Clinical Policy: Durable Medical Equipment and Orthotics and Prosthetics Guidelines

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Coding Implications
Revision Log

See Important Reminder 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.[1] 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.[2] 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® 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**

BURN GARMENTS	CRITERIA	HCPCS
Burn garments [5]	Medically necessary with associated physical and/or occupational therapy when *both* of the following 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.	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 [6]	Not medically necessary, as it is primarily considered a safety device.	**E0617**
Wearable Cardioverter Defibrillator (WCD)[7,8]	Initial requests for wearable cardioverter defibrillators (WCD) are considered medically necessary for 30 days when meeting all of the following: A. Member/enrollee is ≥ 18 years of age with increased risk of sudden cardiac death; B. One of the following: 1. Awaiting cardiac transplant; 2. Previously implanted cardioverter defibrillator (ICD) must be removed due to infection and awaiting re-implantation; 3. Newly indicated ICD delayed due to one of the following; 1. Systemic infection; 2. Left ventricular ejection fraction (LVEF) ≤ 35% and any of the following: i. Myocardial infarction (MI) within the past 40 days; 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.	**K0606**

Compression Therapy Equipment	Criteria	HCPCS
Non-pneumatic compression devices[9,10]	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 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). **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. For glucose monitors please follow the statewide PDL for prior authorization	E2100

HEAT, COLD & LIGHT THERAPY EQUIPMENT	CRITERIA	HCPCS
Ultraviolet panel lights [13,14]	Medically necessary when meeting both of the following: A. Refractory psoriasis; 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. Note: Cabinet-style lights should be reserved for extensive involvement of body surface area.	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	A. Medically necessary when breast pumps are a covered benefit for the member/enrollee. For Breast Pump Rentals After 6 Months: A. <u>Prescriptions that Require Prior Authorization</u> All prescriptions for hospital grade breast pumps after six months of rental B. <u>Documentation for Review</u> The following information should be submitted with an authorization request:	E0604

NEWBORN CARE EQUIPMENT	CRITERIA	HCPCS
	1. Gestational age of infant(s) 2. Birth length and weight of infant(s) 3. Growth record of infant(s) 4. Medication list of beneficiary 5. Documentation of any other pumps used (e.g. personal use manual or electric) and why they do not meet the needs of the beneficiary or infant C. Review of Documentation for Medical Necessity In evaluating a request for prior authorization of a prescription for continued rental of a hospital grade breast pump, the determination of whether the requested service is medically necessary will take into account whether the beneficiary: 1. Is unable to nurse and provide adequately for the infant(s); **AND** 2. Personal use of manual or electric breast pumps do not adequately meet maternal or infant needs; **OR** 3. Takes medications that can be found in breast milk and would harm the infant(s). D. Clinical Review Process Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section C to assess the medical necessity of a prescription for continued rental of a hospital grade breast pump. If the guidelines in Section C are met, the reviewer will prior authorize the service. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.	

OTHER EQUIPMENT	CRITERIA	HCPCS
Enclosed Beds [16, 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. 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. • When the above criteria are met, only basic beds will be considered medically necessary. Upgrades for aesthetic purposes	E0316 E1399 E0328 or E0329 (when combined with E0316 or E1399)

OTHER EQUIPMENT	CRITERIA	HCPCS
	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: • Special lights, sounds, fans, cameras, two-way talk monitors, vibration pads weighted blankets; • Custom wood types, finishes or engravings, special coverings on the outside of the bed; • Custom upgrades where lower cost alternatives are readily available.	
Positioning seat	Medically necessary when all of the following are met: A. Documentation of therapist evaluation and ongoing treatment plan; B. Commercial device must be unable to meet the positioning needs due to height, weight, or disability; C. Other positioning devices in the home must be reviewed to ensure duplication of devices are not already in place. All requests for positioning seats require mandatory secondary review by a medical director and/or therapy advisor.	T5001 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[20]	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 [21]	Medically necessary when all of the following are met: A. Musculoskeletal or neurologic impairment requiring traction equipment; B. One of the following: 1. Diagnosis of temporomandibular joint (TMJ) dysfunction and has received treatment for TMJ condition; 2. Distortion of the lower jaw and neck anatomy (e.g. radical neck dissection) such that a chin halter is unable to be utilized; 3. The treating physician orders and/or documents the medical necessity for greater than 20 pounds of cervical traction in the home setting.	E0849
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

