

# **Vertebral Axial Decompression**

Policy MP-053

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#### Disclaimer:

- 1. Policies are subject to change in accordance with State and Federal notice requirements.
- Policies outline coverage determinations for U of U Health Plans Commercial, CHIP and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.
- 3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
- 4. This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.

### **Description:**

Vertebral axial decompression (VAD) is a type of spinal traction/decompression therapy described as an alternative, noninvasive, nonsurgical procedure of applying traction to the spine via a computer-driven table which controls the level of disc decompression. This technique is promoted 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 VAD, a patient typically wears a pelvic harness, while lying on a specially equipped table. This table on which the patient lies 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, then 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. According to labeled indications from the U.S. Food and Drug Administration (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.

## Policy Statement and Criteria

### 1. Commercial Plans/CHIP

U of U Health Plans does NOT cover vertebral axial decompression as it is considered investigational. The following are examples of vertebral decompression devices (including but not limited to):

- Accu-SPINA<sup>®</sup> System (North American Medical Corp.)
- Antalgic-Trak<sup>®</sup> (Spinetronics)
- Decompression Reduction Stabilization (DRS) System (Integra Lifesciences)
- DRX2000<sup>®</sup>, DRX3000<sup>®</sup>, DRX5000<sup>®</sup> and DRX9000<sup>®</sup> (Axiom)
- Dynatron 900 (Dynatronics)
- Ever-Trac ET-800 (Everyway Medical)
- IDD Therapy<sup>®</sup> (Intervertebral Differential Dynamics Therapy)
- Integrity Spinal Care System (Integra Lifesciences)
- Lordex <sup>®</sup> Spinal Decompression Unit (Lordex)
- MTD 4000 Mettler Traction Decompression System
- NuChoice Medical Healthstar Elite Decompression Therapy
- Rich-Mar Spina-Mobilizor (Naimco Medical)
- Saunders 3D ActiveTrac
- SpineMED<sup>®</sup> Decompression System (SpineMED)
- Triton <sup>®</sup> DTS <sup>™</sup> / Tru-Trac <sup>®</sup> / TX <sup>®</sup> Traction System (Chattanooga Group)
- VAX-D <sup>®</sup> Therapeutic Table (Vat-Tech, Inc.)

#### 2. Medicaid Plans

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: <u>https://medicaid.utah.gov/utah-medicaid-official-publications/</u> or the <u>Utah Medicaid code Look-Up tool</u>

CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.

### **Clinical Rationale**

A limited body of studies are available which have assessed vertebral distraction therapy. The 2006 systematic review by Macario and Pergolizzi highlight the limitations of these studies. They assessed literature from 10 studies between 1975 and 2003, to determine if efficacy of nonsurgical axial/spinal decompression is achieved with motorized traction for chronic discogenic low back pain. Seven studies were randomized controlled trials of motorized traction using various apparatus types, including split-

tabletop, plain tabletop, and friction-free couch with weights. A total of 408 individuals received placebo, and 438 individuals received motorized spinal decompression. Follow-up averaged 28 weeks. None of the studies were blinded, and only three had description of the randomization method. Six of the seven randomized trials reported no difference with motorized spinal decompression, and one study reported reduced pain but not disability. The authors concluded that the efficacy of spinal decompression achieved with motorized traction for discogenic low back pain remains unproven.

Additional studies have continued to support the systematic review including a 2010 retrospective study (Apfel et al.) of 30 patients with chronic low back pain, attributed to disc herniation and/or discogenic low back pain, who underwent 6-weeks of motorized non-surgical spinal decompression with the DRX9000. The main outcomes were changes in pain as measured on a verbal rating scale from 0 to 10 during a flexion-extension, range of motion evaluation and changes in disc height as measured on CT scans. Low back pain decreased from  $6.2 (\pm 2.2)$  to  $1.6 (\pm 2.3)$  and disc height increased from  $7.5 (\pm 1.7)$  to  $8.8 (\pm 1.7)$  mm. The authors concluded that non-surgical spinal decompression was associated with a reduction in pain and an increase in disc height; however, they also note that a randomized controlled study is needed to confirm these results, as this study was limited due to lack of a control group, lack of long term follow-up and small sample size.

In 2013, Wegner et al., stated for chronic LBP without sciatica, there was moderate-quality evidence that traction probably makes little or no difference in pain intensity when compared with sham treatment. No studies reported on the effect of traction on functional status, global improvement or return to work. Adverse effects were reported in seven of the 32 studies.

In a preliminary double-blind RCT, Isner-Horobeti et al. (2016) described the comparison between highforce 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. Patients were enrolled from a French emergency department. Inclusion criteria were lumbar sciatica of fewer than 6 weeks in duration, secondary to disc herniation based on clinical exam, confirmed by lumbar tomodensitometry. Patients excluded had clinical neurologic deficits, sciatic due to something other than disc herniation, or abnormalities on tomodensitometry. For the trial's primary outcome (reduction in radicular pain measured by a 100-mm visual analogue scale), both groups demonstrated significant improvements from baseline to day 28. The authors concluded that there was no significant group by time interaction regarding pain reduction and 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).

