Clinical Policy: Durable Medical Equipment and Orthotics and Prosthetics Guidelines

Reference Number: LA.CP.MP.107c
Date of Last Revision: 04/26 Revision Log

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

Description

DME is defined as equipment that can 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. This policy describes special criteria for select DME items. It is not intended to be an exhaustive list or to designate prior authorization requirements. Medical necessity criteria are based upon federal and state coverage guidelines, Louisiana Healthcare Connection (LHCC) clinical policies, standards of evidence-based practice, and nationally recognized clinical decision support tools, such as InterQual.

Refer to the LA.CP.MP.93 for criteria for Bone-Anchored Hearing Aid
Refer to the LA.CP.MP.99 for criteria for Wheelchair Seating
Refer to the LA.CP.MP.144 for criteria for Mechanical Stretching Devices for Joint Stiffness and Contracture
Refer to the LA.CP.MP.150 for criteria for Home Phototherapy for Neonatal Hyperbilirubinemia.
Refer to the LA.CP.MP.173 for criteria for Implantable Intrathecal or Epidural Pain Pump
Refer to the LA.CP.MP.184 for criteria for Invasive and Non-Invasive Home Ventilators
Refer to the LA.CP.MP.190 for criteria for Outpatient Oxygen Use
Refer to the LA.CP.MP.194 for criteria for Osteogenic Stimulator
Refer to the LA.CP.MP.507c for criteria for Cochlear Implants and Replacements

Policy/Criteria

I. It is the policy of Louisiana Healthcare Connections 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:** Both of the following have been provided to the member/enrollee and/or caregiver, as applicable:[3]

1. Education regarding use of the device, with demonstrated understanding;
2. A trial of the requested device, with demonstrated ability to use it safely and effectively.

II. It is the policy of Louisiana Healthcare Connections that if *a medically necessary, lesser cost item exists and will suit the member/enrollee's medical needs, a higher cost item will be denied.*

III. It is the policy of Louisiana Healthcare Connections that If equipment is needed temporarily, it may be more cost effective to pay for the rental expenses of the equipment. Consideration will be given to the length of time the equipment is needed, to the total rental cost for that period, and the purchase price of the item. If the total cost of the rental exceeds the purchase price, the equipment will be purchased, rather than rented. For rental

reimbursement, the provider cannot charge for features on equipment not medically necessary by the enrollee's condition. (Please refer to the purchase vs rental section in Background).

IV. It is the policy of Louisiana Healthcare Connections that any accessories to a non-covered device are not covered and will not be reimbursed.

B. EQUIPMENT-SPECIFIC CRITERIA

BURN GARMENTS	CRITERIA	HCPCS
Burn garments [5,41]	Burn garments and stockings are approved only for severe burns and major vascular problems.[41] Burn garments are also considered medically with associated physical and/or occupational therapy when *all* of the following criteria are met: A. At risk of a post-burn contracture; B. The garment and physical and/or occupational therapies are being used with the intent of preventing the need for skin grafting or contractures as a result of hypertrophic scarring; C. Garment is requested by the PCP and/or the treating specialist.	A6501 A6502 A6503* A6504 A6505 A6506 A6507 A6508 A6509* A6510 A6511 A6512* A6513

CARDIAC EQUIPMENT	CRITERIA	HCPCS
Non-wearable external defibrillator with integrated ECG analysis [6]	Considered not medically necessary as it is primarily considered a safety device.	E0617*

Compression Therapy Equipment	Criteria	HCPCS
Non-pneumatic compression devices [7,8]	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*

Diabetes Care Equipment	Criteria	HCPCS
Blood glucose monitor with integrated voice synthesizer [7]	Medically necessary for member/enrollee with diabetes who are legally blind (best corrected visual acuity less than 20/200).	E2100*

DIABETES CARE EQUIPMENT	CRITERIA	HCPCS
Continuous Subcutaneous Insulin External Infusion Pumps[41]	Only internal insulin pumps requiring tubing and supplies are covered through the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) program. All other diabetic supplies and equipment are covered through the Louisiana Medicaid Pharmacy program (e.g. Cequr Simplicity™, Omnipod® and V-Go®.) Member/Enrollees must meet either **Criterion A OR B** as follows: Criterion A: The beneficiary has completed a comprehensive diabetes education program and has been on a program of multiple daily injections of insulin (at least three injections per day) with frequent self-adjustments of insulin dosages for at least six months prior to initiation of the insulin pump; and has documented an average frequency of glucose self-testing of at least four times per day during the two months prior to initiation of the insulin pump; and meets two or more of the following criteria while on the multiple daily injection regimen: 1) Glycosylated hemoglobin level (HbAlc) greater than 7.0 percent; 2) History of recurring hypoglycemia; 3) Wide fluctuations in blood glucose levels (regardless of A1C); 4) Demonstrated microvascular complications; 5) Recurrent severe hypoglycemia; 6) Suboptimal diabetes control (A1C exceeds target range for age); 7) Adolescents with eating disorders; 8) Pregnant adolescents; 9) Ketosis-prone individual; 10) Competitive athletes; and 11) Extreme sensitivity to insulin in younger children. Criterion B: The beneficiary with Type I diabetes has been on a pump prior to enrollment in Medicaid and has documented an average frequency of glucose self-testing of at least four times per day during the month prior to Medicaid enrollment. In addition to meeting Criterion A or B above, the beneficiary with diabetes must be insulinopenic per the updated fasting C-peptide testing requirement, or must be autoantibody positive (e.g. islet cell autoantibodies (ICA), glutamic acid decarboxylase (GAD65), the 40K fragment of tyrosine phosphatase (IA2), insulin autoantibodies (IAA), or zinc transporter 8 autoantibodies (ZnT8)). Updated fasting C-peptide testing requirement: 1. Insulinopenia (defined as fasting C-peptide level less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method); and 2. Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose of less than 225 mg/dl. NOTE: Levels only need to be documented once in the medical record. The pump must be ordered by a physician who has familiarity with continuous subcutaneous insulin infusion (CSII) and who works closely with a team of nurses, diabetes educators and dietitians who are knowledgeable in the use of CSII; the follow-up care of the beneficiary must be managed by a physician meeting these same requirements.	E0784 A4224 A4231

HEAT, COLD & LIGHT THERAPY EQUIPMENT	CRITERIA	HCPCS
Ultraviolet panel lights [11,12]	Medically necessary when meeting both of the following: A. Refractory psoriasis; B. MD justifies treatment at home versus alternate sites (e.g. outpatient department at hospital). Panel lights should be considered, if several discrete body areas can be treated individually. Note: Cabinet style lights should be reserved for extensive involvement of body surface area.	E0691* E0692* E0693* E0694*
Cold pad pump [13]	Considered not medically necessary for post-operative management as research does not indicate improved outcomes in pain or edema management with the use of cold compression therapy over the use of other treatments to include conservative treatment, cold therapy alone, compression therapy alone, etc.	E0236*

