Clinical Policy: Durable Medical Equipment and Orthotics and Prosthetics Guidelines

Reference Number: CP.MP.107 Coding Implications
Date of Last Revision: 06/22 Revision Log

See Important Reminder 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. Prosthetic devices are custom-made artificial limbs or other assistive devices for people who have lost limbs as a result of traumatic injuries, vascular disease, diabetes, cancer or congenital disorders.

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

Policy/Criteria

It is the policy of health plans affiliated with Centene Corporation® that durable medical equipment, orthotics, and prosthetics are **medically necessary** when the applicable criteria are met.

CONTENTS

AMBULATORY ASSIST PRODUCTS	CRITERIA	HCPCS
Gait trainers	Medically necessary with therapist evaluation and ongoing treatment when *all* of the following criteria are met: A. Moderate to maximum support for walking is required; B. Cleared medically for weight bearing and can physiologically tolerate upright positioning; C. Evaluated with the requested gait trainer, can tolerate the positioning in the device, and has successfully demonstrated proper use; D. The member/enrollee and caregivers have been trained on the gait trainer and are motivated to continue ongoing use. **Codes E8000-E8002 indicate, "includes all accessories and components" as part of the definition of the code. Additional line items under E1399 should not be included with requests for gait trainers.	E8000 E8001 E8002
Standing Frames	Dynamic standing frames are medically necessary when meeting one of the following: A. Initial request, or replacement request due to physiological changes* and all of the following: 1. Age and ambulatory status, one of the following: a. Age ≥ 18 years and nonambulatory or losing the ability to ambulate; b. Age <18 years and preambulatory, nonambulatory, or losing the ability to ambulate, and one of the following: i. Developmental delay in ambulation and ≥ 18 months of age; ii. Documented neurological or neuromuscular impairment and ≥ 1 year of age; 2. Documentation supports all of the following: a. Patient meets height and weight requirements for requested standing frame; b. Alert and responsive to stimuli; c. No contraindications to supported standing program; d. Caregiver trained, available, and able to safely assist patient with use of standing frame; 3. Unable to stand without support due to decreased motor control or abnormal muscle tone; 4. Care managed by a rehabilitation-related specialist or physician; 5. Prescribed for daily home use; 6. Expected use for ≥ 12 months; 7. Demonstrated ability (through a direct trial) to mobilize in and/or operate the dynamic component; 8. Documented functional need for or benefit from the dynamic component of the stander (not for use as exercise equipment or for exercise benefit).	E0642 **E1399

AMBULATORY ASSIST PRODUCTS	CRITERIA	HCPCS
	B. Replacement request (not due to physiological changes), all of the following: 1. Documentation supports replacement device necessary due to irreparable damage or device exceeds reasonable useful lifetime ≥ 5 years; 2. Physician documentation of proper use and continued benefit; 3. Replacement with identical or nearly identical device; *Changes in physiological condition, such as strength, muscle tone, growth, or weight change, may potentially impact the appropriateness of the standing device currently in use. **Line item justification is required for any additional components submitted under the E1399 code.	

BURN GARMENTS	CRITERIA	HCPCS
Burn garments [11]	Medically necessary with associated physical and/or occupational therapy when *all* of the following criteria are met: A. At risk of a post-burn contracture; B. The garment and physical and/or occupational therapies are being used with the intent of preventing the need for skin grafting or contractures as a result of hypertrophic scarring; C. Garment is requested by the PCP and/or the treating specialist.	A6501 A6502 A6503 A6504 A6505 A6506 A6507 A6508 A6509 A6510 A6511 A6512 A6513

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

COMPRESSION THERAPY EQUIPMENT	CRITERIA	HCPCS
Pneumatic compression devices[12]	Not proven safe and effective for lymphedema of the abdomen, trunk, chest, genitals, or neck; and for arterial insufficiency.	E0675

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

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

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

ORTHOPEDIC CARE EQUIPMENT	CRITERIA	HCPCS
Cervical traction equipment [14]	Medically necessary when all of the following are met: A. The appropriate use of the selected home cervical traction device has been demonstrated and was tolerated; B. One of the following:	E0849

