MOTORIZED SPINAL TRACTION

Policy Number: REHABILITATION 035.12 T2 **Effective Date**: December 1, 2018

Instructions for Use

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Related Policies

- Electrical Stimulation and Electromagnetic Therapy for Wounds
- Home Traction Therapy
- Mechanical Stretching Devices

APPLICABLE LINES OF BUSINESS/PRODUCTS

This policy applies to Oxford Commercial plan membership.

NON-COVERAGE RATIONALE

Motorized spinal traction devices are unproven and not medically necessary for treating neck and low back disorders due to insufficient evidence of efficacy.

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies may apply.

HCPCS Code	Description
S9090	Vertebral axial decompression, per session

DESCRIPTION OF SERVICES

Vertebral axial decompression is a type of spinal traction used in the treatment of back or neck pain.

This involves the use of a computer-driven table to control the disc decompression. For the treatment, a pelvic harness is applied to the patient and the patient lies on the special table and is subjected to a series of cycles as the table is slowly extended and a distraction force is applied via the harness. When the desired tension is reached, it is gradually decreased. The number of sessions varies.

CLINICAL EVIDENCE

Back

In a randomized clinical trial, Thackeray et al. (2016) examined 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, and over 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. At the end of the 1 year time period, the authors concluded that in this patient population there was no evidence that mechanical lumbar traction in combination with an extension-oriented

treatment was superior to extension-oriented exercises alone in the management of these patients at any point in the evaluation period.

A randomized controlled 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 completed 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 analgesics, 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 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.

In an Agency for Healthcare Research and Quality review, Chou et al., 2016 assessed the evidence on the comparative benefits and harms of noninvasive treatments for acute, subacute, and chronic low back pain from 156 studies. Excluded from the review were 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. Outcomes were mostly measured at short-term (up to 6 months) followup. For radicular low back pain, there was low strength of evidence demonstrating that traction was effective compared to physiotherapy and other nonpharmacological interventions on pain control.

Macario et al. (2006) completed a systematic review of the literature to assess the efficacy of nonsurgical spinal decompression achieved with motorized traction for chronic discogenic lumbosacral back pain. The authors found that the efficacy of spinal decompression achieved with motorized traction for chronic discogenic low back pain remains unproven. This may be, in part, due to heterogeneous patient groups and the difficulties involved in properly blinding patients to the mechanical pulling mechanism. Randomized double-blind trials are needed to measure the efficacy of such systems.

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

Neck

Published clinical evidence for treating neck pain with vertebral axial decompression or other types of motorized traction is limited to case studies. Well-designed randomized controlled trials are needed to determine the efficacy of vertebral axial decompression for this indication.

Professional Societies

American College of Physicians (ACP)

In an updated clinical practice guideline on non-invasive treatments for low back pain, the ACP (Qaseem et al., 2017) states that evidence is insufficient to determine the effectiveness of several therapies including traction, 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.

North American Spine Society (NASS)

The NASS evidence-based guidelines (Kriener et al., 2011) on the diagnosis and treatment of degenerative lumbar spinal stenosis consider 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., 2011) 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.

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 web site for more information (product code ITH). Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed March 22, 2018)

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
12/01/2018	• Simplified non-coverage rationale (no change to guidelines) • Archived previous policy version REHABILITATION 035.11 T2

INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

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