

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

Last Review Date: 01/18

Coding Implications
Revision Log

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

Description

DME is defined as equipment that can stand repeated use, is primarily and customarily used to serve a medical purpose, and is generally not useful to a person in the absence of an illness or injury. Orthotic devices are rigid and semi-rigid devices used for the purpose of supporting a weak or deformed body part or restricting or eliminating motion in a disease or injured body part. 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.

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.

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AMBULATORY ASSIST PRODUCTS	CRITERIA	HCPCS
Gait trainers	 Medically necessary with therapist evaluation and ongoing treatment when <i>all</i> of the following criteria are met: Member requires moderate to maximum support for walking; Cleared medically for weight bearing and can physiologically tolerate upright positioning; The member has been evaluated with the requested gait trainer, can tolerate the positioning in the device, and has successfully demonstrated proper use; The member and caregivers have been trained on the gait trainer and are motivated to continue ongoing use. 	E8000 E8001 E8002

BURN GARMENTS	Criteria	HCPCS
Burn garments	Medically necessary with associated physical and/or occupational	A6501
	therapy when <i>all</i> of the following criteria are met:	A6507
	The burn is of documented significance to place the member at risk	
	of a post-burn contracture;	
	The burn 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;	
	The burn garment is requested by the primary care physician and/or	
	the treating specialist.	

CARDIAC	Criteria	HCPCS
EQUIPMENT		
Cardiac event recorder, implantable	Medically necessary for members for evaluation of recurrent unexplained episodes of pre-syncope, syncope, "seizures", palpitations, or dizziness when both of the following criteria are met: A. A cardiac arrhythmia is suspected as the cause of the symptoms; B. Either of the following criteria are met: 1. Members with heart failure, prior myocardial infarction or significant ECG abnormalities (see below): noninvasive ambulatory monitoring, consisting of 30-day pre-symptom external loop recordings or MCT, fails to establish a definitive diagnosis; 2. Members without heart failure, prior myocardial infarction or significant ECG abnormalities (see below) and symptoms occur so infrequently and unpredictably (less frequently than once per month) that noninvasive ambulatory monitoring (MCT or external loop recorders) are unlikely to capture a diagnostic ECG. Significant ECG Abnormalities • Syncope during exertion or supine • Palpitations at the time of syncope • Family history of SCD • Non-sustained VT	E0616



CARDIAC	Criteria	HCPCS
EQUIPMENT		
	 Bifascicular-block (LBBB or RBBB combined with left anterior or left posterior fascicular block) or other intraventricular conduction abnormalities with QRS duration ≥120 ms Inadequate sinus bradycardia (<50 bpm) or sinoatrial block in absence of negative chronotropic medications or physical training Pre-excited QRS complex Prolonged or short QT interval RBBB pattern with ST-elevation in leads V1-V3 (Brugada pattern) Negative T waves in right precordial leads, epsilon waves, and ventricular late potentials suggestive of ARVC 	
	Medically necessary for evaluation of members with suspected atrial fibrillation as a cause of cryptogenic stroke who have had a	
	nondiagnostic Holter monitor or 48 hour telemetry	
External defibrillator	Considered not medically necessary as it is primarily considered a safety	E0617
with integrated ECG	device	
analysis		

COMPRESSION THERAPY	CRITERIA	HCPCS
EQUIPMENT Pneumatic compression devices	For lymphedema of the abdomen, trunk, chest, genitals, or neck; and for arterial insufficiency, is considered experimental/investigational, thus not medically necessary.	E0675

DIABETES CARE	Criteria	HCPCS
EQUIPMENT		
Blood glucose monitor with integrated voice synthesizer	Medically necessary for members 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 members who have both: Refractory psoriasis; MD must justify 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 members with extensive involvement > 54% of body surface area. 	E0691 E0692 E0693 E0694
Cold pad pump	Medically necessary as a replacement for a water pump cold pad that is no longer functioning from normal wear and tear.	E0236