ORTHOPEDIC CARE EQUIPMENT	CRITERIA	HCPCS
	1. Diagnosis of temporomandibular joint (TMJ dysfunction and has received treatment for TMJ condition; 2. Distortion of the lower jaw and neck anatomy (e.g. radical neck dissection) such that a chin halter is unable to be utilized; 3. The treating physician orders and/or documents the medical necessity for greater than 20 pounds of cervical traction in the home setting.	
Halo procedure equipment & Fracture Frames	Halo and fracture frame placement is generally performed on an emergent or inpatient basis and will be reviewed at the appropriate level of care using nationally recognized decision support tools.	E0947 E0948 L0810 L0820 L0830 L0859
Cervical collar, custom molded	Requests for custom molded cervical collar will be reviewed by a licensed physical or occupational therapist. Documentation accompanying the request must state reason why pre-fabricated collar not adequate.	L0170 L0190 L0200
Spinal orthotics	Requests for spinal orthotics will be reviewed using relevant nationally recognized decision support tool criteria for similar codes.	L0700 L0710 L0999 L1000 L1001 L1005
Hip orthotics[4]	Medically necessary when ordered by an orthopedist for treatment of, or postoperatively for: • Total hip arthroplasty; • Slipped capital femoral epiphysis; • Legg-Calvé-Perthes disease; • Hip labral tear; • 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.	L1640 L1680 L1685 L1686 L1690
Legg Perthes orthotics	Medically necessary when ordered by an orthopedist for use in the treatment for Legg-Calvé-Perthes disease in children.	L1700 L1710 L1720 L1730 L1755
Hip-knee-ankle-foot orthotics (HKAFO)	Requests for orthotics will be reviewed on a case by case basis.	L2050 L2060 L2090
Orthotic components	Requests for orthotic components listed will be reviewed using relevant nationally recognized decision support tool criteria for similar codes.	L2570 L2580 L2627 L2628

ORTHOPEDIC CARE EQUIPMENT	CRITERIA	HCPCS
Orthopedic footwear, custom	Requests for custom orthotic components will be reviewed using relevant nationally recognized decision support tool criteria for similar codes. In addition to supporting the medical necessity of foot orthotics, information must be provided to indicate why prefabricated devices cannot meet the need/why custom devices are necessary.	L3230
Shoulder, elbow, wrist, hand, finger orthotics [4]	Medically necessary when ordered immediately post-operative for orthopedic surgeries such as rotator cuff repair, tendon repair, or ORIF. Replacement due to normal wear and tear is considered medically necessary when the item is a lateral purchase and the orthotic is still needed; Coverage is based on contract guidelines for replacement DME.	L3904 L4000 L4010 L4020 L4030 L4130 L4205
Prosthetics and additions: Upper Extremity and Myoelectric	Requests for upper extremity and myoelectric prosthetics will be reviewed using relevant nationally recognized clinical decision support tool criteria for similar codes.	L6000, L6010, L6020, L6026,L6050, L6055, L6100, L6110, L6120, L6130, L6200, L6205, L6250, L6300, L6310, L6320, L6350, L6360, L6370, L6380, L6382, L6384, L6386, L6388, L6400, L6450, L6500, L6550, L6570, L6580, L6582, L6584, L6586, L6588, L6590, L6623, L6624, L6625, L6628, L6638, L6646, L6647, L6648, L6689, L6690, L6692, L6693, L6704, L6707, L6708, L6709, L6711, L6712, L6713, L6714, L6715, L6721, L6722, L6885, L6895, L6900, L6905, L6910, L6915, L6920, L6930, L6940, L6950, L6960, L6965, L6970, L6975, L7040, L7170, L7185, L7186, L7405, L7499
Prosthetics and additions: Lower Extremity	Requests for these prosthetics and additions will be reviewed by a licensed physical or occupational therapist.	L5990

OTHER EQUIPMENT	CRITERIA	HCPCS
Enclosed Beds[17,18,19,20,21,22]	Requests will be reviewed by a medical director and/or therapy advisor to determine medical necessity, based on all of the following: A. Standard bed or standard hospital bed must be unable to meet the positioning needs due to disability;	E0316 E1399 E0328 or E0329 (when