PROSTHETICS AND ORTHOTICS EQUIPMENT	CRITERIA	HCPCS
	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 [22]	Medically necessary when ordered by an orthopedic surgeon for treatment of, or postoperatively for any of the following: • Total hip arthroplasty; • Hip labral tear; • 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. 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.	L1640 L1680 L1685 L1686 L1690
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; 4. Plantar fasciitis when symptoms have been present for at least one month; 5. Posterior tibial tendon dysfunction in adult, as indicated by one or more of the following: a. Stage I disease (tenosynovitis without deformity);	L3000 L3001 L3002 L3003 L3010 L3020 L3030 L3031 L3070 L3080

PROSTHETICS AND ORTHOTICS EQUIPMENT	CRITERIA	HCPCS
	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.	
Shoulder, elbow, wrist, hand, finger orthotics	Medically necessary when ordered immediately post-operative for orthopedic surgeries such as rotator cuff repair, tendon repair, or ORIF. Replacement with the same or similar item due to normal wear and tear is considered medically necessary when the orthotic is still needed.	L3904 L4000 L4010 L4020 L4030 L4205
Prosthetics and additions: Upper Extremity and Myoelectric	Medically necessary when the request specific criteria in A. or B. are met: A. Initial request meets all of the following: 1. Functional needs cannot be met with activity modification and compensatory techniques; 2. Requested prosthesis is anticipated to meet functional needs; 3. Clinical examination findings include all of the following: a. Appropriate residual limb length; b. Limb volume stable; c. Ability to tolerate weight of prosthetic device; d. Environmental exposures appropriate for requested prosthesis; e. Ability to access specialized service and care as necessary; f. Stable condition of extremity to include skin integrity, strength, and ROM sufficient to use requested device; g. Cognitive function necessary to master prosthetic use; 4. Comprehensive prosthetic rehabilitation plan includes all of the following: a. Successful participation in pre-prosthetic training and therapy; b. Method of prosthetic control discussed; c. Functional task training with occupational or physical therapy; d. Concurrent home exercise program; e. Follow-up care schedule planned. B. Replacement request, all of the following: 1. Replacement is requested due to one of the following: a. Current prosthesis no longer functions properly or physiological or surgical changes to residual limb no longer accommodate current prosthesis; b. Irreparable wear to prosthesis or prosthetic components;	L6000, L6010, L6020, L6026, L6028, L6029, L6031, L6032, L6033, L6037, 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, L6700, L6704, L6707, L6708, L6709, L6711, L6712, L6713, L6714, L6715, L6721, L6722, L6885,

PROSTHETICS AND ORTHOTICS EQUIPMENT	CRITERIA	HCPCS
	c. Significant change in member/enrollee condition resulting in poor fit or function of prosthesis or prosthetic components; 2. Irreparable damage to prosthesis or prosthetic components or repair cost > 60% of replacement cost; 3. Prosthesis has been properly cared for following manufacturer's recommendations; 4. Medical documentation includes all of the following: a. Supports continued use and medical need; b. Continued motivation to use the device for functional benefit; 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.	L6895, L6900, L6905, L6910, L6915, L6920, L6930, L6940, L6950, L6960, L6965, L6970, L6975, L7040, L7170, L7185, L7186, L7405, L7406, L7499
Prosthetics and additions: Lower Extremity	Requests for lower extremity prosthetics and additions require mandatory secondary review by a medical director and/or therapy advisor.	L5827 L5990
Breast Prosthetics[23,24,25]	Medically necessary post-mastectomy or for treatment of gender dysphoria. If the request is for a custom prosthetic, accompanying documentation must state the reason why a prefabricated device is not adequate.	L8030 L8035
Myoelectric Rehabilitation Systems[26,27]	Not medically necessary, as there is insufficient evidence in published peer-reviewed literature to support the effectiveness of these devices.	E0738 E0739
Facial Prosthetics[28]	Requests for facial prosthetics are medically necessary when there is loss or absence of facial tissue due to disease, trauma, surgery, or a congenital defect.	L8040, L8041, L8042, L8043, L8044, L8045, L8046, L8047, L8499

