeon for use in the treatment for Legg-Calvé-Perthes disease in children.	L1700 L1710 L1720 L1730 L1755
Ankle-foot Orthotics (AFO)	Requests for AFOs will be reviewed using relevant nationally recognized decision support tool criteria for similar codes.	L1933 L1952
Hip-knee-ankle- foot orthotics (HKAFO)	Requests for HKAFOs require mandatory secondary review by a medical director and/or therapy advisor to determine medical necessity.	L2050 L2060 L2090
Orthotic components	Requests for orthotic components will be reviewed using relevant nationally recognized decision support tool criteria for similar codes.	L2570 L2580 L2627 L2628
Foot orthotics, custom	Medically necessary for arch, heel, or other foot pain when meeting both of the following:  A. Foot condition, as indicated by one of the following:  1. Juvenile idiopathic arthritis;  2. Pes cavus (high arch);  3. Rheumatoid arthritis;	L3000 L3001 L3002 L3003 L3010 L3020



PROSTHETICS	CRITERIA	HCPCS
AND		
ORTHOTICS		
EQUIPMENT		
	4. Plantar fasciitis when symptoms have been present for at	L3030
	least one month;	L3031
	5. Posterior tibial tendon dysfunction in adult, as indicated by	L3070
	one or more of the following:	L3080
	a. Stage I disease (tenosynovitis without deformity);	
	b. Stage II disease (flexible and passively correctable deformity);	
	B. Documentation that adjustment of activities, anti-inflammatory	
	medications, prefabricated orthotics, stretching of calf muscles and	
	plantar surface have failed to improve symptoms.	
	primiting sources in the control of improve symptoms.	
Shoulder, elbow,	Medically necessary when ordered immediately post-operative for	L3904
wrist, hand, finger	orthopedic surgeries such as rotator cuff repair, tendon repair, or	L4000
orthotics	ORIF.	L4010
		L4020
	Replacement with the same or similar item due to normal wear and	L4030
	tear is considered medically necessary when the orthotic is still	L4205
Prosthetics and	needed.  Medically necessary when the request specific criteria in A. or B.	I 6000 I 6010
additions: Upper	are met:	L6000, L6010, L6020, L6026,
Extremity and	A. Initial request meets all of the following:	L6028, L6029,
Myoelectric	Functional needs cannot be met with activity modification	L6031, L6032,
	and compensatory techniques;	L6033, L6037,
	2. Requested prosthesis is anticipated to meet functional needs;	L6050, L6055,
	3. Clinical examination findings include all of the following:	L6100, L6110,
	a. Appropriate residual limb length;	L6120, L6130,
	b. Limb volume stable;	L6200, L6205,
	c. Ability to tolerate weight of prosthetic device;	L6250, L6300,
	d. Environmental exposures appropriate for requested	L6310, L6320,
	prosthesis; e. Ability to access specialized service and care as	L6350, L6360, L6370, L6380,
	necessary;	L6382, L6384,
	f. Stable condition of extremity to include skin integrity,	L6386, L6388,
	strength, and ROM sufficient to use requested device;	L6400, L6450,
	g. Cognitive function necessary to master prosthetic use;	L6500, L6550,
	4. Comprehensive prosthetic rehabilitation plan includes all of	L6570, L6580,
	the following:	L6582, L6584,
	a. Successful participation in pre-prosthetic training and	L6586, L6588,
	therapy;	L6590, L6623,
	b. Method of prosthetic control discussed;	L6624, L6625,
	c. Functional task training with occupational or physical	L6628, L6638,
	therapy; d. Concurrent home exercise program;	L6646, L6647, L6648, L6689,
	e. Follow-up care schedule planned.	L6690, L6692,
	B. Replacement request, all of the following:	L6693, L6700,
	Replacement is requested due to one of the following:	L6704, L6707,