OTHER EQUIPMENT	CRITERIA	HCPCS
	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, 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 include: 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: 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. 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.	combined with E0316 or E1399)
Positioning seat	Requests should have a physician or therapy advisor review to determine medical necessity. Medically necessary with therapist evaluation and ongoing treatment and *all* of the following criteria are met: A. Commercial device must be unable to meet the positioning needs due to height, weight, or disability;	T5001 E1399

OTHER EQUIPMENT	CRITERIA	HCPCS
	B. Other positioning devices in the home must be reviewed to ensure a duplication of devices is not already in place;	
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.	T2028 T2029 K0108 (For wheelchair seating refer to CP.MP.99) K0739 E1399

PUMPS	CRITERIA	HCPCS
Ambulatory infusion pump	Medically necessary when used for one of the following indications: A. Iron Poisoning: administration of deferoxamine for the 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. D. To administer a drug considered reasonable and necessary by either: 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 2. Intermittent infusion, each episode of infusion lasting less than 8 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	E0780 E0781
Gastric suction pump, home model [15]	Medically necessary for home use for gastric suction due to inability to empty gastric secretions through normal gastrointestinal functions.	E2000
Implantable infusion pumps [2]	Medically necessary when meeting both of the following: A. One of the following indications: 1. Chemotherapy for liver cancer: primary hepatocellular carcinoma or Duke's Class D colorectal cancer, in which the metastases are limited to the liver and where either the	E0782 E0783 E0785 E0786

PUMPS	CRITERIA	HCPCS
	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 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. 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 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; 3. Body size insufficient to support the weight and bulk of the device; 4. Presence of another implanted programmable device; 5. Heparin or insulin is the drug intended for administration.	
Male vacuum erection device [1,3]	A vacuum erection device (VED) and tension ring are medically necessary for the treatment of erectile dysfunction when prescribed by a physician.	L7900 L7902
Parenteral pump for medication administration	Medically necessary for uninterrupted parenteral administration of medication via pump.	K0455

RESPIRATORY EQUIPMENT	CRITERIA	HCPCS
Nebulizer, ultrasonic	Not medically necessary, as it provides no clinical advantage over use of a small-volume nebulizer (E0574) and compressor.	E0575
IPPB & supplies	Medically necessary for member/enrollee with respiratory disease when an incentive spirometer is ineffective.	E0500 E0550
Oximeter [16]	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	E0445

RESPIRATORY EQUIPMENT	CRITERIA	HCPCS
	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	
Oxygen tent	Medically necessary when the ability to breathe is impaired and for whom supplemental oxygen is required.	E0455
Intrapulmonary percussive ventilation devices (Volara™, Percussionaire-TRUE-IPV®) 22-24	Current evidence does not support the effectiveness of intrapulmonary percussive ventilation (IPV).	E1399

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

WHEELCHAIRS	CRITERIA	HCPCS
Manual wheelchair	Initial request is medically necessary when meeting all of the following: A. Mobility-related activities of daily living (MRADLs) in the home cannot be met due to mobility limitation, all of the following: 1. Mobility limitation cannot be met with a cane or walker; 2. Mobility limitation can be met with a manual wheelchair; 3. Home provides adequate access and maneuvering space for requested manual wheelchair; 4. Willingness to use a manual wheelchair in the home; B. One of the following: 1. Caregiver is available and willing to assist with wheelchair use; 2. Manual wheelchair can be safely and efficiently propelled by user; C. Wheelchair use will significantly improve MRADLs.	E1229, E1231, E1232, E1233, E1234, E1235, E1236, E1237, E1238, K0009, E1037, E1050, E1060, E1070, E1083, E1084, E1085, E1086, E1087, E1088, E1089, E1090, E1091, E1092, E1093, E1100, E1110, E1130, E1140, E1150, E1160, E1170, E1171, E1172, E1180, E1190,

