

Cigna Medical Coverage Policy- Therapy Services Axial/Spinal Decompression Therapy/Mechanical Traction (Provided in a Clinic Setting)

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GUIDELINES

Experimental, Investigational, Unproven

Nonsurgical axial/spinal decompression therapy is considered to be experimental, investigational, or unproven for 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.

Mechanical traction applied to the thoracic spine is considered experimental, investigational, or unproven for treatment of thoracic conditions or other spinal conditions other than those outlined in this guideline.

Mechanical traction applied to other spinal conditions other than those outlined in this guideline is considered experimental, investigational, or unproven.

Medically Necessary

Cervical

Use of cervical mechanical traction is considered medically necessary in the clinic setting for patients who meet all of the following criteria:

- a. Failure of other evidence-based therapeutic procedures to resolve symptoms after 3 weeks
- b. Only used in combination with other evidence-based treatments including therapeutic exercise. The therapeutic exercise(s) should not cause aggravation or peripheralization of symptoms.
- c. Patient has cervical radiculopathy diagnosis with at least 3 of the following findings:
 - i. Patient reported peripheralization with lower cervical spine (C4-7) mobility testing;
 - ii. Positive shoulder abduction test;
 - iii. Age > or =55;
 - iv. Positive upper limb tension test A
 - v. Positive neck distraction test

Cervical mechanical traction is considered experimental, investigational, or unproven for the treatment of other conditions or when the above criteria are not met.

Lumbar

Use of lumbar mechanical traction is considered medically necessary in the clinic setting for patients who meet all of the following criteria:

- a. Failure of other evidence-based therapeutic procedures to resolve symptoms after 3 weeks
- b. Only used in combination with other evidence-based treatments including therapeutic exercise with extension movements. The therapeutic exercise(s) should not cause aggravation or peripheralization of symptoms.
- c. Patient has sciatica or signs of nerve root compression and either peripheralization with extension movements or a positive crossed straight leg raise test.

Lumbar mechanical traction is considered experimental, investigational, or unproven for treatment of other conditions or when the above criteria are not met. These guidelines are NOT relevant to axial or spinal decompression therapy.

Note: Mechanical traction using a table with moving roller(s) against the spine or paraspinal tissue (e.g., Spinalator) is considered a type of passive mobilization modality (often referred to as “intersegmental traction”) that may have limited value in reducing spinal stiffness and muscle tension and is only appropriate as preparatory or adjunctive to spinal manipulative procedures. It should not be used as a stand-alone therapy. It should only be used for a short duration (1-2 weeks) to facilitate manipulations and to transition into an active therapy program.

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. Traditional mechanical traction is a therapeutic method used to relieve pain by stretching and separating the vertebrae to help to relieve direct nerve pressure and stress on the vertebral discs. Cervical traction is a common nonsurgical treatment for a herniated disc in the neck that relieves pain by opening up the cervical foramen to reduce pressure on compressed nerve roots exiting the spinal canal. Traction can either be applied manually or by spinal traction devices. This guideline focuses on various mechanical traction devices that provide continuous or intermittent forces to the spine. It has been proposed that cervical traction results in an expansion of the intervertebral spaces, an increase joint mobility, and a stretching muscles and ligaments adjacent to the vertebral bodies, which will improve clinical outcomes in those with neck pain. After 2 minutes of sustained traction, the intervertebral spaces begin to widen. Forces between 20 and 50 pounds are frequently used to achieve intervertebral separation. Continuous or static traction can be applied in a steady amount for specific time periods. Intermittent or cyclical traction involves traction being applied and released multiple times during one treatment session. Duration of cervical traction can range from a few minutes to 20 to 30 minutes, one to three times weekly.

Traction is used for treatment of low back pain (LBP) as well and it is provided in combination with other treatment modalities, as is cervical traction. Lumbar traction uses a harness (with Velcro strapping) that is put around the lower rib cage and around the iliac crest. Duration and level of force exerted through this harness can be varied in a continuous or intermittent mode. The exact mechanism through which traction might be effective is still unclear. It has been suggested that spinal elongation, through decreasing lordosis and increasing intervertebral space, inhibits pain (nociceptive) impulses, improves mobility, decreases mechanical stress, reduces muscle spasm or spinal nerve root compression (due to osteophytes), releases luxation of a disc or capsule from the zygapophyseal joint, and releases adhesions around the zygapophyseal joint and the annulus fibrosus. So far, the proposed mechanisms have not been supported by sufficient empirical information.

