BlueCross BlueShield of Alabama

Name of Policy:
Vertebral Axial Decompression

Policy #: 484
Category: Therapy

Latest Review Date: May 2018
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *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 that patient's illness, injury or disease.*

Description of Procedure or Service:

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.

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 to static lumbar traction techniques. An individual session typically includes 15 cycles of tension, and 10 to 15 daily treatments may be administered.

Policy:

Effective for dates of service on or after January 1, 2012:

Vertebral axial decompression does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational.**

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

This evidence review has been updated periodically using the MEDLINE database. The most recent literature review was performed through February 5, 2018.

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.

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. RCTs 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.

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 randomly assigned to a graded activity program with an AccuSPINA device (20 traction sessions during 6 weeks, reaching >50% 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 (visual analog scores [VAS] for back and leg pain, Oswestry Disability Index [ODI], and 36-Item Short-Form Health Survey [SF-36]), with no differences between the treatment groups. For example, VAS 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 recent randomized controlled trial does not support an improvement 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 tomodensitometry 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 may approximate a placebo, similar to the Spina 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 and colleagues (2011) 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 associated 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 randomized controlled trials (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.

Practice Guidelines and Position Statements

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Key Words:

Vertebral axial decompression, VAX-D, Decompression Reduction Stabilization, System, DRS, Accu-Spina System, DRX-3000, DRX90000, DRX, SpineMED Decompression Table, Antalgic-Trak, Lordex Traction Unit, Triton DTS, Spina System, PDS, ActivTrac, Tru-Trac, Intervertebral Differential Dynamics Therapy

Approved by Governing Bodies:

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. 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.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply.
FEP: FEP does not consider investigational if FDA approved. Claims may be reviewed for medical necessity.

Current Coding:

The following CPT code should* NOT *be used to bill for vertebral axial decompression.

CPT Codes:	**97012**	Application of a modality to one or more areas; traction, mechanical

***The correct* HCPCS *code should be used to bill for vertebral axial decompression*.**

HCPCS Codes:	**S9090**	Vertebral axial decompression, per session

References:

1. Beattie PF, Nelson RM, Michener LA, et al. Outcomes after a prone lumbar traction protocol for patients with activity-limiting low back pain: a prospective case series study. Arch Phys Med Rehabil 2008; 89(2):269-274.
2. Centers for Medicare and Medicaid Services. National Coverage Decision for Vertebral Axial Decompression (VAX-D) (160.16). https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=124&ncdver=1&DocID=160.16&ncd_id=160.16&ncd_version=1&basket=ncd*3a%24160.16*3a%241*3a%24Vertebral+Axial+Decompression+(VAX-D)&bc=gAAAAAgAAAAAAA%3d%3d&. Accessed March 7, 2017.
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4. Gose EE, Naguszewski WK, Naguszewski RK. Vertebral axial decompression therapy for pain associated with herniated or degenerated discs or facet syndrome: an outcome study. Neurol Res 1998; 20(3):186-190.

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6. 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 - Dec 2016; 39(9):645-654.
7. Macario A, Richmond C, Auster M et al. Treatment of 94 outpatients with chronic discogenic low back pain with the DRX9000: a retrospective chart review. Pain Pract 2008; 8(1):11-17.
8. Ramos G, Martin W. Effects of vertebral axial decompression on intradiscal pressure. J Neurosurg 1994; 81(3):350-353.
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11. 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 2001; 23(7):780-784.

Policy History:

Medical Policy Panel, October 2011
Medical Policy Group, October 2011 **(2):** New policy
Medical Policy Administration Committee, October 2011
Available for comment October 19 through December 31, 2011
Medical Policy Panel, October 2012
Medical Policy Group, October 2012 **(2):** Literature search through August 2012. Policy unchanged.
Medical Policy Panel, October 2013
Medical Policy Group, December 2013 **(2):** Literature search through August 2013. Policy statement unchanged.
Medical Policy Panel, October 2014
Medical Policy Group, October 2014 **(3)**: 2014 Updates to Description & Key Points; no change in policy statement
Medical Policy Panel, June 2016
Medical Policy Group, June 2016 **(7)**: 2016 Updates to Description & Key Points; no change in policy statement
Medical Policy Panel, April 2017
Medical Policy Group, April 2017 **(7):** 2017 Updates to Description, Key Points & References; no change in policy statement.
Medical Policy Panel, May 2018
Medical Policy Group, May 2018 **(7):** Updates to Key Points; no change in policy statement.

hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.