WHEELCHAIRS	CRITERIA	HCPCS
	Replacement is medically necessary when meeting all of the following: A. Documentation supports at least one of the following: 1. Growth features of current wheelchair have been maximized; 2. Repair or replacement of parts no longer effective; 3. Current wheelchair in use ≥ 5 years; 4. Change in functional status of patient documented; B. Mobility-related activities of daily living (MRADLs) in the home cannot be met due to mobility limitation, all of the following: 1. Mobility limitation cannot be met with a cane or walker; 2. Mobility limitation can be met with a manual wheelchair; 3. Home provides adequate access and maneuvering space for requested manual wheelchair; 4. Willingness to use a manual wheelchair in the home; C. One of the following: 1. Caregiver is available and willing to assist with wheelchair use; 2. Manual wheelchair can be safely and efficiently propelled by user; D. Wheelchair use will significantly improve MRADLs.	E1195, E1200, E1221, E1222, E1223, E1224, E1240, E1250, E1260, E1270, E1280, E1285, E1290, E1295
Power seat elevator on power wheelchair	Medically necessary as a component on a power wheelchair when all of the following are met: A. A licensed, certified medical professional (i.e. physical or 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.	E2300
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

WHEELCHAIRS	CRITERIA	HCPCS
Wheelchair repair	Requests for wheelchair repairs specifically using codes K0108, K0739, or E1399, are medically necessary when reviewed by a physician or therapy advisor and when meeting the following criteria: A. Wheelchair is less than 5 years old (as evident by the age/date of purchase information provided); B. Cost of repairs is less than the cost of replacement; 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).	K0108 K0739 E1399

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 up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

Background
DME items have the following characteristics:

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

Member/Enrollee's Home
For purposes of rental and purchase of DME, a member/enrollee's home may be his/her 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	Revision Date	Approval Date
Policy created	06/09	06/09
Removed A6503, E0656, E0657, E0221, E0270, E0840, E0850, E0855, E0856, E0860, E0870, E0880, E0890, E0800, E0930, E0941, E0942, E0945, E0946, L2861, L5969, E0746, E2120, E0457, E0459, E0462, E0744, E0762, L8685, Q4114, Q4130 as they are not on DME or O&P PA list Removed L5782, L6621, L6686, L6687, L6688, L6694, L6695, L6696, L6697, L6698, L6880, L6881, L6682, L7007, L7008, L7009, L7045, L7180, L7181, L7190, L7191, L7366, L7404, L8680, L8682, L8683, L8686, L8687, L8688 because other criteria now exists	01/17	02/17

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Added implantable cardiac event recorder as medically necessary in some cases of cryptogenic stroke Added E1801, E1818, L0648, L0650, L0651, L6020, L6026, L6500, Q4111 as they are on PA and no other criteria exists		
Added background section on use of mobile devices as speech generating devices.	09/17	09/17
Removed the following codes because other criteria now exists: E0670, L2999, L3981, B9002, B9004, B9006. Classified L7900 (vacuum erection device), and L7902 as not medically necessary per Medicare LCD. Revised language for Ambulatory Infusion Pumps –section C. to state opioid drugs rather than morphine. Added criteria for prolonged and intermittent infusions under Ambulatory Infusion Pumps, section D.	01/18	01/18
Revised section on Orthotic Care Equipment, Hip/Knee/Ankle/Foot Orthotics (L2050, L2060, L2090) noting that when requested, they would be reviewed on a case by case basis. Added E0770, Peroneal Nerve Stimulation as investigational and not medically necessary to section on Stimulator Equipment.	07/18	07/18
Added A6511 to section on Burn garments. Deleted section for enteral pumps and supplies because other criteria exists. Added reference to CP.MP.117, Spinal Cord Stimulation in section on Implantable neurostimulator.	12/18	12/18
Changed section "Parenteral pumps and supplies" to "Parenteral pumps for medication administration", changed criteria from TPN use only to uninterrupted medication administration, per code description. In implantable infusion pump, replaced chronic non-malignant pain criteria with a reference to CP.MP.173 intrathecal pain pumps. Other minor rewording for clarity with no clinical significance. Updated flexion/extension devices according to current InterQual availability: removed E1801 and added E1802 & E1812.	04/19	04/19
Added E1399 miscellaneous component code criteria under Gait Trainers; Added E1399, K0108, and K0739 as miscellaneous equipment codes requiring physician or therapy advisor review under Specialized Supply or Equipment. Removed E1811, E1815, and E1818 for flexion/extension devices, as they are included in CP.MP.144 Mechanical Stretch devices.	05/19	06/19
Gait trainers: Removed code E1399 and replaced it with a note stating E1399 is not necessary.Under Ambulatory Assist Products: Added criteria for standing frames for codes E1399 and E0642; Under Heat, Cold & Light Therapy Equipment: Changed coverage recommendation for Cold Pad Pump to "Not medically necessary; Under Orthopedic Care Equipment: Added criteria for traction equipment for E0849 that targets Temporomandibular Joint Dysfunction; Moved Fracture Frames with codes E0947 and E0948 to the section with Halo Procedure Equipment as criteria and indications are the same; Changed male vacuum erection devices from	11/19	12/19

