Mechanical Devices for the Treatment of Back Pain

Coverage Policy

Coverage for exercise equipment varies across plans. Refer to the customer’s benefit plan document for coverage details.

The use of the following mechanical devices is considered experimental, investigational, or unproven for the treatment of any condition:

- quantitative muscle testing and treatment devices (e.g., MedX, Isostation B-200, Cybex, Kin-Com, and Biodex)
- patient-operated spinal unloading devices (e.g., LTX 3000™, Orthotrac™ Pneumatic Vest, Posture Pump Elliptical Back Rocker)

Overview

This Coverage Policy addresses quantitative muscle testing and treatment devices and patient-operated spinal unloading devices.

See Axial/Spinal Decompression Therapy/Mechanical Traction (Provided in a Clinic Setting) (CPG 275) and
General Background

Back pain may originate from the vertebrae, intervertebral discs, spinal cord, nerve roots, facet joints, ligaments, muscles, and sacroiliac, atlanto-axial, and atlanto-occipital joints. Most back pain will resolve spontaneously or can be treated with conservative and noninvasive therapies, such as analgesics, anti-inflammatory drugs, muscle relaxants, exercise, physical therapy, immobilization and trigger-point injections with local anesthetics. Other nonsurgical methods of treatment include the use of traction, chiropractic care with spinal manipulation, transcutaneous electrical stimulators, spinal orthotic devices, acupuncture, and thermal techniques. Surgery may be required for the conditions with underlying pathology as determined by radiological findings.

Various noninvasive treatments have been proposed for use as treatment of low back pain, including quantitative muscle testing and treatment devices and patient-operated spinal unloading devices e.g., LTX 3000™, Orthotrac™ Pneumatic Vest). Most of these devices require special training of the clinician and, in some cases, certification, and are generally used by physical therapists as part of rehabilitation programs and are not typically used in a home setting.

U.S. Food and Drug Administration (FDA)

Classification of devices by the FDA proposed for the treatment of back pain varies. Some have received approval through the FDA as isokinetic testing and evaluation systems (e.g., Isostation, Cybex Systems, KinCom, Biodex Systems). According to the FDA, an isokinetic testing and evaluation system is a rehabilitative exercise device intended for medical purposes, such as to measure, evaluate, and increase the strength of muscles and the range of motion of joints. Powered traction devices consist of powered devices intended for medical purposes for use in conjunction with traction accessories, such as belts and harnesses, to exert therapeutic pulling forces on the person's body. These devices are regulated by the FDA as Class II devices.

The MEDX Lumbar Extension machine received approval from the FDA as an exerciser, measuring (i.e., exercise measuring equipment) and is also regulated as a Class II device.

Both the LTX 3000 and the Orthotrac Pneumatic Vest are considered Class I devices, further classified as nonpowered traction apparatus, and are subject to the lowest level of regulatory control by the FDA. These types of devices present minimal potential harm to the user and are simple in design.

Quantitative Muscle Testing Devices

Quantitative muscle testing devices have been used to quantify muscle strength and an individual’s response to rehabilitation and therapy. Manual muscle testing is most commonly performed and is used to identify differences in strength between muscles, using qualitative grading to describe the strength of muscles. Newer computerized technologies have been proposed to quantify muscle strength, and some authors have reported that quantifying muscle activity and strength may prove useful in the diagnosis and management of individuals with low back pain. The MedX extension machine (MEDX Corp, Ocala, FL) and Isostation B200 (Isotechnologies, Inc., Hillsborough, NC) are two devices that have been designed for muscle testing, and to improve spinal muscle strength through pelvic stabilization and isolation of specific groups of lumbar muscles. However, evidence in the peer-reviewed scientific literature does not show that use of these devices for muscle testing demonstrates better diagnostic utility than the established method of manual muscle testing.

MedX: The MedX lumbar/cervical extension machine is a device that can provide both functional muscle testing of the spine and spinal therapy. It provides resistance over a full range of isolated lumbar motion (72 degrees) or over a preselected limited range. The machine is capable of setting isometric test points every three degrees within an individual's range of motion. During the test, a computer software system plots the individual’s actual range of motion and strength in comparison to that of age- and gender-matched norms. In exercise mode, the compound weight stack can provide resistance from 10–400 foot pounds in increments of one foot pound. It is proposed that use of this device can specifically test the strength of the lumbar spine and, through rehabilitation, the device can strengthen muscles. The rehabilitation program typically lasts 12 weeks, with computerized strength and motion testing performed every four weeks.
Isostation B-200: The Isostation B-200 lumbar dynamometer is a device that can measure position, torque and velocity. It allows measurement of increasing fatigue by measuring the reduction speed in performance and noting increasing motion as muscle substitution becomes necessary. The device has been recommended for use in the treatment of persons with low back pain.