PUMPS	CRITERIA	HCPCS
Ambulatory infusion pump [29,30]	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.	E0780 E0781

PUMPS	CRITERIA	HCPCS
	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	
Gastric suction pump, home model [31]	Medically necessary for home use for gastric suction due to inability to empty gastric secretions through normal gastrointestinal functions.	E2000
Implantable infusion pumps [30] **Note: For treatment of chronic intractable pain using opioid drugs see CP.MP.173 Implantable Intrathecal Pain Pumps.*	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 disease is unresectable, or the patient refuses excision of the tumor; 2. Anti-spasmodic drugs for severe spasticity: administered intrathecally to treat chronic intractable spasticity in member/enrollee unresponsive to less invasive medical therapy including both of the following: 1. A 6-week trial of noninvasive methods, such as oral anti-spasmodic drugs, that failed to adequately control the spasticity or produced intolerable side effects; 2. 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; 3. Body size insufficient to support the weight and bulk of the device;	E0782 E0783 E0785 E0786

PUMPS	CRITERIA	HCPCS
	4. Presence of another implanted programmable device; 5. Heparin or insulin is the drug intended for administration.	
Parenteral pump for medication administration [31]	Medically necessary for uninterrupted parenteral administration of medication via pump.	K0455
Vacuum erection device [32,33]	Medically necessary for the treatment of erectile dysfunction when prescribed by a physician.	L7900 L7902

RESPIRATORY EQUIPMENT	CRITERIA	HCPCS
Nebulizer, ultrasonic [34]	Not medically necessary, as it provides no clinical advantage over use of a small-volume nebulizer (E0574) and compressor. * Health plans affiliated with Centene Corporation® review requests on a case by case basis.	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™, Percussionaire-TRUE-IPV®)[36,37,38,39]	Current evidence does not support the effectiveness of intrapulmonary percussive ventilation (IPV).	E1399

WALKERS	CRITERIA	HCPCS
Walker, standard [40]	Requests for standard walkers are considered medically necessary when meeting all of the following: A. Mobility-related activities of daily living (MRADLs) in the home cannot be met due to mobility limitation; B. Walker is able to be safely used by member/enrollee; C. Functional mobility deficit will be sufficiently resolved with the use of a walker.	E0130 E0135 E0141 E0143

WALKERS	CRITERIA	HCPCS
Walker, heavy duty [29]	Requests for heavy duty walkers (E0148, E0149) are considered medically necessary when meeting the above standard walker criteria and the member/enrollee weighs more than 300 pounds. Requests for heavy duty, multiple braking system, variable wheel resistance walkers (E0147) are considered medically necessary when meeting the above standard walker criteria and the member/enrollee is unable to use a standard walker due to a severe neurologic disorder or other condition causing the restricted use of one hand.	E0148 E0149 E0147

