8.03.09	Vertebral Axial Decompression		
Original Policy Date:	June 28, 2007	**Effective Date:**	June 1, 2025
Section:	8.0 Therapy	**Page:**	Page 1 of 10

Policy Statement

I. 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

Coding

See the Codes table for details.

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.

Summary of Evidence

For individuals with chronic lumbar pain who receive vertebral axial decompression, the evidence includes 2 systematic reviews and 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 that the technology results in an improvement in the net health outcome.

Additional Information

Not applicable.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable member health services contract language. To the extent there are conflicts between this Medical Policy and the member health services 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 law may prohibit health plans from denying FDA-approved Healthcare Services as investigational or experimental. In these instances, Blue Shield of California may be obligated to determine if these FDA-approved Healthcare Services are Medically Necessary.

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 1 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.
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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 in individuals 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.[1,]

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.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
Systematic Reviews
Vanti et al (2021) published a systematic review with meta-analysis that evaluated the efficacy of mechanical traction with or without other conservative treatments on pain and disability in adults with lumbar radiculopathy.[2,] A list of studies included in the meta-analysis is found in Table 1. The characteristics of trials included in the systematic review and results of the meta-analysis are summarized in Tables 2 and 3, respectively. Of note, only analyses that included more than 1 RCT are summarized in Table 3. Briefly, results demonstrated that supine mechanical traction added to physical therapy had significant effects on pain and disability, whereas, prone mechanical traction added to physical therapy did not demonstrate these effects.

Wang et al (2022) published a meta-analysis evaluating the efficacy of mechanical traction for pain associated with lumbar disc herniation.[3] Six RCTs (N=239) were included in the analysis (Table 1). Characteristics of the review and results are listed in Tables 2 and 3, respectively. Overall, results demonstrated that mechanical traction was significantly better than conventional physical therapy in improving pain scores and disability scores. Heterogeneity was low among studies. The results are limited by relatively small sample sizes, short-term follow-up, and no standardized control groups among studies.

Table 1. Summary of Trials/Studies Included in SR & M-A

Study	Vanti et al (2021)[2]	Wang et al (2022)[3]
Al Amer et al (2019)	●	
Bilgilisoy Filiz et al (2018)	●	●
Demirel et al (2017)		●
Fritz et al (2007)	●	
Isner-Horobeti et al (2016)		●
Kotb et al (2017)	●	
Moustafa and Diab (2013)		●
Ozturk et al (2006)	●	●
Prasad et al (2012)		●
Sherry et al (2001)	●	
Thackeray et al (2016)	●	
Unlu et al (2008)	●	

M-A: meta-analysis; SR: systematic review.

Table 2. SR & M-A Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Vanti et al (2021)[2]	1998 to 2019	8	Adults with lumbar radiculopathy using mechanical traction.	567 (44 to 120)	RCTs	Up to 3 months post-intervention
Wang et al (2022)[3]	Searched through 2022	6	Adults with lumbar disc herniation receiving traction therapy combined with routine physical therapy.	239 (19 to 79)	RCTs	NR

M-A: meta-analysis; NR: not reported; RCT: randomized controlled trial; SR: systematic review.

Table 3. SR & M-A Results

Study	Pain (change in VAS)	Disability (ODI or RMDQ)
Vanti et al (2021)[2]		
Mechanical traction in *prone* position plus physical therapy vs. physical therapy		
N	263	263
Pooled effect (95% CI)	−0.29 (−0.58 to 0.01)	−0.10 (−0.34 to 0.14)
p value	.05	.43
Mechanical traction in *supine* position plus physical therapy vs. physical therapy		
N	185	139
Pooled effect (95% CI)	−0.58 (−0.87 to −0.29)	−0.78 (−1.45 to −0.11)
p value	.00	.02
Wang et al (2022)[3]	Pain (change in VAS)	Disability (ODI)
Mechanical traction vs. conventional physical therapy		
N	239	222
MD (95% CI)	-1.39 (-1.81 to -0.98)	-6.34 (-10.28 to -2.39)
p value	<.00001	.002

CI: confidence interval; M-A: meta-analysis; MD: mean difference; ODI: Oswestry Disability Index; RMDQ: Roland & Morris Disability Questionnaire; SR: systematic review; VAS: visual analog scale.

Randomized Controlled Trials

Results from RCTs not included in the systematic reviews are as follows. Key characteristics and results from these RCTs are summarized in Tables 4 and 5, respectively.

Schimmel et al (2009) published results from a randomized sham-controlled trial of intervertebral axial decompression.[4,] 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 non-therapeutic level of traction (<10% body weight). In addition to traction, the device provided massage, heat, relaxing blue light, and music during the treatment sessions. While the physiotherapist who conducted the lumbar traction was unblinded, 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 there were no significant differences between treatment groups. For example, visual analog scale scores for low back pain (the primary outcome) 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.

