Anthem

# Medical Policy

**Subject:** Self-Operated Spinal Unloading Devices
**Document #:** DME.00025
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## Description/Scope

This document addresses self-operated spinal unloading devices, which are designed to support the upper body's weight and transfer that weight to the hips via a mechanical or pneumatic mechanism. Self-operated spinal unloading has been suggested as a conservative treatment for pain related to spinal disc disease or joint dysfunction. Several self-operated spinal unloading devices are currently available on the market, such as the LTX 3000™ and the Lumbar Hometrac®.

## Position Statement

**Investigational and Not Medically Necessary:**

Self-operated spinal unloading devices including, but not limited to, gravity-dependent and pneumatic devices, are considered **investigational and not medically necessary** for all indications including, but not limited to, the treatment of low back pain and scoliosis.

## Rationale

Self-operated spinal unloading devices have been proposed for the treatment of spine-related pain and scoliosis. However, evidence to support their efficacy is limited.

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 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.

A Cochrane Review (2013) assessed the effects of traction compared to placebo, sham traction, reference treatments, and no treatment in people with low back pain. The review included 16 randomized controlled trials (RCT) of both manual and machine delivered traction. The review concluded that:

> These findings indicate that traction, either alone or in combination with other treatments, has little or no impact on pain intensity, functional status, global improvement and return to work among people with LBP. There is only limited-quality evidence from studies with small sample sizes and moderate to high risk of bias. The effects shown by these studies are small and are not clinically relevant.

The North American Spine Society (2020) 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

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

## Background/Overview

*Description of Back Pain*

Pain felt in the lower back may come from the spine, muscles, nerves, or other structures in that region of the back. It may also radiate from other areas like the mid or upper back, a hernia in the groin, or a problem in the testicles or ovaries. However, most back problems are due to injury from stress or strain that can cause temporary or permanent damage to various structures of the lower back. Examples of such structures include intervertebral discs and various ligaments and tendons of the spine. Damage to peripheral nerves or even the spinal cord itself may also occur. Most low back injuries heal without intervention, but if symptoms persist for longer than a few weeks, treatment may be warranted.

Treatments for low back pain include non-prescription analgesic medications, such as aspirin or other non-steroidal anti-inflammatory drugs, or short-term bed rest. For some individuals, other prescription medications may be needed, including opioids for severe pain. Physical exercise may also be effective to speed recovery from back injuries. In the most severe or chronic cases, invasive treatment methods, including injections of steroids and surgical procedures, may be indicated.

*Description of Scoliosis*

Scoliosis is a condition where the back is abnormally curved. Most cases of scoliosis are mild and do not need treatment. A few cases do need treatment so that other problems will not develop in later years, such as breathing problems due to chest constriction. If spinal curves progress above 25 to 30 degrees in a child who is still growing, spinal bracing can help slow the progression of the curve. There are many different kinds of braces available and each has a different appearance and method of application. The selection of a brace and the manner in which it is used are determined by many factors including the specific characteristics of the curvature and individual and physician preference.

More severe curvatures of the spine may require surgery to address the risk of progressing even after bone growth stops. Surgical

correction involves improving the curvature and fusing the bones and a brace may be required after surgery to stabilize the spine.

*Functional Description of Self-Operated Spinal Unloading Devices*

Self-operated spinal unloading devices, also known as self-operated thoracic-lumbo-sacral orthoses have been proposed for the treatment of back pain. These devices are designed to support the upper body's weight and transfer that weight to the hips via a mechanical or pneumatic mechanism. This weight transfer is theorized to stabilize and decompress the spine, relieving stress from the lower back resulting from bearing the upper body's weight. Self-operated spinal unloading devices have been suggested as a conservative treatment for pain related to spinal disc disease or joint dysfunction. Several spinal unloading devices are currently available on the market, including the LTX 3000 and the Lumbar Hometrac (Saunders Medical Inc., Ozark, AL).

## Definitions

Scoliosis: A condition where the back is abnormally curved.

Spinal unloading devices: Devices designed to alleviate stress on the lower back by transferring the weight of the upper body to the hips.

Spinal traction: A form of decompression therapy, performed manually or mechanically, that relieves pressure on the spine.

