Clinical Practice Guideline: **Axial/Spinal Decompression Therapy**

Date of Implementation: **July 13, 2006**

Product: **Specialty**

GUIDELINES

American Specialty Health – Specialty (ASH) considers nonsurgical axial/spinal decompression therapy to be unproven due to insufficient scientific evidence of efficacy in the treatment of neck, low back, and related disorders. This includes any motorized mechanical traction device that is promoted as providing 'decompression therapy' (e.g., VAX-D, IDD Therapy® [Intervertebral Differential Dynamics Therapy], DRS, DRX, DRX-2000, DRX-3000, DRX-5000, DRX-9000, Accu-SPINA™, Lordex Power Traction device, Mettler Traction Device [MTD 4000], Tru Trac 401, Integrity Spinal Care System Alpha-SPINA System, Dynatron DX2, Dynapro™ DX2, Spinerx LDM, or any other device that claims to create spinal decompression).

The research evidence concerning nonsurgical axial/spinal decompression therapy is lacking and of low quality. Any estimate of treatment effect is uncertain, as is the clarity of risk, benefit, and burden to the patient.

There are significant burdens placed upon health plan members due to high out-of-pocket costs, time spent receiving the intervention, and the unsubstantiated/misleading marketing about the alleged proven effectiveness and safety of nonsurgical axial/spinal decompression therapy. These burdens have been recognized as significant by some professional licensing boards and state justice departments.

Similar conclusions have been reached by a broad range of health care organizations. Professionals and groups, who are proponents of nonsurgical axial/spinal decompression therapy, should pursue further investigation using experimental study designs and rigorous methodologies.

HCPCS/CPT Code	HCPCS/CPT Code Description
S9090	Vertebral Axial Decompression, per session; {most accurately describes services for the application of spinal decompression motorized traction devices}
Other CPT codes that have been associated with the use of nonsurgical spinal decompression therapy are:	
64722	Decompression; unspecified nerve(s) (specify) {a surgical code}
97012	Application of a modality to 1 or more areas; traction, mechanical

DESCRIPTION/BACKGROUND

Traction as a treatment option for low back pain and sciatica has existed for many years. Its use has progressed from continuous static traction to intermittent motorized traction. The most recent form of intermittent motorized traction is commonly referred to as axial/spinal decompression therapy. Developers and manufacturers of the equipment along with clinicians often consider it to be a unique form of traction. Proponents of nonsurgical axial/spinal decompression therapy claim it to be a safe and effective alternative to surgical interventions. Companies demonstrate intense marketing programs and claim high success rates. Axial/spinal decompression therapy is intended to create negative pressure within the spine so that as the spinal column is elongated, pressure is taken off the nerve root(s), and herniated disc material may be pulled back into place. Axial/spinal decompression therapy is generally performed using a specially designed computerized mechanical table that separates in the middle. Depending on the type of table being used, a patient is strapped in a prone or supine position to the lower part of the table using a pelvic harness and may hold handgrips at the top of the table. The table is then mechanically separated in the middle creating a distractive force to relieve pressure within the spine that may be causing pain. The amount of distractive force is tailored for each patient and usually lasts about 60 seconds. Depending on the device utilized, static, intermittent, or cycled distractive force may be applied. Typical treatment protocols include 20 sessions, each lasting 30 to 40 minutes. The process of distraction and relaxation is fully computerized using a programmable logic controller and is monitored by a licensed health care practitioner. The American Medical Association (AMA), Food and Drug Administration (FDA), and Centers for Medicare & Medicaid Services (CMS) all consider axial/spinal decompression therapy to be a form of traction. However, this therapy involves a special table and protocol that isn't the same as conventional or traditional traction with claims of spinal decompression.

The tables utilized for axial/spinal decompression therapy are classified by the FDA as powered traction equipment. Examples of axial/spinal decompression therapy tables (and their manufacturers) include:

- VAX-D Table (VAX-D Manufacturing, Palm Harbor, FL)
- Decompression, Reduction, Stabilization (DRS) System (North American Medical Corporation, Atlanta, GA)
- DRX 2000 and DRX 9000 (Axiom Worldwide, Tampa, FL)
- Spina System (North American Medical Corporation, Atlanta, GA)

Two popular units will be described here. Due to the number of available products, it would be impractical to provide information on all of them.

VAX-D

The manufacturer suggests that use of the VAX-D table applies distractive forces in a gradual, progressive fashion through extension of the lower end of the table. The level of tension is preset on a control panel and can be increased, allowing for various decompression phases and a rest phase. Various decompression phases allow alternating cycles of distraction and relaxation. Typically, a treatment cycle consists of 15 cycles of tension and relaxation. The patient lies prone on the VAX-D table. The table is split, allowing the table to slowly extend, thus decreasing load bearing in the intervertebral discs and/or intervertebral joint spaces. The VAX-D manufacturer claims specific parameters of their system make the device inherently safe. These safety features include the use of air pressure as the energy source; the ramp characteristics employed in applying the distraction tensions; the release rate of the distraction and relaxation cycles; the cycle periodicity; the upper limits on the distraction tensions; the positioning of the patient and the means of fixing the upper body; and the ability of the patient to release the handgrips if the distraction tension causes pain or discomfort. Information regarding the range and incidence of adverse effects that occur during VAX-D therapy is limited. Complications reported with VAX-D include:

