MOTORIZED SPINAL TRACTION

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INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Medical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Medical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Motorized spinal traction devices are unproven and not medically necessary for treating neck and low back disorders.

There is insufficient evidence from peer-reviewed published studies to conclude that spinal unloading devices are effective in the management of neck or low back pain or that they improve health outcomes. The indications for use, patient selection criteria, risks, and comparison to alternative technologies have not been established by the U.S. Food and Drug Administration (FDA) for motorized traction therapy. (Accessed April 20, 2017)
A randomized clinical trial by Unlu et al. (2008) compared the use of motorized traction, ultrasound and low-power laser (LPL) therapies in 60 patients (equally distributed) with acute leg pain and low back pain caused by lumbar disc herniation. Treatment consisted of 15 sessions over a 3 week period. All patients had pre- and post-treatment magnetic resonance imaging (MRI). Additional outcomes measurements included physical examination of the lumbar spine, visual analog scale, Roland Disability Questionnaire and Modified Oswestry Disability Questionnaire to evaluate functional disability at baseline, after each session, and at 1 and 3 months after treatment. The authors reported similar improvement across treatment conditions for the outcomes measured (pain intensity and functional disability) at the end of the 3-week treatment period, and at 1 and 3-month follow-up assessments. Additionally, there were similar reductions in disc herniation on post-treatment MRI evaluations. The authors concluded that all the modalities were effective in the treatment of these patients with acute lumbar disc herniation. The study is limited by lack of a comparison group that did not receive treatment for similar complaints and small sample size.
Shealy and Borgmeyer (1997) completed a randomized study of decompression reduction stabilization (DRS) versus traction therapy. Pain reduction was the only outcome measure evaluated in this randomized study. Patients were randomized to complete either 20 sessions of DRS therapy or traction therapy. All patients received ice packs and TENS for 30 minutes after their assigned therapy. Pain reduction was defined as good or excellent improvement. The scale used to quantify the pain was not described. The authors concluded that 86% of patients with ruptured intervertebral discs had good to excellent results after DRS therapy compared to 55% of the traction treated patients. Of the patients with facet arthrosis, 75% obtained good to excellent results with DRS therapy as compared to 55% of the traction-treated group. The procedure related complications were not analyzed nor were follow-up evaluations completed. The primary author is the developer of the DRS system.

Schimmel et al. (2009) conducted a randomized controlled trial of 60 patients to evaluate the efficacy of Intervertebral Differential Dynamics Therapy® (IDD) on low back pain vs. sham therapy. Both groups received 20 sessions in the Accu-SPINA device. The IDD group received traction weight that was systematically increased until 50% of a person's body weight plus 4.45 kg (10 lb) was reached. The SHAM group received a non-therapeutic traction weight of 4.45 kg in all sessions. Outcomes were measures using visual analog scale (VAS), Oswestry Disability Index (ODI) and Short-Form 36 (SF-36) 2, 6 and 14 weeks after initiation of treatment. VAS improved from 61 (+/-25) to 32 (+/-27) in the IDD group and from 53 (+/-26) to 36 (+/-27) in the SHAM group. Leg pain, ODI and SF-36 scores improved in both groups. The authors found no difference between the IDD Therapy and the SHAM therapy; however, patients in both groups reported a decrease in low back and leg pain and an increase in functional status and quality of life.

Gose et al. (1998) completed a multicenter, retrospective chart review of 778 patients treated with VAX-D at 22 medical centers. VAX-D therapy was considered successful in 71% of the low back pain patients. The majority of the patients reported some improvements in pain of at least one level (92%); spinal mobility (77%) and ability to carry out the usual activities of daily living (63%) following VAX-D therapy. Although this study involved a larger number of patients compared to previous studies, it lacks a comparison group, had poorly defined patient selection criteria and did not discuss safety.

Apfel et al. (2010) conducted a retrospective study of 30 patients with chronic low back pain attributed to disc herniation and/or discogenic low back pain. All patients 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 (± 2.2) to 1.6 (± 2.3) and disc height increased from 7.5 (± 1.7) to 8.8 (± 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 note that a randomized controlled is needed to confirm these results. The study is further limited by lack of a control group, lack of long term follow-up and small sample size.

In a retrospective chart audit by Macario et al. (2008), 100 outpatients with discogenic low back pain lasting more than 12 weeks were treated with a 20 month course of motorized spinal decompression via the DRX9000. Overall, this preliminary analysis suggests that treatment with the DRX9000 nonsurgical spinal decompression system reduced patient's chronic low back pain with patients requiring fewer analesics, and achieving better function. However, without control groups, it is difficult to know how much of the benefit was placebo, spontaneous recovery, or the treatment itself. Randomized double-blind trials are needed to measure the efficacy of such systems.