NEWBORN CARE EQUIPMENT	CRITERIA	HCPCS
Donor Milk[41]	Donor human milk is covered outpatient for use by medically vulnerable infants. Louisiana Healthcare Connections considers donor milk medically necessary when the following criteria are met: A. The enrollee is less than 12 months of age with one or more of the following conditions: 1. Post-surgical nutrition; 2. Organ transplantation; 3. Renal disease; 4. Short gut syndrome; 5. Malabsorption syndrome; 6. Feeding or formula intolerance; 7. Failure to thrive; 8. Inborn errors of metabolism; 9. Immunologic disorders; 10. Congenital heart disease or other congenital anomalies; or 11. Neonatal abstinence syndrome. B. The enrollee's caregiver is medically or physically unable to produce breast milk at all or in sufficient quantities, is unable to participate in breastfeeding despite optimal lactation support, or has a contraindication to breastfeeding; or the enrollee is medically; or physically unable to receive caregiver breast milk or participate in breastfeeding; and C. The enrollee's caregiver has received education on donor human milk, including the risks and benefits; and D. A bank accredited by, and in good standing with, the Human Milk Banking Association of North America supplied the donor human milk. Note: Prior authorization is not required for donor human milk. Donor human milk is, however, subject to post payment medical review.	T2101

Electric Breast Pumps[41]	An electric breast pump is a mechanical device powered by batteries or electricity that nursing mothers use to extract milk from their breasts. Louisiana Healthcare Connections considers personal-use, double, electric breast pumps a coverable item for nursing mothers. A new breast pump is covered for each viable pregnancy. The breast pump may be obtained at the gestational age of 32 weeks to expectant mothers who meet the criteria and intend to breastfed their infant. NOTE: Single, manual, and hospital-grade breast pumps are not covered items under Louisiana Medicaid. In order to be covered by Louisiana Healthcare Connections, a breast pump must meet these criteria: 1. Have an adjustable suction pressure rate with either written instructions or an automatic mechanism to prevent a suction greater than 250 mm Hg; 2. Be adaptable for simultaneous pumping of both breasts (double collection); 3. Automatically cycle with an adjustable variable cycling rate, typically 30 to 60 or more cycles per minute; 4. Include a battery option and adapter to be used as an alternate power source when electricity is not immediately available; 5. Breast shields (flanges) that are adjustable and flexible, or flanges that are available in several different sizes if rigid, including larger sizes; 6. Accessories necessary for pumping two breasts simultaneously for electric pumps; 7. At least two collection bottles with spill-proof standard size caps, that are bisphenol-A (BPA) and diethylhexyl phthalate (DEHP) free; and 8. Accessories and supplies must be compatible with the pump provided. Materials must be of durable quality for withstanding repeated boiling, washing and pumping use Louisiana Healthcare Connections will allow replacement of a breast pump older than three years and after expiration of manufacturer's warranty. Note: Prior authorization is not required. This electric breast pump is, however, subject to post payment medical review. Required documentation changes for electric breast pumps are outlined in bold below: ☐ A prescription from the prescribing physician for the electric pump; ☐ Documentation of education/training on breastfeeding by the prescribing physician, licensed breastfeeding practitioner, or healthcare professional; ☐ Documentation that Louisiana Medicaid has not purchased a breast pump within the past three years for the same delivery; and ☐ A completed Electric Breast Pump Request Form signed by the prescribing physician and the mother or her authorized representative.	E0603 E0604*

NEWBORN CARE EQUIPMENT	CRITERIA	HCPCS
	NOTE: Single, manual, and hospital-grade breast pumps are still not covered. Electric breast pump supplies will be available to the nursing mother once every 180 days. DME providers must obtain PA for replacement supplies. A.	
Human Milk Storage Bags[41]	Human milk storage bags are designed to safely store and protect expressed human milk for feeding a child. The following criteria will be applied for coverage of human milk storage bags: A. Prescription signed by prescribing physician; B. Documentation that enrollee is lactating (This can be included in the prescription or submitted separately); C. Storage bags are limited to 100 bags per month; and D. The Medicaid fee on file is for a one-month supply of storage bags	A4287

OTHER EQUIPMENT	CRITERIA	HCPCS
Enclosed Beds [14, 15, 16, 17,41]	Requests will be reviewed by a medical director and/or therapy advisor to determine medical necessity, based on all of the following: A. Standard bed or standard hospital bed must be unable to meet the positioning needs due to disability; B. Less intensive alternatives to improve the member's/enrollee's safety have been tried and ruled out (to include documentation of why they could not meet medical needs). Considerations include, but are not limited to: 1. Rail protectors; 2. Mattress placed on the floor; 3. Removal of all safety hazards; 4. Bed alarms; 5. Video/audio monitors; 6. Child protection devices such as locks on doors, windows, cabinets, furniture anchors, gates at steps and doors; 7. Physician-directed medication to address seizures, behaviors and sleep; 8. Environmental modification to encourage calming behaviors and sleep; 9. Established routines addressing sensory needs and/or behavior modification to assist with improved naptime or night time behaviors and sleep; C. Medical diagnosis to include, but not limited to: 1. Cerebral palsy; 2. Developmental delay; 3. Genetic or neurological disorder that would cause vertigo, disorientation, or uncontrolled movement of the body or extremities; 4. Uncontrolled seizure disorder; 5. Severe behavior disorder; D. Healthcare provider evaluation (typically from an occupational or physical therapist) to include:	E0316* E1399 E0328 or E0329 (when combined with E0316* or E1399)

OTHER EQUIPMENT	CRITERIA	HCPCS
	1. Specific information on functional status; 2. Documentation of home evaluation; 3. Documentation of education provided to caregivers on proper use of a bed enclosure, noting: they are to be used for medical support, improved safety transitioning in and out of the bed, and improved safety while sleeping; E. Name of and invoice for the bed or enclosure being requested. Note: • Enclosed beds should not be used as a discipline measure or as a restraint during times of high agitation or aggression. To limit sensory deprivation, enclosed beds should be used at night for sleeping and only for short rests or naps during the day. • When the above criteria is met, only basic beds will be considered medically necessary. Upgrades for aesthetic purposes or upgrades that do not meet the rules for durable medical equipment (DME) would 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	Requests should have a physician or therapy advisor review to determine medical necessity. Medically necessary with therapist evaluation and ongoing treatment and *all* of the following criteria are met: A. Commercial device must be unable to meet the positioning needs due to height, weight, or disability; B. Other positioning devices in the home must be reviewed to ensure a duplication of devices is not already in place.	T5001* E1399
Specialized supply or equipment	Requests for not otherwise specified supplies or miscellaneous equipment codes will have a physician or therapy advisor review to determine medical necessity.	E0240 T2028* T2029* K0108 K0739 E1399 (For wheelchair seating refer to LA.CP.MP.99)
ROMTech® PortableConnect® Device [18]	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
Special Needs Car Seat[41]	A special needs car seat is designed for safe transport of the moderately to severely disabled child. A special needs car seat is covered when all of the following criteria apply: 1. Special needs car seat must be medically necessary and appropriate. The physician must submit a full description of the enrollee's postural condition including head and trunk control and height and weight. Weight must be between 20-105 pounds; 2. Enrollee's condition is of such severity that he/she cannot be safely transported using a standard car seat, car seat belts, or modified vest travel restraints;	E1399 T5001*

