# Motorized Spinal Traction

**Guideline Number**: MMG085.N
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Instructions for Use

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## 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 guideline 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 Guidelines 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.

## 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.

Amjad et al. (2022) conducted a randomized controlled trial (RCT) 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 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 12 treatment sessions over 4 weeks, and then all outcome measures were again recorded. By using the ANCOVA test, a statistical ($p < 0.05$) 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. The between-group difference was 1.07 ±0.32 cm ($p < .001$) for VAS, 5.65 ±1.48 points ($p < .001$) for ODI-U, 13.93 ±5.85 s ($p = 0.002$) for BME, 2.62 ±0.27 cm ($p < .001$) for lumbar flexion, 0.96 ±0.28 ($p < .001$) for lumbar extension, 5.77 ±2.39 ($p = 0.019$) for RP and 6.33 ±2.52 ($p = 0.016$) for BP domain of SF-36. For these outcomes, a medium to large effect size (d = 0.61-2.47, 95% CI: 0.09-3.14) was observed. The authors 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. Limitations to this RCT include additional therapy time given to the interventional group compared to the control group. The “high-technology” intervention and additional therapy time vs control may have significantly impacted patient-reported outcome measures (PROMs) and led to the potential Hawthorne effect. Due to the nature of the treatment, it was not possible to maintain patients’ blinding, which may also have caused the Hawthorne effect. In addition, the lack of follow-up after therapy ceased was another limitation. The short terms follow-up did not allow for assessment of intermediate and long-term outcomes.

A random cross over study performed by Lee et al. (2021) evaluated real-time standard spinal traction (ST) with that of lordotic curve-controlled traction (LCCT). The study included 40 participants with mild non-radicular low back pain (LBP) and randomly assigned for either standard ST or LCCT. Each participant had initial x-rays taken in a standing position. After 10 minutes of traction, another radiograph was taken in the supine position and real-time shooting was performed during both standard ST and LCCT procedures. The following angles were measured: intervertebral disc angle of all segments, disc distance anterior and posterior and all measurements were taken by a radiologist who was blinded to the study. The disc distance was defined as the distance between inferior endplate of upper vertebrae and the superior endplate of opposing lower vertebrae while applying standard ST to straighten the spine or LCCT to be applied posteriorly to maintain the lordotic curve. Standard ST was applied and gradually increased to the maximum level tolerated or until the force was 1/3 of the patient’s weight. LCCT participants had a magnetic marker attached to L4/L5 disc space by physical palpation. The authors found that during standard ST the force of traction decreased the lordotic curve and had more effect on the posterior and overstretching which causes pain, muscle spasms, damage to facet joints and soft tissue without effect on discs. The LCCT group with the same amount of force showed greater distance increase in discs and fewer muscle spasms. The authors concluded that the LCCT preserved the lordotic curve whereas standard ST only straightened it. The authors felt the newly developed LCCT device was useful for increasing the disc space evenly while maintaining the lordotic curve. Limitations included small sample size and lack of long-term efficacy for low back pain; further studies are warranted.

Tanabe et al. (2021) performed a randomized controlled trial (RCT) to evaluate the efficacy and safety of traction on chronic low back pain (CLBP) patients using recently developed equipment capable of precise traction force control. The study included 95 patients with non-specific CLBP from 28 clinics and hospitals, distributed throughout Japan, between December 2016 and March 2017. Participants were randomly assigned to group A (n = 49), intermittent traction with vibration (ITV) mode; and group B (n = 46), intermittent traction only (ITO) mode. All patients were followed up weekly for 2 periods after study-initiation. The primary outcome measures were disability level including pain, and quality of life. Statistical analysis was performed using linear mixed model. Two types of traction devices sold in the market under the same category of classification (MINATO Medical

Science, ST-2L/2CL and OG Wellness Technologies, OL-6500/6000) were used. The devices consist of two main parts: a holding part for the upper body with arm holders, and a moving part for the lower body. The upper body unit automatically measures the height of the arm pit to maintain the counter force against traction. The lower body unit produces a position of 90/90° traction adjusting the thigh length. Comparing to pre-traction data, both traction modes showed improvement except the first intervention of ITO treatment. The differences in Japan Low Back Evaluation Questionnaire (JLEQ) scores over time showed improvements in the treatment to which vibrational force was added in contrast to the conventional traction treatment; Mean difference was significant to compare ITV treatment and ITO treatment (−1.75 ($p = 0.001$), 95% CI; -2.69 to -0.80). However, neither difference between the two sequences ($p = 0.884$) nor carryover effect ($p = 0.527$) was observed. The authors concluded that lumbar traction could provide immediate effect in terms of the pain intensity and functional status in patients with CLBP, and a traction method added vibrational force on preload seemed to be promising. In addition, the study contributes to some evidence of the efficacy of lumbar traction. Limitations of the study include a short follow-up period of 2 weeks which did not allow for assessment of intermediate and long-term outcomes. Further investigation is needed before clinical usefulness of this procedure is proven.

