Clinical Policy: DME and O&P Criteria

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Effective Date: 01/18
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Coding Implications
Revision Log

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 Pennsylvania Health and Wellness® that the durable medical equipment, orthotics, and prosthetics which are not addressed in InterQual© criteria are **medically necessary** when the applicable guidelines are met.

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AMBULATORY ASSIST PRODUCTS	CRITERIA	HCPCS
Gait trainers	Medically necessary with therapist evaluation and ongoing treatment when *all* 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 therapy when *all* of the following criteria are met: • 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.	A6501 A6507

CARDIAC EQUIPMENT	CRITERIA	HCPCS
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 • 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	E0616

CARDIAC EQUIPMENT	CRITERIA	HCPCS
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	For lymphedema of the abdomen, trunk, chest, genitals, or neck; and for arterial insufficiency, is considered experimental/investigational, thus not medically necessary. Refer to InterQual subset CP: Durable Medical Equipment, Pneumatic Compression Devices for requests for other pneumatic compression therapy.	E0670 E0675

DIABETES CARE EQUIPMENT	CRITERIA	HCPCS
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 EQUIPMENT	CRITERIA	HCPCS
Breast pumps	Medically necessary for members for the following: • 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.	E0604

ORTHOTICS AND PROSTHETICS	CRITERIA	HCPCS
Orthotic/Prosthetic fitting	Medically necessary when performed in conjunction with a medically necessary orthotic or prosthetic.	L6380, L6382, L6384, L6386, L6388, L8499
Traction equipment & fracture frames	Home traction therapy is unproven and considered experimental/investigational, not medically necessary.	E0849, E0947, E0948
Rollabout chair	Medically necessary when used in lieu of a wheelchair for members who would qualify for a wheelchair (except for the ability to self-propel a manual wheelchair).	E1031
Flexion/extension devices	Considered medically necessary for the following: • < 6 months following surgery or intervention to improve motion/stiffness in a joint; • Has been compliant with both therapy and home exercise programs.	E1801, E1810, E1811, E1815, E1818
Halo procedure equipment	Halo 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.	L0810, L0820, L0830, L0859
Cervical collar, custom molded	Requests for custom molded cervical collar will be reviewed on a case-by-case basis. Documentation accompanying the request must state reason why pre-fabricated collar is not adequate.	L0170, L0190, L0200
Spinal orthotics	Requests for spinal orthotics will be reviewed on a case-by-case basis using related InterQual subset CP: Durable Medical Equipment Orthoses, Spinal.	L0700, L0710, L0999, L1000, L1001, L1005
Hip orthotics	Medically necessary when ordered by an orthopedist for treatment of, or postoperatively 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.	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 (KAFO/HKAFO)	Requests for orthotics will be reviewed on a case-by-case basis using related InterQual subset CP: Durable Medical Equipment Orthoses, Lower Extremity, Knee-Ankle-Foot (KAFO) and Ankle-Foot (AFO).	L2050, L2060, L2090,
Lower extremity orthotic components	Requests for orthotic components listed will be reviewed on a case-by-case basis using related	L2570, L2580, L2627, L2628, , L2999

ORTHOTICS AND PROSTHETICS	CRITERIA	HCPCS
	InterQual subset CP: Durable Medical Equipment Orthoses, Lower Extremity, Knee.	
Orthopedic footwear, custom	Requests for orthotics will be reviewed on a case-by-case basis using related InterQual subset CP: Durable Medical Equipment Orthoses, Lower Extremity, Knee-Ankle-Foot (KAFO) and Ankle-Foot (AFO)	L3230, L5990
Post-surgical 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 due to normal wear and tear is considered medically necessary when the item is a lateral purchase and the orthotic is still needed.	L3720, L3730, L3740, L3760, L3900, L3901, L3904, L3960, L3962, L3981, L3999, L4000, L4010, L4020, L4030, L4130, L4205
Shoulder, elbow, wrist, hand, finger orthotics, non-post-surgical	Requests for these prosthetics and additions will be reviewed on a case-by-case basis using related InterQual subset CP: Durable Medical Equipment Orthoses, Upper Extremity. Replacement due to normal wear and tear is considered medically necessary when the item is a lateral purchase and the orthotic is still needed.	L6000, L6010, L6020, L6026, L6050, L6055, L6100, L6110, L6120, L6130, L6200, L6205, L6250, L6300, L6310, L6320, L6350, L6360, L6370, 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 EQUIPMENT	CRITERIA	HCPCS
Positioning seat	Medically necessary with therapist evaluation and ongoing treatment and *all* of the following criteria are met: • 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;	T5001
Specialized supply or equipment	• Requests for not otherwise specified supplies will have a physician review to determine medical necessity.	T2028 T2029

PUMPS	CRITERIA	HCPCS
Enteral pumps and supplies (food pumps)	Medically necessary for members dependent upon tube feedings for 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.	B9000 B9002 B9004 B9006
Parenteral pumps and supplies	Medically necessary for members dependent on parenteral nutrition (TPN) as their source of nutrition and/or requires parenteral administration of medication via pump.	K0455
Gastric suction pump, home model	Medically necessary for members with a medical need for gastric suction in the home.	E2000

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 Second home 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. A second invasive or non-invasive ventilator is considered medically necessary as a backup in case of mechanical/electrical failure, or if required for a different purpose from the first ventilator, based on the member's medical needs. Examples include:	E0465 E0466

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.	

STIMULATOR EQUIPMENT	CRITERIA	HCPCS
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 because it is considered experimental/investigational or unproven.	E0745
Functional neuromuscular stimulator	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;	E0764

STIMULATOR EQUIPMENT	CRITERIA	HCPCS
	• Member has demonstrated a willingness to use the device long-term; • 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.	
Implantable neurostimulator	Diaphragmatic pacing is medically necessary for the treatment of chronic 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. See CP.MP.12 Vagus Nerve Stimulation for criteria for implantation of stimulator for epilepsy and depression.	L8681 L8684 L8689

SURGICAL SUPPLIES	CRITERIA	HCPCS
Ambulatory infusion pump	Medically necessary for members when used for one of the following indications: • Iron Poisoning: when used in the administration of deferoxamine for the treatment of acute iron poisoning and iron overload; • 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; • With morphine when used in the treatment of intractable pain caused by cancer.	E0781
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:	E0782 E0783 E0785 E0786

SURGICAL SUPPLIES	CRITERIA	HCPCS
	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, 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.	
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.	L8600, L8609, L8610, L8612, L8615, L8659

WOUND CARE	CRITERIA	HCPCS
Gamma Graft	Experimental/investigational, considered not medically necessary.	Q4111
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.

Reviews, Revisions, and Approvals	Date	Approval Date

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