PROSTHETICS	Criteria	HCPCS
AND		
ORTHOTICS		
EQUIPMENT		- 1-11
	a. Current prosthesis no longer functions properly or	L6708, L6709,
	physiological or surgical changes to residual limb no	L6711, L6712,
	longer accommodate current prosthesis; b. Irreparable wear to prosthesis or prosthetic components;	L6713, L6714, L6715, L6721,
	c. Significant change in member/enrollee condition	L6722, L6885,
	resulting in poor fit or function of prosthesis or prosthetic	L6895, L6900,
	components;	L6905, L6910,
	2. Irreparable damage to prosthesis or prosthetic components	L6915, L6920,
	or repair cost > 60% of replacement cost;	L6930, L6940,
	3. Prosthesis has been properly cared for following	L6950, L6960,
	manufacturer's recommendations;	L6965, L6970,
	4. Medical documentation includes all of the following:	L6975, L7040,
	a. Supports continued use and medical need;	L7170, L7185,
	b. Continued motivation to use the device for functional	L7186, L7405,
	benefit;	L7406, L7499
	c. Functional level continues to be appropriate for prosthesis and components in use;	
	d. Replacement with same or similar prosthesis and/or	
	components.	
	All requests for upper extremity and myoelectric prosthetics and	
	additions require mandatory secondary review by a medical director	
	and/or therapy advisor.	
Prosthetics and	Requests for lower extremity prosthetics and additions require	L5827
additions: Lower	mandatory secondary review by a medical director and/or therapy	L5990
Extremity	advisor.	
Breast 23 24 25	Medically necessary post-mastectomy or for treatment of gender	L8030
Prosthetics <sup>23,24,25</sup>	dysphoria. If the request is for a custom prosthetic, accompanying	L8035
	documentation must state the reason why a prefabricated device is not adequate.	
Myoelectric	Not medically necessary, as there is insufficient evidence in	E0738
Rehabilitation	published peer-reviewed literature to support the effectiveness of	E0739
Systems <sup>26,27</sup>	these devices.	
Facial Prosthetics <sup>28</sup>	Requests for facial prosthetics are medically necessary when there	L8040, L8041,
	is loss or absence of facial tissue due to disease, trauma, surgery, or	L8042, L8043,
	a congenital defect.	L8044, L8045,
		L8046, L8047,
		L8499

PUMPS	Criteria	HCPCS
Ambulatory infusion	Medically necessary when used for one of the following indications:	E0780
pump <sup>29,30</sup>	A. Iron poisoning when used in the administration of deferoxamine	E0781
	for the treatment of acute iron poisoning and iron overload;	
	B. Chemotherapy for liver cancer when used in the treatment of	
	primary hepatocellular carcinoma or colorectal cancer where the	
	disease is unresectable or where the patient refuses surgical	
	excision of the tumor;	



PUMPS	Criteria	HCPCS
	C. With opioid drugs when used for intractable pain caused by	
	cancer;	
	D. To administer a drug considered reasonable and necessary by	
	either:	
	1. Prolonged infusion of at least eight 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 eight	
	hours);	
	2. Intermittent infusion, each episode of infusion lasting less than	
	eight hours, and both of the following criteria:	
	a. Does not require the return to the physician's office prior	
	to the beginning of each infusion.	
	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	
Gastric suction pump,	Medically necessary for home use for gastric suction due to inability	E2000
home model <sup>31</sup>	to empty gastric secretions through normal gastrointestinal functions.	
Implantable infusion	Medically necessary when meeting both of the following:	E0782
pumps 30	A. One of the following indications:	E0783
*Note: For treatment	1. Chemotherapy for liver cancer: primary hepatocellular	E0785
of chronic intractable	carcinoma or Duke's Class D colorectal cancer, in which the	E0786
pain using opioid	metastases are limited to the liver and where either the	
drugs see CP.MP.173	disease is unresectable, or the patient refuses excision of the	
Implantable	tumor;	
Intrathecal Pain	2. Anti-spasmodic drugs for severe spasticity: administered	
Pumps.	intrathecally to treat chronic intractable spasticity in	
	member/enrollee unresponsive to less invasive medical	
	therapy including both of the following:	
	a. 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;	
	b. Prior to pump implantation, there has been a favorable	
	response to a trial of intrathecal dose of the anti-spasmodic	
	drug;	
	3. 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	
	purpose for which it is being administered;	
	B. None of the following contraindications to implantation of an	
	infusion pump:	
	1. Known allergy or hypersensitivity to the drug being used	
	(e.g., oral baclofen, morphine, etc.);	
	2. Active infection;	1



