
Medical Policy



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***Current Policy Effective Date: 7/1/23**
(See policy history boxes for previous effective dates)

Title: Lumbar Traction Devices for The Treatment of Low Back Pain

Description/Background

Traction is the use of a pulling force to treat muscle and skeletal disorders. Lumbar traction has historically been used to treat low back pain in conjunction with other treatment modalities in an outpatient setting (facility) as part of a directly supervised physical therapy regimen. Typically, these modalities are used short term. Types of traction include continuous/intermittent traction, mechanical traction, manual traction (unspecific or segmental traction), autotraction, gravity-dependent traction and pneumatic traction.

Continuous/Intermittent Traction

Continuous spinal traction is applied for up to several hours at a time with the use of a small weight. Intermittent traction is similar to continuous traction but alternately applies and releases the traction force at certain intervals.

Manual/Mechanical Traction

Manual traction is a technique in which a therapist uses their hands to perform spinal decompression. The therapist provides a very specific and controlled distraction force to the spine or joint in order to alleviate pain or compression. Mechanical traction involves a mechanical device with traction alternately applied and with-drawn every few seconds. This is probably the most popular form of traction in use. Some examples of mechanical traction devices include the Chattanooga New Lumbar Home Traction, Saunders Lumbar Hometrac and the Enshey Traction Bed.

Autotraction

Autotraction is defined as the use of one's own weight to create the traction force (i.e., the patient determines the traction force). By utilizing positional and gravity assisted traction principles, autotraction can provide multi-plane traction. Some of the brand names of these devices include the Spinalator Spinalign massage intersegmental traction table, the Arthrotronic stabilizer, the Quantum 400 intersegmental traction table and the Anatomotor.

Gravity-dependent Traction

Axial spinal unloading devices (gravity-dependent traction (i.e., axial spinal unloading devices) are designed to support the upper body's weight and transfer that weight to the hips via a mechanical or pneumatic mechanism. Patient-operated spinal unloading has been suggested as a conservative treatment for pain related to spinal disc disease or joint dysfunction. Several patient-operated spinal unloading devices are currently available on the market, including the Orthotrac Pneumatic Vest™ (manufactured by Kinesis Medical, Minneapolis, MN) and the LTX 3000™ (manufactured by Spinal Designs International, Minneapolis, MN).

Pneumatic Traction

Pneumatic home lumbar traction devices have been developed which manufacturers claim can apply up to 200 pounds of traction force. Examples of these pneumatic devices include autotraction devices include the Spinalator Spinalign massage intersegmental traction table, the Arthrotronic stabilizer, the Quantum 400 intersegmental traction table and the Anatomotor. It is proposed that these devices mimic the traction offered in a clinical setting by providing a friction-free split surface that actively moves, enabling vertebral separation by inducing a pulling force. It is suggested that when using these devices, the patient can be positioned so that the lumbar curve is in any degree of flexion, neutral or in extension. Each of these devices has both a patient-controlled pressure valve that limits the amount of force transmitted to the user and a hand-held pump for immediate release of pressure.

Regulatory Status

Table 1. FDA Registered Devices for Lumbar Traction

Device	Company	Class Type	Approval Date
Orthotrac Pneumatic Vest	Orthofix Inc.	Class I	October 2000
Quantum Intersegmental Roller Traction Table	LSI International, Inc.	Class II	October 2000
DRX5000	Axiom USA, Inc.	Class II	September 2002
SpineRx-LDM	Spine Rx Technology	Class II	September 2003
Extentrac Elite	Advanced Back Technologies, Inc.	Class II	June 2004
Bass Antalgic-Trak	Traction Masters, Inc.	Class II	September 2004
Triton/Tru-Trac/TX/Triton DTS Traction	Chattanooga Group	Class II	February 2006
CTBox Cervical/Lumbar Traction System	Circular Traction Supply, Inc.	Class II	February 2007
GraviLax Traction System	Therapeutic Clinical Technologies	Class II	March 2008
TM-400	ITO Co., Ltd	Class II	July 2008
MTD 4000	Mettler Electronics, Corporation	Class II	August 2009
Lo-Bak TRAX	Berthiaume Chiropractic	Class I	July 2011