Isokinetic Testing Devices: Other types of quantitative muscle testing and strengthening devices, referred to as isokinetic testing devices, measure muscle strength by applying a constant resistance over a range of motion and speed. Based on testing results, strengthening exercises may be recommended. Isokinetic exercise is exercise performed using a specialized apparatus that controls the speed of contraction within the range of motion. The exercise device provides variable resistance to movement, but allows movement at a constant speed. The device registers the force applied to it by the user, and offers the same amount of force as resistance. Cybex, Kin-Com, and Biodex are machines that provide isokinetic testing and muscle strengthening exercise. Evidence in the published scientific literature was not found demonstrating the utility of these specific devices for muscle testing or strengthening therapy.

Literature Review: There is limited evidence in the published peer-reviewed scientific literature evaluating the use of quantitative muscle testing devices. These devices have not been shown to be equally effective as other standard exercise equipment utilized in rehabilitation programs, nor is there sufficient evidence to suggest that use of quantitative muscle testing devices improves clinical health outcomes when compared to standard manual muscle testing.

A randomized controlled trial was conducted by Choi et al. (2005) to assess the effects of a lumbar extension muscle strengthening program used on individuals who underwent lumbar microdiscectomy or percutaneous endoscopic discectomy. A total of 75 individuals were randomized into a control group (n=40) or an exercise group (n=35). Six weeks after surgery, the exercise group underwent a 12-week lumbar extension exercise program using the MedX lumbar extension machine. All individuals completed the visual analog scale and Oswestry disability index to evaluate pain and disability. Return to work data was also evaluated. The authors noted significant improvements in the exercise group versus the control group when assessing lumbar extensor power (51.67% versus 17.55%, respectively; p<0.05), the cross-sectional area of multifidus and longissimus muscle (29.23% versus 7.2%, respectively; p<0.05), and the visual analog scale score (2.51 versus 4.30, respectively; p<0.05). The number of people who returned to work four months after surgery was also higher in the exercise group, although not statistically significant (p>0.05). Additionally, the Oswestry disability index scores were better in the exercise group compared to the control group (24.6 versus 30.6, respectively). The difference in pain status between groups was comparable at the end of one year. Long-term effects of the exercise program were not evaluated.

Patient-Operated Spinal Unloading Devices
Some spinal unloading devices may be operated by the individual in a home setting. Generally, the use of spinal unloading devices is proposed as a method of treatment for persons with subacute or chronic low back pain and who have failed either standard medical or surgical therapy.

LTX 3000™: The LTX 3000 (Spinal Designs International, Minneapolis, MN) is a gravity-dependent axial spinal unloading device that consists of an adjustable seat strap and rib support pads that are used to stabilize the upper body by engaging the lowest portion of the rib cage. After adjusting rib support pads, the individual lowers the seat strap to induce unloading of the spine. Theoretically, unloading occurs as a result of the downward force provided by body mass. Proper training in adjustment and use of the device is required for safe use in the home. The LTX 3000 is often used as part of rehabilitation programs, such as the Low Back Rehabilitation Program, the ReSpond Program, and, more recently, the LIFEBACK™ Spine Programs. These programs are proposed for those persons who have reached maximum therapeutic benefit of physical therapy or chiropractic care and whose pain limits activities of exercise and/or work. According to the manufacturer, recommended use of the device is 3–4 times a day for sessions of 10–15 minutes lasting 2–3 months.

Orthotrac™ Pneumatic Vest: The Orthotrac Pneumatic Vest (Orthofix, Inc., Huntersville, NC) is a custom-made device intended to be worn 2–3 times a day for 30–60 minutes each session. It is a spinal decompression orthotic device that is theoretically designed to offload and stabilize the lower back, using air pressure to provide
support. It is suggested that pneumatic lifters “unload” some of the weight from the patient’s lumbar spine. It is proposed that when worn, the device applies a decompressive force to the spine, transferring the weight from the upper torso to the hips, preventing compression and aggravation of the lower back. The amount of force on the spine is controlled by the individual through a manual inflation device, with pressure prescribed to offload approximately 50% of the person’s weight. The individual can deflate the device to reduce pressure at any time. It is suggested that use of the device alleviates pain and improves function and quality of life.

**Posture Pump Elliptical Back Rocker:** The Posture Pump Elliptical Back Rocker (PMT Medical, Inc., Akron, OH) uses a dual inflation mechanism that gradually lifts, stretches and separates the joints and is suggested to relieve back stiffness and discomfort. The manufacturer suggests that two angled air cells create a multivectored force that promotes disc and joint lubrication. The built-in rocking mechanism exercises the abdominal muscles and is proposed to shape and stretch the lower back.