Sherry et al. (2001) completed an Australian study of 40 patients with chronic low back pain (>3 months), associated leg pain and disc protrusion documented by MRI or CT were treated with either VAX-D or transcutaneous electrical nerve stimulation (TENS). Nineteen patients were randomized to receive VAX-D. Of these patients, 13 (68.4%) had successful treatment which as defined as a 50 percent or greater reduction in the patient's pain and an improvement in their disability rating. None of the 21 patients in the TENS group had success. Six-month follow up of the 13 "success" cases showed that 7 of the 10 who could still be evaluated, still met the criteria for success.

A study by Ramos (2004) compared the effects of two different regimens of VAX-D treatments on the level of low back pain. One group of patients received an average course of treatment consisting of 18 daily sessions and the other group received half that number of daily treatments. The treatment parameters were the same for all patients except for the number of treatments completed. Seventy-six percent of the higher dosage group achieved remission of low back pain compared to 43% of the lower dosage group. This study did not compare results to patients treated with other modalities or no treatment at all.

Beattie et al. (2008) conducted a prospective case series study of 296 patients to examine outcomes after administration of a prone lumbar traction protocol, using the VAX-D system. All patients had low back pain with evidence of a degenerative and/or herniated intervertebral disk at one or more levels of the lumbar spine. Patients involved in litigation or and those receiving workers' compensation were excluded. Patients underwent an 8-week course of prone lumbar traction consisting of five 30-minute sessions a week for 4 weeks, followed by one 30-min
session a week for 4 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. Intention-to-treat strategies were used to account for those patients lost to follow-up. A total of 250 (84.4%) patients completed the treatment protocol with 247 (83.4%) of patients available on 30 day follow-up and 241 (81.4%) patients available at 180 day follow-up. The researchers noted significant improvements for all post-intervention outcome scores when compared with pre-intervention scores (p < 0.01). The authors concluded that causal relationships between the outcomes and the intervention cannot be made until further study is performed using randomized comparison groups.

Deen, Rizzo and Fenton (2003) published a case report of a patient with a large lumbar disc protrusion who experienced sudden, severe exacerbation of radicular pain during a VAX-D session. A follow up lumbar MRI showed marked enlargement of the protrusion and urgent microdiscectomy was required. The authors noted that manufacturer information targeted at the general public emphasizes that the treatment is completely risk free.

The Work Loss Data Institute's clinical practice guideline Low back - lumbar & thoracic (acute & chronic) (2011) does not recommend the use of powered traction devices such as vertebral axial decompression (VAX-D).

**Neck**

A literature search identified a single small case series by Gundersen et al. (2004) was that designed to measure the improvement of neck and arm pain patients. Four adult subjects having reported chronic neck and arm pain received motorized cervical traction therapy. The treatment protocol ranged from 3-6 sessions per week. The duration of the treatment period was unclear. Outcome variables included the Neck Disability Index, Activities Discomfort Scale, and Quadruple Visual Analog Scale. Baseline and end-of-treatment outcomes were reported solely for disability (Neck Disability Index). Three of the four subjects demonstrated clinically significant improvement.

Confidence in the results of this study is very low due to limitations posed by its design (case series). The absence of reported baseline demographic data, reporting of all outcomes of interest, and apparent lack of assessor blinding contributed to a high risk of bias. Additionally, the treatment protocol was not explicitly described, the baseline measures of disability (minimal to moderate) suggested the subjects were not typical of broader populations, the statistical analysis was limited to a simple descriptive measure (percentage of change), the absence follow-up data did not allow for judgments about sustained effects, and adverse event monitoring was not reported.

The clinical evidence was reviewed on April 21, 2017 with no additional information identified that would change the unproven conclusion.

**Professional Societies**

**North American Spine Society (NASS)**

The NASS evidence-based guideline (Kriener et al., 2011) on the diagnosis and treatment of degenerative lumbar spinal stenosis considers 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 NASS evidence-based guideline (Bono et al., 2010) on the diagnosis and treatment of cervical radiculopathy from degenerative disorders recommends that future outcome studies for patients in this population treated only with ancillary treatments (such as traction) should include subgroup analysis.

**Workers Compensation Board (WCB) of British Columbia, Evidence Based Practice Group**

The WCB conducted a systematic review (2005) of vertebral axial decompression for low back pain and concluded that there is no evidence that the VAX-D system is effective in treating chronic low back pain associated with herniated disc, degenerative disc, posterior facet syndrome, sciatica or radiculopathy.

**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

Powered traction equipment is regulated by the FDA but products are too numerous to list. See the following website for more information (product code ITH): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed April 20, 2017)

**CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)**

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. (Accessed March 10, 2017)
REFERENCES


POLICY HISTORY/REVISION INFORMATION

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