Kansas City
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Vertebral Axial Decompression

Policy Number: 8.03.09 **Last Review:** 11/2018
Origination: 11/2005 **Next Review:** 11/2019

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for vertebral axial decompression. This is considered investigational.

When Policy Topic is covered

Not Applicable

When Policy Topic is not covered

Vertebral axial decompression is considered **investigational**.

Description of Procedure or Service

Populations	Interventions	Comparators	Outcomes
Individuals: • With chronic lumbar pain	Interventions of interest are: • Vertebral axial decompression	Comparators of interest are: • Standard conservative therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

Vertebral axial decompression is a type of lumbar traction that has been investigated as a technique to reduce intradiscal pressure and relieve low back pain associated with herniated lumbar discs or degenerative lumbar disc disease.

For individuals who have chronic lumbar pain who receive vertebral axial decompression, the evidence includes small 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.

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.

Regulatory Status

Several devices used for vertebral axial decompression have been cleared for marketing by the U.S. Food and Drug Administration 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 the Food and Drug Administration, 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. Food and Drug Administration product code: ITH.

Rationale

This evidence review was created in May 1997 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through February 5, 2018.

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.

Vertebral Axial Decompression for Chronic Lumbar Pain

Randomized Controlled Trials

Schimmel et al (2009) published results from a randomized sham-controlled trial of intervertebral axial decompression.[1] 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 bllue 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.

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.[2] 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, 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 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. Summary 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 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

Adapted from Isner-Horobeti et al (2016).[2]
CI: confidence interval; FTT: finger-toe test; RCT: randomized controlled trial; VAS: visual analog scale.

Overall, this trial suggested some rapid short-term within-subjects 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 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 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.[3] 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.[4,5]

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.

Supplemental Information

Practice Guidelines and Position Statements

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

Medicare issued a national noncoverage policy (160.16) for vertebral axial decompression in 1997.[6]

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in March 2018 did not identify any ongoing or unpublished trials that would likely influence this review.

References

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3. 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):780-784. PMID 11680522
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Billing Coding/Physician Documentation Information

64722 Decompression; unspecified nerve(s) (specify)
97012 Application of a modality to one or more areas; traction, mechanical
S9090 Vertebral axial decompression, per session

ICD10 Codes:
M51.04-M51.07 Thoracic, thoracolumbar and lumbosacral intervertebral disc disorders with myelopathy code range
M51.14-M51.17 Thoracic, thoracolumbar and lumbosacral intervertebral disc disorders with radiculopathy code range
M51.24-M51.27 Other thoracic, thoracolumbar and lumbosacral intervertebral disc displacement code range
M51.34-M51.37 Other thoracic, thoracolumbar and lumbosacral intervertebral disc degeneration code range
M54.5 Low back pain

Additional Policy Key Words

IDD

Policy Implementation/Update Information

11/1/05 New policy added to the medical section.
11/1/06 No policy statement changes.
11/1/07 No policy statement changes.
11/1/08 No policy statement changes.

11/1/09 No policy statement changes.
11/1/10 No policy statement changes.
11/1/11 No policy statement changes.
11/1/12 No policy statement changes.
11/1/13 No policy statement changes.
11/1/14 No policy statement changes.
11/1/15 No policy statement changes.
3/1/16 No policy statement changes.
11/1/16 No policy statement changes.
11/1/17 No policy statement changes.
11/1/18 No policy statement changes.