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

ORTHOPEDIC	Criteria	HCPCS
CARE EQUIPMENT		
Traction equipment	Home traction therapy is unproven and	E0849, E0947, E0948
& fracture frames	considered experimental/investigational, not	
	medically necessary.	
Rollabout chair	Medically necessary when used in lieu of a	E1031
	wheelchair for members who would qualify for a	
	wheelchair (except for the ability to self-propel a	
	manual wheelchair).	
Flexion/extension	Considered medically necessary for the	E1801, E1810, E1811, E1815,
devices	following:	E1818
	• < 6 months following surgery or intervention	
	to improve motion/stiffness in a joint;	
	Has been compliant with both therapy and	
	home exercise programs.	
Halo procedure	Halo placement is generally performed on an	L0810, L0820, L0830,
equipment	emergent or inpatient basis and will be reviewed	L0859
	at the appropriate level of care using nationally	
	recognized decision support tools.	
Cervical collar,	Requests for custom molded cervical collar will	L0170, L0190, L0200
custom molded	be reviewed by a licensed physical or	
	occupational therapist. Documentation	
	accompanying the request must state reason why	
	pre-fabricated collar not adequate.	
Spinal orthotics	Requests for spinal orthotics will be reviewed	L0700, L0710, L0999, L1000,
	using relevant nationally recognized decision	L1001, L1005
	support tool criteria for similar codes	
Hip orthotics	Medically necessary when ordered by an	L1640, L1680, L1685, L1686,
	orthopedist for treatment of, or postoperatively	L1690
	for, total hip arthroplasty, slipped capital femoral	
	epiphysis, Legg-Calvé-Perthes disease, and hip	
	dysplasia for Charcot-Marie-Tooth disease.	
	Lateral replacements are considered medically	
	necessary in pediatrics due to growth for	
	diagnoses such as hip dysplasia with Charcot-	
	Marie-Tooth disease.	X 4 = 00 X 4 = 10 X 4 = 20
Legg Perthes	Medically necessary when ordered by an	L1700, L1710, L1720,
orthotics	orthopedist for use in the treatment for Legg-	L1730, L1755
	Calvé-Perthes disease in children.	



ORTHOPEDIC	CRITERIA	HCPCS
CARE EQUIPMENT		
Hip-knee-ankle-foot	Requests for orthotics will be reviewed on a case	L2050, L2060, L2090
orthotics	by case basis.	
(KAFO/HKAFO)		
Orthotic components	Requests for orthotic components listed will be	L2570, L2580, L2627, L2628
	reviewed using relevant nationally recognized	
	decision support tool criteria for similar codes.	
Orthopedic footwear,	Requests for custom orthotic components will be	L3230
custom	reviewed using relevant nationally recognized	
	decision support tool criteria for similar codes.	
Shoulder, elbow,	Medically necessary when ordered immediately	L3720, L3730, L3740, L3760,
wrist, hand, finger orthotics	post-operative for orthopedic surgeries such as	L3900, L3901, L3904, L3960,
orthotics	rotator cuff repair, tendon repair, or ORIF.	L3962, 3999, L4000, L4010, L4020, L4030, L4130, L4205
	Replacement due to normal wear and tear is	L4020, L4030, L4130, L4203
	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.	
Prosthetics and	Requests for these prosthetics and additions will	L5990, L6000, L6010, L6020,
additions	be reviewed by a licensed physical or	L6026, L6050, L6055, L6100,
	occupational therapist.	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

OTHER	CRITERIA	HCPCS
EQUIPMENT		
Positioning seat	Medically necessary with therapist evaluation and ongoing treatment and <i>all</i> of the following criteria are met:	T5001
	• Commercial device must be unable to meet the positioning needs of the member due to height, weight, or disability;	
	• Other positioning devices in the home must be reviewed to ensure a duplication of devices is not already in place;	



OTHER	Criteria	HCPCS
EQUIPMENT		
Specialized supply or	 Requests for not otherwise specified supplies will have a physician 	T2028
equipment	review to determine medical necessity.	T2029

