Motorized Spinal Traction

UnitedHealthcare® Commercial Medical Policy

MOTORIZED SPINAL TRACTION

Policy Number: 2020T0546M

Effective Date: June 1, 2020

Table of Contents

<table>
<thead>
<tr>
<th>Coverage Rationale</th>
<th>Page</th>
</tr>
</thead>
</table>
| 1
| Applicable Codes | 1
| Description of Services | 1
| Clinical Evidence | 1
| U.S. Food and Drug Administration | 3
| Centers for Medicare and Medicaid Services | 3
| References | 4
| Policy History/Revision Information | 4
| Instructions for Use | 4

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 and Coverage Determination Guidelines may apply.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S9090</td>
<td>Vertebral axial decompression, per session</td>
</tr>
</tbody>
</table>

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

There is insufficient evidence from peer-reviewed published studies to conclude that spinal unloading devices are effective in the management of low back pain or that they improve health outcomes. Additional well-designed controlled trials are needed to determine the efficacy for this service.

Koçak et al. (2017) studied and compared the efficiency of conventional motorized traction (CMT) with non-surgical spinal decompression (NSD) using the DRX9000TM device, a different form of motorized spinal traction, in patients with low back pain associated with lumbar disc herniation. Forty-eight patients were randomized into two different groups; the first group underwent CMT and the second group underwent NSD. Both groups underwent the therapy for six weeks. Participants were assessed before and after the sessions: pain was assessed using the Visual Analog Scale (VAS), functional status assessed using the Oswestry Disability Index (ODI), quality of life assessed using the Short Form-36 (SF-36), state of depression mood assessed using the Beck Depression Inventory (BDI), and the global
assessment of the illness using the Patient’s Global Assessment of Response to Therapy (PGART) and Investigator’s Global Assessment of Response to Therapy (IGART) scales. The authors concluded the study findings showed both CMT and NSD treatments were effective methods in controlling pain, in enhancing functional status, and in reducing depressive mood in patients with chronic LBP associated with LDH. Limitations included lack of control group without motorized spinal traction, no sham groups and the inability to perform long-term follow-up of the participants; future studies are warranted.

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.

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.

Apfel et al. (2010) conducted a retrospective case series 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.

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 measured 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.

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.

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.
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 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.

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.

**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 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., 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.

**Other**

The Work Loss Data Institute's clinical practice guideline for low back pain (2014) does not recommend the use of powered traction devices such as VAX-D.

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

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

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](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm). (Accessed March 25, 2020)

**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 April 6, 2020)
REFERENCES


POLICY HISTORY/REVISION INFORMATION

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/01/2020</td>
<td>Supporting Information</td>
</tr>
<tr>
<td></td>
<td>Updated Clinical Evidence and References sections to reflect the most current information</td>
</tr>
<tr>
<td></td>
<td>Archived previous policy version 2019T0546L</td>
</tr>
</tbody>
</table>

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare 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 reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Medical Policies 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.