Eltrac 471	Mark Job Inc. STL International, Inc.	Class II Class I	September 2015 December 2016
Teeter Manual Inversion Table; Teeter Forward Rotation Decompression Device; Teeter Portable Decompression Device			

Medical Policy Statement

The use of mechanical, autotraction, gravity-dependent (axial spinal unloading) and pneumatic lumbar traction devices are experimental and investigational in any setting. These devices have not been scientifically demonstrated to be safe and effective for the treatment of low back pain, herniated disc or other indications and have not been shown to improve patient outcomes.

Inclusionary and Exclusionary Guidelines

Exclusions:

Non-established lumbar traction devices include, but are not limited to

- Pneumatic lumbar traction devices (e.g., Saunders Lumbar HomeTrac, Saunders STx, Orthotrac Pneumatic Vest).
- Autotraction devices (e.g., the Spinalator Spinalign massage intersegmental traction table, the Arthrotronic stabilizer, the Quantum 400 intersegmental traction table and the Anatomotor)
- Axial spinal unloading (gravity-dependent traction) devices (e.g., LTX 3000, Triton DTS, Z-Grav Spinal Decompression Table).
- Conventional lumbar traction using a pelvic harness attached to pulleys and weights, now considered to be obsolete.
- Mechanical traction devices (e.g., Chattanooga New Lumbar Home Traction, Saunders Lumbar Hometracs and the Enshey Traction Bed)
- Pettibon System (i.e., spine and posture correction and muscular development, therapeutic wobble chair, lumbar traction devices, weighting system).
- Lumbar lordotic curve-controlled traction devices (e.g., Kinetrac-9900)

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

E0830

E0941

E1399

Rationale

To date, no research has examined the reliability or predictive validity of manual unloading tests of the lumbar spine to identify potential responders to lumbar mechanical traction. Swanson et al (2016) conducted a study to determine (1) the intra and inter-rater reliability of a manual unloading test of the lumbar spine and (2) the criterion referenced predictive validity for the manual unloading test.¹ Ten volunteers with low back pain (LBP) underwent a manual unloading test to establish reliability. In a separate procedure, 30 consecutive patients with LBP (age 50.86 ± 11.51) were assessed for pain in their most provocative standing position (visual analog scale (VAS) 49.53 ± 25.52 mm). Patients were assessed with a manual unloading test in their most provocative position followed by a single application of intermittent mechanical traction. Post traction, pain in the provocative position was reassessed and utilized as the outcome criterion. The test of unloading demonstrated substantial intra and inter-rater reliability $K = 1.00$, $P = 0.002$, $K = 0.737$, $P = 0.001$, respectively. There were statistically significant within group differences for pain response following traction for patients with a positive manual unloading test ($P < 0.001$), while patients with a negative manual unloading test did not demonstrate a statistically significant change ($P > 0.05$). There were significant between group differences for proportion of responders to traction based on manual unloading response ($P = 0.031$), and manual unloading response demonstrated a moderate to strong relationship with traction response $\Phi = 0.443$, $P = 0.015$. The authors concluded the manual unloading test appears to be a reliable test and has a moderate to strong correlation with pain relief that exceeds minimal clinically important difference following traction supporting the validity of this test.

Autotraction

There are only two published randomized clinical studies comparing autotraction to other forms of traction; the results of these studies are conflicting. Telso and Merlo (1993) from Italy reported on a randomized clinical trial comparing conventional passive traction to autotraction.² The investigators measured subjective response concerning overall improvement, pain intensity using visual analog scale, qualitative pain severity using the McGill Pain Questionnaire, and pain-related disability using the Oswestry Low Back Pain Disability Score. The favorable response to autotraction was 75 percent versus the 22 percent of patients to conventional passive traction.