PUMPS	Criteria	HCPCS
	<ol> <li>Body size insufficient to support the weight and bulk of the device;</li> <li>Presence of another implanted programmable device;</li> <li>Heparin or insulin is the drug intended for administration.</li> </ol>	
Parenteral pump for medication administration <sup>31</sup>	Medically necessary for uninterrupted parenteral administration of medication via pump.	K0455
Vacuum erection device <sup>32,33</sup>	Medically necessary for the treatment of erectile dysfunction when prescribed by a physician.	L7900 L7902

RESPIRATORY EQUIPMENT	Criteria	HCPCS
Nebulizer, ultrasonic <sup>34</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 35	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
Intrapulmonary percussive ventilation devices (Volara <sup>™</sup> , Percussionaire-TRUE-IPV®) <sup>36,37,38,39</sup>	Not medically necessary, as current evidence does not support the effectiveness of intrapulmonary percussive ventilation (IPV) devices.	E1399

WALKERS	Criteria	HCPCS
Walker,	Requests for standard walkers are considered medically necessary when	E0130
standard <sup>40</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.	



WALKERS	Criteria	HCPCS
Walker, heavy duty <sup>40</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.	E0148 E0149
	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.	E0147

WHEELCHAIRS	Criteria	HCPCS
Manual	Initial requests for manual wheelchairs are medically necessary	E1050, E1060,
wheelchair 41	when meeting all of the following:	E1070, E1083,
	A. Mobility limitation interferes with ability to participate in	E1084, E1085,
	mobility-related activities of daily living, all of the following:	E1086, E1087,
	1. Mobility limitation cannot be met with a cane or walker;	E1088, E1089,
	2. Manual wheelchair will significantly improve	E1090, E1092,
	member/enrollee's ability to participate in mobility-related	E1093, E1100,
	activities of daily living;	E1110, E1130,
	3. Home provides adequate access and maneuvering space for	E1140, E1150,
	requested manual wheelchair;	E1160, E1170,
	4. Willingness by member/enrollee or caregiver to use a	E1171, E1172,
	manual wheelchair in the home;	E1180, E1190,
	B. One of the following:	E1195, E1200,
	1. Caregiver is able to assist with wheelchair use;	E1221, E1222,
	2. Member/enrollee is able to safely and efficiently self-propel	E1223, E1224,
	manual wheelchair.	E1240, E1250,
		E1260, E1270,
	Replacement requests for manual wheelchairs are medically	E1280, E1285,
	necessary when documentation supports one of the following:	E1290, E1295
	A. Replacement necessary due to loss, theft, or irreparable damage	
	and both of the following:	
	1. Documentation supports continued medical necessity;	
	2. Replacement is with the same or similar equipment;	
	B. All of the following:	
	1. Replacement is due to one of the following reasons:	
	a. Replacement necessary after reasonable useful lifetime	
	of five years or more;	
	b. Change in member/enrollee status requiring different	
	equipment than currently in use and growth features of	
	current equipment have been maximized;	
	2. Mobility limitation interferes with ability to participate in	
	mobility-related activities of daily living, all of the	
	following:	
	a. Mobility limitation cannot be met with a cane or	
	walker;	
	b. Manual wheelchair will significantly improve the	
	member/enrollee's ability to participate in mobility-	
	related activities of daily living;	