OTHER EQUIPMENT	CRITERIA	HCPCS
	3. There is expected long-term need for the car seat; and 4. Special needs car seat must accommodate at least 36 months growth. If applicable, the car seat must be equipped with leg extensions to allow for growth over the 36-month period. Consideration must be given to the manufacturers' weight limitations.	
Blood Pressure Devices[41]	Medically necessary when used for one of the following indications: A. Beneficiaries receiving hemodialysis in the home setting; B. Pregnant beneficiaries with a diagnosis of chronic hypertension C. Beneficiaries under the age of 21 years diagnosed with hypertension or hypotension. Only electronic blood pressure devices may be covered for enrollees under the age of 21 years and for those who are pregnant.	A4660 A4670 A4663

PROSTHETICS AND ORTHOTICS EQUIPMENT	CRITERIA	HCPCS
Cervical traction equipment [19]	Medically necessary when all of the following are met: A. The appropriate use of the selected home cervical traction device has been demonstrated and was tolerated; B. One of the following: 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 collar will be reviewed by a licensed physical or occupational therapist. Documentation accompanying the request must state reason why pre-fabricated collar not adequate.	L0170 L0190 L0200
Spinal Orthotics	Requests for spinal orthotics will be reviewed using relevant nationally recognized decision support tool criteria for similar codes.	L0700, L0710, L0999, L1000 L1001, L1005*
Hip orthotics [20]	Medically necessary when ordered by an orthopedist for treatment of, or postoperatively for any of the following: A. Total hip arthroplasty; B. Hip labral tear; C. Hip disorders in children when used to stabilize the hip and/or to correct and maintain hip abduction. Lateral replacements due to growth are considered medically necessary in pediatrics for diagnoses such as hip dysplasia with Charcot-Marie-Tooth disease. 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 orthopedist for use in the treatment for Legg-Calvé-Perthes disease in children.	L1700 L1710 L1720 L1730 L1755

PROSTHETICS AND ORTHOTICS EQUIPMENT	CRITERIA	HCPCS
Microprocessor-controlled knee-ankle-foot orthoses (KAFO)[21]	There is insufficient clinical evidence to support the effectiveness of electronic KAFOs over the use of standard KAFOs.	L2006*
Hip-knee-ankle-foot orthotics (HKAFO)	Requests for HKAFO orthotics will be reviewed on a case by case basis.	L2050 L2060 L2090
Orthotic components	Requests for orthotic components listed will be reviewed using relevant nationally recognized decision support tool criteria for similar codes.	L2570 L2580 L2627 L2628
Foot orthotics, custom	Medically necessary for arch, heel, or other foot pain when indicated by both of the following: A. Presence of at least one of the following conditions: 1. Diplegic cerebral palsy; 2. Juvenile idiopathic arthritis; 3. Pes cavus (high arch); 4. Rheumatoid arthritis; 5. Plantar fasciitis when symptoms have been present for 3 months or more; 6. Posterior tibial tendon dysfunction in adult, as indicated by one or more of the following: a. Stage I disease (tenosynovitis without deformity); b. Stage II disease (flexible and passively correctable deformity); B. Documentation that adjustment of activities, anti-inflammatory medications, prefabricated orthotics, physical therapy intervention and stretching of calf muscles and plantar surface have failed to improve symptoms.	L3000 L3001 L3002 L3003 L3010 L3020 L3030 L3031* L3070 L3080
Orthopedic footwear[41]	**Orthopedic shoes and correction** are considered medically necessary when ALL of the following are met:: A. Needed to protect gains from surgery or casting (qualifies as an emergency prior authorization (PA); B. To prevent clinical deterioration of the foot as with enrollees with severe diabetes; C. Medically necessary to prevent clinical deterioration of the foot as with beneficiaries with severe peripheral vascular disease; or D. Attached to braces. **Shoes for diabetics:** Special shoes and corrections considered medically for diabetics. Coverage is provided for extra-depth or custom molded shoes, as well as inserts or modifications, when the physician: A. Documents that the member/enrollee has diabetes; B. Certifies that the beneficiary is being treated under a comprehensive plan of care for their diabetes and that they need therapeutic shoes; and C. Documents that the beneficiary has one or more of the following conditions: a. previous amputation of the foot or part of the foot due to complications that resulted from diabetes; b. history of previous foot ulceration;	L3201, L3202, L3203, L3204, L3206, L3207, L3208, L3209, L3211 L3212, L3213, L3214, L3215, L3216, L3217, L3219, L3221, L3222, L3224, L3225, L3230, L3250, L3251, L3252, L3253, L3254, L3255, L3265, L3257*, L3260, L3230

PROSTHETICS AND ORTHOTICS EQUIPMENT	CRITERIA	HCPCS
	c. Pre-ulcerative callus formation, or peripheral neuropathy with a history of callus formation d. Foot deformity; or e. Poor circulation Custom footwear: In addition to supporting the medical necessity of foot orthotics, information must be provided to indicate why prefabricated devices cannot meet the need/why custom devices are necessary.	
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; Coverage is based on contract guidelines for replacement DME.	L3904 L4000 L4010 L4020 L4030 L4205
Prosthetics and additions: Upper Extremity and Myoelectric	Requests for upper extremity and myoelectric prosthetics will be reviewed by a medical director and/or therapy advisor when the request specific criteria in A. or B. is met: D. Initial request meets all of the following: 1. Medical record documentation supports all of the following: a. Functional needs cannot be met with activity modification and compensatory techniques; b. Requested prosthesis is anticipated to meet functional needs; 2. 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; 3. 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. E. 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; 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;	L6000, L6010, L6020, L6026, L6050, L6055, L6100, L6110, L6120, L6130, L6200, L6205, L6250, L6300, L6310, L6320, L6350, L6360, L6370, L6380*, L6382*, L6384*, L6386*, L6388*, L6400, L6450, L6500, L6550, L6570, L6580, L6582, L6584, L6586, L6588, L6590, L6623, L6624, L6625, L6628, L6638*, L6646*, L6647*,L6648*, L6689, L6690, L6692, L6693, L6704, L6707, L6708, L6709, L6711, L6712, L6713, L6714, L6715*, L6721, L6722, L6885, L6895, L6900, L6905, L6910, L6915, L6920, L6930, L6940, L6950, L6960, L6965, L6970, L6975, L7040, L7170, L7185, L7186, L7405, L7499

