| 8.03.09 | Vertebral Axial Decompression | | |
|---|---|---|---|
| **Original Policy Date:** | June 28, 2007 | **Effective Date:** | June 1, 2024 |
| **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.

## Related Policies

- N/A

## Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the 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 mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

## 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

### 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 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) | | |

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

A search of ClinicalTrials.gov in February 2024 did not identify any ongoing or unpublished trials that would likely influence this review.

## 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 April 20, 2017. Accessed February 15, 2024.
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 15, 2024.
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 15, 2024.

## Documentation for Clinical Review

- No records required

## Coding

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

| 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 |

| Effective Date | Action |
|---|---|
| 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. |

## Definitions of Decision Determinations

**Medically Necessary:** 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, are: (a) consistent with Blue Shield 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 patient; 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/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

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.

We are 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.

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

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. 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 contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member 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**<br><br>**Policy Statement:**<br>I. Vertebral axial decompression is considered **investigational**. | **Vertebral Axial Decompression 8.03.09**<br><br>**Policy Statement:**<br>I. Vertebral axial decompression is considered **investigational**. |