

<b>8.03.09</b>	<b>Vertebral Axial Decompression</b>		
<b>Original Policy Date:</b>	June 28, 2007	<b>Effective Date:</b>	June 1, 2021
<b>Section:</b>	8.0 Therapy	<b>Page:</b>	Page 1 of 8

## Policy Statement

Vertebral axial decompression is considered **investigational**.

**NOTE:** Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

## Policy Guidelines

The following CPT code may be used to describe vertebral axial decompression:

- **97012:** Application of a modality to 1 or more areas; traction, mechanical

The following HCPCS code is specific to vertebral axial decompression:

- **S9090:** Vertebral axial decompression, per session

## Description

Vertebral axial decompression applies traction to the vertebral column to reduce intradiscal pressure, and in doing so, potentially relieves low back pain associated with herniated lumbar discs or degenerative lumbar disc disease.

## Related Policies

- N/A

## Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. 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.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

## Regulatory Status

Several devices used for vertebral axial decompression have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Examples of these devices include the VAX-D®, Decompression Reduction Stabilization (DRS®) System, Accu-SPINA® System, DRX-3000®, DRX9000®, SpineMED Decompression Table®, Antalgic-Trak®, Lordex® Traction Unit, and Triton® DTS. According to labeled indications from the FDA, vertebral axial decompression may be used as a treatment modality for patients with incapacitating low back pain and for decompression of the intervertebral discs and facet joints.

FDA product code: ITH.

## Rationale

### Background

Vertebral axial decompression (also referred to as mechanized spinal distraction therapy) is used as traction therapy to treat chronic low back pain. Specific devices available are described in the Regulatory Status section.

In general, during treatment, the patient wears a pelvic harness and lies prone on a specially equipped table. The table is slowly extended, and a distraction force is applied via the pelvic harness until the desired tension is reached, followed by a gradual decrease of the tension. The cyclic nature of the treatment allows the patient to withstand stronger distraction forces compared with static lumbar traction techniques. An individual session typically includes 15 cycles of tension, and 10 to 15 daily treatments may be administered.

### Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

### Vertebral Axial Decompression for Chronic Lumbar Pain

#### Clinical Context and Therapy Purpose

The purpose of vertebral axial decompression is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard conservative therapy, in patients with chronic lumbar pain due to disc-related causes.

The question addressed in this evidence review is: Does the use of vertebral axial decompression improve the net health outcome in patients with chronic lumbar pain due to disc-related causes?

The following PICO was used to select literature to inform this review.

#### Populations

The relevant population of interest is individuals with chronic lumbar pain due to disc-related causes.

#### Interventions

The therapy being considered is vertebral axial decompression.

Vertebral axial decompression applies traction to the vertebral column to reduce intradiscal pressure, and in doing so, potentially relieves low back pain associated with herniated lumbar discs or degenerative lumbar disc disease.

### **Comparators**

The following practice is currently being used to treat chronic lumbar pain due to disc-related causes: standard conservative therapy.

Conservative management includes nonsteroidal anti-inflammatory medications, back braces, and physical therapy; other nonsurgical treatments could include muscle relaxants, narcotic pain medications, or epidural steroid injections.<sup>1</sup>

### **Outcomes**

The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity.

Follow-up for patients receiving vertebral axial decompression would ideally be 6 months or longer.

### **Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

### **Review of Evidence**

#### **Randomized Controlled Trials**

Schimmel et al (2009) published results from a randomized sham-controlled trial of intervertebral axial decompression.<sup>2</sup> Sixty subjects with chronic symptomatic lumbar disc degeneration or bulging disc with no radicular pain and no prior surgical treatment (dynamic stabilization, fusion, or disc replacement) were randomized to a graded activity program with an Accu-SPINA device (20 traction sessions during 6 weeks, reaching >50% of body weight) or to a graded activity program with a nontherapeutic level of traction (<10% body weight). In addition to traction, the device provided massage, heat, relaxing blue light, and music during the treatment sessions. Neither patients nor evaluators were informed about the intervention received until after the 14-week follow-up assessment and the intention-to-treat analysis was performed (93% of subjects completed follow-up). Both groups showed improvements in validated outcome measures (visual analog scale scores for back and leg pain, Oswestry Disability Index, 36-Item Short-Form Health Survey) but no significant differences between treatment groups. For example, visual analog scale scores for low back pain decreased from 61 to 32 in the active group and from 53 to 36 in the sham group. Evidence from this RCT did not support improvements in health outcomes with vertebral axial decompression.

Isner-Horobeti et al (2016) reported on a preliminary double-blind RCT comparing high-force traction (50% body weight; n=8) with low-force traction (10% body weight; n=9) for individuals with acute low back pain and radiculopathy due to lumbar disc herniation.<sup>3</sup> Patients were enrolled from a French emergency department. Inclusion criteria were lumbar sciatica of fewer than 6 weeks in duration, secondary to disc herniation based on clinical exam, confirmed by lumbar tomodensitometry. Patients with clinical neurologic deficits, sciatica due to something other than disc herniation, or abnormalities on tomography were excluded. For the trial's primary outcome (reduction in radicular pain measured by a 100-mm visual analog scale), both groups demonstrated significant improvements from baseline to day 28 ( Table 1). However,

there was no significant interaction effect (group-by-time) regarding pain reduction. Similar findings were seen for lumbo-pelvic-hip mobility (measured by the finger-toe test) and nerve root compression (measured by the straight leg raise test).