PROSTHETICS AND ORTHOTICS EQUIPMENT	CRITERIA	HCPCS
	c. Functional level continues to be appropriate for prosthesis and components in use; d. Replacement with same or similar prosthesis and/or components; e. Updated practitioner's order on file or order not required (for loss or irreparable damage).	
Prosthetics and additions: Lower Extremity	Requests for these prosthetics and additions will be reviewed by a licensed physical or occupational therapist.	L5990
Breast Prosthetics[22, 23, 24]	Medically necessary post-masectomy or for treatment of gender dysphoria and documentation supports that prefabricated prosthetics will not suffice.	L8030 L8035*
MyoPro® Orthosis[25]	Not medically necessary, as there is insufficient evidence in published peer-reviewed literature to support the use of this technology over other technologies and currently available alternatives.	L8701* L8702*

PUMPS	CRITERIA	HCPCS
Ambulatory infusion pump [26,27]	Medically necessary when used for one of the following indications: A. Iron Poisoning: administration of deferoxamine for the treatment of acute iron poisoning and iron overload; B. Chemotherapy for liver cancer: treatment of primary hepatocellular carcinoma or colorectal cancer where this disease is unresectable; OR, where the patient refuses surgical excision of the tumor; C. With opioid drugs when used for intractable pain caused by cancer. D. To administer a drug considered reasonable and necessary by either: 1. Prolonged infusion of at least 8 hours because of proven improved clinical efficacy (i.e., proven or generally accepted to have significant advantages over intermittent bolus administration regimens or infusions lasting less than 8 hours) or 2. Intermittent infusion, each episode of infusion lasting less than 8 hours, and both of the following criteria: a. Does not require the return to the physician's office prior to the beginning of each infusion. b. Strictly controlled rate of infusion is necessary because systemic toxicity or adverse effects of the drug are unavoidable without infusing it at a controlled rate as indicated in the Physician's Desk Reference, or the U.S. Pharmacopeia Drug Information. c. Note: An infusion pump used to deliver nutritional requirements. Please refer to *LA.CP.MP.163 TPN IDPN*.	E0780* E0781
Gastric suction pump, home model [28]	Medically necessary for home use for gastric suction due to inability to empty gastric secretions through normal gastrointestinal functions.	E2000*
Implantable infusion pumps [26]	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	E0782* E0783 E0785 E0786

PUMPS	CRITERIA	HCPCS
	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 intrathecal to treat chronic intractable spasticity in patients unresponsive to less invasive medical therapy including both of the following: a. A 6-week trial of noninvasive methods, such as oral anti-spasmodic drugs, that failed to adequately control the spasticity or produced intolerable side effects; b. Prior to pump implantation, there has been a favorable response to a trial of intrathecal dose of the anti-spasmodic drug; 3. Opioid drugs for treatment of chronic intractable pain- see LA.CP.MP.173 Implantable Intrathecal Pain Pumps; 4. Other uses when all of the following are met: a. The drug is reasonable and necessary for the treatment of the individual; b. It is medically necessary that the drug be administered by an implanted infusion pump. The infusion pump has been FDA-approved for the drug being administered and the purpose for which it is being administered; B. None of the following contraindications to implantation of an infusion pump: 1. Known allergy or hypersensitivity to the drug being used (e.g., oral baclofen, morphine, etc.); 2. Active infection; 3. Body size insufficient to support the weight and bulk of the device; 4. Presence of another implanted programmable device; 5. Heparin or insulin is the drug intended for administration.	
Parenteral pump for medication administration [28]	Medically necessary for uninterrupted parenteral administration of medication via pump.	K0455
Disposable (elastomeric) Infusion Pumps and IV supplies[41]	A. Medically necessary when one of more of the following criteria are met: 1. Device will be used for short-term antibiotic infusion therapy (less than 30-day duration); 2. Device is expected to increase beneficiary compliance with antibiotic therapy; 3. Caregiver cannot administer the antibiotic by pump; 4. To avoid hospitalization of an immuno-compromised beneficiary, which may increase the risk of further infection; or 5. Outside of antibiotic therapy, the beneficiary has no need for hospitalization. 6. Documentation includes all of the following: a) Information on the underlying diagnosis or condition; b) Physician's order and documentation supporting medical necessity; and c) Name of the antibiotic, dosage, the duration of therapy, and the frequency of administration. B. Disposable (Elastomeric) Infusion Pumps are not covered when the antibiotic being administered: 1. Is not considered medically necessary to the treatment of the beneficiary's illness; 2. Is used for pain management;	A4221 A4222 A4300* A4301* A4305 A4306

PUMPS	CRITERIA	HCPCS
	3. Exceeds the frequency or duration ordered by the physician; 4. Is a chemotherapeutic agent; or 5. Is not FDA-approved. C. The following standards will be considered when determining medical necessity of IV supplies for use with disposable (Elastomeric) infusion pumps: 1. The aseptic technique is acceptable for IV catheter insertion and site care; 2. Nonsterile gloves are acceptable for the insertion of a peripheral IV catheter and for changing any IV site dressing; 3. Sterile technique may be medically necessary. Examples of medical necessity include, but are not limited to, a beneficiary who is immuno-compromised; 4. Peripheral IV site is rotated at least weekly, but no more frequently than every 72 hours; 5. IV administration set (with or without dial flow regulator), extension set (with or without dial flow regulator), and any add-on devices are changed every 72 hours; or One IV access catheter is used per insertion.	
Respiratory Suction Pumps[19,41]	Purchase of a respiratory suction pump may be considered for beneficiaries who have difficulty raising and clearing secretions secondary to: 1. Cancer or surgery of the throat or mouth; 2. Dysfunction of the swallowing muscles; 3. Enrollee is in an unconscious or obtunded state; or 4. Tracheostomy. Suction machines may be considered only if the machine specified is medically required and appropriate for home use without technical or professional supervision. Accessories and supplies may be considered when they are medically necessary and used with a medically necessary suction pump. Sterile suction catheters are considered to be medically necessary only for tracheostomy suctioning	E0600 A4605 A4606 A4624 A4628 A7000 A7001 A7002 A7047

RESPIRATORY EQUIPMENT	CRITERIA	HCPCS
Nebulizer, ultrasonic [31]	Not medically necessary, as it provides no clinical advantage over use of a small-volume nebulizer (E0574) and compressor.	E0575*
IPPB & supplies	Medically necessary for member/enrollee with respiratory disease when an incentive spirometer is ineffective.	E0500* E0550
Oximeter [32]	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	E0445

