Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 3/1/24**
(See policy history boxes for previous effective dates)

Title: Vertebral Axial Decompression

Description/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 to 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 (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, Triton® DTS and Dynatron DX2 Traction Unit. 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.

Medical Policy Statement

Vertebral axial decompression, any method, is considered experimental/investigational. The safety and effectiveness of this therapy have not been proven.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

S9090 *97012

* Established codes may be considered investigational for the purpose of this policy.

Rationale

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 are 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 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 (2021)[2,]	Wang (2022)
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)	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; 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)		
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

M-A: meta-analysis; SR: systematic review.
CI: confidence interval; NNT: number needed to treat.

Randomized Controlled Trials

Results from RCTs not included in the systematic review 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 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. 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 intention-to-treat analysis was performed (93% of subjects completed follow-up). Both groups showed improvements in validated outcome measures (visual analog scores [VAS] for back and leg pain, Oswestry Disability 36-Index, and Short-Form Health Survey), but there were no significant differences between the treatment groups. For example, visual analog 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 randomized controlled trial does not support an improvement 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)	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; 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)[3,]					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)[3,]		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.

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 to the control group. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

ONGOING AND UNPUBLISHED CLINICAL TRIALS

An online search of www.ClinicalTrials.gov did not identify ongoing or unpublished trials that would likely influence this review.

PRACTICE GUIDELINES AND POSITION STATEMENTS

American College of Physicians

The American College of Physicians published a clinical practice guideline in 2017 on noninvasive treatments for acute, subacute, and chronic low back pain.(5) Regarding vertebral axial decompression (referred to in the guideline as traction tables/devices), the guideline stated that "low-quality evidence showed no clear differences between traction and other active treatments, between traction plus physiotherapy versus physiotherapy alone, or between different types of traction in patients with low back pain with or without radiculopathy." Based on insufficient evidence, no recommendation was made related to traction devices.

North American Spine Society
The North American Spine Society published guidelines in 2020 on the treatment of low back pain.(6) 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.

Government Regulations
National:
Vertebral Axial Decompression (VAX-D) (160.16)
Medicare National Coverage Determinations Manual Chapter 1, Part 2 (Sections 90-160.26) Coverage Determinations; Long standing decision since 1997.

Vertebral axial decompression is performed for symptomatic relief of pain associated with lumbar disk problems. The treatment combines pelvic and/or cervical traction connected to a special table that permits the traction application.

There is insufficient scientific data to support the benefits of this technique. Therefore, VAX-D is not covered by Medicare.

Local:
There is no local coverage determination on this topic.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

References

1. Peloza J. Non-Surgical Treatments for Lower Back Pain. Spine-health. Updated April 20, 2017. https://www.spine-health.com/conditions/lower-back-pain/non-surgical-treatments-lower-back-pain. Accessed September 28, 2023.
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* 2009; 18(12):1843-50. PMID 19484433
5. Qaseem A, Wilt TJ, McLean RM, et al. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians. *Ann Intern Med*. Apr 04 2017; 166(7): 514-530. PMID 28192789
6. 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 September 28, 2023.
7. 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&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD%7cEd&PolicyType=Both&s=27&KeyWord=vertebral+axial+decompression&KeyWordLookUp=Title&KeyWordSearchType=Exact&kq=true&bc=IAAAACAAAAAA&. Accessed September 28, 2023.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through September 28, 2023, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
01/01/08	11/26/07	1/28/08	Joint policy established
11/1/09	8/18/09	8/18/09	Routine maintenance
11/1/11	8/16/11	8/16/11	Routine maintenance
1/1/13	10/16/12	10/16/12	Routine maintenance; policy reformatted to mirror BCBSA. Title changed from “Spinal Distraction Therapy for Low Back Pain” to “Vertebral Axial Decompression”.
7/1/14	4/10/14	4/15/14	Routine maintenance
9/1/15	6/19/15	7/16/15	Routine maintenance
9/1/16	6/21/16	6/21/16	Routine maintenance
9/1/17	6/20/17	6/20/17	Routine maintenance DX2 added
9/1/18	6/19/18	6/19/18	Routine maintenance
9/1/19	6/18/19		Routine maintenance
3/1/20	12/17/19		Routine maintenance
3/1/21	12/15/20		Routine maintenance
3/1/22	12/14/21		Routine maintenance
3/1/23	12/20/22		Routine maintenance (slp)
3/1/24	12/19/23		Routine maintenance (slp) Vendor managed: eviCore

Next Review Date: 4th Qtr, 2024

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: VERTEBRAL AXIAL DECOMPRESSION

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.