**Literature Review:** There are few published clinical trials evaluating the safety and efficacy of patient-operated spinal unloading devices compared to other well-accepted pain treatment modalities for the treatment of back pain. In a preliminary study, Dallolio (2005) reported on a case series of 41 subjects with radicular pain due to degenerative discopathy. The individuals were treated with an Orthotrac pneumatic lumbar vest for 60 minutes, three times a day, for five weeks. The authors reported, “Thirty-two subjects showed a significant subjective and clinical improvement with subsequent better quality of life.” All subjects reported a decrease or a disappearance of radicular pain. The authors acknowledged the device seemed to be effective for spinal decompression; however, further multicenter and interdisciplinary studies involving larger numbers of individuals are required to confirm those results. The study was limited by lack of controls, lack of comparative treatments, short-term outcomes, and a small study population.

Two published literature sources address the mechanical responses and safety of the LTX 3000 specifically. Podein and laizzo (1998) studied lumbar unloading in 17 healthy subjects who had not experienced a significant episode of low back pain within six months, using the LTX 3000. In this case series, the authors addressed the safety of the device by measuring forces applied to the body and associated changes in physiological responses (e.g., heart rate, blood pressure, respiratory rate) during spinal unloading. The authors noted that the applied forces of spinal unloading did cause changes in physiological responses but that the changes were reversible, clinically unimportant and not contraindications to use of the device by the general population. Nonetheless, due to a small sample population and limited evaluation measures, strong conclusions regarding the safety and efficacy of the device cannot be made.

All other data reviewed were obtained from the device manufacturers. The literature lacks published clinical studies to support the safety and efficacy of spinal unloading devices for the treatment of back pain and specific patient-selection criteria have not been established. In addition, there is mixed evidence in the literature supporting the use of back braces and lumbar supports, in general, for the treatment of back pain. For example, a Cochrane systematic review concluded that there is still a need for high-quality randomized trials assessing the effectiveness of lumbar supports (Van Duijvenbode, et al., 2008).

**Professional Societies/Organizations**  
**American College of Physicians (ACP):** The ACP Clinical Practice Guideline on Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain (Qaseem, et al 2017) provides treatment guidance based on the efficacy, comparative effectiveness, and safety of noninvasive pharmacologic and non-pharmacologic treatments for acute (<4 weeks), subacute (4 to 12 weeks), and chronic (>12 weeks) low back pain in primary care.

Non-pharmacologic interventions evaluated were numerous and included interdisciplinary or multicomponent rehabilitation (physical therapy plus psychological therapy with some coordination), psychological therapies, exercise and related interventions (such as yoga or tai chi), complementary and alternative medicine therapies (spinal manipulation, acupuncture, and massage), passive physical modalities (such as heat, cold, ultrasound, TENS, electrical muscle stimulation, interferential therapy, short-wave diathermy, traction, LLLT, and lumbar supports/braces), and taping.

- **Acute or Subacute Low Back Pain - Other Therapies:** Evidence was insufficient to determine the effectiveness of transcutaneous electrical nerve stimulation (TENS), electrical muscle stimulation,
inferential therapy, short-wave diathermy, traction, superficial cold, motor control exercise (MCE), Pilates, tai chi, yoga, psychological therapies, multidisciplinary rehabilitation, ultrasound, and taping.

- Chronic Low Back Pain - Other Therapies: Evidence was insufficient to determine the effectiveness of electrical muscle stimulation, interferential therapy, short-wave diathermy, traction, or superficial heat or cold.
- Radicular Low Back Pain – Traction: Low-quality evidence showed no clear differences between traction and other active treatments, between traction plus physiotherapy versus physiotherapy alone, or between different types of traction in patients with low back pain with or without radiculopathy

Use Outside of the US
National Institute for Health and Clinical Excellence (NICE): NICE guideline Low back pain and sciatica in over 16s: assessment and management (November 2016) states “Do not offer traction for managing low back pain with or without sciatica”.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Experimental/Investigational/Unproven when used to report quantitative muscle testing and treatment devices or patient-operated spinal unloading devices for the treatment of any condition:

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<tr>
<th>CPT® Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>97750</td>
<td>Physical performance test or measurement (eg, musculoskeletal, functional capacity), with written report, each 15 minutes</td>
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<tr>
<td>97799</td>
<td>Unlisted physical medicine/rehabilitation service or procedure</td>
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<tr>
<th>HCPCS Codes</th>
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<tr>
<td>E0830</td>
<td>Ambulatory traction device, all types, each</td>
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<td>E0941</td>
<td>Gravity-assisted traction device, any type</td>
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<tr>
<td>E1399</td>
<td>Durable medical equipment, miscellaneous</td>
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<tr>
<td>L1499</td>
<td>Spinal orthosis, not otherwise specified</td>
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References