- The development of a sharp burning, radiating pain during therapy
- Stress to the shoulder girdle and rotator cuff muscles
- Overstretching of the soft tissue of the back

Decompression, Reduction, Stabilization (DRS) System

Manufacturers recommend the Decompression, Reduction, Stabilization (DRS) System for treatment of low back pain. This device uses a bed that is split into two cushions. The patient can step onto a foot pad, have a pelvic and chest harness attached, after which the patient and bed are lowered to a horizontal position. Distraction tension is applied by the pelvic harness while the patient's upper body is secured to the locked upper cushion via the chest harness. The DRS System is marketed for the treatment of low back pain 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 reduction in intradiscal pressures, which promotes retraction of herniated disc material and facilitates influx of oxygen, proline, and other substrates.

EVIDENCE REVIEW

Currently, there is not adequate scientific evidence which proves that axial/spinal decompression is an effective single intervention or adjunct to conservative therapy for back pain. In addition, axial/spinal decompression devices have not been adequately studied as alternatives to back surgery.

Proponents of nonsurgical axial/spinal decompression therapy assert this form of traction is, however, unique for being proven able to reduce the relative pressure measured within intervertebral discs (decompression). The evidence typically cited to support this claim is from a study by Ramos, 1994. An evaluation of this study shows the conclusions are based upon data from only three subjects. This study demonstrated a number of methodological flaws likely to invalidate the results. These included not using a closed transducer system, not taking into account temperature effects, absent hydrostatic conditions (in degenerative discs), and no attempt reported to calibrate negative readings.

Regardless of the flaws, this study is not sufficient to arrive at conclusions about the translation of basic science research into clinical care settings. The author (Ramos) concluded additional study is needed to establish the relationship of negative intradiscal pressures with clinical outcomes. The results from an early uncontrolled, retrospective study (Gose et al., 1998) regarding the benefits of the VAX-D table appeared to be encouraging. However, the findings need to be validated in prospective, randomized, controlled clinical trials because the study was poorly designed. A subsequent randomized study (Sherry et al., 2001) compared VAX-D to transcutaneous electrical nerve stimulation (TENS) in the treatment of patients with chronic (> 3 months in duration) low back pain. 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%. No confirmatory conclusions can be drawn from this study given detailed statistics regarding the outcomes for each group was not included in the analysis. Furthermore, patients were not blinded to the treatment received. 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..." In 2007, they requested that the Agency for Healthcare Research and Quality (AHRQ) commission an evidence-based technology assessment. The AHRQ report "Decompression Therapy for the Treatment of Lumbosacral Pain" concluded the current evidence regarding the efficacy of axial/spinal decompression therapy is too limited in quality and quantity to allow for evidence-based conclusions. Adverse event reporting for axial/spinal decompression therapy was viewed as infrequent. The Centers for Medicare & 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.

In review of a single study of DRS therapy (Shealy and Borgmeyer, 1997), the authors reported on a comparison of DRS therapy to conventional traction for both ruptured lumbar discs and chronic facet arthrosis. This study suffered from three major flaws: one of the authors was affiliated with the treatment center that conducted the trial; the scale used to quantify the results was not clearly defined; and the study consisted of a small sample size lacking clearly defined methods of randomization.

Macario and Pergolizzi (2006) conducted a systematic review of the literature to assess the efficacy of nonsurgical axial/spinal decompression that is achieved with motorized traction for chronic discogenic low back pain. The authors reviewed data from 10 studies between 1975 and 2003. Seven 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. In the author's opinion, the efficacy of spinal decompression achieved with motorized traction for discogenic low back remains unproven. Daniel (2007) reported that there is very limited evidence in the scientific literature to support the effectiveness of non-surgical axial/spinal decompression therapy. One randomized controlled trial, one clinical trial, one case series and seven other papers were available in the published literature for review by the author as part of an intended systematic review. Due to the limited evidence a systematic review was not done, and each study was reviewed individually. The author noted many of the reviewed studies utilized the VAX-D unit. Furthermore, the intervention has not been compared to exercise, spinal manipulation, standard medical care, or other less expensive conservative treatments.

In a prospective case series study, Beattie et al. (2008) examined outcomes after an intervention of a prone lumbar traction protocol using the VAX-D system. A total of 296 subjects with low back pain and evidence of a degenerative and/or herniated intervertebral disc at one or more levels of the lumbar spine were included in this study. Patients underwent an 8-week course of prone lumbar traction, using the VAX-D system, consisting of five 30-minute sessions a week for four weeks, followed by one 30-min session a week for four additional weeks. The numeric pain rating scale and the Roland-Morris Disability Questionnaire were completed at pre-intervention, discharge (within two weeks of the last visit), and at 30 days and 180 days after discharge. 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 noted that causal relationships between the outcomes and the intervention cannot be made. This study lacked a comparison group.