RESPIRATORY EQUIPMENT	CRITERIA	HCPCS
	D. Other conditions not listed above	
Oxygen tent [32]	Medically necessary when the ability to breathe is impaired and for whom supplemental oxygen is required.	E0455*
Intrapulmonary percussive ventilation devices (Volara™, Percussionaire- TRUE-IPV®)[33,34,35,36]	Current evidence does not support the effectiveness of intrapulmonary percussive ventilation (IPV).	E1399
Humidifiers[41]	Humidifiers are medically necessary if CPAP, bi-level positive airway pressure (BIPAP), or oxygen therapy has been prescribed for use in connection with medically necessary DME for purposes of moisturizing the oxygen. Humidifiers are used to prevent dry mouth, stuffy, congested, or runny nose and dry, burning, itching, or bleeding nose.	E0555 E0560 E0561 E0562
Apnea Monitors[41]	Requests for apnea monitors are considered medically necessary when meeting one of the following (A-D): A. Apnea of prematurity- sudden cessation of breathing that lasts for at least 20 seconds or is accompanied by bradycardia or oxygen desaturation cyanosis in an infant younger than 37 weeks gestational age. B. Apnea of infancy- an unexplained episode of cessation of breathing for 20 seconds or longer or a shorter respiratory pause associated with bradycardia, cyanosis, pallor, and/or marked hypotonia. The term apnea of infancy generally refers to infants with gestational age of 37 weeks or more at the onset of apnea. Bradycardia for infants is defined as a resting heartbeat of less than 80 beats per minute at one month of age, less than 70 beats per minute at 2-3 months of age, and less than 60 beats per minute at three months of age or older C. Monitoring for subsequent siblings of Sudden Infant Death Syndrome (SIDS) victims less than eight months of age 1. May be approved for a maximum of eight months D. Following an Apparent Life-Threatening Event (ALTE) 1. (ALTE) is characterized by some combination of central apnea or occasionally obstructive apnea, color change (usually cyanotic or pallid but occasionally erythematous or plethoric), and a marked change in muscle tone (usually marked limpness), choking, or gagging, which required vigorous intervention or cardiopulmonary resuscitation (CPR). Note: Children requiring home oxygen therapy, central hypo-ventilator, tracheotomy, and/or home ventilator support will be considered on a case-by-case basis. Note: Approval following apneic episodes resistant to treatment, such as Ondine's Curse, shall be considered on a case-by-case basis.	E0619 A4556 A4557

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

WALKERS	CRITERIA	HCPCS
Walker, standard [37, 41]	Requests for standard walkers are considered medically necessary when meeting all of the following: A. Prescribed by a physician for a beneficiary with a medical condition that impairs ambulation; B. Member/enrollee has a potential for ambulation; and C. Member/enrollee has a need for greater stability and security than can be provided by a cane or crutches.	E0130 E0135 E0141 E0143
Walker, heavy duty [37,]	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
Enhancement Accessories[41]	Enhancement accessories of walkers, canes and crutches not medically necessary. An enhancement accessory does not contribute significantly to the therapeutic function of the walker, cane or crutch. It may include, but is not limited to style, color, hand operated brakes (other than those described in the section above on heavy duty, multiple braking system, variable wheel resistance walker), seat attachments, tray attachments, or baskets (or equivalent).	E0153 E0154 E0155 E0156 E0157 E0158 E0159 E1399

WHEELCHAIRS	CRITERIA	HCPCS
Manual wheelchair [38]	Initial request is 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 is medically necessary when documentation supports one of the following:	E1037*, E1038, 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,

WHEELCHAIRS	CRITERIA	HCPCS
	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 liftetime 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; 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.	E1260, E1270, E1280, E1285, E1290, E1295
Custom Manual Wheelchairs[41]	A custom manual wheelchair is constructed to the specific body measurements and medical needs of the Member/Enrollee. General criteria for a custom manual wheelchair include inability to walk and propel a standard wheelchair. In addition to the required documentation needed for all PA requests, PA requests for a custom manual wheelchair must include: A. Physician prescription for a custom manual wheelchair that includes: 1. Documentation the Member/Enrollee is unable to propel a standard wheelchair; and 2. Diagnosis or limitations to justify the need for a custom manual wheelchair; and B. **Custom Wheelchair** form with medical justification for the requested wheelchair and **ALL** modifications. All medical justification must be documented on the form. Indicating, "*See attached*" in a field on the form is not sufficient. Attaching documentation to the form without completing the fields on the form related to that documentation may result in denial of the PA. Note: Backup chairs, either motorized or manual, will be denied as not medically necessary.[53]	E1220, E1225, E1226, E1227, E1228, E1229*, E1296, E1297, E1298, K0008*, K0009
Custom Motorized Wheelchair[41]	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;	E1239*, K0013*, K0014, K0898

WHEELCHAIRS	CRITERIA	HCPCS
	Provision of the feature will improve functional independence with an activity, such as but not limited toThe term ***motorized*** shall have the same meaning as power, electric or any means of propulsion other than manual. A motorized wheelchair must be medically necessary. Requests for custom motorized wheelchairs are medically necessary when reviewed by a physician or therapy advisor and when meeting the following criteria: A. Member/Enrollee's condition is such that the requirement for a motorized wheelchair is long term (at least six months). B. Is not functionally ambulatory. 'Not functionally ambulatory' means the Member/Enrollee's ability to ambulate is limited such that without use of a wheelchair, he/she would otherwise be generally bed or chair confined; C. Unable to operate a wheelchair manually due to severe weakness of the upper extremities due to a congenital or acquired neurological or muscular disease/condition or is unable to propel any type of manual wheelchair because of other documented health problems; and D. Capable of safely and independently operating the controls for a motorized wheelchair and can adapt to or be trained to use a motorized wheelchair effectively All wheelchairs and modifications required to meet the needs of a particular Member/Enrollee are subject to PA. The PA request must include documentation on the **Custom Wheelchair** form of medical justification for the requested wheelchair and modification. Prior authorization will be made for only one wheelchair at a time. In addition to the required documentation needed for all PA requests, PA requests for motorized wheelchair must include: A. Physician's prescription for a motorized wheelchair; B. Medical documentation from a physician and/or physical/occupational therapist is required to support the provisions set forth regarding Member/Enrollee criteria as noted above; C. **Custom Wheelchair** form, seating evaluation performed, signed and dated by the physical therapist or occupational therapist that performed the seating evaluation. The seating evaluation shall: 1. Indicate the appropriateness of the specific wheelchair requested and all modifications and/or attachments to the specific wheelchair and its ability to meet the Member/Enrollee's long term medical needs. Options that are primarily beneficial in allowing the Member/Enrollee to perform leisure or recreational activities are not covered; 2. Member/Enrollee's diagnosis or condition is such that a motorized wheelchair is medically necessary; and 3. Therapist and Physician has seen the seating evaluation and motorized wheelchair recommendation. D. Documentation indicating that the Member/Enrollee is capable of safely and independently operating the controls for a motorized wheelchair and can adapt to or be trained to use the motorized wheelchair effectively. It is not sufficient for a Medicaid provider of motorized wheelchairs to indicate that a Member/Enrollee is capable of safely operating the controls for a motorized wheelchair and can	