A study by Ljunggren et al (1984), however, found no differences in effectiveness between autotraction and manual traction.³ Forty-nine patients with lumbago-sciatica and prolapsed lumbar intervertebral discs, comparable concerning clinical data were randomized for autotraction and manual traction given by the same therapist for a period of one week while strict bed rest was prescribed. A blind overall assessment at specified intervals after hospitalization showed that the two traction modalities are equally efficient. The author concluded that, as treatment for hospitalized patients with lumbar intervertebral disc prolapses, the relatively simple manual traction variety should be preferred, if any.

Another 2 randomized clinical studies compared protocols that included autotraction with conservative management by a primary care physician; the results of these studies are conflicting. Moreover, since these latter 2 studies did not compare autotraction to other forms of manipulation, no conclusions about the comparative efficacy of autotraction can be drawn from them. Blomberg et al (1993, 1994) reported on the results of a controlled, multi-center clinical trial comparing outpatients with acute or subacute LBP who were randomly allocated to

either standardized but optimized conventional activating treatment by primary health care teams (n = 53) or specific manual treatment such as manipulation, specific mobilization, muscle stretching, autotraction and cortisone injections (n = 48).⁴ The treatment effect was evaluated by standardized telephone interviews 3, 7, 14, 21 and 90 days after the start of treatment. The authors reported that, in the early phase of treatment as well as at the 90 days' follow-up, the group receiving manual treatment had significantly less pain, less disability, faster rate of recovery and lower drug consumption than patients receiving conventional treatment, indicating that this type of treatment is superior to conventional treatment.

Seferlis (1998) also compared a program that included autotraction to conventional management but found no differences in effectiveness.⁵ One hundred eighty patients, 95 men and 85 women aged 19-64 years, were randomized to three groups: an intensive training program, a manual therapy program that included autotraction or standard treatment by a general practitioner. No significant differences were found between the three groups in pain intensity, functional status after one, three and 12 months.

Gravity-dependent Traction

Janke et al (1997) conducted a study evaluating the biomechanical responses evoked using a gravity-dependent, self-operated traction device.⁶ These responses were determined by radiographs and were correlated with the body weight of the patient who was supported by a seat strap. The LTX 3000 Lumbar Rehabilitation System (Spinal Designs International, Minneapolis, MN) was used to administer the lumbar fraction. No previous study has been conducted on this device. For each of the 14 healthy male patients (age range, 19-69 years), lumbar lengthening, alterations in spinal curvature, and thoracic spine movement were assessed using radiographs taken: 1) before traction; 2) at 2, 10, and 15 minutes after the onset of traction; and 3) 2 minutes after traction was completed. Strain on the buttocks-supporting seat strap was recorded continuously during study sessions. The entire patient pool displayed an average maximal lumbar lengthening of 6.39 +/- 4.21 mm. The amount of lumbar lengthening was influenced by the degree of thoracic immobilization and by the amount of prior LTX 3000 (Spinal Designs International) use. Significant curvature reduction was observed during and after traction for the entire patient pool. Strain measurements correlated well with the measured response in the radiographs. The authors concluded that the proper use of the LTX 3000 (Spinal Designs International) appears to induce significant lumbar lengthening and curvature reduction in health patients. Measurements of body weight supported by the seat strap could help determine if thoracic immobilization has been achieved and if the patient is responding to the lumbar unloading.

Podein and Iazzo (1998) measured forces applied to the body and associated changes in physiologic responses during axial spinal unloading (gravity-dependent traction) using the LTX 3000 Lumbar Rehabilitation System. Lumbar unloading was induced in 17 healthy subjects.⁷ The following parameters were measured: (1) percent-age of total body weight unloaded; (2) forces applied onto and below the rib cage and local changes in cutaneous blood flow; (3) alteration of the applied forces to the seat strap associated with lumbar lengthening; and (4) changes in respiratory rates, respiratory minute volumes, heart rate, and blood pressure.