Cheng et al. (2020) completed a systematic review of seven articles and a meta-analysis of literature including 403 participants. The criteria assessed in the randomized control trial included participants with low back pain (with or without sciatica), and those with herniated disc(s) confirmed by magnetic resonance imaging (MRI) or computed tomography (CT). The analysis compared participants that received any type of traction to the lumbar spine with sham or no traction and pain measurements before and after intervention. The authors concluded that lumbar traction was effective in the short term for reducing low back pain in those with a lumbar herniated disc, but further studies are needed to determine long term effectiveness. Several limitations of the study were identified including methodology, small sample size, differing interventions and outcome assessments contributing the heterogeneity; in addition only two trials used sham controls.

Tadano et al. (2019) conducted a qualitative study as part of a randomized clinical trial (RCT) (UMIN-CTR 000024329, date opened: October 13, 2016) to examine the biomechanical change at the lumbar area under lumbar traction and confirm its reproducibility and accuracy as a mechanical intervention. A total of 133 patients with non-specific chronic low back pain (CLBP) from 28 orthopedic clinics to assess and determine traction conditions while undergoing a biomechanical experiment. Two types of commercially available motorized traction devices (MINATO Medical Science, ST-2 L/2CL and OG Wellness Technologies, OL-6500/6000) were used and incorporated into other measuring tools including an infrared rangefinder and large extension strain gauge. The finite element method was used to analyze the real data of pelvic girdle movement at the lumbar spine level. Self-report assessments with representative two conditions were analyzed according to the qualitative coding method. Thirty-eight participants provided available biomechanical data. Distraction force lineally correlated with the movement of traction unit at the pelvic girdle. After applying vibration force to preloading, the strain gauge showed proportional vibration of the shifting distance without a phase lag qualitatively. Finite element model (FEM) simulation provided at least 3.0-mm shifting distance at the lumbar spine under 100 mm of body traction. Ninety-five participants provided a treatment diary and were classified as no pain, improved, unchanged, and worsened. Approximately 83.2% of participants reported a positive response. The authors concluded that the current study, which combined a biomechanical experiment with FEM simulation and analysis of patients' perspective, found that lumbar traction operates as an actual mechanical intervention therapy for patients with chronic LBP, and it provided the possibility of an immediate effect after traction. The identification of an appropriate loading mode, a limitation to this study, may still be an essential step for ascertaining the clinical utility of lumbar traction. In addition, only the distance on the lumbar skin was assessed rather than direct assessment of the shift of discs or vertebral bodies. The findings of this study need to be validated by well-designed studies. Further investigation is needed before clinical usefulness of this procedure is proven.

A randomized controlled trial (RCT) was performed by Lee et al. (2019) to compare the effects of the newly developed lumbar lordotic curve-controlled traction (L-LCCT) (Kinetrac-9900, Hanmed Co., Gimhae, Korea) and traditional traction (TT) on functional changes in patients and morphological changes in the vertebral disc. Participants were recruited between June 2016 and February 2017. The study included a total of 40 patients with lumbar intervertebral disc disease at the L4-5 or L5-S1 level, as confirmed by magnetic resonance imaging, who were recruited and divided into two groups (L-LCCT, n = 20; or TT, n = 20). Participants received a total of 15 traction treatment sessions over a five-week study period. The comprehensive health status changes of the patients were recorded using pain and functional scores (the visual analogue scale (VAS), the Oswestry Disability Index (ODI), and the Roland–Morris Disability Questionnaire (RM) and morphological changes (in the lumbar central canal area) before and after traction treatment. The L-LCCT (Kinetrac-9900, Hanmed Co., Gimhae, Korea) was used to maintain the natural lordotic curve of the spine by supporting the lumbar curve at the L3–5 intervertebral disc space. After the patient assumed a supine position, the chest and pelvis were belted. Initially, a magnetic marker was attached to the skin at the L4 intervertebral disc space by physical palpation and an automated tracking system (Figure 1). The automated tracking system ensured a lumbar lordotic curve during L-LCCT by elevating L3–5. A magnetic surface marker was attached to the patient's L4 area, where the lordotic curve is in maximum. As the highest lordotic point moved during traction, the auto-tracking system followed the magnetic surface marker, and thus constantly maintained the lordotic curve. The TT method was applied to patients without supporting the lumbar lordotic curve. The authors followed the same protocol as for L-LCCT, except without the lordotic curve modification, and with the patient lying in a supine position. Results revealed pain scores were decreased after traction in both groups ($p < 0.05$). However, functional scores and morphological changes improved after treatment in the L-LCCT group only ($p < 0.05$). The authors concluded that L-LCCT is a viable option for resolving the technical limitations of TT by maintaining the lumbar lordotic curve in patients with lumbar intervertebral disc disease. A small sample size makes it difficult to decide whether these conclusions can be generalized to a larger population. Further investigation is needed before clinical usefulness of this procedure is proven.