WHEELCHAIRS	Criteria	HCPCS
	<ul> <li>c. Home provides adequate access and maneuvering space for requested manual wheelchair;</li> <li>d. Willingness by member/enrollee or caregiver to use a manual wheelchair in the home;</li> <li>3. One of the following:</li> <li>a. Caregiver is able to assist with wheelchair use;</li> <li>b. Member/enrollee is able to safely and efficiently self-propel manual wheelchair.</li> </ul>	
Power seat elevator on power wheelchair <sup>42</sup>	<ul> <li>Medically necessary as a component on a power wheelchair when all of the following are met:</li> <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> </ul>	E2298
Robotic Arm, Wheelchair- mounted (JACO) <sup>43</sup>	Not medically necessary, as 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 and other DME repairs	<ul> <li>Medically necessary when meeting all of the following:</li> <li>A. 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> <li>One month's rental for a standard manual wheelchair is considered medically necessary if a member/enrollee owned wheelchair is being repaired.<sup>41</sup></li> </ul>	K0108 K0739 E1399
	Requests for wheelchair or other DME repairs specifically using codes K0108, K0739, or E1399 require mandatory secondary review by a medical director or therapy advisor.	

#### **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.

### **CENTENE**° orporation

## CLINICAL POLICY DME and O&P Criteria

#### **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.

#### 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		Approval
	Date	Date
Policy created	06/09	06/09
Under Wound Care, removed HCPCS code Q4111, GammaGraft, as code	09/20	09/20
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 remove, replaced "member" with "member/enrollee."		
Replaced "members" with "members/enrollees" in the disclaimer of the		
policy.		
Added note to the description stating that if a lower cost, medically	11/20	12/20
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.	0.4/5.4	0.1/0.1
Added criteria for enclosed beds to "Other Equipment" section of policy.	04/21	04/21
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.	0 = /0.1	0 = /0.1
Updated policy to remove neuromuscular stimulator, functional	07/21	07/21
neuromuscular stimulator, and peroneal nerve stimulator, which was		



Reviews, Revisions, and Approvals	Revision Date	Approval Date
transferred to 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." Updated references.		
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 $\geq 18$ months of age; Documented neurological or neuromuscular impairments and $\geq 1$ 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.	08/21	08/21
Removed requirement for replacement requests not due to physiological changes to meet existing criteria and reformatted criteria. Contents table renumbered.	9/21	
Annual review. 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 CP.MP.99 for wheelchair seating in Specialized supply or Equipment section.	12/21	12/21
Removed cardiac event monitor (E0616) criteria from cardiac equipment section of policy and moved to CP.MP.243 Implantable Loop Recorders. Removed invasive home ventilator criteria (E0465) and moved to CP.MP.184 Home Ventilators. Added statement that current evidence does not support the effectiveness of intrapulmonary percussive ventilation (E1399).	06/22	06/22
Annual review. Updated policy statement in I. and added general criteria I.A.1. and I.A.2. Removed ambulatory assist products and updated I.B. policy table. Retired gait trainers and standing frame criteria, defer to standard IQ criteria. Updated pneumatic compression device criteria and added non-pneumatic compression device criteria. Added "one month's rental for a standard manual wheelchair is considered medically necessary if a member/enrollee owned wheelchair is being repaired" to wheelchair repair. Added foot orthotics, custom criteria and codes. Removed "male" from male vacuum erection device. Added criteria section for walkers. Minor verbiage and formatting updates with no impact on criteria. References reviewed, updated, and reformatted. Internal specialist review.	12/22	12/22