The average pressure applied to the rib cage for thoracic immobilization without unloading was 73 ± 26 mm Hg. Lumbar unloading caused these pressures to increase by approximately 30%, causing complete but temporary occlusion of cutaneous blood flow in this region. Significant, but normal, reactive hyperemia occurred upon release of the rib support pads ($p \leq 0.05$). Axial

spinal unloading using an LTX 3000 induced changes in heart rate, blood pressure, and respiratory rates of magnitudes similar to those reported with the use of other traction devices. The authors concluded that the forces applied to the rib cage by the LTX 3000 for proper lumbar unloading appears to cause changes in physiologic responses, but these changes were reversible and can be considered clinically unimportant and thus should not be contraindications to the use of this device by the general population.

Pneumatic Traction

Dallolio (2005) presented a preliminary study on the conservative treatment of chronic LBP using the Orthotrac device, a pneumatic custom made lumbar vest, which permits both support-stabilization and decompression.⁸ The study included 41 patients (23 males and 18 females, between the ages of 19 and 25 years) with radicular pain due to degenerative discopathy including: dark disc, discal protrusion with neural foramina involvement, stenosis of the foramina, syndrome of the facets, Grade I listhesis. Patients had to wear the Orthotrac vest according to a precise protocol, 60 minutes 3 times a day for 5 weeks. Thirty-two patients (78%) showed a significant subjective and clinical improvement with subsequent better quality of life and reported a decrease or disappearance of radicular pain. However, only short-term results have been reported. The author concluded that further multicenter and interdisciplinary studies on a greater number of patients in order to confirm the preliminary results.

There are a lack of published peer-reviewed studies that have specifically evaluated the safety and effectiveness of the Saunders Lumbar HomeTrac or Saunders STx home pneumatic traction devices for back pain. In addition, there is a lack of well-designed studies comparing the safety and effectiveness of the Saunders Lumbar HomeTrac or Saunders STx with lumbar traction provided by a physical therapist. Well-designed controlled clinical studies demonstrating reductions in pain and disability and improvements in function are especially important in evaluating pain interventions because of the susceptibility of this symptom to placebo effects. One is unable to determine from uncontrolled observations whether any noted improvements are due to the application of home lumbar traction, the impact of any other interventions that the patient was concurrently receiving, or the waxing and waning natural history of chronic back pain.

Published studies of traction as a treatment for low back pain lack methodological rigor and reach conflicting conclusions. A 2007 update of the Cochrane review of traction for low back pain, with or without sciatica, concluded from a review of 25 randomized controlled trials that intermittent or continuous traction as a single treatment for low back pain cannot be recommended for mixed groups of patients with low back pain with or without sciatica.⁹ Traction cannot be recommended for patients with sciatica because of inconsistent results and methodological problems in most of the studies. A 2007 Agency for Healthcare Research and Quality (AHRQ) technology assessment concluded that currently available evidence is too limited in quality and quantity to allow for formulation of evidence-based conclusions regarding the efficacy of decompression therapy as a therapy for chronic back pain when compared with other nonsurgical treatment options.

Home Traction

van der Heijden and colleagues (1995) reviewed the literature on traction for back pain, and concluded that “the available RCTs do not allow clear conclusions to be drawn about the effectiveness of cervical or lumbar traction.” A Prodigy Clinical Practice Recommendation

states, based on the literature, that “traction does not appear to be effective for low back pain or radiculopathy.”^{13,14}

Several additional systematic evidence reviews have been published more recently that have reached these same conclusions about the lack of adequate evidence of lumbar traction for back pain.^{15,16} A Cochrane review on traction for LBP with or without sciatica (Clarke et al, 2007) noted that various types of traction are used in the treatment of patients with LBP, often in conjunction with other treatments. These investigators concluded that that traction is probably not effective. Neither continuous nor intermittent traction by itself was more effective in improving pain, disability or work absence than placebo, sham, or other treatments for patients with a mixed duration of LBP, with or without sciatica. They also noted that while there was moderate evidence that autotraction was more effective than mechanical traction for global improvement in patients with sciatica, these studies had methodological limitations and inconsistent results.

