Vertebral Axial Decompression

Number: 0180

Policy
Aetna considers vertebral axial decompression (e.g., by means of the VAX-D Spinal Decompression System, the Accu-SPINA System, Axiom Worldwide DRX2000, Axiom DRX3000, Axiom DRX5000, the Axiom DRX9000, the DRS (Decompression Reduction Stabilization) System, DRX, the Alpha-SPINA System, the Dynatron DX2, the Lordex Lumbar Spine System, the Saunders 3D ActiveTrac, Spinex LDM, Tru Tac 401, NuChoice Medical Healthstar Elite Decompression Therapy, the Antalgic-Trak, the Cert Health Sciences SpineMED Decompression Table, Integrity Spinal Care System, MTD 4000 Mettler Traction Decompression System, or Internal Disc Decompression (IDD) Therapy, also known as Intervertebral Differential Dynamics Therapy) experimental and investigational. Currently, there is no adequate scientific evidence that proves that
Vertebral axial decompression is an effective adjunct to conservative therapy for back pain. In addition, vertebral axial decompression devices have not been adequately studied as alternatives to back surgery.

See also CPB 0569 - Lumbar Traction Devices
(../500_599/0569.html).

Background
Vertebral decompression therapy is also referred to as mechanized spinal distraction therapy or intervertebral differential dynamics therapy (IDD). It is purported to create negative pressure on the spine, so that the vertebrae are elongated, pressure is taken off the roots of the nerve and a disc herniation may be pulled back into place. The underlying mechanism of action is based on the fact that herniated and degenerated discs cause pain by applying pressure on spinal nerves.

Vertebral decompression therapy is generally performed using a specially designed computerized mechanical table that separates in the middle. An individual is strapped in a prone (face down) position to the lower part of the table using a pelvic harness. The individual holds onto handgrips at the top of the table. The table is then mechanically separated in the middle and distractive force is applied to relieve pressure on the spine that may be causing pain. The amount of distractive force is tailored for each individual and usually lasts about one minute. Depending on the device utilized, static, intermittent or cycled distractive force may be applied. The process of distraction and relaxation is
fully computerized using a programmable logic controller and is monitored by a licensed healthcare practitioner.

Vertebral axial decompression (VAX-D) therapy for the management of low back pain (LBP) uses a computer-driven table to control the level of disc decompression.

Although results from an early uncontrolled, retrospective study (Gose et al, 1998) regarding the benefits of the VAX-D table appeared to be encouraging, the findings need to be validated in prospective, randomized, controlled clinical trials because the study was poorly designed. In addition, there has been no follow-up publication indicating whether any reported improvements were temporary or permanent. Thus, there is still insufficient scientific evidence to support the effectiveness of the VAX-D table in treating patients with LBP associated with herniated discs and degenerative disc problems. The Center for Medicare and Medicaid Services (CMS) Technology Advisory Committee did not recommend coverage of the VAX-D system because of the absence of scientific data on its effectiveness.

A subsequent randomized study (Sherry et al, 2001) compared VAX-D to transcutaneous electrical nerve stimulation (TENS) in the treatment of patients with chronic (greater than 3 months in duration) LBP. Successful outcome was defined as a 50% decrease in pain using the visual analog pain scale and an improvement in the level of functioning as measured by patient-nominated disability ratings.
The TENS-treated group (n = 21) reported a success rate of 0 %, while the group treated with VAX-D (n = 19) showed a success rate of 68.4 %. It is difficult to conclude from this study that VAX-D is effective in treating chronic back pain since detailed statistics regarding the outcomes for each group were not included in the analysis. Furthermore, patients were not blinded to the treatment received, thus, there may have been a negative placebo effect in the TENS-treated group.

The Australian Medical Services Advisory Committee (MSAC) (2001) performed an assessment of the literature on VAX-D therapy. The Committee concluded that “there is currently insufficient evidence pertaining to the effectiveness of vertebral axial decompression (VAX-D) therapy...”.

An evidence review by the Workers Compensation Board of British Columbia (Martin et al, 2005) concluded: "To date there is no evidence that the VAX-D system is effective in treating chronic LBP associated with herniated disc, degenerative disc, posterior facet syndrome, sciatica or radiculopathy".