PUMPS	Criteria	HCPCS
Enteral pumps and	Medically necessary for members dependent upon tube feedings for	B9000
supplies (food pumps)	nutritional support as sole source of nutrition and member cannot	
	tolerate gravity or syringe feedings or requires a controlled rate of	
	infusion.	
	Portable pumps are covered in lieu of stationary pumps if	
	condition requires continuous feeding and/or the member is able	
	to leave the home for prolonged periods such as for physician	
	office visits or medical therapies.	
Parenteral pumps and	Medically necessary for members dependent on parenteral nutrition	K0455
supplies	(TPN) as their source of nutrition and/or requires parenteral	
	administration of medication via pump.	
Gastric suction pump,	Medically necessary for members with a medical need for gastric	E2000
home model	suction in the home.	
Male vacuum erection	A vacuum erection device (VED) and tension ring are not medically	L7900,
device	necessary for the treatment of erectile dysfunction.	L7902

RESPIRATORY EQUIPMENT	Criteria	HCPCS
Nebulizer, ultrasonic	Medically necessary for members when used for delivery of pentamidine or aerosolized antibiotics.	E0575
IPPB & supplies	Medically necessary for members with respiratory disease when an incentive spirometer is ineffective.	E0500 E0550
Oximeter	 Medically necessary when used as a monitoring and alarm device for any of the following: To monitor individuals on a home ventilator or with a tracheostomy To determine appropriate home oxygen requirements To wean an individual from home oxygen To monitor an unstable respiratory condition Not medically necessary when used for the following: Oximetry when used as a diagnostic procedure Monitoring of a stable respiratory condition Asthma management Other conditions not listed above 	E0445
Oxygen tent	Medically necessary for members whose ability to breathe is impaired and supplemental oxygen is required. Example diagnosis includes croup.	E0455
Ventilator	Medically necessary for members with a long-term/chronic condition or disease affecting the ability to effectively maintain adequate respiratory status. Examples of conditions may include neuromuscular disease, thoracic restrictive disease, or chronic respiratory failure following COPD.	E0465 E0466
Second home ventilator	A second invasive or non-invasive ventilator is considered medically necessary if required for a different purpose from the first ventilator, based on the member's medical needs. Examples include:	



RESPIRATORY EQUIPMENT	CRITERIA	HCPCS
	 Two different types of ventilators are needed for each day, e.g., negative pressure ventilator with chest shell for one indication and a positive pressure ventilator with nasal mask the rest of the day; Member is confined to a wheelchair and requires a wheel-chair mounted ventilator during the day and another ventilator of the same type for use while in bed. Without both pieces of equipment, member may be prone to medical complications, unable to achieve appropriate medical outcomes, or may not be able to use the equipment effectively. Members residing in remote areas with poor emergency access may also be considered for a second ventilator. 	

STIMULATOR	Criteria	HCPCS
EQUIPMENT		
Neuromuscular stimulator	Medically necessary (E0745) when used as one component of a comprehensive rehab program for the treatment of disuse atrophy when the nerve supply to the atrophied muscle is intact and has any of the following indications for disuse atrophy: • Contractures due to burn scarring; • Previous casting or splinting of a limb; • Major knee surgery with failure to respond to physical therapy; • Recent hip replacement until physical therapy begins. Neuromuscular electrical stimulation for any other indication (e.g., idiopathic scoliosis [E0744], heart failure) is not medically necessary	E0745
Functional neuromuscular stimulator	 because it is considered experimental/investigational or unproven. Medically necessary for members with a spinal cord injury (SCI) who meet ALL the following criteria: Member has intact lower motor units (L1 and below (both muscle and peripheral nerve); Member has muscle and joint stability adequate for weight bearing upper and lower extremities to allow balance and control to maintain an upright support posture independently; Member has brisk muscle contraction to stimulation and sensory perception electrical stimulation sufficient for muscle contraction; Member can transfer independently and demonstrates independent standing tolerance for at least 3 minutes; Member can demonstrate hand and finger function to manipulate controls; Member has no hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis; Member is at least 6 months post recovery from SCI and restorative surgery; Member is highly motivated, committed, and has the cognitive ability to use such devices for walking; Member has demonstrated a willingness to use the device long-term; 	E0764