According to CPT, mechanical traction is described as the force used to create a degree of tension of soft tissues and/or to allow for separation between joint surfaces. The degree of traction is controlled through the amount of force (pounds) allowed, duration (time), and angle of pull (degrees) using mechanical means. Terms often used in describing pelvic(lumbar)/cervical traction are intermittent or static (describing the length of time traction is applied).

GENERAL BACKGROUND

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; and
- Overstretching of the soft tissue of the back.

Decompression, Reduction, Stabilization (DRS) System

Manufacturers recommend the 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. 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.

LITERATURE REVIEW

Cervical

Although traction has been used as a treatment for neck pain for decades, its effectiveness is unproven. Large, well designed, randomized controlled trials are needed that evaluate the effect of cervical traction as an adjunct treatment in both chronic and acute neck pain syndromes. Regardless, cervical traction remains a common treatment modality in the treatment of neck pain and radiculopathy. Borman et al. (2008) evaluated cervical for the treatment of chronic neck pain. Patients received standard care (hot pack, ultrasound and exercise) or cervical traction + standard care. The main outcome measures of the treatment were pain intensity by visual analog scale (VAS), disability by neck disability index (NDI), and quality of life assessed by Nottingham Health Profile (NHP). Both groups improved significantly in pain intensity and the scores of NDI and physical status of NHP at the end of the therapies ($p < 0.05$). Authors concluded that there was no specific effect of traction over standard physical therapy interventions in patients with chronic neck pain. Young et al. (2009) conducted a randomized controlled trial (RCT) on 81 patients with cervical radiculopathy to examine the effects of manual therapy and exercise, with or without the addition of cervical traction, on pain, function, and disability. Patients were randomly assigned to 1 of 2 groups: a group that received manual therapy, exercise, and intermittent cervical traction and a group that received manual therapy, exercise, and sham intermittent cervical traction. Patients were treated, on average, 2 times per week for an average of 4.2 weeks. Results demonstrated there were no significant differences between the groups for any of the primary or secondary outcome measures at 2 weeks or 4 weeks. Authors concluded that the addition of mechanical cervical traction to a multimodal treatment program of manual therapy and exercise adds no significant additional benefit to pain, function, or disability in patients with cervical radiculopathy.

Raney et al. (2009) sought to determine a clinical prediction rule to identify those patients that were likely to benefit from cervical traction and exercise. Patients were randomly selected into the following groups: exercise only, exercise with mechanical traction, or exercise with over-door traction for patients with cervical radiculopathy. Sixty-eight patients (38 female) were included in data analysis of which 30 had a successful outcome. A CPR with five variables was identified: (1) patient reported peripheralization with lower cervical spine (C4-7) mobility testing; (2) positive shoulder abduction test; (3) age $>$ or $= 55$; (4) positive upper limb tension test A; and (5) positive neck distraction test. Having at least three out of five predictors present resulted in a +LR equal to 4.81 (95% CI = 2.17-11.4), increasing the likelihood of success with cervical traction from 44 to 79.2%. If at least four out of five variables were present, the +LR was equal to 23.1 (2.5-227.9), increasing the post-test probability of having improvement with cervical traction to 94.8%. This preliminary CPR provides the ability to a priori identify patients with neck pain likely to experience a dramatic response with cervical traction and exercise. Before the rule can be

implemented in routine clinical practice, future studies are necessary to validate the rule. In 2014, Fritz et al. examined the effectiveness of cervical traction in addition to exercise for specific subgroups of patients with neck pain. Patients with neck pain and signs of radiculopathy were randomized to 4 weeks of treatment with exercise, exercise with mechanical traction, or exercise with over-door traction. Secondary outcomes favored mechanical traction at several time points. The validity of the subgrouping rule was supported on the Neck Disability Index at the 6-month time point only. Authors concluded that adding mechanical traction to exercise for patients with cervical radiculopathy resulted in lower disability and pain, particularly at long-term follow-ups.