WHEELCHAIRS	CRITERIA	HCPCS
Manual wheelchair [41]	Initial requests for manual wheelchairs are medically necessary when meeting all of the following: A. Mobility limitation interferes with ability to participate in mobility-related activities of daily living, all of the following: 1. Mobility limitation cannot be met with a cane or walker; 2. Manual wheelchair will significantly improve member/enrollee's ability to participate in mobility-related activities of daily living; 3. Home provides adequate access and maneuvering space for requested manual wheelchair; 4. Willingness by member/enrollee or caregiver to use a manual wheelchair in the home; B. One of the following: 1. Caregiver is able to assist with wheelchair use; 2. Member/enrollee is able to safely and efficiently self-propel manual wheelchair. Replacement requests for manual wheelchairs are medically necessary when documentation supports one of the following: 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;	E1050, E1060, E1070, E1083, E1084, E1085, E1086, E1087, E1088, E1089, E1090, E1092, E1093, E1100, E1110, E1130, E1140, E1150, E1160, E1170, E1171, E1172, E1180, E1190, E1195, E1200, E1221, E1222, E1223, E1224, E1240, E1250, E1260, E1270, E1280, E1285, E1290, E1295

WHEELCHAIRS	CRITERIA	HCPCS
	c. Home provides adequate access and maneuvering space for requested manual wheelchair; d. Willingness by member/enrollee or caregiver to use a manual wheelchair in the home; 3. One of the following: a. Caregiver is able to assist with wheelchair use; b. Member/enrollee is able to safely and efficiently self-propel manual wheelchair.	
Power seat elevator on power wheelchair [42]	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.	E2298
Robotic Arm, Wheelchair-mounted (JACO)[43]	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	Medically necessary when meeting all of the following: A. 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). One month's rental for a standard manual wheelchair is considered medically necessary if a member/enrollee owned wheelchair is being repaired.[41] 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.	K0108 K0739 E1399

** It is the policy of health plans affiliated with Centene Corporation® that determinations for services that are considered **not medically necessary** must be considered on a case-by-case basis by a physician or ad hoc committee and must be made in accordance with the Benefit Plan Contract provisions and applicable state and federal requirements. Denials will require medical director review.

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

Background
DME items have the following characteristics:

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

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

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

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

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

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

prosthetics. Orthotics and Prosthetics items include, but are not limited to, braces, artificial limbs and eyes.

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

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

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

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E1815, and E1818 for flexion/extension devices, as they are included in PA.CP.MP.144 Mechanical Stretching Devices for Joint Stiffness and Contracture.		
Gait trainers: Removed code E1399 and replaced it with a note stating E1399 is not necessary. Under Ambulatory Assist Products: Added criteria for standing frames for codes E1399 and E0642; Under Heat, Cold & Light Therapy Equipment: Changed coverage recommendation for Cold Pad Pump to "Not medically necessary; Under Orthopedic Care Equipment: Added criteria for traction equipment for E0849 that targets Temporomandibular Joint Dysfunction; Moved Fracture Frames with codes E0947 and E0948 to the section with Halo Procedure Equipment as criteria and indications are the same; Changed male vacuum erection devices from not medically necessary to medically necessary; Added hip labral tears as an indication for a Hip Orthotic; Added clarification to prosthetics and additions section to avoid inappropriate application; For positioning seat, added a requirement for review by therapist or MD; Under Other Equipment: Added criteria for E1399, K0108 and K0739 when they are used for wheelchair repairs; Added criteria for E2300 Seat Elevators; Under Stimulator Equipment: Added E0770 when the diagnosis is spinal cord injury to the coverage criteria detailed under Neuromuscular stimulator.	04/21	
Clarified that E0617 is a non-wearable external defibrillator. Stylist changes in several sections moving from bullet points to Letters & Numbers. Remove references to InterQual to make the policy more timeless. Insert "independent" to indicate the type of therapist review required.	04/21	
Removed criteria for flexion/extension devices, and associated codes E1802, E1810, and E1812 as they are now in CP.MP.144 Mechanical Stretch Devices. Removed criteria for E0466, non-invasive ventilators, and second non-invasive ventilators, as this is now included in CP.MP.184 Non-invasive home ventilators. Clarified that back up ventilator is necessary in the case of a wheelchair mounted ventilator if the ventilator could not reach from the wheelchair to the bed. Restructured second/backup ventilator criteria, and removed "may be considered" from the remote geographic access indication.	04/21	
Code E0780 added to criteria for ambulatory infusion pump. Moved ambulatory and implantable infusion pump criteria into pumps section. Updated table of contents.	04/21	
Under Wound Care, removed HCPC's code Q4111, GammaGraft, as code is included in CP.MP.185 Skin Substitutes for Chronic Wounds. Removed "member" from criteria and	04/21	