WHEELCHAIRS	CRITERIA	HCPCS
	adapt to or be trained to use it effectively. Such documentation shall include: 1. Signed and dated statement from the Member/Enrollee's physician and/or, physical/occupational therapist that he/she has determined that the Member/Enrollee has the cognitive, motor and perceptual abilities needed to safely operate the controls of a motorized wheelchair. This statement -must be verified by the notes and recommendation of the physician, physical therapist or occupational therapist making such statement; and 2. Signed and dated statement from the Member/Enrollee's physician or physical/occupational therapist that he or she has determined that the Member/Enrollee can adapt to or be trained to use the motorized wheelchair effectively. This statement must be verified by the notes and recommendation of the physician, physical therapist or occupational therapist making such statement. Note: Backup chairs, either motorized or manual, will be denied as not medically necessary.[53] D.	
Power seat elevator on power wheelchair[39]	Medically necessary as a component on a power wheelchair when all of the following are met: E. A licensed, certified medical professional (i.e. physical or occupational therapist) is involved with the assessment, prescription, trials and training of equipment; F. Adequate cognitive function to safely use the seat elevating feature; G. A clear functional need for the feature is indicated; H. 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)[40]	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	Requests for wheelchair or other DME repairs specifically using codes K0108, K0739, or E1399, are medically necessary when reviewed by a physician or therapy advisor and when meeting the following criteria: A. 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). All repairs and modifications of wheelchairs must be completed within one month, unless there is a justifiable reason for a delay.[53] One month's rental for a standard manual wheelchair is considered medically necessary if a member/enrollee owned wheelchair is being repaired.[32]	K0108 K0739 E1399

WOUND CARE	CRITERIA	HCPCS
Whirlpool tub	Considered not medically necessary.	E1310*

Coding Implications
Codes referenced in this clinical policy are for informational purposes only and may not support medical necessity. 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

Purchase versus Rental
If equipment is needed temporarily, it may be more cost effective to pay for the rental expenses of the equipment. Consideration will be given to the length of time the equipment is needed, to the total rental cost for that period, and the purchase price of the item. If the total cost of the rental exceeds the purchase price, the equipment will be purchased, rather than rented. For rental reimbursement, the provider cannot charge for features on equipment not medically necessary by the enrollee's condition.

Purchasing Guidelines – Equipment
Louisiana Healthcare Connections requires that all DME suppled to eligible beneficiaries must come with a warranty from the provider that lasts a minimum of one year. Providers who make or sell prosthetic or orthotic items must provide a warranty which lasts at least 90 days, from the time the item is delivered to the enrollee. If the items fails to work during those 90 days, , the manufacturer or dealer must repair or replace the item. Louisiana Healthcare Connections does not reimburse for costs associated with replacement parts or repairs to the equipment. Louisiana Healthcare Connections reimbursement includes:

1. All elements of the manufacturer's warranty;

2. All routine or special equipment servicing, to the extent the same servicing is provided to non-Medicaid persons;

3. All adjustments and modifications needed to make the item safe, useful and functional for the enrollee during the entire first year (including customized wheelchairs);

4. Delivery, set-up and installation of the DME by trained and qualified provider staff, in the area of the home where the equipment will be used or the appropriate room within the home;

5. Adequate training and instruction provided to the enrollee or the enrollee's responsible caregiver by the provider's trained and qualified staff, in a language understood by the enrollee or caregiver regarding the manufacturer's recommendations for the safe, sanitary, effective, and appropriate use of the item; and

6. Honoring the required one-year provider warranty for all requests or prescriptions requesting equipment repair made on or before the 366th day of service. Providers cannot disregard an

enrollee's requests for warranty equipment repairs or modifications and may not delay needed repairs or modifications, otherwise permitted by DME policy, until the provider's or manufacturer's warranty has expired.

Provider Responsibilities – Rental Equipment
When rental equipment is furnished to an enrollee the provider must:

1. Ensure and maintain documentation on file that the equipment is routinely serviced and maintained by qualified provider staff, as recommended by the product manufacturer;

2. Repair, or replace all expendable parts or items, such as masks, hoses, tubing and connectors, and accessory items necessary for the effective and safe operation of the equipment;

3. Substitute similar equipment at no additional cost to Louisiana Healthcare Connections if the equipment becomes broken because of normal use while the original rental equipment is being repaired;

4. Replace equipment that is beyond repair at no additional charge and maintain documentation of the replacement;

5. Maintain documentation that is signed and dated by both the provider and the enrollee or enrollee's responsible caregiver at the time of delivery, which attests to the fact that instruction has been provided by trained and qualified provider staff to the enrollee or caregiver regarding the enrollee's or caregiver's responsibility for cleaning the equipment and performing the general maintenance on the equipment, as recommended by the manufacturer; and

6. Maintain documentation that is signed and dated by both the provider and the enrollee or enrollee's responsible caregiver, which attests that the enrollee or the caregiver was provided with the manufacturer instructions, servicing manuals, and operating guides needed for the routine service and operation of the specific type or model of equipment provided.

Limitations for Replacement of Equipment
Louisiana Healthcare Connections will not replace equipment that is lost, destroyed or damaged as a result of misuse, abuse, neglect, loss, or wrongful disposition of equipment by the enrollee, the enrollee's caregiver(s), or the provider. At a minimum, examples of equipment misuse, abuse, neglect, loss or wrongful disposition by the enrollee, the enrollee's caregiver, or the provider include, but are not limited to the following:

1. Failure to clean and maintain the equipment as recommended by the equipment manufacturer;

2. Failure to store the equipment in a secure and covered area when not in use; and

3. Loss, destruction or damage to the equipment caused by the malicious, intentional or negligent acts of the enrollee, the enrollee's caregiver, or the provider.

If equipment is stolen or destroyed in a fire, the provider must obtain, in a timely manner, a completed police or insurance report that describes the specific medical equipment that was stolen or destroyed. The police or insurance report must be submitted with the new PA request.

Louisiana Healthcare Connections may replace equipment when the enrollee's medical necessity changes. The provider must submit the documentation required to justify the purchase of the replacement equipment.

Equipment Maintenance and Repair
Louisiana Healthcare Connections will reimburse for the maintenance and repair of equipment only when the following
conditions are met:

1. Equipment is covered by Louisiana Healthcare Connections;

2. Equipment is the personal property of the enrollee;

3. Item is still medically necessary;

4. Equipment is used exclusively by the enrollee;

5. No other payment source is available to pay for the needed repairs;

6. Equipment damage is not due to misuse, abuse, neglect, loss or wrongful disposition by the enrollee, the enrollee's caregiver, or the provider (see examples of misuse, abuse, neglect, loss or wrongful disposition under "Limitations for Replacement of Equipment" above);

7. Equipment maintenance is performed by a qualified technician;

8. Maintenance is not currently covered under a manufacturer's or provider's warranty agreement; and

9. Maintenance is not performed on a duplicate type of item already being maintained for the enrollee during the maximum limit period.

