Policy Statement

Vertebral axial decompression is considered investigational.

Policy Guidelines

The following CPT code may be used to describe vertebral axial decompression:
- **97012**: Application of a modality to 1 or more areas; traction, mechanical

The following HCPCS code is specific to vertebral axial decompression:
- **S9090**: Vertebral axial decompression, per session

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 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 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: IFH.
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 technology improves the net health outcome. Broadly defined, health outcomes are the 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 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 technology, two domains are examined: the relevance, and 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 blue 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.1 Patients were...
enrolled from a French emergency department. Inclusion criteria were lumbar sciatica of fewer than six 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

<table>
<thead>
<tr>
<th>Outcome Measures</th>
<th>High-Force Traction Group (n=8)</th>
<th>Low-Force Traction Group (n=9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radicular pain (VAS, mm)</td>
<td>Value (95% CI) p</td>
<td>Value (95% CI) p</td>
</tr>
<tr>
<td>Lumbar spine mobility (FTT, mm)</td>
<td>-28.8 (-41.8 to -3.7) &lt;0.001</td>
<td>-34.8 (-52.6 to 017) &lt;0.001</td>
</tr>
<tr>
<td>Straight leg raise test (elevation angle)</td>
<td>33.1° (13.3° to 53.0°) &lt;0.01</td>
<td>36.0° (17.3° to 54.7°) &lt;0.01</td>
</tr>
</tbody>
</table>

Adapted from Isner-Horobeti et al (2016).1
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 et al (2009) RCT, which used traction at 10% body weight traction as a placebo. The lack of significant interaction term suggests 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.2,3

Summary of Evidence
For individuals who have chronic lumbar pain who receive vertebral axial decompression, the evidence includes RCTs. The 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 1997.4

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


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. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

IE

The following services may be considered investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
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</tr>
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<tbody>
<tr>
<td>CPT®</td>
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<td>HCPCS</td>
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<tr>
<td>ICD-10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedure</td>
<td>F07L0YZ</td>
<td>Range of Motion and Joint Mobility Treatment of Musculoskeletal System - Lower Back / Lower Extremity using Other Equipment</td>
</tr>
<tr>
<td></td>
<td>F07L6CZ</td>
<td>Therapeutic Exercise Treatment of Musculoskeletal System - Lower Back / Lower Extremity using Mechanical Equipment</td>
</tr>
<tr>
<td></td>
<td>F07L6HZ</td>
<td>Therapeutic Exercise Treatment of Musculoskeletal System - Lower Back / Lower Extremity using Mechanical or Electromechanical Equipment</td>
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<tr>
<td></td>
<td>F07L6YZ</td>
<td>Therapeutic Exercise Treatment of Musculoskeletal System - Lower Back / Lower Extremity using Other Equipment</td>
</tr>
<tr>
<td></td>
<td>F07L7ZZ</td>
<td>Manual Therapy Techniques Treatment of Musculoskeletal System - Lower Back / Lower Extremity</td>
</tr>
</tbody>
</table>

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.
### Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**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 (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. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

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.