Spinal Unloading Devices

Three studies examined the surface electromyographic (EMG) changes during axial spinal unloading using the LTX 3000 in normal subjects to determine the optimal time for effective traction.¹⁷⁻¹⁹ They reported on the short-term effect of LTX3000 on spinal curvature. They also have reported on the biomechanical and physiologic changes during axial spinal unloading the LTX 3000. However, there is a lack of evidence regarding the clinical value of LTX 3000 in improving clinical outcomes (reduction in pain and disability, improvements in function) in patients with LBP.

There are a lack of published peer-reviewed studies that have specifically evaluated the safety and effectiveness of the Saunders Lumbar HomeTrac or Saunders STx (The Saunders Group, Chaska, MN) home pneumatic traction devices for back pain. In addition, there is a lack of well-designed studies comparing the safety and effectiveness of the Saunders Lumbar HomeTrac or Saunders STx with lumbar traction provided by a physical therapist. Well-designed controlled clinical studies demonstrating reductions in pain and disability and improvements in function are especially important in evaluating pain interventions because of the susceptibility of this symptom to placebo effects. One is unable to determine from uncontrolled observations whether any noted improvements are due to the application of home lumbar traction, the impact of any other interventions that the patient was concurrently receiving, or the waxing and waning natural history of chronic back pain.

The Orthotrac™ Pneumatic Vest (Orthofix, Inc., McKinney, TX) is an inflatable pneumatic vest that has been promoted for use in relieving back pain from a variety of causes (e.g., herniated disc, spinal stenosis, facet syndrome, randomized thesis, etc.). The Orthotrac was evaluated in a study of 41 patients with radicular pain due to degenerative discopathy.^{6,8} The investigator reported that, after 5 weeks, 32 patients (78 %) have showed improvements on a SF-36 inventory, and all patients referred a decrease or disappearance of radicular pain. The investigator concluded, however, that “further multicenter and interdisciplinary studies on a greater number of patients are obviously needed to confirm these preliminary results.” The primary limitations of this study was the uncontrolled nature of this study, its short duration, and the subjective endpoints.

Hahne et al (2010) determined the effectiveness and adverse effects of conservative treatments for people who have lumbar disc herniation with associated radiculopathy

(LDHR).²⁰ These investigators searched 10 computer databases for trials published in English between 1971 and 2008. Trials focusing on people with referred leg symptoms and radiological confirmation of a lumbar disc herniation were included if at least 1 group received a conservative and non-injection treatment. A total of 18 trials involving 1,671 participants were included. Seven (39 %) trials were considered of high quality. Meta-analysis on 2 high-quality trials revealed that advice is less effective than microdiscectomy surgery at short-term follow-up, but equally effective at long-term follow-up. Individual high-quality trials provided moderate evidence that stabilization exercises are more effective than no treatment, that manipulation is more effective than sham manipulation for people with acute symptoms and an intact annulus, and that no difference exists among traction, laser, and ultrasound. One trial showed some additional benefit from adding mechanical traction to medication and electrotherapy methods. Adverse events were associated with traction (anxiety, fainting, lower limb weakness, and pain) and ibuprofen (gastrointestinal events). The authors concluded that advice is less effective than microdiscectomy in the short-term but equally effective in the long-term for individuals who have LDHR. Moderate evidence favors stabilization exercises over no treatment, manipulation over sham manipulation, and the addition of mechanical traction to medication and electrotherapy. There was no difference among traction, laser, and ultrasound. Adverse events were associated with traction and ibuprofen. They stated that additional high-quality trials would allow firmer conclusions regarding adverse effects and effectiveness.