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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 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.	04/21	
Annual Review Complete. Added criteria for enclosed beds to "Other Equipment" section of policy. Added references and codes E0316, E1399 and E0328 or E0329 (when combined with E0316 or E1399) for enclosed beds. Replaced "investigational" with "not proven safe and effective" in the following sections: Pneumatic compression devices, neuromuscular stimulator, and peroneal nerve stimulators. Updated policy to remove neuromuscular stimulator, functional neuromuscular stimulator, and peroneal nerve stimulator, which was transferred to PA.CP.MP.48 Neuromuscular Electrical Stimulation (NMES). Replaced existing Standing Frames criteria with new initial request and replacement request criteria. Revised section on pneumatic compression devices to state that they are not proven safe and effective for lymphedema of the abdomen, trunk, chest, genitals, or neck, and for arterial insufficiency. Added criteria for Wheelchair-mounted Assistive Robotic Arm (JACO). Changed "review date" in the header to "date of last revision" and "date" in the revision log header to "revision date." Reorganized Standing Frame criteria and required that replacement requests also meet existing criteria for the initial request. For initial request under 18, added "and one of the following:	02/06/2023	

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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. Removed requirement for replacement requests not due to physiological changes to meet existing criteria and reformatted criteria. Contents table renumbered. References reviewed and updated. Added burn garment HCPCS codes A6502, A6503, A6504, A6505, A6506, A6508, A6509, A6510, A6512 and A6513 to policy. Made note for HCPCS code K0108 to refer to PA.CP.MP.99 for wheelchair seating in Specialized supply or Equipment section. Removed cardiac event monitor (E0616) criteria from cardiac equipment section of policy and moved to PA.CP.MP.243 Implantable Loop Recorders. Removed invasive home ventilator criteria (E0465) and moved to PA.CP.MP.184 Home Ventilators. Added statement that current evidence does not support the effectiveness of intrapulmonary percussive ventilation (E1399). Updated references. Specialist reviewed. Manual Wheel Chair "Mobility limitation in the community" ** It is the policy of health plans affiliated with Centene Corporation® that determinations for services that are considered **not medically necessary** must be considered on a case-by-case basis by a physician or ad hoc committee and must be made in accordance with the Benefit Plan Contract provisions and applicable state and federal requirements. Denials will require medical director review.		
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	10/2023	02/12/2024

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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.		
Annual Review. Updated verbiage in Newborn Care Equipment, Breast Pumps for inclusivity. Added new criteria section titled Lumbar-Sacral Orthotics (LSO) and Added 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, L0641, L0642, L0643, L0648, L0649, L0650, L0651. 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. References reviewed, updated, and reformatted.	06/2024	04/2025
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. Minor update to description with no impact on criteria. Minor update to "Considered not medically necessary" statements 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	09/2025	

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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 therapy...failed 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. Added criteria I.A.1. “Equipment is necessary and reasonable…” along with corresponding note. Added codes E0680 and E0681 to non-pneumatic compression devices. References reviewed and updated. Reviewed by internal specialist.		
Ad-hoc review; Added affirmative language to the Newborn Care Equipment section for Breast Pump Rentals After 6 Months as indicated in the PA DHS Medical Assistance (MA) Bulletin # 01-25-41, 05-25-01, 08-25-42, 09-25-44, 10-25-07, 24-25-40, 25-25-03, 31-25-46, 33-25-40, 47-25-01	01/2026	5/21/2026

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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.

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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.

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