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	Effective Date
Converted corporate to local policy.	12/20		
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 LA.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." Added "and may not support medical necessity" to coding implications" Reorganized Standing Frame criteria and required that replacement requests also meet existing criteria for the initial request. For initial request under 18, added "and one of the following: Developmental delay in ambulation and ≥ 18 months of age; Documented neurological or neuromuscular impairments and ≥ 1 year of age." Required that documentation supports meeting height and weight requirements, alert and responsive to stimuli, no contraindications to standing program, and caregiver trained, available, and able to safely assist. Removed requirement for "able to tolerate upright position." Added informational note. 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 LA.CP.MP.99 for wheelchair seating in Specialized supply or Equipment section.	5/21	4/14/22	
Added policy clarification in the description section. Removed cardiac event monitor (E0616) criteria from cardiac equipment section of policy and moved to LA.CP.MP.243 Implantable Loop Recorders. Removed invasive home ventilator criteria (E0465) which is now in LA.CP.MP.184c Home Ventilators. Added statement that current evidence does not support the effectiveness of intrapulmonary percussive ventilation (E1399). Updated policy statement in I. and added general criteria I.A.1. and I.A.2. Removed	4/23		

Reviews, Revisions, and Approvals	Revision Date	Approval Date	Effective Date
ambulatory assist products and updated I.B. policy table. Retired gait trainers and standing frame criteria, defer to standard IQ criteria. Removed pneumatic compression device criteria. Added "one month's rental for a standard manual wheelchair is considered medically necessary if a member/enrollee owned wheelchair is being repaired" to wheelchair repair. Added foot orthotics, custom criteria and codes. Added criteria section for apnea monitor, blood pressure device, glucometer, humidifiers, power wheelchair (custom), respiratory suction pump, special needs car seat. Added "Walkers" section. Revised cervical traction criteria and coding. Revised Orthopedic Footwear criteria and coding. Renamed "Newborn Care Equipment section" to "Breast Milk and Supplies" and added criteria for donor milk, and milk storage bags. Updated criteria and coding for electric breast pump. Removed male vacuum erection device as it is non-covered. Added clarification regarding non-covered codes. Minor verbiage and formatting updates with no impact on criteria. References reviewed, updated, and reformatted. Internal specialist review.			
Updated criteria for Custom Wheelchairs.	6/23	8/24/23	
Removed "Diabetes Care Equipment" table and Updated page number table. Removed retired policies: 502c and 519c from Description.	9/23		
Added Section IV to policy and Criteria section. Added Diabetes Care Equipment table. Updated codes and non-covered codes. Included major vascular problems to Burn Garments criteria. Note added to ambulatory infusion pumps regarding use for TPN.	2/24	4/18/24	
Rearranged order and formatting without changes to criteria. Updated name to Newborn Care Equipment. Added new criteria section titled Lumbar-Sacral Orthotics (LSO) and included codes L0450, L0452, L0454, L0455, L0456, L0457, L0458, L0460, L0462, L0464, L0466, L0467, L0468, L0469, L0470, L0472, L0480, L0482, L0484, L0486, L0488, L0490, L0491, L0492, L0621, L0622, L0623, L0624, L0625, L0626, L0627, L0628, L0629, L0630, L0631, L0632, L0633, L0634, L0635, L0636, L0637, L0638, L0639, L0640, L0643, L0648, L0649, L0650, L0651, L0700, L0710, L0999, L1000, L1001, L1005. Renamed original "Spinal Orthotics" criteria "Other Spinal Orthotics". Updated manual wheelchair initial request criteria A., A.2. and 4., B.1. and 2., and removed C. Reformatted and updated manual wheelchair replacement request criteria. Deleted codes E1091 and K0009. Added coverage and criteria on disposable (Elastomeric) infusion pumps per IB 24-34. Reviewed by internal specialist. References reviewed and updated. Added Breast prosthetics for post mastectomy and codes. Included new required documentation for	10/24	1/27/24	

Reviews, Revisions, and Approvals	Revision Date	Approval Date	Effective Date
electric breast pump per IB 24-7. All codes reviewed and updated for coverage. References reviewed and updated.			
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. Removed all codes that do not require prior auth and reviewed on nationally recognized clinical decision support tools,InterQual. References reviewed and updated.	2/25	5/13/25	6/14/25
Annual Review. Reference reviewed and updated.	04/26	7/7/26	8/7/26

References

1. National coverage determination: Durable medical equipment (DME) reference list (280.1). Centers for Medicare and Medicaid Services website. https://www.cms.gov/medicare-coverage-database/search.aspx. Published May 16, 2023. Accessed September 4, 2024.
2. Local coverage article. Knee orthoses – policy article (A52465). Centers for Medicare & Medicaid Services website. http://www.cms.hhs.gov/mcd/search.asp. Published October 1, 2015 (revised January 23, 2024). Accessed October 15, 2024.
3. DMEPOS quality standards. Centers for Medicare & Medicaid Services website. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/DMEPOSQuality/DMEPOSQualBooklet-905709.html. Published December 2022. Accessed September 23, 2024.
4. Medicare Claims Processing Manual. Chapter 20 – Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). Centers for Medicare & Medicaid Services website. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c20.pdf#:~:text=)%20Usually%20this%20is%20the%20least%20costly,a%20more%20expensive%20item%20may%20be%20medically. Published March 28, 2024. Accessed October 29, 2024.
5. Local coverage article. Surgical dressings (A54563). Centers for Medicare & Medicaid Services website. http://www.cms.hhs.gov/mcd/search.asp. Published October 1, 2015 (revised January 1, 2024). Accessed September 4, 2024.
6. Rea TD, Eisenberg MS. Automated external defibrillators. UpToDate. http://www.utdol.com. Published March 5, 2024. Accessed September 6, 2024.
7. National coverage determination. Pneumatic compression devices (280.6). Centers for Medicare & Medicaid Services website. http://www.cms.hhs.gov/mcd/search.asp. Published January 14, 2002. Accessed September 6, 2024.