Chiu et al. (2011) investigated the efficacy of intermittent cervical traction in the treatment of chronic neck pain over a 12-week period in a RCT of 79 patients. The experimental group received intermittent cervical traction and the control group received infrared irradiation alone twice a week over a period of six weeks. The authors concluded that there were no significant differences between the two groups. Graham et al. (2013) completed a systematic review on physical modalities for acute to chronic neck pain. Of 103 reviews eligible, 20 were included and 83 were excluded. Moderate evidence of benefit in the short term was noted for intermittent traction over placebo for chronic neck pain. No benefit was noted for continuous traction over placebo for whiplash associated disorder (WAD). Moderate evidence of no benefit for continuous traction was noted, as it was no better than placebo for acute whiplash associated disorder, chronic myofascial neck pain or subacute to chronic neck pain. Improved design and long term follow up were suggested for future research.

Yang et al. (2017) performed a comprehensive search of current literature and conduct a meta-analysis of randomized controlled trials (RCTs) to assess the neck pain relieving effect of intermittent cervical traction (ICT). The meta-analysis included seven RCTs. The results indicated that patients who received ICT for neck pain had significantly lower pain scores than those receiving placebos did immediately after treatment. The pain scores during the follow-up period and the neck disability index scores immediately after treatment and during the follow-up period did not differ significantly. Authors concluded that ICT may have a short-term neck pain-relieving effect. Some risks of bias were noted in the included studies, reducing the evidence level of this meta-analysis. According to Blanpied et al. (2017), for patients with chronic neck pain with mobility deficits, clinicians should provide a multimodal approach that may included intermittent mechanical/manual traction. They also report that for patients with chronic neck pain with radiating pain, clinicians should provide mechanical intermittent cervical traction, combined with other interventions such as stretching and strengthening exercise plus cervical and thoracic mobilization/manipulation. However, Bier et al. (2018) states that the physical therapist is advised not to use traction. Romeo et al. (2018) conducted a review and meta-analysis of randomized controlled trials (RCTs) on the effect of cervical traction combined with other physical therapy procedures versus physical therapy procedures alone on pain and disability on patients with cervical radiculopathy (CR). Five studies met the inclusion criteria. Mechanical traction had a significant effect on pain at short- and intermediate-terms and significant effects on disability at intermediate term. Manual traction had significant effects on pain at short- term. Authors conclude that the current literature lends some support to the use of the mechanical and manual traction for CR in addition to other physical therapy procedures for pain reduction, but yielding lesser effects on function/disability.

Lumbar

According to the Philadelphia Panel Evidence-Based Clinical Practice Guidelines on Selected Rehabilitation Interventions for Low Back Pain publication (2001), mechanical traction for chronic LBP was not effective or beneficial for pain, function, patient global assessment, and return to work. This was based on four (4) RCTs of mechanical traction versus placebo or no treatment and rated as level I (good evidence). A larger Cochrane Collaboration systematic review by Clarke et al. (2009) determined similar results (25 RCTs). Available studies in this review involved mixed groups of acute, sub-acute and chronic patients with LBP with and without sciatica and were all consistent, indicating that continuous or intermittent traction as a single treatment for LBP is not likely effective for these patients. Traction for patients with sciatica cannot be judged effective at present either, due to inconsistent results and methodological problems in most studies (Clarke et al., 2009). An updated Cochrane review published in 2013 by Wegner et al. indicated that traction, either alone or in combination with other treatments, has little or no impact on pain intensity, functional status, global improvement and return to work among people with LBP (with or without sciatica). The effects shown by the included studies were small and not clinically relevant. These conclusions were applicable to both manual and mechanical traction.