Macario et al. (2008) discussed the retrospective chart audit of 100 patients with discogenic low back pain (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, three withdrew their protected health information, and three were excluded because their LBP duration was less than 12 weeks. The remaining 94 subjects 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 decompression, however caution should be taken with this interpretation given it was not provided as a singular treatment. They stated that randomized double-blind trials are needed to measure the effectiveness of such systems. Schimmel et al. (2009) conducted a randomized sham-controlled trial of intervertebral axial decompression. 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 Accu-SPINA 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 in both groups. 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 for back and leg pain, Oswestry Disability Index, and Short-Form 36), with no differences between the treatment groups. The authors reported that the added axial, intermittent, mechanical traction of IDD Therapy to a standard graded activity program has been shown not to be effective.

Apfel et al. (2010) conducted a retrospective cohort study of adults with chronic LBP attributed to disc herniation and/or discogenic LBP who underwent a six-week treatment protocol of motorized non-surgical spinal decompression via the DRX9000. The main outcomes were changes in pain as measured on a verbal rating scale during a flexion-extension range of motion evaluation and changes in disc height as measured on CT scans. The authors identified 30 patients with lumbar disc herniation and an average duration of LBP of 12.5 weeks. During treatment, low back pain decreased from 6.2 (SD 2.2) to 1.6 (2.3, $p<0.001$) and disc height increased from 7.5 (1.7) mm to 8.8 (1.7) mm ($p<0.001$). Increase in disc height and reduction in pain were significantly correlated ($r=0.36$, $p=0.044$). Reported limitations of this study are no control group and small sample size. The authors reported that a randomized controlled trial is needed to confirm the efficacy and elucidate the mechanism of this treatment modality. Choi et al. (2015) sought to identify how spinal decompression therapy and general traction therapy influence the pain, disability, and straight leg raise (SLR) ability of patients with intervertebral disc herniation. The subjects were 30 patients with chronic lumbar pain who were divided into a spinal decompression therapy group using a spinal decompression device (SDTG, *n*=15), and a general traction therapy group (GTTG, *n*=15). Both groups received conservative physical therapy three times a week for four weeks. A comparison of the two groups found no statistically significant differences. Authors concluded that spinal decompression therapy and general traction therapy are effective at improving the pain, disability, and SLR of patients with intervertebral disc herniation. Limitations of the study from a methodology standpoint do not allow conclusions to be confirmed. Kang et al. (2016) conducted a study to clarify the difference in therapeutic effects between traction and decompression therapies, and their clinical therapeutic significance. For the experimental group, 15 subjects were randomly selected to receive decompression therapy and trunk stabilization exercise. For the control group, 16 subjects were randomly selected to receive traction therapy and trunk stabilization exercise. Authors concluded that decompression therapy was demonstrated to be more effective clinically than conventional traction therapy as an intervention method for disk disease.

Demirel et al., (2017) sought to determine whether non-invasive spinal decompression therapy (NSDT) was effective in resorption of herniation, increasing disc height in patients with lumbar disc herniation (LHNP). A total of twenty patients diagnosed as LHNP and suffering from pain at least 8 weeks were enrolled to the study. Patients were randomly allocated in study (SG) and control groups (CG). Both groups received combination of electrotherapy, deep friction massage and stabilization exercise for fifteen sessions. SG received additionally NSDT 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 MRI which performed at baseline and three months after therapy. Both treatments had positive effect for improving pain, functional restoration, and reduction in thickness of herniation. Although reduction of herniation size was higher in SG than CG, no significant differences were found between groups and any superiority to each other ($p > 0.05$). Given the study design, the study showed that physiotherapy was helpful but that adding NSDT did not confer additional benefits. Amjad et al. (2022) sought to determine the effects of non-surgical spinal decompression (NSD) therapy in addition to routine physical therapy on pain, lumbar range of motion (ROM), functional disability, back muscle endurance (BME), and quality of life (QOL) in patients with lumbar radiculopathy. A total of 60 patients with lumbar radiculopathy were randomly allocated into two groups, an experimental (n = *30*) and a control (n = *30*) group, through a computer-generated random number table. Baseline values were recorded before providing any treatment by using a visual analogue scale (VAS), Urdu version of Oswestry disability index (ODI-U), modified-modified Schober's test (MMST), prone isometric chest raise test, and Short Form 36-Item Survey (SF-36) for measuring the pain at rest, functional disability, lumbar ROM, BME, and QOL, respectively. All patients received twelve treatment sessions over 4 weeks, and then all outcome measures were again recorded. By using the ANCOVA test, a statistically significant ($p < 0.05$) between-group improvement was observed in VAS, ODI-U, BME, lumbar ROM, role physical (RP), and bodily pain (BP) domains of SF-36, which was in favor of NSD therapy group. For these outcomes, a medium to large effect size ($d = 0.61$-2.47, 95% CI: 0.09-3.14) was observed. It was concluded that a combination of non-surgical spinal decompression therapy with routine physical therapy is more effective, statistically and clinically, than routine physical therapy alone in terms of improving pain, lumbar range of motion, back muscle endurance, functional disability, and physical role domain of quality of life, in patients with lumbar radiculopathy, following 4 weeks of treatment.

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