## Coding

*The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.*

**When services are Investigational and Not Medically Necessary:**
When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

**HCPCS**

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|---|---|
| E1399 | Durable medical equipment, miscellaneous [when specified as a spinal unloading device] |
| L1499 | Spinal orthosis, not otherwise specified [when specified as a spinal unloading device] |

**ICD-10 Diagnosis**

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|---|---|
| | All diagnoses |

## References

**Peer Reviewed Publications:**


1. Hales J, Larson P, Iaizzo PA. Treatment of adult lumbar scoliosis with axial spinal unloading using the LTX3000 Lumbar Rehabilitation System. Spine (Phila Pa 1976). 2002; 27(3):E71-E79.
2. Janke AW, Kerkow TA, Griffiths HG, et al. The biomechanics of gravity-dependent traction of the lumbar spine. Spine (Phila Pa 1976). 1997; 22(3):253-260.
3. Podein RJ, Iaizzo PA. Applied forces and associated physiologic responses induced by axial spinal unloading with the LTX 3000 Lumbar Rehabilitation System. Arch Phys Med Rehabil. 1998; 79(5):505-513.
4. Urquhart JC, Alrehaili OA, Fisher CG, et al. Treatment of thoracolumbar burst fractures: extended follow-up of a randomized clinical trial comparing orthosis versus no orthosis. J Neurosurg Spine. 2017; 27(1):42-47.


**Government Agency, Medical Society, and Other Authoritative Publications:**


1. AOSpine Vaccaro AR, Oner C, Kepler CK, et al.; AOSpine Spinal Cord Injury & Trauma Knowledge Forum. AOSpine thoracolumbar spine injury classification system: fracture description, neurological status, and key modifiers. Spine (Phila Pa 1976). 2013; 38(23):2028-37.
2. North American Spine Society. Evidence-based clinical guidelines for multidisciplinary spine care: Diagnosis & treatment of low back pain. 2020. Available at: https://www.spine.org/Portals/0/assets/downloads/ResearchClinicalCare/Guidelines/LowBackPain.pdf. Accessed on August 7, 2023.
3. Qaseem A, Wilt TJ, McLean RM, Forciea MA.; Clinical Guidelines Committee of the American College of Physicians. Noninvasive treatments for acute, subacute, and chronic low back pain: a clinical practice guideline from the American College of Physicians. Ann Intern Med. 2017; 166(7):514-530.
4. Wegner I, Widyahening IS, van Tulder MW, et al. Traction for low-back pain with or without sciatica. Cochrane Database Syst Rev. 2013; (8):CD003010.


## Websites for Additional Information

1. National Library of Medicine. Medical Encyclopedia: Back pain. Available at:https://medlineplus.gov/backpain.html. Accessed on August 7, 2023.
2. National Library of Medicine. Medical Encyclopedia: Scoliosis. Available at: http://www.nlm.nih.gov/medlineplus/ency/article/001241.htm. Accessed on August 7, 2023.

## Index

**The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.**

## Document History

| Status | Date | Action |
|---|---|---|
| Reviewed | 08/10/2023 | Medical Policy & Technology Assessment Committee (MPTAC) review. Revised References and Websites sections. |
| Reviewed | 08/11/2022 | MPTAC review. Updated References section. |
| Reviewed | 08/12/2021 | MPTAC review. Updated Rationale, Background/Overview, Definitions, and References sections. |
| Reviewed | 08/13/2020 | MPTAC review. |
| Reviewed | 11/07/2019 | MPTAC review. Updated Websites and Index sections. Updated Coding section; added E1399. |
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| Reviewed | 02/13/2014 | MPTAC review. Updated References section. |
| Reviewed | 02/14/2013 | MPTAC review. |
| Reviewed | 02/16/2012 | MPTAC review. |
| Reviewed | 02/17/2011 | MPTAC review. Updated title to replace “Patient” with “Self”. |
| Reviewed | 05/13/2010 | MPTAC review. Updated References section. |
| Reviewed | 05/21/2009 | MPTAC review. Updated Rationale, Background and References sections. |
| Reviewed | 05/15/2008 | MPTAC review. Updated References and Index sections. |
| | 02/21/2008 | The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting. |
| Reviewed | 05/17/2007 | MPTAC review. |
| | 11/29/2006 | Added Saunders Lumbar Hometrac to index section. |
| Reviewed | 06/08/2006 | MPTAC review. References updated. |
| Revised | 07/14/2005 | MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization. |

| Pre-Merger Organizations | Last Review Date | Document Number | Title |
|---|---|---|---|
| Anthem, Inc. | 04/27/2004 | DME.00025 | Patient-Operated Spinal Unloading Devices |
| WellPoint Health Networks, Inc. | 09/23/2004 | 9.07.03 | Spinal Unloading Devices for Treatment of Low Back Pain |

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Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.