Reviews, Revisions, and Approvals	Revision Date	Approval Date
not medically necessary to medically necessary; Added hip labral tears as an indication for a Hip Orthotic; Added clarification to prosthetics and additions section to avoid inappropriate application; For positioning seat, added a requirement for review by therapist or MD; Under Other Equipment: Added criteria for E1399, K0108 and K0739 when they are used for wheelchair repairs; Added criteria for E2300 Seat Elevators; Under Stimulator Equipment: Added E0770 when the diagnosis is spinal cord injury to the coverage criteria detailed under Neuromuscular stimulator.		
Clarified that E0617 is a non-wearable external defibrillator.	03/20	
Removed criteria for flexion/extension devices, and associated codes E1802, E1810, and E1812 as they are now in CP.MP.144 Mechanical Stretch Devices. Removed criteria for E0466, non-invasive ventilators, and second non-invasive ventilators, as this is now included in CP.MP.184 Non-invasive home ventilators. Clarified that back up ventilator is necessary in the case of a wheelchair mounted ventilator if the ventilator could not reach from the wheelchair to the bed. Restructured second/backup ventilator criteria, and removed "may be considered" from the remote geographic access indication.	05/20	
Code E0780 added to criteria for ambulatory infusion pump. Moved ambulatory and implantable infusion pump criteria into pumps section. Updated table of contents.	07/20	
Under Wound Care, removed HCPCS code Q4111, GammaGraft, as code is included in CP.MP.185 Skin Substitutes for Chronic Wounds. Removed "member" from criteria and reworded, without impact on criteria. When not possible to remove, replaced "member" with "member/enrollee." Replaced "members" with "members/enrollees" in the disclaimer of the policy.	09/20	09/20
Added note to the description stating that if a lower cost, medically necessary item exists and will meet the member's needs, the lower cost item will be approved. Updated policy to remove diaphragmatic nerve stimulation criteria, which was transferred to CP.MP.203 Diaphragmatic Phrenic Nerve Stimulation. Nebulizer, ultrasonic: changed to not medically necessary with supporting statement. Blood glucose monitor with integrated voice synthesizer: revised language from diabetics to member/enrollee with diabetes. Implantable infusion pumps: Added contraindications. Gastric suction pump: added requirement of inability to empty gastric secretions through normal gastrointestinal functions. Wheelchair criteria added to its own table. Criteria for manual added and coding updated. Direction added to use nationally recognized criteria for upper extremities and myoelectric prosthetics. Split lower extremity prosthetics into its own row. Removed codes from Shoulder, elbow, wrist, hand, finger orthotics that were duplicated in IQ, L3720, L3730, L3740, L3760, L3900, L3901, L3960, L3962 and L3999. Updated table of contents. References reviewed and updated.	11/20	12/20

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Added criteria for enclosed beds to "Other Equipment" section of policy. Added references and codes E0316, E1399 and E0328 or E0329 (when combined with E0316 or E1399) for enclosed beds. Replaced "investigational" with "not proven safe and effective" in the following sections: Pnuematic compression devices, neuromuscular stimulator, and peroneal nerve stimulators.	04/21	04/21
Updated policy to remove neuromuscular stimulator, fuctional neuromuscular stimulator, and peroneal nerve stimulator, which was 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.	07/21	07/21
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 ≥ 18 months of age; Documented neurological or neuromuscular impairments and ≥ 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