Table 4. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Schimmel et al (2009)[4,]	Netherlands	10	NR	N=60 patients with chronic symptomatic lumbar disc degeneration or bulging disc with no radicular pain and no prior surgical treatment	Graded activity program with an Accu-SPINA device (>50% of body weight; n=31)	Graded activity program with a non-therapeutic level of traction (<10% body weight; n=29)

NR: not reported; RCT: randomized controlled trial.

Table 5. Summary of Key RCT Results

Study	VAS score
Schimmel et al (2009)[4,]	
	Week 14
Accu-SPINA device, n	30
Mean (SD)	32 (± 26.8)
Sham traction, n	26
Mean (SD)	36 (± 27.1)
p value (between-group)	.695

CI: confidence interval; MD: mean difference; RCT: randomized controlled trial; SD: standard deviation; VAS: visual analogue scale.
[1] Defined as at least a 50% improvement in the patient's pain and an improvement in their disability rating.
The purpose of the study limitations tables (see Tables 6 and 7) is to display notable limitations identified in each study.

Table 6. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Schimmel et al (2009)[4,]					1. Not sufficient duration for benefit (14 weeks)

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 7. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Schimmel et al (2009)[4,]		4. Physiotherapist who conducted the lumbar traction was unblinded			4. Power not met	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

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.

North American Spine Society

The North American Spine Society published guidelines in 2020 on the treatment of low back pain.[5,] Their recommendation related to lumbar traction is as follows: "In patients with subacute or chronic low back pain, traction is not recommended to provide clinically significant improvements in pain or function."

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.[6,]

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 8.

Table 8. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06525896	Non-surgical Spinal Decompression Therapy and Outcomes (RESTORE)	42	Aug 2026

NCT: national clinical trial.

References

1. Peloza 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 July 7, 2024. Accessed February 21, 2025.
2. Vanti C, Turone L, Panizzolo A, et al. Vertical traction for lumbar radiculopathy: a systematic review. Arch Physiother. Mar 15 2021; 11(1): 7. PMID 33715638
3. Wang W, Long F, Wu X, et al. Clinical Efficacy of Mechanical Traction as Physical Therapy for Lumbar Disc Herniation: A Meta-Analysis. Comput Math Methods Med. 2022; 2022: 5670303. PMID 35774300
4. 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
5. North American Spine Society. Evidence-based clinical guidelines for multidisciplinary spine care: diagnosis & treatment of low back pain. 2020. https://www.spine.org/Portals/0/assets/downloads/ResearchClinicalCare/Guidelines/LowBackPain.pdf. Accessed February 21, 2025.
6. 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. Accessed February 20, 2025.

Documentation for Clinical Review

- No records required

Coding

The list of codes in this Medical Policy is intended as a general reference and may not cover all codes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy.

Type	Code	Description
CPT®	97012	Application of a modality to 1 or more areas; traction, mechanical
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.
06/01/2022	Annual review. No change to policy statement. Literature review updated.
06/01/2023	Annual review. No change to policy statement. Literature review updated.
06/01/2024	Annual review. No change to policy statement. Policy guidelines and literature review updated.
06/01/2025	Annual review. No change to policy statement. Literature review updated

Definitions of Decision Determinations

Healthcare Services: For the purpose of this Medical Policy, Healthcare Services means procedures, treatments, supplies, devices, and equipment.

Medically Necessary: Healthcare 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 of California, are: (a) consistent with Blue Shield of California 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 member; 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 or Experimental: Healthcare Services which do not meet ALL of the following five (5) elements are considered investigational or experimental:

A. The technology must have final approval from the appropriate government regulatory bodies.
   - This criterion applies to drugs, biological products, devices and any other product or procedure that must have final approval to market from the U.S. Food and Drug Administration ("FDA") or any other federal governmental body with authority to regulate the use of the technology.
   - Any approval that is granted as an interim step in the FDA's or any other federal governmental body's regulatory process is not sufficient.
   - The indications for which the technology is approved need not be the same as those which Blue Shield of California is evaluating.

B. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.

- The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the body of studies and the consistency of the results are considered in evaluating the evidence.
- The evidence should demonstrate that the technology can measure or alter the physiological changes related to a disease, injury, illness, or condition. In addition, there should be evidence, or a convincing argument based on established medical facts that such measurement or alteration affects health outcomes.

C. The technology must improve the net health outcome.
   - The technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.

D. The technology must be as beneficial as any established alternatives.
   - The technology should improve the net health outcome as much as, or more than, established alternatives.

E. The improvement must be attainable outside the investigational setting.
   - When used under the usual conditions of medical practice, the technology should be reasonably expected to satisfy Criteria C and D.

Feedback

Blue Shield of California is interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration. Our medical policies are available to view or download at www.blueshieldca.com/provider.

For medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

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.

Disclaimer: 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 member health services contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member health services 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:** I. Vertebral axial decompression is considered **investigational**.	**Vertebral Axial Decompression 8.03.09** **Policy Statement:** I. Vertebral axial decompression is considered **investigational**.