ASURIS NORTHWEST HEALTH

Medical Policy Manual Medicine, Policy No. 45

Vertebral Axial Decompression

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Vertebral axial decompression (VAD) is a type of spinal traction used to reduce intradiscal pressure as a treatment of back pain.

MEDICAL POLICY CRITERIA

Vertebral axial decompression is considered **investigational**.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

None

BACKGROUND

Vertebral axial decompression is a type of spinal traction that has been investigated as a technique to reduce intradiscal pressure and relieve pain associated with herniated intervertebral discs or degenerative disc disease. The therapy may also be called axial spinal distraction or motorized spinal traction, and the devices used for the therapy may also be referred to as power or motorized traction equipment.

During vertebral axial decompression, a patient typically wears a pelvic harness, while lying on a specially equipped table. This table is slowly extended, and a distraction force is applied via the pelvic harness until the desired tension is reached. This is followed by a gradual decrease of the tension, and the cycle is repeated. The cyclic nature of the treatment allows the patient to withstand stronger distraction forces compared with static lumbar traction techniques. The level of tension is individually calibrated and recorded. An individual session typically includes 15 cycles of tension, lasting approximately 30 minutes, and a total of 10 to 15 daily treatments may be administered.

Regulatory Status

Several devices used for vertebral axial decompression have received 510(k) marketing clearance from the US Food and Drug Administration (FDA). According to the FDA-labeled indications, 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. Numerous devices have received FDA 510k approval as powered traction equipment, including but not limited to the following:

- Accu-SPINA® System (North American Medical Corp.)
- Antalgic-Trak® (Spinetronics)
- Decompression Reduction Stabilization (DRS) System (Integra Lifesciences)
- DRX2000®, DRX3000®, and DRX9000® (Axiom)
- Dynatron 900 (Dynatronics)
- Ever-Trac ET-800 (Everyway Medical)
- IDD Therapy® (Intervertebral Differential Dynamics Therapy)
- Integrity Spinal Care System (Integra Lifesciences)
- Lordex ® Spinal Decompression Unit (Lordex)
- Rich-Mar Spina-Mobilizor (Naimco Medical)
- SpineMED® Decompression System (SpineMED)
- Triton ® DTS ™ / Tru-Trac ® / TX ® Traction System (Chattanooga Group)
- VAX-D ® Therapeutic Table (Vat-Tech, Inc.)

EVIDENCE SUMMARY

Clinically relevant health outcomes for treatments for spinal pain include relief of pain and improvement in functioning. These are subjective outcomes that can be influenced by nonspecific effects, placebo response, and the natural history of the disease. Therefore, data from adequately powered, blinded, randomized controlled trials (RCTs) with sufficient long-term follow-up are required to control for the nonspecific effects and to determine whether observed treatment effects from vertebral axial decompression (VAD) provide a significant advantage over placebo/sham treatment or other non-surgical treatment options. The following discussion is focused on systematic reviews, technology assessments and RCTs.

SYSTEMATIC REVIEWS AND TECHNOLOGY ASSESSMENTS

Vanti (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.[1] Three studies met the inclusion criteria with a pooled total of 90 patients. Meta-analysis was not possible due to the heterogeneity of the included studies. The authors reported very low-quality evidence for a large effect of vertical traction (VT) added

to bed rest when compared to bed rest alone (g = - 1.01; 95% CI = -2.00 to - 0.02). Similarly, VT added to medication may have a large effect on pain relief when compared to medication alone (g = - 1.13; 95% CI = -1.72 to - 0.54, low quality evidence). Effects of VT added to physical therapy on pain relief were very small when compared to physical therapy without VT (g = - 0.14; 95% CI = -1.03 to 0.76, low quality evidence). The authors conclude VT may be an effective treatment only for reducing pain in LR at short-term, and may be preferred to passive treatments as bed rest and medications. VT does not demonstrate significant effects on activity limitation due to LR. The included studies are low quality and limited by small sample size.

A 2007 a technology assessment conducted by the Agency for Health Care Research and Quality (AHRQ) conclude that “Currently available evidence is too limited in quality and quantity to allow for the formulation of evidence-based conclusions regarding the efficacy of decompression therapy as a therapy for chronic back pain when compared with other non-surgical treatment options.[2] Of the studies examined for assessment of efficacy, neither included patients over 65 years of age. Adverse event reporting for decompression therapy is infrequent. There was one case report of an enlargement of an existing disc protrusion, and other studies reported worsening of pain in some patients.”

RANDOMIZED CONTROLLED TRIALS

Results from a randomized sham-controlled trial of intervertebral axial decompression were published by Schimmel in 2009.[3] 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 randomly assigned to a graded activity program with an AccuSPINA device (20 traction sessions during six weeks, reaching >50% 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, blue relaxing 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 scores [VAS] for back and leg pain, Oswestry Disability Index, and Short-Form 36 [SF-36]), with no significant differences between the treatment groups. For example, VAS 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 recent RCT does not support an improvement in health outcomes with vertebral axial decompression.

Two small randomized studies (n=27; n=64) reported little to no difference between patients treated with or without mechanical traction.[4, 5]

In 2001, Sherry conducted a randomized trial comparing vertebral axial decompression (using the VAX-D device) with transcutaneous electrical nerve stimulation (TENS).[6] While a 68% success rate was associated with VAX-D compared with a 0% success rate associated with TENS therapy, the results are difficult to interpret without a true placebo control.

PRACTICE GUIDELINE SUMMARY

AMERICAN COLLEGE OF PHYSICIANS AND THE AMERICAN PAIN SOCIETY

The American College of Physicians (ACP) and the American Pain Society (APS) jointly published an evidence-based clinical practice guideline on low back pain.[7] They reported a Grade D recommendation for intermittent or continuous traction by any method (i.e., free weights and pulley, motorized equipment, inversion techniques, or overhead harness). The guideline also included the following statement: "[t]he panel recommends against offering the intervention. The panel found at least fair evidence that the intervention is ineffective or that the associated harms outweigh the benefits."

NORTH AMERICAN SPINE SOCIETY

The North American Spine Society (NASS) published evidence-based guidelines regarding vertebral axial decompression, and considered the evidence to be insufficient to recommend the use of any type of traction in the treatment of lumbar disc herniation with radiculopathy and lumbar spinal stenosis.[8, 9]

SUMMARY

There is not enough research to show that vertebral axial decompression (VAD) improves health outcomes for people with back pain. In addition, there are no clinical guidelines based on research that recommend spinal traction by any method, including VAD. Therefore, vertebral axial decompression is considered investigational.

REFERENCES

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CODES

Codes	Number	Description
CPT	None	
HCPCS	S9090	

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