Lordotic Curve-Controlled Traction

Lee and colleagues (2020) stated that lumbar traction is widely used as a non-operative treatment for lumbar intervertebral disc disease.²¹ The effect of traditional traction (TT) using linear-type traction devices remains controversial for various reasons, including technical limitations. These researchers compared the effects of a newly developed lumbar lordotic curve-controlled traction (L-LCCT) device (the Kinetrac-9900) device and TT on functional changes in patients and morphological changes in the vertebral disc. A total of 40 patients with lumbar intervertebral disc disease at the L4 to L5 or L5 to S1 level as confirmed by magnetic resonance imaging (MRI) were recruited and divided into 2 groups (L-LCCT or TT). The comprehensive health status changes of the patients were recorded using pain and functional scores (the visual analog scale [VAS], the Oswestry Disability Index [ODI], and the Roland-Morris Disability Questionnaire [RMDQ]) and morphological changes (in the lumbar central canal area) before and after traction treatment. Pain scores were significantly decreased after traction in both groups ($p < 0.05$). However, functional scores and morphological changes improved significantly after treatment in the L-LCCT group only ($p < 0.05$). The authors suggested that L-LCCT is a viable option for resolving the technical limitations of TT by maintaining the lumbar lordotic curve in patients with lumbar intervertebral disc disease. These researchers stated that future studies should be carried out to re-establish traction guidelines such as intensity, interval, and treatment frequency, with the goal of obtaining the best results.

The authors stated that this study had several drawbacks. First, although these investigators recruited a sufficient sample size, more subjects of different ages are needed to generalize these findings. As disease status could vary from individual to individual, these findings need to be carefully re-evaluated before they could be applied clinically. Age, sex, race, and individual physical factors should also be considered in future studies. Second, vertebral discs could differ in several characteristics including resilience, softness, or severity. In this study, disc disease patients with relatively mild disabilities and low ODI scores were recruited.

Regarding geometric status, pain threshold and functional outcome differences could also lead to different outcomes. Third, although this study recruited patients with more than 3 months of unrelenting intervertebral disc disease, there was no control group without disc disease in this study. As it is possible that disc disease could have resolved spontaneously, a control group with stricter requirements should be included in future studies. Finally, these researchers obtained immediate responses from patients following traction sessions, and the final outcome measurement was performed after completing 15 sessions of traction (approximately 1.5 months). This did not reflect the long-term efficacy of traction treatment; thus, the long-lasting effects of the treatment should be determined in future studies.

Pettibon System

The Pettibon System is a comprehensive rehabilitation program for the spine's hard and soft tissues. The System's use of specially developed weights, exercises, traction devices as well as other products directly acknowledges that lasting spinal correction is related to the strengthening of targeted muscles.

In 2004, Morningstar et al investigated the possible benefits of using Pettibon corrective procedures to reduce the curvature associated with idiopathic scoliosis.²² A patient with a 35 degrees left convex thoracolumbar scoliosis was treated using Pettibon corrective procedures as well as devices. Initial and follow-up outcome measures included a Borg pain scale, a Functional Rating Index, a balance test, and radiographic analysis. The patient was treated using a combination of manipulative and rehabilitative procedures designed to restore normal sagittal curves and reduce the severity of the coronal curvatures. After six weeks of treatment, the post treatment radiograph revealed a 20 degrees left convex thoracolumbar scoliosis, as well as decreases in the Borg pain scale from six to two, and Functional Rating Index score from 18/40 to 7/40 after the trial period. Her balance time increased from 18 seconds to 56 seconds. The subjective and objective results of this case study require further investigations.

In 2008, Schwab provided a case report describing the effect of exercise-based chiropractic treatment on chronic and intractable low back pain.²³ The patient was treated with Pettibon manipulative and rehabilitative techniques. At 4 weeks, spinal decompression therapy was incorporated. After 12 weeks of treatment, the patient's self-reported numeric pain scale had reduced from 6 to 1. There was also overall improvement in muscular strength, balance times, self-rated functional status, low back Oswestry scores, and lumbar lordosis using pre- and posttreatment radiographic information. This case suggests promising interventions with otherwise intractable low back pain using a multimodal chiropractic approach that includes isometric strengthening, neuromuscular reeducation, and lumbar spinal decompression therapy. However further controlled trials are needed to confirm results.

