National Imaging Associates, Inc.	
Clinical guidelines DURABLE MEDICAL EQUIPMENT	Original Date: August 2, 2011 Page 1 of 9
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Physical Medicine – Clinical Decision Making	Last Review Date: June 2017
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Policy Statement

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

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

Purpose

To outline the medical necessity of Durable Medical Equipment.

Scope

This policy will apply to all physical medicine participating network practitioners, including chiropractors, physical therapists, occupational therapists, and speech language pathologists.

Definition

- 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 a 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 peer reviewed medical literature.

*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.

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

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 visit associated with instruction on the DME would not be covered

DME

DME may be subject to medical necessity review. This would include: Transcutaneous electrical nerve stimulation 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.

TENS is considered a 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, acute and chronic headaches, deep abdominal pain, and chronic temporomandibular joint (TMJ) pain, adhesive capsulitis (frozen shoulder), chronic low back pain, neuropathic pain, pelvic

pain, phantom pain, stump pain, and all other indications because there is inadequate scientific evidence to support its efficacy for these specific types of 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.

The use of form-fitting conductive garments is not considered medically necessary.

The following forms of electrical stimulation are not considered 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

On June 8, 2012, the Centers for Medicare & Medicaid Services (CMS) rendered a decision memo for TENS for chronic low back pain. It states that TENS is not reasonable and necessary for the treatment of chronic low back pain.

In an evidence-based review, the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology evaluated the effectiveness of TENS in the treatment of pain in neurological disorders (Dubinsky 2010). There are conflicting reports of TENS compared to sham TENS in the treatment of chronic low back pain (LBP), with two, Class II studies showing benefit, while two, Class I studies and another Class II study not showing benefit. Because the Class I studies are stronger evidence, TENS is established as ineffective for the treatment of chronic LBP. The authors concluded that TENS is not recommended for the treatment of chronic LBP.

Guidelines on treatment of LBP from the National Collaborating Centre for Primary Care (Savigny 2009) found insufficient evidence for the use of TENS in LBP and recommended against its use for that indication.

Evidence is insufficient to support the use of knee braces as a treatment for patellofemoral pain syndrome.

Home Traction Devices

Home traction therapy is unproven and not medically necessary for treating low back and neck disorders with or without radiculopathy. The majority of studies are office based with mixed results. The quality of peer reviewed studies for home traction are limited as well to conclude that it is effective in the management of neck or low back pain or that it improves health outcomes. The indications for clinical application, patient selection criteria, risks, and comparison to alternative technologies have not been established for home traction therapy.

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. Lumbar auto-traction devices are considered experimental and investigational. This would include, but is not limited to: the Spinalator, the Arthrotonic stabilizer, the Anatomotor, Saunders Lumbar Hometrac, etc. Axial spinal uploading (gravity-dependent traction) devices are considered experimental and investigation for the treatment of low back pain and leg-related low back pain. This would include, but is not limited to: the LTX 3000, VAX-D, and other decompression or traction devices, tables, weights or vests.

Orthotics, Prosthetics, Bracing and Assistive Devices

No definitive evidence as yet supports the use of orthoses in painful conditions of the cervical or lumbar spine. They should, therefore, be used only after individual consideration of the indications in each case.

Studies suggest that wearing a wrist splint can provide relief from carpal tunnel symptoms within a few weeks; however, the effect is only temporary.

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.

There is insufficient evidence to support the use of insoles or foot orthoses as either a treatment for LBP or in the prevention of LBP. Foot orthoses produce small short-term benefits in function and may also produce small reductions in pain for people with plantar fasciitis, but they do not have long-term beneficial effects compared with a sham device. Foot orthotics have no proven value for knee pain (other than medial osteoarthritis), pes planus (flat feet), pronation, corns and calluses, hip osteoarthritis, and lower leg injuries. Customized and prefabricated orthoses have similar effectiveness in the treatment of plantar fasciitis. Spinal Pelvic Stabilizers (Foot Levelers, Inc.) are specialized custom molded inserts designed to prevent foot injuries and improve foot alignment; these are considered experimental and investigational because their value in treatment of foot

disease has not been proven. The available evidence does not reveal any clear advantage of foot orthoses over simple insoles or physiotherapy for patellofemoral pain. While foot orthoses may help relieve knee pain over the short term, the benefit may be marginal. There is moderate evidence to support the use of foot orthotics in the treatment of chronic ankle instability to help improve postural control.
Overall, the evidence appears to suggest that custom foot orthotics and prefabricated orthotics have similar effectiveness. Therefore, prefabricated orthotics should be prescribed when there is a clinical indication for foot orthotics.

HCPCS 2018 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.

Strapping

The application of casts, splints, or straps is performed in an attempt to provide temporary immobilization or fixation to correct, protect, or stabilize a fracture, dislocation, or documented joint instability as a result of injury, disease or surgery.

The use of casting, splinting or strapping may be considered medically necessary for a patient who has experienced a fracture, dislocation or who has ligamentous instability following an acute injury, or as the result of a disease or surgery.

The application of casting, splinting or strapping **should not** be reported when any kind of treatment or restorative service aimed at correcting, protecting, or stabilizing the fracture, dislocation, or instability is concurrently done.

Strapping uses rigid material in order to restrict joint and/or muscular movement. Tape is typically worn for a relatively short duration (<18 hours). In contrast, kinesiology (kinesio) taping (KT) is a therapeutic taping method that utilizes a latex-free elastic tape, which is purported to give support and stability to joints and muscles without affecting circulation, range of motion, and biomechanics. It is also used for preventive maintenance, edema, and to treat pain. KT methods use highly-specific designed tape, which may be pre-cut for certain joints, and reportedly can be used by patients of every age and condition for 1-5 days per application. The consensus findings of peer reviews did not support the application of KT in clinical settings.

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