References

1. Local coverage determination. Vacuum erection devices (L34824). Centers for Medicare & Medicaid Services website. http://www.cms.hhs.gov/mcd/search.asp. Published October 1, 2015 (revised January 1, 2020). Accessed November 15, 2021.
2. National coverage determination. Infusion pumps (280.14). Centers for Medicare & Medicaid Services website. http://www.cms.hhs.gov/mcd/search.asp. Published December 17, 2004. Accessed November 15, 2021.
3. Cunningham GR, Khera M. Treatment of male sexual dysfunction. UpToDate. www.uptodate.com. Published July 28, 2021. Accessed November 15, 2021.
4. Durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) quality standards. Centers for Medicare & Medicaid Services website. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/DMEPOSQuality/DMEPOSQualBooklet-905709.html. Published January 9, 2018. Accessed November 15, 2021.
5. Kapur VK, et al. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline . *J Clin Sleep Med*. 2017 Mar 15;13(3):479-504. doi: 10.5664/jcsm.6506
6. Deveza LA. Overview of the management of osteoarthritis. UpToDate. www.uptodate.com. Published March 24, 2021. Accessed November 15, 2021.
7. Olek MJ, Narayan RN, Frohman EM, Froham TC. Symptom management of multiple sclerosis in adults. UpToDate. www.uptodate.com. Published March 3, 2021. Accessed November 15, 2021.
8. 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. https://www.resna.org/Portals/0/Documents/Position%20Papers/RESNA_App%20of%20Seat%20Elevation%20Devices%202019.pdf. Published 2019. Accessed November 15, 2021.
9. Local coverage article. Surgical dressings (A54563). Centers for Medicare & Medicaid Services website. http://www.cms.hhs.gov/mcd/search.asp. Published October 1, 2015 (revised May 1, 2021). Accessed November 16, 2021.
10. National coverage determination. Pneumatic compression devices (280.6). Centers for Medicare & Medicaid Services website. http://www.cms.hhs.gov/mcd/search.asp. Published January 14, 2002. Accessed November 16, 2021.
11. National coverage determination. Home blood glucose monitors (40.2). Centers for Medicare & Medicaid Services website. http://www.cms.hhs.gov/mcd/search.asp. Published June 19, 2006. Accessed November 16, 2021.
12. Local coverage determination. Cervical traction devices (L33823). Centers for Medicare & Medicaid Services website. http://www.cms.hhs.gov/mcd/search.asp. Published October 1, 2015. Accessed November 16, 2021.
13. Local coverage determination. Suction pumps (L33612). Centers for Medicare & Medicaid Services website. http://www.cms.hhs.gov/mcd/search.asp. Published October 1, 2015 (revised January 1, 2020). Accessed November 16, 2021.
14. Local coverage determination. Noninvasive ear or pulse oximetry for oxygen saturation (L33923). Centers for Medicare & Medicaid Services website. http://www.cms.hhs.gov/mcd/search.asp. Published October 1, 2015 (revised October 1, 2019). Accessed November 16, 2021.

15. Restraint and seclusion. The Joint Commission website. https://www.jointcommission.org/standards/standard-faqs/critical-access-hospital/provision-of-care-treatment-and-services-pc/000001668/. Published March 4, 2020. Accessed November 16, 2021.
16. Enclosure bed: A protective and calming restraint. American Nurse Association website. https://www.myamericannurse.com/use-enclosure-beds/. Published January 13, 2015. Accessed November 16, 2021.
17. Operations Manual Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals. Centers for Medicare & Medicaid Services. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf. Published May 21, 2020 (revised February 21, 2020). Accessed November 16, 2021.
18. National coverage determination: Hospital beds (280.7). Centers for Medicare and Medicaid Services website. https://www.cms.gov/medicare-coverage-database/new-search/search.aspx. Effective date not posted, long standing policy. Accessed November 16, 2021.
19. Addressing sensory integration across the lifespan: the role of occupational therapy. American Occupational Therapy Association website. https://www.aota.org. Published 2015. Accessed April 9, 2021.
20. Huang PP, Durbin DR. Promoting safety in children with disabilities. UpToDate. www.uptodate.com. Published May 20, 2021. Accessed November 16, 2021.
21. 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):267-275. doi:10.1080/17483107.2018.1428692.
22. 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):1463-1474. doi:10.1002/ppul.24135
23. 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):458-466.e1. doi:10.1016/j.jamcollsurg.2019.06.004
24. Aboussouan LS. Role of mucoactive agents and secretion clearance techniques in COPD. UpToDate. www.uptodate.com. Updated December 4, 2020. Accessed April 27, 2022.

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 prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.