Policy Number	**DME101.041**
Policy Effective Date	**05/15/2024**
Policy End Date	**12/31/2025**

Pneumatic Traction and Spinal Unloading Devices

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

This medical policy has become inactive as of the end date above. There is no current active version and this policy is not to be used for current claims adjudication or business purposes.

Pneumatic traction and spinal unloading devices **are considered experimental, investigational, and/or unproven** in any setting (e.g., home, office, rehabilitation clinic).

Examples of pneumatic traction and spinal unloading devices include, but are not limited to:

- LTX 3000™ Lumbar Rehabilitation System,
- Orthotrac Pneumatic Vest™,
- Saunders Lumbar STx™,
- Saunders Lumbar Hometrac™ Deluxe,
- Pronex™ cervical traction,
- Saunders Cervical HomeTrac™,
- Ctrac™ MeDevice, OR
- Any other devices:

- Defined as “thoracic-lumbo-sacral orthosis (with pneumatics)”, and/or
- Defined as “pneumatic orthosis”, and/or
- That operate in a similar manner, and/or
- That are identified through the U.S. Food and Drug Administration (FDA) 510K system as substantially equivalent to any of the devices listed here.

Policy Guidelines

None.

Description

Traction is the application of a mild stretch to muscles, ligaments, and tissue to provide relief of pain resulting from a variety of conditions, such as muscle spasm, nerve root compression, osteoarthritis, degenerative joint disease, and others. Traction is frequently used to treat the spine, most often either the cervical or the lumbar spine. When used on the spine, traction promotes separation of the intervertebral joint spaces to reduce impingement of structures in the area. The goal of traction is usually short-term pain relief, returning the patient to normal range of motion, and return to work.

Although traction can be accomplished in a variety of ways, home traction is commonly achieved using a system of pulleys, weights, and counterweights connected to a stand (either freestanding or attached to the bed) or “over-the-door” equipment. Some pneumatic devices are worn like a garment or brace. These are inflated by the patient and are designed to lift the patient’s body weight off the spine and relieve intervertebral compression. Other pneumatic devices, such as Ctrac for carpal tunnel, are designed to relieve pressure on nerves or other structures by stretching ligaments in the area. Some of these devices allow the patient to be ambulatory during treatment (such as the Orthotrac Pneumatic Vest), while others require the patient to remain stationary. The LTX-3000 system is a gravity-dependent spinal unloading device that promotes controlled spinal distraction by suspending the patient in a seated position, with the body weight supported from the rib cage by means of a brace-type device fastened around the lower chest.

All of these devices are designed to be used on an intermittent basis, usually two or three times per day.

Regulatory Status
These devices are considered a Class I device by the U.S. Food and Drug Administration (FDA). This classification requires notification of the FDA prior to marketing but does not require submission of clinical data regarding efficacy.

Rationale

A PubMed literature search through February 2024 focused on pneumatic traction devices, pneumatic orthoses, and spinal unloading devices. Following is a summary of the key literature to date.

In 2005, Dallolio (1) reported on a case series of 41 patients with radicular back pain who were treated with an Orthotrac pneumatic lumbar vest, worn for 60 minutes for three times a day for five weeks. A total of 72% of patients reported symptom improvement. However, the lack of a control group limits scientific interpretation.

Orthofix, Inc. has sponsored a randomized controlled trial (RCT) comparing the Orthotrac Pneumatic Vest with an EZ form brace. (2) The target enrollment was 150 patients who had been recently diagnosed with radiating leg pain from disc bulge, protrusion or herniation; A preliminary report of patients (number unreported) completing the 12-week follow-up was presented in 2003. The patients, who were carefully selected to show relief from spine unloading, showed subjective improvements in lower back and leg pain that were 6- to 8-fold greater (5 to 7 points on a visual analogue scale [VAS] for pain) than observed in the group treated with the EZ brace. The study was completed October 2006 but final study results were not published.

In 2017, Urquhart and colleagues published the results of a small randomized controlled trial comparing the use of thoracic lumbar sacral orthosis (TLSOs) to no orthosis in 36 subjects with acute Association of Osteosynthesis (AO) Type A3 thoracolumbar burst fractures who were followed for up to 10 years. A total of 16 subjects were assigned to the TLSO group and 20 to the no TLSO group. The primary outcome, measurements on the Roland Morris Disability Questionnaire (RMDQ) score at the last 5- to 10-year follow-up visit, was 3.6 ± 0.9 (mean ± SE) for the TLSO group and 4.8 ± 1.5 for the control group (p=0.486). Additionally, no differences were reported between the two groups with regard to time-weighted average treatment effects for RMDQ, the mental and physical component summary, or for average pain. The authors concluded that, “Compared with patients treated with a TLSO, patients treated using early mobilization without orthosis maintain similar pain relief and improvement in function for 5-10 years.” The current evidence does not demonstrate that the use of TLSOs for the treatment of thoracolumbar burst fractures leads to improvement in net health outcomes. (3)

Lee and colleagues (2020) stated that lumbar traction is widely used as a non-operative treatment for lumbar intervertebral disc disease. (4) 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 inpatients 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.