One study attempted to determine which subcategory of patients with LBP would most benefit from mechanical traction. Fritz et al. (2007) determined that patients with sciatica, signs of nerve root compression, and either peripheralization with extension movements or a positive crossed straight leg raise test were most likely to benefit from a combined traction and extension-oriented physical therapy intervention. The authors reported

improvements in both disability (Oswestry Disability Questionnaire) and fear-avoidance beliefs (Fear Avoidance Belief Questionnaire) in the combined traction/extension-oriented approach group at two weeks compared to the group that received just an extension-oriented approach. This study provides some initial evidence for the use of traction for the subgroup of patients mentioned above. The primary limitation to this study is the type of traction table used is not one that is typically found in most clinical settings. The authors used a mechanical traction table allowing for modifications of a subject's position in flexion/extension, rotation or side-bending (3-dimensional ActiveTrac table, The Saunders Group, Inc.). The following parameters were utilized: static traction for a maximum of 12 minutes (10 minutes at desired intensity and one minute ramp up/down) at 40% - 60% of the patient's body weight for a maximum of 12 sessions during a 6 week period (four sessions/week during the first two weeks then one session/week during weeks three through six). Thackeray et al. (2016) examined the effectiveness of mechanical traction in patients with lumbar nerve root compression and within a predefined subgroup. One hundred twenty patients with low back pain with nerve root compression were recruited from physical therapy clinics. Using predefined subgrouping criteria, patients were stratified at baseline and 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. No significant differences in disability or pain outcomes were noted between treatment groups at any time point, nor was any interaction found between subgroup status and treatment. Authors concluded that patients with lumbar nerve root compression presenting for physical therapy can expect significant changes in disability and pain over a 6-week treatment period. There is no evidence that mechanical lumbar traction in combination with an extension-oriented treatment is superior to extension-oriented exercises alone in the management of these patients or within a predefined subgroup of patients.

Bilgilişoy Filiz et al. (2018) compared the effects of mechanical lumbar traction either in the supine or in the prone position with conventional physical therapy (PT) in patients with chronic low back pain and lumbosacral nerve root involvement in terms of disability, pain, and mobility. Participants (N = 125) were randomly assigned to receive 15 sessions of PT with additional mechanical lumbar traction either in the supine position (supine traction group) or in the prone position (prone traction group) or only PT without traction (PT only group). Patients were assessed at baseline and at the end of the PT sessions in terms of disability, pain, and mobility. Disability was assessed using the modified Oswestry Disability Index; pain was assessed using a visual analog scale, and lumbar mobility was assessed using the modified lumbar Schober test. One hundred eighteen patients completed the trial. All groups improved significantly for all outcomes. In the between-group analysis, improvements of Oswestry Disability Index and visual analog scale were found significantly better in the prone traction group compared with the PT only group. Authors concluded that the addition of traction in the prone position to other modalities resulted in larger immediate improvements in terms of pain and disability, and the results suggest that when using traction, prone traction might be first choice. Kuligowski et al. (2019) completed a study that enrolled 37 people aged 22-35. The subjects underwent radiological evaluation (MRI), which constituted the basis for assigning them to one of two groups: a protrusion group (PRO) or an extrusion group (EXT). During the experiment, the patient was in the supine position while the therapist administered three-dimensional traction using a manual therapy belt. Authors concluded the following: 1. The type of intervertebral disc damage determines the functional status of young people with degenerative disc disease. 2. The study demonstrated and confirmed a positive effect of traction on the functional status of subjects with lumbar disc herniation. 3. Traction techniques are safe and can be successfully used in the treatment of lumbar disc herniation as noted on MRI.

Hirayama et al. (2019) sought to develop a clinical prediction rule (CPR) that predicts treatment responses to mechanical lumbar traction (MLT) among patients with lumbar disc herniation (LDH). The subjects included 103 patients diagnosed with LDH for which they underwent conservative therapy. The subjects received MLT for 2 weeks, and the application of any other medication was left at the discretion of the attending physician. The patients whose ODI after 2 weeks of treatment improved by $\geq 50\%$ of that at the initial evaluation were defined as responders. Of the 103 subjects, 24 were responders, and the five predictors selected for the CPR were limited lumbar extension range of motion, low-level fear-avoidance beliefs regarding work, no segmental hypomobility in the lumbar spine, short duration of symptoms, and sudden onset of symptoms. For the patients with at least three of the five predictors, the probability of their ODI greatly improving increased from 23.3% to 48.7% compared with the patients without these predictors (positive likelihood ratio, 3.13). Cheng et al. (2020) evaluated the effectiveness of traction in improving low back pain, functional outcome, and disk morphology in patients with herniated intervertebral disks. Seven articles involving 403 participants were included for quantitative analysis. Compared with the control group, the participants in the traction group showed significantly greater improvements in pain and function in the short term, with standard mean differences of 0.44 (95% confidence interval (CI): 0.11-