STIMULATOR EQUIPMENT	CRITERIA	HCPCS
	 Member has successfully completed a training program consisting of at least 32 physical therapy sessions with the device over a 3-month period. 	
	 Exclusion criteria includes members with any of the following: Cardiac pacemaker; Severe scoliosis or severe osteoporosis; Skin disease or cancer at area of stimulation; Irreversible contracture; 	
	Autonomic dysflexia.	
Peroneal nerve stimulators	Peroneal nerve stimulators, (e.g., NESS L300, NESS L300 Plus, L300 Go System, WalkAide, ODFS Dropped Foot Stimulator) are considered investigational, not medically necessary, for all indications including, but not limited to, members with foot drop in cerebral palsy, multiple sclerosis, traumatic brain injury, stroke or an incomplete spinal cord injury.	E0770
Implantable	Diaphragmatic pacing is medically necessary for the treatment of chronic	L8681
neurostimulator	ventilatory insufficiency due to bilateral paralysis or severe paresis of the diaphragm in members with partial or complete ventilatory insufficiency that retain sufficient function in the phrenic nerves, lungs and diaphragm to accommodate electrical stimulation.	L8684 L8689
	See CP.MP.12 Vagus Nerve Stimulation for criteria for implantation of stimulator for epilepsy and depression.	

SURGICAL SUPPLIES	Criteria	HCPCS
Ambulatory infusion pump	 Medically necessary for members when used for one of the following indications: A. Iron Poisoning: when used in the administration of deferoxamine for the treatment of acute iron poisoning and iron overload; B. Chemotherapy for liver cancer: when used in the treatment of primary hepatocellular carcinoma or colorectal cancer where this disease is unresectable; OR, where the patient refuses surgical excision of the tumor; C. With opioid drugs when used in the treatment of intractable pain caused by cancer. D. To safely 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 member to return to the physician's office prior to the beginning of each infusion. 	E0781



SURGICAL SUPPLIES	CRITERIA	HCPCS
SUITEES	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 Physicians Desk Reference, or the U.S. Pharmacopeia Drug Information	
Implantable infusion pumps	Medically necessary for members when used for one of the following indications: A. Chemotherapy for liver cancer 1. 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; B. Anti-spasmodic drugs for severe spasticity 1. When administered intrathecal to treat chronic intractable spasticity in patients unresponsive to less invasive medical therapy including both of the following: a. A 6-week trial of noninvasive methods, such as oral antispasmodic drugs, that failed to adequately control the spasticity or produced intolerable side effects; b. Prior to pump implantation, member responded favorably to a trial of intrathecal dose of the anti-spasmodic drug; C. Opioid drugs for treatment of chronic intractable pain 1. When administered intrathecal or via epidural for the treatment of severe chronic intractable pain of malignant of nonmalignant origin in patients whose life expectancy is at least 3 months and who have proven unresponsive to less invasive medical therapy as indicated by both of the following: a. Member history indicates inadequate response to noninvasive methods of pain control such as systemic opioids; b. Preliminary trial of intraspinal opioid drug administration provided adequate pain relief with minimal side effects; D. Other uses of implantable infusion pumps when all of the following are met: 1. The drug is reasonable and necessary for the treatment of an individual member; 2. 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.	E0782 E0783 E0785 E0786
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



WOUND CARE	Criteria	HCPCS
GammaGraft	Experimental/investigational, considered not medically	Q4111
	necessary	
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 a member's illness or injury;
- The equipment is manufactured primarily for use in the home environment but is not limited to use in the home.

Member's Home

For purposes of rental and purchase of DME, a member'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'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, to 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 who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.

Members 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	Date	Approval Date
Policy created	06/09	06/09
Updated HCPCS codes for existing criteria to current DME PA list	01/15	02/15
Ventricular assist device replacement parts removed d/t removal from DME		
PA list		
Added traction equipment/ fracture frame		
Removed protective helmet d/t existing InterQual criteria available		
Removed emergency response system criteria as no longer on the DME PA list		
Added male vacuum erection device		
Removed Q4100 & Q4118 skin substitutes as no longer on the DME PA list		
Added ambulatory infusion pump criteria		
Added specific criteria for gait trainers and positioning chairs		
Specialist Review (PT & OT)		
2015 codes added: L6026 and L7259 to prosthetic section and L3981 added to	03/15	
shoulder orthotic section		
Updated HCPCS codes per 2016 CMS mandate, removed deleted codes.	02/16	02/16
Changed "lymphedema pumps" to "pneumatic compression devices" for		
lymphedema or arterial insufficiency.		
Updated template.		