Thackeray et al. (2016) conducted a randomized clinical trial by examining the effectiveness of mechanical traction in patients (n=120) with low back pain and nerve root compression. Patients were randomized to receive an extension-oriented treatment approach with or without the addition of mechanical traction, during a 6-week period, patients received up to 12 treatment visits. Primary outcomes of pain and disability were collected at 6 weeks, 6 months, and 1 year by assessors blinded to group allocation. In conclusion, at the end of the 1 year time period, there was no evidence in this patient population showing mechanical lumbar traction in combination with an extension-oriented treatment was superior to extension-oriented exercises alone.

Lastly in 2016, Lurie et al., determine the options for non-surgical management include drugs, physiotherapy, spinal injections, lifestyle modification, and multidisciplinary rehabilitation. However, few high-quality randomized trials have looked at conservative management. The systematic review concluded that there is insufficient evidence to recommend any specific type of non-surgical treatment.

Demirel et al., (2017) studied a total of twenty patients diagnosed with lumbar disc herniation and suffering from pain at least eight weeks were enrolled to the study. Patients were allocated in study (SG)

and control groups (CG) randomly. Both groups received combination of electrotherapy, deep friction massage and stabilization exercise for fifteen sessions. SG received additionally non-invasive spinal decompression therapy different from CG. Numeric Analog Scale, Straight leg raise test, Oswestry Disability Index (ODI) were applied at baseline and after treatment. Disc height and herniation thickness were measured on Magnetic Resonance Imagination which performed at baseline and three months after therapy. No significant differences were found between groups and any superiority to each other.

An Agency for Healthcare Research and Quality (AHRQ) review, (Chou et al.) completed in 2016, evaluated 156 studies for evidence on the comparative benefits and harms of noninvasive treatments for acute, subacute, and chronic low back pain. Studies conducted among patients with low back pain related to cancer, infection, inflammatory arthropathy, high-velocity trauma, or fracture or low back pain associated with severe or progressive neurological deficits, were excluded from the review. Outcomes were mostly measured at short-term (up to 6 months) follow-up. For radicular low back pain, there was low strength of evidence demonstrating that traction was effective compared to physiotherapy and other non-pharmacological interventions on pain control. Overall, there is insufficient evidence to support the isolated use of mechanical traction as a treatment for chronic low back pain.

The North American Spine Society (NASS) has also reviewed the literature and in their last guidelines published in 2011 for lumbar spinal stenosis and 2012 for radiculopathy. They 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.

The American College of Physician's (ACP) also supports the NASS position in their clinical practice guideline (Qaseem et al., 2017) on non-invasive treatments for acute, subacute, or chronic low back pain. They state the evidence is insufficient to determine the effectiveness of several therapies including traction tables or devices, for acute, subacute, or chronic low back pain. Low-quality evidence showed no clear differences between traction and other active treatments, between traction with physiotherapy versus physiotherapy alone, or between different types of traction in patients with low back pain with or without radiculopathy.

The American College of Occupational and Environmental Medicine state that decompression through traction is a treatment that utilizes a therapeutic table and traction mechanism. Its intent is to reduce intradiscal pressure, thus allowing for disc decompression. The theory is that decompression will externally decompress the nerve root and help relieve pain and other symptoms. However, decompression through traction and spinal decompressive devices are not recommended for treatment of acute, subacute, chronic, post-operative low back pain, or radicular pain syndromes. Traction has long been used to treat sciatica with a belief that this therapy produces negative intradiscal pressures that result in improved rates of disc resorption. Nonetheless, this has not been borne out and more studies show a lack of efficacy (1314, 1318, 1324-1326) than show efficacy for those patients. (1323, 1327, 1328) Traction is non-invasive, does not have adverse effects, but is moderately costly. There are interventions that are effective that should be employed. However, traction is not recommended for treatment of low back conditions or radicular pain syndromes.

Lastly, the Centers for Medicare and Medicaid Services (CMS) states that Medicare does not cover Vertebral Axial Decompression (VAX-D). See the National Coverage Determination (NCD) for Vertebral Axial Decompression (VAX-D) (160.16). Local Coverage Determinations (LCDs) do not exist at this time. In 2007, the CMS Technology Advisory Committee (TAC), requested that the AHRQ commission an evidence-based technology assessment. The AHRQ report "Decompression Therapy for the Treatment of Lumbosacral Pain" concluded that the current evidence regarding the efficacy of axial/spinal decompression therapy is too limited in quality and quantity to allow for evidence-based conclusions. In their opinion, there was not enough adverse event reporting for axial/spinal decompression therapy. Therefore, CMS-TAC did not recommend coverage of the VAX-D system as there was lack of scientific data on its effectiveness.

### **Applicable Coding**

#### **CPT Codes**

No applicable codes

#### **HCPCS** Codes

#### **S9090** Vertebral axial decompression, per session

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