0.77) and 0.42 (95% CI: 0.08-0.76), respectively. The standard mean differences were not significant to support the long-term effects on pain and function, nor the effects on herniated disk size. Authors concluded that compared with sham or no traction, lumbar traction exhibited significantly more pain reduction and functional improvements in the short term, but not in the long term. There is insufficient evidence to support the effect of lumbar traction on herniated disk size reduction.

Vanti et al. (2020) evaluated the effects of different types of traction added to or compared with conservative treatments on pain and disability in a systematic review and meta-analysis. Eight studies met the inclusion criteria, and 5 were meta-analyzed. Meta-analyses of results from low-quality studies indicated that supine mechanical traction added to physical therapist treatments had significant effects on pain. Analyses of results from high-quality studies of prone mechanical traction added to physical therapist intervention for pain and disability were not significant. These results were also evident at short-term follow-up (up to 3 months after intervention). Authors concluded that literature suggests that, for pain and disability in lumbar radiculopathy, there is short-term effectiveness of supine mechanical traction when added to physical therapist intervention.

The North American Spine Society's clinical practice guideline on "Diagnosis and treatment of degenerative lumbar spinal stenosis" (2011) noted that there is insufficient evidence to make a recommendation for or against traction, electrical stimulation or transcutaneous electrical nerve stimulation for the treatment of patients with lumbar spinal stenosis.

According to the AHRQ publication on Non-Invasive Techniques for Low Back Pain (Chou, et al., 2016):

- For low back pain with or without radicular symptoms, a systematic review included 13 trials that found no clear differences with inconsistent effects of traction versus placebo, sham, or no treatment in pain, function, or other outcomes, though two trials reported favorable effects on pain in patients with radicular back pain (SOE: insufficient for pain and function).
- For low back pain with or without radicular symptoms, a systematic review included five trials that found no clear differences between traction versus physiotherapy versus physiotherapy alone.
- For low back pain with or without radicular symptoms, a systematic review included 15 trials of traction versus other interventions that found no clear between traction versus other active interventions in pain or function (SOE: low for pain and function).
- A systematic review included five trials that found no clear differences between different types of traction.
- Eleven trials of traction in a systematic review reported no adverse events or no difference in risk of adverse events versus placebo or other interventions. Three subsequent trials reported findings consistent with the systematic review.

Overall, there is insufficient evidence to support the isolated use of mechanical traction as a treatment for chronic LBP.

According to the American College of Physician's clinical practice guideline on noninvasive treatments for acute, subacute, and chronic low back pain, evidence was insufficient to determine the effectiveness of traction tables/devices (Qaseem, et al., 2017). Foster et al. (2018) summarize that passive electrical or physical modalities, such as traction, interferential therapy, short-wave diathermy, are generally ineffective and not recommended. Chou et al. (2018) states that clinicians should not offer traction for neck and back pain given lack of effectiveness.

Nonsurgical axial/spinal decompression therapy

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 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, the Centers for Medicare & Medicaid Services (CMS) Technology Advisory Committee 2007, 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 CMS Technology Advisory Committee did not recommend coverage of the VAX-D system because of the absence of scientific data on its effectiveness.

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. 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 and associates (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. 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.

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.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when used to report the use of cervical and lumbar mechanical traction when criteria in the applicable policy statements listed above are met:

CPT®*	Description
97012	Application of a modality to 1 or more areas; traction, mechanical

Considered Experimental, Investigational, Unproven when used to report nonsurgical axial/spinal decompression therapy and mechanical traction applied to thoracic spine:

CPT®*	Description
64722	Decompression; unspecified nerve(s) (specify)
97012	Application of a modality to 1 or more areas; traction, mechanical

HCPCS Codes	Description
S9090	Vertebral axial decompression, per session

*Current Procedural Terminology (CPT®) ©2020 American Medical Association: Chicago, IL.

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