Reviews, Revisions, and Approvals	Revision Date	Approval Date
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" 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.	10/23	10/23
Updated verbiage in Newborn Care Equipment, Breast Pumps for inclusivity. Added new criteria section titled Lumbar-Sacral Orthotics (LSO) and included codes L0450, L0452, L0454, L0455, L0456, L0457, L0458, L0460, L0462, L0464, L0466, L0467, L0468, L0469, L0470, L0472, L0480, L0482, L0484, L0486, L0488, L0490, L0491, L0492, L0621, L0622, L0623, L0624, L0625, L0626, L0627, L0628, L0629, L0630, L0631, L0632, L0633, L0634, L0635, L0636, L0637, L0638, L0639, L0640, L0643, L0648, L0649, L0650, L0651, L0700, L0710, L0999, L1000, L1001, L1005. Renamed original "Spinal Orthotics" criteria "Other Spinal Orthotics". Updated manual wheelchair initial request criteria A., A.2. and 4., B.1. and 2., and removed C. Reformatted and updated manual wheelchair replacement request criteria. Deleted codes E1091 and K0009. Reviewed by internal specialist.	05/24	05/24
Annual review. Minor rewording to description with no clinical significance. Replaced codes K1032 and K1033 with E0678 and E0679 under non-pneumatic compression devices. Added additional note to enclosed bed section. Removed halo procedure and equipment criteria due to no prior auth. Removed lumbar sacral orthotics criteria, defer to IQ. Updated verbiage and coding in spinal orthotics section. Updated criteria under hip orthotics. Added section and code L2006 for microprocessor-controlled knee-ankle-foot orthoses (KAFO). Removed code L4130 under shoulder, elbow, wrist, hand, finger orthotics. Updated code E2300 to E2298 under power seat elevator on power wheelchair. Updated wheelchair repairs section to include wheelchair and other DME repairs. References reviewed and updated.	11/24	11/24
Annual review. Minor update to description with no impact on criteria.  Minor update to "Considered not medically necessary" statements	07/25	07/25



Reviews, Revisions, and Approvals	Revision	Approval
throughout relies for electry Haden have compared near even a citation C	Date	Date
throughout policy for clarity. Under burn garments removed criteria C.		
Garment requested by Added wearable cardioverter defibrillator criteria		
along with HCPCS code K0606. Updated blood glucose monitor criteria		
from < 20/200 to 20/200 or worse in both eyes." Minor verbiage update to		
ultraviolet panel lights with no impact to criteria. Removed limit and cost		
criteria from breast pump section. Minor verbiage updates to enclosed beds		
section with no impact to criteria. Minor verbiage updates to positioning		
seat section with no impact to criteria. Updated criteria in A. under cervical		
traction equipment to "Musculoskeletal or neurologic impairment" Added		
HCPCS codes L0720 and L1006 to spinal orthotics section. Removed		
HCPCS code L2006 and Microprocessor controlled KAFO criteria. Added		
AFO section with HCPCS codes L1933 and L1952. Under custom foot		
orthotics removed previous criteria A.1. Diplegic cerebral palsy, updated		
criteria in A.4 from three months to one month and removed "physical		
therapyfailed to improve symptoms." Removed HCPCS codes L3230 and		
custom orthopedic footwear criteria. Minor rewording to shoulder, elbow,		
wrist, hand, finger orthotics with no impact to criteria. Added HCPCS codes		
L6028, L6029, L6031, L6032, L6033, L6037, L6700, and L7406 to upper		
extremity and myoelectric prosthetics and additions. Added HCPCS code		
L5827 to lower extremity prosthetics and additions. Updated previous		
"MyoPro Orthosis" section to "Myoelectric Rehabilitation Systems"		
removed HCPCS codes L8701 and L8702 and added E0738 and E0739 with		
updated "Not medically necessary" statement. Added "Facial Prosthetics"		
section and included HCPCS codes L8040, L8041, L8042, L8043, L8044,		
L8045, L8046, L8047, and L8499 previously included in "Other surgical		
supplies section." Minor verbiage updates to implantable infusion pumps		
section with no impact to criteria. Removed HCPCS codes E0455 and		
oxygen tent criteria. Removed HCPCS codes L8600, L8609, L8610, L8612,		
L8615, L8631, and L8659 and "Other surgical supplies" section. Removed		
HCPCS codes E1310 and "Whirlpool tub" section. References reviewed and		
updated. Reviewed by internal specialist.		
Added criteria I.A.1. "Equipment is necessary and reasonable" along with	08/25	08/25
corresponding note. Added codes E0680 and E0681 to non-pneumatic		
compression devices.		

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### CLINICAL POLICY DME and O&P Criteria

#### **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 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.



**Note: For Medicaid members/enrollees**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note:** For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed <u>prior to</u> applying the criteria set forth in this clinical policy. Refer to the CMS website at <a href="http://www.cms.gov">http://www.cms.gov</a> for additional information.

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