In a prospective, longitudinal, case series, Beattie et al (2008) examined outcomes after administration of a prone lumbar traction protocol. A total of 296 subjects with low LBP and evidence of a degenerative and/or herniated intervertebral disk at 1 or more levels of the lumbar spine were included in this study. Patients who were involved in litigation and those receiving workers’ compensation were excluded. Patients underwent an 8-week course of
prone lumbar traction, using the VAX-D system, consisting of five 30-min sessions a week for 4 weeks, followed by one 30-min session a week for 4 additional weeks. The numeric pain rating scale (NRS) and the Roland-Morris Disability Questionnaire (RMDQ) were completed at pre-intervention, discharge (within 2 weeks of the last visit), and at 30 days and 180 days after discharge. Intention-to-treat strategies were used to account for those subjects lost to follow-up. A total of 250 (84.4 %) subjects completed the treatment protocol. On the 30-day follow-up, 247 (83.4 %) subjects were available; on the 180-day follow-up, data were available for 241 (81.4 %) subjects. These researchers noted significant improvements for all post-intervention outcome scores when compared with pre-intervention scores (p < 0.01). The authors concluded that traction applied in the prone position using the VAX-D for 8 weeks was associated with improvements in pain intensity and RMDQ scores at discharge, and at 30 and 180 days after discharge in a sample of patients with activity-limiting LBP. Moreover, the authors noted that causal relationships between these outcomes and the intervention should not be made until further study is performed using randomized comparison groups.

The DRS System is marketed for the treatment of LBP associated with herniated and degenerated discs. According to the manufacturer, the DRS System applies pressures on the disc in a graduated manner, which bypasses the inherent neurological mechanisms that lead to firing of stretch receptors in the paravertebral structures.
This decreased resistance to the distractive forces allows a marked reduction in intradiscal pressures, which promotes retraction of herniated disc material and facilitates influx of oxygen, proline and other substrates.

Similar to the VAX-D table, there is little scientific evidence to support the effectiveness of the DRS System or the Internal Disc Decompression (IDD) Therapy in treating LBP. Further investigation is needed to determine their value in the management of patients with LBP.

An assessment by the Washington State Department of Labor and Industries Office of the Medical Director (Wang, 2004) concluded that "[p]ublished literature has not substantially shown whether powered traction devices are more effective than other forms of traction, other conservative treatments, or surgery".

The Agency for Healthcare Research and Quality's technology assessment on decompression therapy for the treatment of lumbosacral pain (Jurecki-Tiller et al, 2007) concluded that "[c]urrently 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. 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 1
case report of an enlargement of an existing disc protrusion, and other studies reported worsening of pain in some patients.

Macario and associates (2008) discussed the retrospective chart audit of 100 patients with discogenic LBP lasting more than 12 weeks treated with a 2-month course of motorized spinal decompression via the DRX9000. Patients at a convenience sample of 4 clinics received 30-min DRX9000 sessions daily for the first 2 weeks tapering to 1 session/week. Treatment protocol included lumbar stretching, myofascial release, or heat prior to treatment, with ice and/or muscle stimulation afterwards. Primary outcome was verbal NRS 0 to 10 before and after the 8-week treatment. Of the 100 subjects, 3 withdrew their protected health information, and 3 were excluded because their LBP duration was less than 12 weeks. The remaining 94 subjects (63 % female, 95 % white, age = 55 (SD 16) year, 52 % employed, 41 % retired, LBP median duration of 260 weeks) had diagnoses of herniated disc (73 % of patients), degenerative disc disease (68 %), or both (27 %). Mean NRS equaled 6.05 (SD 2.3) at presentation and decreased significantly to 0.89 (SD 1.15) at end of 8-week treatment (p < 0.0001). Analgesic use also appeared to decrease (charts with data = 20) and activities of daily living improved (charts with data = 38). Follow-up (mean of 31 weeks) on 29/94 patients reported mean 83 % LBP improvement, NRS of 1.7 (SD 1.15), and satisfaction of 8.55/10 (median of 9). The authors concluded that this retrospective chart audit provides preliminary data that chronic LBP may improve with DRX9000 spinal
They stated that randomized double-blind trials are needed to measure the effectiveness of such systems.

The Work Loss Data Institute's clinical practice guideline on "Low back - lumbar & thoracic (acute & chronic)" (2011) did not recommend the use of powered traction devices/Lordex/VAX-D.

The Work Loss Data Institute’s guideline on “Neck and upper back (acute & chronic)” (2013) listed VAX-D as one of the interventions that were considered, but are not recommended.

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<tr>
<th>CPT Codes / HCPCS Codes / ICD10 Codes</th>
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<td>Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by &quot;+&quot;:</td>
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<td>ICD-10 codes will become effective as of October 1, 2015:</td>
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<td>Other CPT codes related to the CPB:</td>
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<td>64722</td>
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<td>97012</td>
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<td>HCPCS codes not covered for indications listed in the CPB:</td>
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<td>ICD-10 codes not covered for indications listed in the CPB (not all-inclusive):</td>
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<td>M40.00 - M54.9</td>
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The above policy is based on the following references:

7. Medical Services Advisory Committee (MSAC). Vertebral axial decompression (VAX-D) therapy for low back pain. Assessment Report. MSAC application 1012. Canberra,


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