Reviews, Revisions, and Approvals	Date	Approval Date
Removed oral device criteria and codes which are now covered in Interqual Retitled to CP.MP.107		
Moved language from Policy/Criteria sections A, B, and C to background and removed definitions of necessary and reasonable. Deleted diagnostic equipment table and moved oximetry to respiratory table, and biofeedback to other equipment table. Clarified that oximetry for diagnostic screening is not a DME use.	07/16	07/16
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 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	01/17	02/17
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

References

- 1. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD): Vacuum erection devices (VED) (L34675). 01/01/17. <a href="https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34824&ver=11&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD%7cEd&PolicyType=Both&s=All&KeyWord=vacuum+erection+device&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAACAAAAA&
- 2. CMS. National coverage determination (NCD) for infusion pumps (280.14). 2/18/2005.

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- https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=223&ncdver=2&DocID=280.14&bc=gAAAABAAAAAA&CMS.
- 3. NCD for neuromuscular electrical stimulation (NMES) (160.12). 10/1/2006. http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=175&ncdver=2&bc=AgAAgAAAAAA&
- 4. CMS. NCD for phrenic nerve stimulator. http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=244&ncdver=1&bc=AAAAQAAAAAA&
- 5. Cunningham GR, Khera. Treatment of male sexual dysfunction. In: UpToDate, Snyder PJ O'Leary MP (Ed), UpToDate, Waltham, MA. Accessed 1/16/2018.
- 6. Department of Health and Human Services, CMS. Durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) quality standards. ICN 905709 09/2017.
- 7. 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.
- 8. Hayes Medical Technology Directory. Diaphragmatic/phrenic nerve stimulation. August 11, 2011. Archived September 11, 2016.
- 9. Hayes Medical Technology Directory. Functional electrical stimulation for rehabilitation following spinal cord injury. November 16, 2017. Accessed January 16, 2018.
- 10. Hayes Search & Summary. Intermittent pneumatic compression for peripheral arterial disease. July 12, 2013 Accessed 1/16/17.
- 11. Deveza LA. Overview of the management of osteoarthritis. In: UpToDate, Hunter D (Ed), UpToDate, Waltham, MA. Accessed 1/16/2017.
- 12. Kryger MH, Malhotra A. Management of obstructive sleep apnea in adults. In: UpToDate, Collop N (Ed), UpToDate, Waltham, MA. Accessed 1/16/2017.
- 13. Marion DW. Pacing the diaphragm: Patient selection, evaluation, implantation, and complications. In: UpToDate, Shefner JM (Ed), UpToDate, Waltham, MA. Accessed 1/16/2017.
- 14. Scottish Intercollegiate Guidelines Network (SIGN). Management of obstructive sleep apnea/hypopnea syndrome in adults. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2003 Jun. 35 p. (SIGN publication; no. 73).
- 15. Hayes Health Technology Brief. Implantable Cardiac Loop Recorders for Detection of Atrial Fibrillation Following Cryptogenic Stroke. June 2017. Accessed 1/16/18.
- 16. Hayes Search and Summary. Bioness L300 Foot Drop System (Bioness Inc.) for Patients with Stroke or Traumatic Brain Injury. April 6, 2018
- 17. Hayes Technology Brief. Functional Electrical Stimulation (FES) for Treatment of Foot Drop in Multiple Sclerosis Patients. July 2015, Annual Review June 27, 2017
- 18. Olek MJ, Narayan RN, Frohman EM, Froham TC. Symptom management of multiple sclerosis in adults. In: UpToDate, Gonzalez_Scarano F (Ed), UpToDate, Waltham, MA. Accessed July 17, 2018

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. This clinical policy is not intended to recommend treatment for members. Members 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 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 and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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

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