8. Evidence analysis research brief: Dayspring (Koya Medical Inc.) for treatment of lymphedema. Hayes. www.hayesinc.com. Published March 27, 2023. Accessed September 6, 2024.
9. National coverage determination. Home blood glucose monitors (40.2). Centers for Medicare & Medicaid Services website. http://www.cms.hhs.gov/mcd/search.asp. Published June 19, 2006. Accessed September 6, 2024.
10. Local coverage determination: Glucose Monitors (L33822). Centers for Medicare and Medicaid Services website. https://www.cms.gov/medicare-coverage-database/search.aspx. Published October 1, 2015 (updated April 1, 2024). Accessed September 10, 2024.
11. National coverage determination. Treatment of psoriasis (250.1). http://www.cms.hhs.gov/mcd/search.asp. Published January 1, 1966. Accessed September 6, 2024.
12. Elmets CA, Lim HW, Stoff B, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy. J Am Acad Dermatol. 2019; 81(3):775-804.
13. Local coverage determination: Heating pads and heat lamps (L33784). Centers for Medicare and Medicaid Services website. https://www.cms.gov/medicare-coverage-database/search.aspx. Published October 1, 2015 (updated January 1, 2020). Accessed September 10, 2024.
14. Restraint and seclusion - Enclosure beds, side rails and mitts. The Joint Commission website. https://www.jointcommission.org/standards/standard-faqs/critical-access-hospital/provision-of-care-treatment-and-services-pc/000001668/. Published April 11, 2016 (updated July 20, 2022). Accessed September 23, 2024.
15. Enclosure bed: A protective and calming restraint. American Nurse Association website. https://www.myamericannurse.com/use-enclosure-beds/. Published January 13, 2015. Accessed September 23, 2024.
16. State Operations Manual Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals. Centers for Medicare & Medicaid Services. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf. Published May 21, 2004 (revised April 19, 2024). Accessed September 23, 2024.
17. National coverage determination: Hospital beds (280.7). Centers for Medicare and Medicaid Services website. http://www.cms.hhs.gov/mcd/search.asp. Published January 1, 1966. Accessed September 23, 2024.
18. Evolving evidence review: ROMTech/PortableConnect (ROM Technologies Inc.) for telerehabilitation following total knee arthroplasty. Hayes. https://www.hayesinc.com/. Published August 15, 2024. Accessed September 23, 2024.
19. Local coverage determination. Cervical traction devices (L33823). Centers for Medicare & Medicaid Services website. http://www.cms.hhs.gov/mcd/search.asp. Published October 1, 2015 (revised January 1, 2020). Accessed September 23, 2024.
20. Kemker BP 3rd, Kankaria R, Patel N, Golladay G. Hip and Knee Bracing: Categorization, Treatment Algorithm, and Systematic Review. *J Am Acad Orthop Surg Glob Res Rev*. 2021;5(6):e20.00181-12. Published 2021 Jun 7. doi:10.5435/JAAOSGlobal-D-20-00181
21. Deems-Dluhy S, Hoppe-Ludwig S, Mummidisetty CK, Semik P, Heinemann AW, Jayaraman A. Microprocessor Controlled Knee Ankle Foot Orthosis (KAFO) vs Stance

Control vs Locked KAFO: A Randomized Controlled Trial. Arch Phys Med Rehabil. 2021 Feb;102(2):233-244. doi: 10.1016/j.apmr.2020.08.013. Epub 2020 Sep 22. PMID: 32976844.
22. Women's Health and Cancer Rights Act (WHCRA). Centers for Medicare & Medicaid Services website. Women's Health and Cancer Rights Act (WHCRA) | CMS. Published September 10, 2024. Accessed October 8, 2024.
23. The World Professional Association for Transgender Health, Inc. (WPATH). Position statement on medical necessity of treatment, sex reassignment, and insurance coverage in the U.S.A. https://www.wpath.org/newsroom/medical-necessity-statement. Published December 21, 2016. Accessed June 19, 2024.
24. Coleman E, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. Int J Transgend Health. 2022;23(Suppl 1):S1 to S259. Published 2022 Sep 6. doi:10.1080/26895269.2022.2100644
25. Evolving evidence review: MyoPro Orthosis (Myomo Inc.) for Upper Extremity Paralysis/Paresis After Stroke. Hayes. www.hayesinc.com. Published March 6, 2023 (annual review March 18, 2024). Accessed October 1, 2024.
26. National coverage determination. Infusion pumps (280.14). Centers for Medicare & Medicaid Services website. http://www.cms.hhs.gov/mcd/search.asp. Published December 17, 2004. Accessed October 1, 2024.
27. Local coverage article. External infusion pumps (L33794). http://www.cms.hhs.gov/mcd/search.asp. Published October 1, 2015 (revised July 1, 2024). Accessed October 1, 2024.
28. Local coverage determination. Suction pumps (L33612). Centers for Medicare & Medicaid Services website. http://www.cms.hhs.gov/mcd/search.asp. Published October 1, 2015 (revised January 1, 2024). Accessed October 1, 2024.
29. Local coverage determination. Vacuum erection devices (L34824). Centers for Medicare & Medicaid Services website. http://www.cms.hhs.gov/mcd/search.asp. Published October 1, 2015 (revised January 1, 2020). Accessed October 1, 2024.
30. Khera M. Treatment of male sexual dysfunction. UpToDate. www.uptodate.com. Published October 24, 2023. Accessed October 1, 2024.
31. Local coverage determination: Nebulizers (L33370). Centers or Medicare and Medicaid Services website. https://www.cms.gov/medicare-coverage-database/search.aspx. Published October 15, 2015 (revised January 1, 2024). Accessed October 1, 2024.
32. Local coverage determination. Oxygen and oxygen equipment (L33797). http://www.cms.hhs.gov/mcd/search.asp. Published October 1, 2015 (revised April 1, 2023). Accessed October 2, 2024.
33. Evidence analysis research brief: Volara (Hillrom) for respiratory therapy. Hayes. www.hayesinc.com. Published March 18, 2024. Accessed October 2, 2024.
34. Lauwers E, Ides K, Van Hoorenbeeck K, Verhulst S. The effect of intrapulmonary percussive ventilation in pediatric patients: A systematic review. *Pediatr Pulmonol*. 2018;53(11):1463 to 1474. doi:10.1002/ppul.24135
35. Huynh TT, Liesching TN, Cereda M, et al. Efficacy of Oscillation and Lung Expansion in Reducing Postoperative Pulmonary Complication. *J Am Coll Surg*. 2019;229(5):458 to 466.e1. doi:10.1016/j.jamcollsurg.2019.06.004
36. Aboussouan LS. Role of mucoactive agents and secretion clearance techniques in COPD. UpToDate. www.uptodate.com. Updated November 16, 2023. Accessed October 2, 2024.

37. Local coverage determination: Walkers (L33791). Centers for Medicare and Medicaid Services website. https://www.cms.gov/medicare-coverage-database/search.aspx. Published October 1, 2015 (revised January 1, 2020). Accessed November 18, 2022.
38. Local coverage determination: Manual wheelchair bases (L33788). Centers for Medicare and Medicaid Services website. https://www.cms.gov/medicare-coverage-database/search.aspx. Published October 1, 2015 (revised January 1, 2020). Accessed October 2, 2024.
39. Schiappa V, Piriano J, Bernhardt L, et al. RESNA Position on the Application of Seat-Elevation Devices for Power Wheelchair Users Literature Update. Rehabilitation Engineering and Assistive Technology Society of North America. https://www.resna.org/Portals/0/Documents/Position%20Papers/RESNA_App%20of%20Seat%20Elevation%20Devices%202019.pdf. Published September 25, 2019. Accessed October 2, 2024.
40. Beaudoin M, Lettre J, Routhier F, Archambault PS, Lemay M, Gélinas I. Long-term use of the JACO robotic arm: a case series. *Disabil Rehabil Assist Technol*. 2019;14(3):267 to 275. doi:10.1080/17483107.2018.1428692
41. Louisiana Department of Health Durable Medical Equipment Provider Manual. Chapter Eighteen of the Medicaid Services Manual. https://www.lamedicaid.com/provweb1/providermanuals/manuals/DME/DME.pdf.

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. LHCC 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.

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 LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. 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. LHCC 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 LHCC has no control or right of control. Providers are not agents or employees of LHCC.

This clinical policy is the property of LHCC. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.