DynaMed Plus

In 2023, DynaMed Plus stated that "the addition of traction to physical therapy may provide some benefit" (Dynamed Level 2- Representing research results addressing clinical outcomes, and using some method of scientific investigation, but not meeting the quality criteria to achieve Level 1 evidence labeling). (5)

Summary of Evidence

The lack of published studies does not permit scientific conclusions about pneumatic traction and spinal unloading devices alone or in comparison to other types of back orthoses. The literature regarding pneumatic traction and spinal unloading devices is, in general, of poor quality. Without appropriate scientific evidence, the potential benefits of these devices cannot be evaluated therefore, pneumatic traction and spinal unloading devices are considered experimental, investigational, and/or unproven in any setting (e.g., home, office, rehabilitation clinic).

Practice Guidelines and Position Statements

North American Spine Society (NASS)

The 2011 NASS Clinical Practice Guideline (6) on the diagnosis and treatment of degenerative lumbar spinal stenosis states: "There is insufficient evidence to make a recommendation for or

against traction, electrical stimulation or TENS for the treatment of patients with lumbar spinal stenosis. (Grade of Recommendation: Insufficient Evidence) An extensive review of all articles cited found no direct comparison of ancillary treatments (traction, electrical stimulation or TENS) to an untreated control group. In 2012, NASS published a clinical practice guideline for the treatment of lumbar disc herniation with radiculopathy stating that there is insufficient evidence to make a recommendation for or against the use of traction with a grade of recommendation: I (Insufficient Evidence). A RCT with long-term follow up and validated outcome measures would assist in providing evidence to assess the efficacy of traction in the treatment of lumbar disc herniation with radiculopathy. (7) In 2014, NASS updated their clinical guidelines and stated there was no update or change in the Medical and Interventional treatment for lumbar spinal stenosis. "An updated systematic review of the literature yielded no studies to adequately address any of the medical/interventional treatment questions posed", i.e., traction, electrical stimulation or TENS. (8)

The North American Spine Society (2020) Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care issued the following recommendation: "In patients with subacute or chronic low back pain, traction is not recommended to provide clinically significant improvements in pain or function. Grade of Recommendation: A " (9)

American Physical Therapy Association (APTA)

The 2012 clinical practice guidelines linked to the international classification of functioning, disability and health from the orthopedic section of the physical therapy association (10) states that there is conflicting evidence for the efficacy of intermittent lumbar traction for patients with low back pain. There is preliminary evidence that a subgroup of patients with signs of nerve root compression along with peripheralization of symptoms or a positive crossed straight leg raise may benefit from intermittent lumbar traction in the prone position. There is moderate evidence that clinicians should not utilize intermittent or static lumbar traction for reducing symptoms in patients with acute or subacute, nonradicular low back pain or patients with chronic low back pain. (Recommendation based on conflicting evidence.)

In 2017, the APTA revised the clinical practice guidelines for neck pain. The revision includes the following recommendations (11):
"For patients with chronic neck pain with mobility deficits: Clinicians should provide a multimodal approach of the following:

- Thoracic manipulation and cervical manipulation or mobilization,
- Mixed exercise for cervical/scapulothoracic regions: neuromuscular exercise (e.g., coordination, proprioception, and postural training), stretching, strengthening, endurance training, aerobic conditioning, and cognitive affective elements,
- Dry needling, laser, or intermittent mechanical/manual traction."

"For patients with chronic neck pain with radiating pain: Clinicians should provide mechanical intermittent cervical traction, combined with other interventions such as stretching and strengthening exercise plus cervical and thoracic mobilization/manipulation."

Academy of Orthopaedic Physical Therapy (AOPT)

In a 2021 update to the 2012 Academy of Orthopaedic Physical Therapy (AOPT), formerly the Orthopaedic Section of the American Physical Therapy Association (APTA), clinical practice guideline (CPG) for low back pain (LBP), AOPT stated that: "Physical therapists should not use mechanical traction for patients with chronic LBP with leg pain, based on the lack of benefit when added to other interventions. (12)

American College of Physicians (ACP)

In 2017, the ACP developed a guideline for noninvasive treatments for acute, subacute, and chronic low backpain to present the evidence and provide clinical recommendations on noninvasive treatment of low back pain. This guideline states the following (13):
"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."

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	None
HCPCS Codes	E0830, E0849, E0856

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/31/2025	Document became inactive.
05/15/2024	Document updated with literature review. Coverage unchanged. References 9 and 12 added, others updated.

06/01/2023	Reviewed. No changes.
12/01/2022	Document updated with literature review. Coverage unchanged. References 3 and 4 added; several removed.
09/01/2021	Reviewed. No changes.
11/15/2020	Document updated with literature review. Coverage unchanged. Reference 26 added.
10/15/2019	Reviewed. No changes.
03/15/2018	Document updated with literature review. Coverage unchanged.
07/01/2016	Reviewed. No changes.
09/15/2015	Document updated with literature review. Coverage unchanged. Rationale and references revised. Title changed from Pneumatic Traction and Spinal Uploading Devices
09/15/2014	Reviewed. No changes.
11/01/2013	Literature reviewed. No change.
06/01/2008	Policy reviewed without literature review; new review date only. This policy is no longer scheduled for routine literature review and update.
08/15/2007	Revised/updated entire document