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) follow-up. 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.

Wegner et al. (2013) conducted a systematic review to determine if traction was more effective than reference treatments, placebo, sham traction or no treatment for low back pain (LBP) with or without sciatica, with a focus on pain intensity, functional status, global improvement and return to work. The authors included randomized controlled trials (RCTs) using traction, including mechanical traction, manual traction (unspecific or segmental traction), computerized traction, auto-traction, underwater traction, bed rest traction, inverted traction, continuous traction and intermittent traction. This is an update of a Cochrane review first published in 1995, and previously updated in 2006. This systematic review included a total of 32 RCTs involving 2,762 participants. For people with mixed symptom patterns (acute, subacute and chronic LBP with and without sciatica), there was low- to moderate-quality evidence that traction may make little or no difference in pain intensity, functional status, global improvement or return to work when compared to placebo, sham traction or no treatment. When comparing the combination of physiotherapy plus traction with physiotherapy alone, or when comparing traction with other treatments, there was very-low- to moderate-quality evidence that traction may make little or no difference in pain intensity, functional status or global improvement. For people with LBP with sciatica and acute, subacute or chronic pain, there was low- to moderate-quality evidence that traction probably has no impact on pain intensity, functional status or global improvement. No studies reported the effect of traction on return to work. For chronic LBP without sciatica, there was moderate-quality evidence that traction makes any difference in pain intensity when compared with sham treatment. No studies reported on the effect of traction on functional status, global improvement or return to work. Adverse effects were reported in seven of the 32 studies which included increased pain, aggravation of neurological signs and subsequent surgery. Four studies reported that there were no adverse effects. The remaining studies did not mention adverse effects. The authors concluded 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. The authors state that the use of traction as treatment for non-specific LBP is not supported by the best available evidence. Traction is no better than standard interventions for (acute, subacute and chronic) LBP. They also noted that few participants were identified for any of the principal outcome measurements and, as a result, none of the findings should be considered robust. These conclusions are applicable to both manual and mechanical traction. Further research with randomized controlled trials is needed to validate these findings.

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 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.

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 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.

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.

### Clinical Practice Guidelines

#### *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 evidenced based guideline (Kriener et al., 2020) on the diagnosis and treatment for low back pain considers the evidence to be insufficient to recommend the use of traction for patients with subacute or chronic low back pain.

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.

## 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. Refer to the following website for more information (product code ITH). Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed December 15, 2022)

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# Guideline History/Revision Information

| Date | Summary of Changes |
|---|---|
| 09/01/2023 | • Updated reference link to reflect current policy title for *Electromagnetic Therapy for Wounds* |
| 06/01/2023 | **Supporting Information**<br>• Updated *Clinical Evidence* and *References* sections to reflect the most current information<br>• Archived previous policy version MMG085.M |

# Instructions for Use

This Medical Management Guideline 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 guideline, 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 Management Guideline is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare West Medical Management 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.

Member benefit coverage and limitations may vary based on the member's benefit plan Health Plan coverage provided by or through UnitedHealthcare of California, UnitedHealthcare Benefits Plan of California, UnitedHealthcare of Oklahoma, Inc., UnitedHealthcare of Oregon, Inc., UnitedHealthcare Benefits of Texas, Inc., or UnitedHealthcare of Washington, Inc.