



Louisiana

Vertebral Axial Decompression

Policy # 00135

Original Effective Date: 08/06/2001

Current Effective Date: 12/20/2017

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers vertebral axial decompression to be **investigational**.*

Background/Overview

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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Several devices used for vertebral axial decompression have been cleared for marketing by the U.S. FDA through the 510(k) process. 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 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.

Centers for Medicare and Medicaid Services (CMS)

Medicare has issued a national noncoverage policy (160.16) for vertebral axial decompression in 1997.⁶

Rationale/Source

VERTEBRAL AXIAL DECOMPRESSION FOR CHRONIC LUMBAR PAIN

Assessment of efficacy for therapeutic interventions involves a determination of whether an intervention improves health outcomes. The optimal study design for a therapeutic intervention is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes.

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We limited our literature review to RCTs given the likelihood of selection bias for treatments related to pain. We focused on identifying RCTs with sham controls and blinded outcome measures with independent assessors given the potential for placebo effects with pain treatments.

Randomized Controlled Trials

In 2009, Schimmel et al published results from a randomized sham-controlled trial of intervertebral axial decompression. 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, blue relaxing 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 intention-to-treat analysis was performed (93% of subjects completed follow-up). Both groups showed improvements in validated outcome measures (visual analog scale [VAS] scores for back and leg pain, Oswestry Disability Index, 36-Item Short-Form Health Survey), but no significant differences between treatment groups. For example, VAS 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.

In 2016, Isner-Horobeti et al 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. Patients were enrolled from a French emergency department. Inclusion criteria were lumbar sciatica of less than 6 weeks in duration, secondary to disc herniation based on clinical exam, confirmed by lumbar tomodensitometry. Patients with clinical neurologic deficits, sciatic 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 VAS), both groups demonstrated significant improvements from baseline to day 28 (see Table 1). However, there was no significant group by time interaction in terms of pain reduction. Similar findings were seen for lumbo-pelvic-hip mobility (measured by the finger-toe test), nerve root compression (measured by the straight leg raise test).

Table 1: Summary Results From Isner-Horobeti et al (2016)

Outcome Measures for Change From Baseline to Day 28	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 017)	<0.001
Lumbar spine mobility (FTT, 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

CI: confidence interval; finger-toe test; VAS: visual analog scale.

Overall, this trial suggested some rapid short-term within-subjects improvements with a high-dose lumbar traction. Although lumbar traction was not compared with a placebo, the comparison with low-level traction

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may approximate a placebo, similar to the Schimmel et al RCT, which used traction at 10% body weight traction as a placebo. The lack of significant interaction term suggests that the active intervention is not associated with improved outcomes. However, the trial's small size may 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 (TENS). While a 68% success rate was associated with VAX-D compared with a 0% success rate with TENS, 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.

SUMMARY OF EVIDENCE

For individuals who have 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 the effects of the technology on health outcomes.

References

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Policy History

Original Effective Date: 08/06/2001

Current Effective Date: 12/20/2017

07/19/2001 Medical Policy Committee review

08/06/2001 Managed Care Advisory Council approval

07/15/2003 Medical Policy Committee review

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08/25/2003	Managed Care Advisory Council approval
12/07/2004	Medical Director review
12/21/2004	Medical Policy Committee review. Format revision. No substance change to policy.
01/31/2005	Managed Care Advisory Council approval
07/07/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
04/04/2007	Medical Director review
04/18/2007	Medical Policy Committee approval. No change to coverage eligibility.
04/02/2009	Medical Director review
04/15/2009	Medical Policy Committee approval. No change to coverage eligibility.
04/08/2010	Medical Director review
04/21/2010	Medical Policy Committee approval. No change to coverage eligibility.
04/07/2011	Medical Policy Committee review
04/13/2011	Medical Policy Implementation Committee approval. No change to coverage eligibility.
04/12/2012	Medical Policy Committee review
04/25/2012	Medical Policy Implementation Committee approval. No change to coverage eligibility.
05/02/2013	Medical Policy Committee review
05/22/2013	Medical Policy Implementation Committee approval. No change to coverage eligibility.
08/07/2014	Medical Policy Committee review
08/20/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
12/03/2015	Medical Policy Committee review
12/16/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/01/2016	Medical Policy Committee review
12/21/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
12/07/2017	Medical Policy Committee review
12/20/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date:	12/2018

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT)[®]‡, copyright 2016 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	S9090
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

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