Policy Statement
This policy will be used to define Durable Medical Equipment as well as support the medical necessity of the billed DME.

Purpose
To outline the medical necessity of Durable Medical Equipment (DME).

Scope
This policy will apply to all participating network practitioners.

Definition
- Durable Medical Equipment (DME) is any equipment that provides therapeutic benefits to a patient for certain conditions and/or illnesses defined below
- DME consist of items which:
  - Are used to treat a defined illness or injury
  - Are not useful to a person in the absence of illness or injury
  - Are reusable and durable enough for repeated use
  - Are appropriate for use outside of a medical setting such as home, at school, or at work
- DME includes but is not limited to: back supports/braces, cervical collars, foot orthotics, electrical stimulation units, traction devices, and wheelchairs and assistive devices for gait.
- The use of any DME must have evidence of efficacy in the peer reviewed guideline, systematic review, and/or randomized controlled trial medical literature. The use of these devices is not considered medically necessary in the absence of scientific evidence in this peer reviewed medical literature.

Medical Necessity
Durable Medical Equipment and services are medically necessary when the following criteria are met:
1. The equipment is expected to provide improvement in specific, measurable functional deficits related to a documented illness or injury; and
2. The DME is provided by a health care professional; and
3. The equipment does not have significant non-medical uses; and
4. The clinical records clearly establish the medical need for the DME

1 The “Original Date” above reflects the date the Policy was initiated by HSM Physical Health, Inc., (HSM). The “Adoption Date” above indicates the date that the Magellan Healthcare NIA Clinical Guideline Task Force reviewed and approved the Policy. HSM was acquired by National Imaging Associates, Inc., (NIA) in 2015 and is now a wholly owned subsidiary of NIA. National Imaging Associates, Inc., is a subsidiary of Magellan Healthcare, Inc.
Clinical documentation must include the following elements:
1. A diagnosis that justifies the equipment or supply being requested
2. A treatment plan (anticipated start and end date) for the use of the DME
3. Documented measurable functional deficit(s)
4. Expected outcomes and benefit related to a measurable functional deficit
5. Documentation of the healthcare providers training/education, supervision, and monitoring of the use of the DME as evidenced by the identification of provider type and signature in the record.
6. Documentation of a trial of conservative services that failed to improve a measurable functional deficit unless contraindicated
7. When appropriate, documentation of a trial of in-office care, such as cervical traction, that provided improvement in a measurable functional deficit
8. If an insurance plan does not cover a DME, then any visits associated with instruction on the DME would not be covered

DME may be subject to medical necessity review. This would include: TENS or other electrical stimulation units, traction devices or chairs, etc. Additionally, any DME with a purchase or rental price of more than $200 will be subject to review.

Specific Durable Medical Equipment:

Electrical Stimulation for Pain
Transcutaneous electrical nerve stimulation (TENS) uses electrical stimulation at a painful site via the application of electrodes from the device to the surface of the skin. TENS devices generate electrical output, usually by a portable battery operated method.

Magellan considers TENS medically necessary DME when used as an adjunct or as an alternative to common conservative treatments for the initial 30 days of acute post-operative pain and for some forms of chronic musculoskeletal and neuropathic pain causing significant documented disruption of function unresponsive to at least a 1 month trial of conservative care including but not limited to manual therapy, active care, and pharmacotherapy. Please note that not all health plans reimburse for rental or purchase of home TENS units.

TENS is considered experimental and investigational for acute non-operative pain, chronic headaches, chronic deep abdominal pain, and chronic temporomandibular joint (TMJ) pain. A trial of TENS use for at least 30 days but not to exceed 90 days must be monitored by the healthcare provider. This trial period must include documentation of the effect on the patient’s pain and measurable function to determine the effectiveness of the TENS unit. Treatment for long-term use is considered medically necessary if the trial period produced significant improvement in the patient’s pain and measurable functional deficit(s). This documentation must include how the patient used the unit, the duration of use each time the unit was used, as well as the results of use. Concurrent chiropractic and/or physical therapy services are not indicated for the treatment of the same condition during the trial period.

Magellan does not consider the use of form-fitting conductive garments medically necessary.
Magellan considers the following forms of electrical stimulation not medically necessary:
This list is not all-inclusive.
- Noninvasive neuron blockage devices
- Electroceutical therapy devices
- Bioelectric treatment systems
- Electro-Acuscope Therapy System
- Electrical stimulation of the sacral nerve roots or lumbosacral plexus for treatment of chronic pelvic or abdominal pain
- High-frequency pulsed electromagnetic stimulation
- Vagus nerve stimulation
- Bone growth stimulators

**Home Traction Devices:**
Magellan considers home cervical traction devices as medically necessary when the following criteria are met:
1. There is documented sub-acute or chronic neck pain (defined as present for 3 months or longer) **and**
2. The patient has failed a 30-day trial of chiropractic and/or physical therapy treatment excluding the use of cervical traction; **and**
3. The patient has utilized in-office cervical traction with documented improvement in pain and a measurable functional deficit; **and**

Any device billed at more than $200 will be subject to review for medical necessity.

There is insufficient evidence from peer-reviewed published studies to conclude that lumbar spinal traction devices are effective at improving specific, measurable and functional deficits related to low back pain and leg-related low back pain. Magellan considers lumbar auto-traction devices experimental and investigational. This would include the Spinalator, the Arthrotonic stabilizer, the Anatomotor, Saunders Lumbar Hometrac, etc. Magellan also considers axial spinal uploading (gravity-dependent traction) devices experimental and investigation for the treatment of low back pain and leg-related low back pain. This would include the LTX 3000, VAX-D, and other decompression or traction devices, tables, weights or vests.

**Orthotics, Prosthetics, Bracing and Assistive Devices**
The use of these devices must be necessary for the treatment of an illness or injury and to improve documented, measurable, and functional deficit(s). The documentation must include the reason the equipment is needed and the duration of its need.

A brace, orthotic, or prosthetic is a rigid or semi-rigid device. It is used to support and/or substitute a documented weak or deformed body part that is causing a documented measurable functional deficit.

The use of assistive devices is considered a standard of practice for general mobility needs and reduction in patients at risk of falling. Clinical documentation must support the use of these devices.
HCPCS 2015 Code L0631: Lumbar-sacral orthosis, sagittal control, with rigid anterior and posterior panels, posterior extends from sacrococcygeal junction to t-9 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise. The clinical record must clearly document that this service involved customization of the lumbar orthosis in order for it to be reimbursable.
REFERENCES


Reviewed/Approved by Michael Pentecost, MD, Chief Medical Officer