The absence of controlled studies precludes any conclusions regarding effectiveness of the above traction devices. These devices are considered experimental/investigational.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

North American Spine Society (NASS)¹⁰

The NASS evidence-based clinical guideline for the diagnosis and treatment of cervical radiculopathy from degenerative disorders notes that regarding the role of traction in the treatment of cervical radiculopathy from degenerative disorders that cervical halter traction and combinations of medications, physical therapy, injections and traction have been associated with improvements in patient reported pain in uncontrolled case series. They note that such modalities may be considered recognizing that no improvement relative to the natural history of cervical radiculopathy has been demonstrated.

The NASS evidence-based clinical guideline for diagnosis and treatment of lumbar disc herniation with radiculopathy notes that there is insufficient evidence to make a recommendation for or against the use of traction in the treatment of lumbar disc herniation with radiculopathy.

American College of Physicians/ American Pain Society¹¹

A joint clinical practice guideline from the American College of Physicians and the American Pain Society for the diagnosis and treatment of low back pain notes that intermittent or continuous traction in patients with or without sciatica have not been proven effective for chronic low back pain.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might impact this policy are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04507074	The effect of traction forces in people with obesity suffering from chronic low back pain	60	Jun 2023
NCT02793440	Effectiveness of lumbar traction in lumbar disk herniation	412	Jan 2023
NCT04513730	Positional device aimed at patients with low back pain	20	Dec 2021 (completed)
NCT03488498	Weight bath traction in chronic low back pain	300	Dec 2020 (completed)

NCT: national clinical trial

Government Regulations National:

There is no NCD available for traction.

Local:

L33823, Cervical Traction Devices, effective for services performed on or after 01/01/20.¹²

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding “reasonable and necessary” criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the “reasonable and necessary” criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the “reasonable and necessary” criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Cervical traction devices (E0840-E0855 and E0860) are covered only if both of the following criteria are met:

1. The beneficiary has a musculoskeletal or neurologic impairment requiring traction equipment; and
2. The appropriate use of a home cervical traction device has been demonstrated to the beneficiary and the beneficiary tolerated the selected device.

If criteria 1 and 2 are not met, cervical traction will be denied as not reasonable and necessary.

Cervical traction applied via attachment to a headboard (E0840) or a free-standing frame (E0850) has no proven clinical advantage compared to cervical traction applied via an over-the-door mechanism (E0860). If an E0840 or E0850 is ordered, it will be denied as not reasonable and necessary.

Cervical traction devices described by code E0849 or E0855 are covered only when criteria 1 and 2 above and either criterion A, B or C below has been met:

- A. The beneficiary has a diagnosis of temporomandibular joint (TMJ) dysfunction; and has received treatment for the TMJ condition; or,
- B. The beneficiary has distortion of the lower jaw or neck anatomy (e.g., radical neck dissection) such that a chin halter is unable to be utilized; or,
- C. The treating physician orders and/or documents the medical necessity for greater than 20 pounds of cervical traction in the home setting.

If the criteria for cervical traction are met but the additional criteria for E0849 or E0855 are not met, they will be denied as not reasonable and necessary.

E0856 describes a cervical traction device that can be used with ambulation. Therefore, it will be denied as not reasonable and necessary.

The Saunders Lumbar HomeTrac is covered under CPT E0900.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

References

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through March 2023, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
1/1/19	10/16/18	10/16/18	Joint policy established
1/1/20	10/15/19		Routine policy maintenance, no change in policy status.
1/1/21	10/20/20		Routine policy maintenance. No change in policy status.
7/1/21	5/17/21		Added Pettibon System and Lumbar lordotic curve-controlled traction devices to policy, updated rationale added references# 13-23.
7/1/22	4/19/22		Routine policy maintenance, no change in policy status.
7/1/23	4/18/23		Routine policy maintenance, no change in policy status. Vendor managed: Northwood. (ds)

Next Review Date: 2nd Qtr. 2024

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: LUMBAR TRACTION DEVICES FOR THE TREATMENT OF LOW BACK PAIN

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- *Duplicate (back-up) equipment is not a covered benefit.*