**Table 1. RCT Results for Change From Baseline to Day 28**

Outcome Measures	High-Force Traction Group (n=8)		Low-Force Traction Group (n=9)	
	Value (95% CI)	p	Value (95% CI)	p
Radicular pain (VAS, mm)	-28.8 (-41.8 to -3.7)	<0.001	-34.8 (-52.6 to -17)	<0.001
Lumbar spine mobility (Finger-toe test, mm)	-14.4 (-25.6 to -3.1)	<0.10	-17.6 (-28.3 to -7.0)	<0.001
Straight leg raise test (elevation angle)	33.1° (13.3° to 53.0°)	<0.01	36.0° (17.3° to 54.7°)	<0.001

Adapted from Isner-Horobeti et al (2016).<sup>3</sup>

CI: confidence interval; RCT: randomized controlled trial; VAS: visual analog scale.

Overall, this trial suggested some rapid short-term within-subject improvements with high-dose lumbar traction. Although lumbar traction was not compared with a placebo, the comparison with low-level traction may approximate a placebo, similar to the Schimmel et al (2009) RCT, which used traction at 10% body weight traction as a placebo. The lack of significant interaction term suggests the active intervention is not associated with improved outcomes. However, the trial's small size might mean that it was underpowered.

Sherry et al (2001) conducted an RCT comparing vertebral axial decompression (using the VAX-D device) with transcutaneous electrical nerve stimulation.<sup>4</sup> While a 68% success rate was associated with VAX-D compared with a 0% success rate with transcutaneous electrical nerve stimulation, without a true placebo control, the results are difficult to interpret scientifically. In 2007, 2 small randomized trials (N=27, N=64) found little to no difference between patients treated with or without mechanical traction.<sup>5,6</sup>

### Summary of Evidence

For individuals with chronic lumbar pain who receive vertebral axial decompression, the evidence includes RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Evidence for the efficacy of vertebral axial decompression on health outcomes is limited. Because a placebo effect may be expected with any treatment that has pain relief as the principal outcome, RCTs with sham controls and validated outcome measures are required. The only sham-controlled randomized trial published to date did not show a benefit of vertebral axial decompression compared with the control group. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

### Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

No guidelines or statements were identified.

### U.S. Preventive Services Task Force Recommendations

Not applicable.

**Medicare National Coverage**

In 1997, Medicare issued a national noncoverage policy (160.16) for vertebral axial decompression.<sup>7</sup>

**Ongoing and Unpublished Clinical Trials**

A search of [ClinicalTrials.gov](https://clinicaltrials.gov) in March 2021 did not identify any ongoing or unpublished trials that would likely influence this review.

**References**

1. Pelozo J. Non-Surgical Treatments for Lower Back Pain. Spine-health. <https://www.spine-health.com/conditions/lower-back-pain/non-surgical-treatments-lower-back-pain>. Updated April 20, 2017. Accessed March 1, 2021.
2. Schimmel JJ, de Kleuver M, Horsting PP, et al. No effect of traction in patients with low back pain: a single centre, single blind, randomized controlled trial of Intervertebral Differential Dynamics Therapy. *Eur Spine J*. Dec 2009; 18(12): 1843-50. PMID 19484433
3. Isner-Horobeti ME, Dufour SP, Schaeffer M, et al. High-Force Versus Low-Force Lumbar Traction in Acute Lumbar Sciatica Due to Disc Herniation: A Preliminary Randomized Trial. *J Manipulative Physiol Ther*. Nov 2016; 39(9): 645-654. PMID 27838140
4. Sherry E, Kitchener P, Smart R. A prospective randomized controlled study of VAX-D and TENS for the treatment of chronic low back pain. *Neurol Res*. Oct 2001; 23(7): 780-4. PMID 11680522
5. Fritz JM, Lindsay W, Matheson JW, et al. Is there a subgroup of patients with low back pain likely to benefit from mechanical traction? Results of a randomized clinical trial and subgrouping analysis. *Spine (Phila Pa 1976)*. Dec 15 2007; 32(26): E793-800. PMID 18091473
6. Harte AA, Baxter GD, Gracey JH. The effectiveness of motorised lumbar traction in the management of LBP with lumbo sacral nerve root involvement: a feasibility study. *BMC Musculoskelet Disord*. Nov 29 2007; 8: 118. PMID 18047650
7. Centers for Medicare & Medicaid Services. National Coverage Decision (NCD) for Vertebral Axial Decompression (VAX-D) (160.16). 1997; <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=124&Keyword=vertebral%20axial%20decompress&KeywordLookup=Title&KeywordSearchType=Exact&bc=CAAAAAAAAAAAAA>. Accessed March 1, 2021.
8. Blue Cross Blue Shield Association. Medical Policy Reference Manual, No. 8.03.09 (April 2021).

**Documentation for Clinical Review**

- No records required

**Coding**

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

Type	Code	Description
CPT®	97012	Application of a modality to 1 or more areas; traction, mechanical

Type	Code	Description
HCPCS	S9090	Vertebral axial decompression, per session

### Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
06/28/2007	New Policy Adoption
04/03/2009	BCBSA Medical Policy adoption
01/06/2012	Policy revision without position change
10/31/2014	Policy revision without position change
08/01/2016	Policy revision without position change
06/01/2017	Policy revision without position change
06/01/2018	Policy revision without position change
06/01/2019	Policy revision without position change
06/01/2020	Annual review. No change to policy statement. Literature review updated
06/01/2021	Annual review. No change to policy statement. Literature review updated.

### Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

### Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

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*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. 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 covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*

**Appendix A**

POLICY STATEMENT (No changes)	
BEFORE	AFTER
Vertebral Axial Decompression 8.03.09  Policy Statement: Vertebral axial decompression is considered <b>investigational</b> .	Vertebral Axial Decompression 8.03.09  Policy Statement: Vertebral axial decompression is considered <b>investigational</b> .