Policy Number	**DME101.046**
Policy Effective Date	**02/15/2025**
Policy End Date	**12/31/2025**

Traction Devices for Use in the Home

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For Illinois only: Illinois Public Act 103-0458 [Insurance Code 215 ILCS 5/356z.61] (HB3809 Impaired Children) states all group or individual fully insured PPO, HMO, POS plans amended, delivered, issued, or renewed on or after January 1, 2025 shall provide coverage for therapy, diagnostic testing, and equipment necessary to increase quality of life for children who have been clinically or genetically diagnosed with any disease, syndrome, or disorder that includes low tone neuromuscular impairment, neurological impairment, or cognitive impairment.

Coverage

This medical policy has become inactive as of the end date above. There is no current active version and this policy is not to be used for current claims adjudication or business purposes.

Traction devices for use in the home **are considered experimental, investigational, and/or unproven** for the treatment of cervical neck pain and/or lumbar back pain.

Policy Guidelines

None.

Description

Traction is the application of a mild stretch to muscles, ligaments, and tissue to provide relief of pain resulting from a variety of conditions, such as muscle spasm, nerve root compression, osteoarthritis, degenerative joint disease, and others. Traction is frequently used to treat the spine, most often either the cervical or the lumbar spine. When used on the spine, traction promotes separation of the intervertebral joint spaces to reduce impingement of structures in the area. The goal of traction is usually short-term pain relief, returning the patient to normal range of motion, and return to work.

Although traction can be accomplished in a variety of ways, home traction is commonly achieved using a system of pulleys, weights, and counterweights connected to a stand (either freestanding or attached to the bed) or "over-the-door" equipment and connected to a harness or belt worn by the patient.

Regulatory Status
Home traction devices are classified as Class I devices by the U.S. Food and Drug Administration (FDA). This classification only requires registration with the FDA prior to marketing and does not require either a 510(k) clearance nor submission of clinical data regarding efficacy. There are numerous FDA registered traction devices including foam or rigid collars, and over-the-door pulley, pneumatic, or mechanical systems. The FDA has described these devices as "A non-powered orthopedic traction apparatus is a device that consists of a rigid frame with nonpowered traction accessories, such as cords, pulleys, or weights, and that is intended to apply a therapeutic pulling force to the skeletal system." Refer to the FDA website at <https://www.fda.gov> for the most current listing of devices. (1)

Rationale

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function--including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the

intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice. The following is a summary of the key literature to date.

Although traction has been a commonly used treatment modality and numerous studies have been conducted, there has been little scientific evidence of the effectiveness of traction for cervical neck and/or lumbar back pain. In 2003, Harte et al. conducted a computer-aided search for RCTs from 1966 through 2001 to assess the efficacy of traction for treatment of low back pain (LBP) with or without radiating pain, taking into account the clinical technique or parameters used. (2) RCTs were included if: participants were over the age of 18 years, with LBP with or without radiating pain. The intervention group received traction as the main or sole treatment, while the comparison group received sham traction or another conservative treatment. The study was conducted in 2 strands. Strand 1 assessed methodologic quality using a specific criteria list recommended by the Cochrane Back Review Group. The strength of the evidence was then rated using the Agency for Health Care Policy and Research system. Strand 2 applied further inclusion criteria based on recommended clinical parameters. For Strand 1: 1 study scored 9 points (maximum score, 10 points); the other 12 scored between 0 and 3 points, indicating that most were of poor quality. Nine studies reported negative findings, but only 1 study was of a high quality. Three studies reported positive findings and 1 study was inconclusive. For Strand 2: only 4 trials having low methodologic quality were included, 2 of which reported negative findings, and 2 positive findings. Authors concluded that the evidence for use of traction in LBP was inconclusive, and that further trials are needed before firm conclusions and recommendations can be made.

Smith et al. performed a review and critical analysis of literature related to the treatment of LBP. (3) No evidence was found for use of traction. Authors concluded that additional RCTs are needed.

Beursken et al. conducted an RCT of 151 patients in which high-dose traction was compared to sham traction. (4) The sham traction was given with a specially developed brace that tightens in the back during traction. To the patient, the experience is that of traction. The patients and outcome assessor were blinded for the assigned treatment. One hundred fifty-one patients with at least six weeks of non-specific LBP were included. Intention to treat analysis showed no differences between the groups on all outcome measures (patients' global perceived effect, severity of main complaints, functional status and pain); all 95% confidence intervals included the value zero. The number of withdrawals from treatment, loss to follow-up, and protocol deviations was low. Consequently, the per-protocol analysis showed results similar to the intention to treat analysis. Subgroup analyses did not show any group for which traction might

seem promising. Overall, data did not support the claim that traction is effective for patients with LBP.

Reust et al. performed a double-blind RTC evaluating traction therapy for LBP with sciatica. (5) The study included 60 patients hospitalized for sciatica with or without signs of sensory or motor deficiency. Patients were randomized to 3 treatment groups: “placebo traction” (5kg), “light traction” (15kg) and ‘normal traction” (50kg). Clinical evaluation after 4, 8, and 12 traction sessions showed no difference between the three groups.

In a criteria-based appraisal of review articles on conservative treatment of neck pain/disorders, Hoving et al. selected 25 review articles, 12 of which were systematic reviews. (6) Reviewers found the evidence inconclusive for traction for neck pain and also stated more research is necessary to formulate stronger conclusions.

Van der Heijden et al. conducted a systematic analysis of the literature to assess the efficacy of traction for patients with neck or back pain, that included RCTs comparing traction with other treatments. (7) A computer-aided search of the literature was conducted for relevant articles, followed by blinded assessment of the methods of the studies. The main outcome measures were 1) scoring for quality of the designated conduct of studies (based on a methodological checklist with four main categories: study population, interventions, measurement of effect, and data presentation) and the main conclusions of author(s) with regard to traction; and 2) calculation of confidence intervals and power of the studies. Only three studies scored more than 50 points (maximum score = 100 points), suggesting that most of the selected studies were of poor quality. None of these three studies showed favorable results for traction. Only four studies, of which one scored more than 50 points, had an acceptable power (1- beta > 80%). Authors concluded that the available reports of studies on the efficacy of traction for back and neck pain do not allow clear conclusions due to the methodological flaws in their design and conduct. Most studies lacked power (1-beta) due to small sample sizes. To date, no conclusions can be drawn about whether a specific traction modality for back or neck pain is effective, or more efficacious than other treatments. There are no clear indications, however, that traction is an ineffective therapy for back and neck pain. Further trials are needed in which much more attention should be paid to proper design and conduct, as well as to clear descriptions of crucial methodological features and results.

In a 2008 Cochrane Review to assess the effects of mechanical traction for neck disorders, Graham et al. selected RCTs that examined adults with neck disorders who received mechanical traction alone or in combination with other treatments compared to a placebo or another treatment. (8) The outcomes of interest were pain, function, disability, global perceived effect, patient satisfaction, and quality of life measures. Of the seven selected RCTs (total participants = 958), only one (N = 100) had a low risk of bias. It found no statistically significant difference (SMD -0.16: 95%CI: -0.59 to 0.27) between continuous traction and placebo traction in reducing pain or improving function for chronic neck disorders with radicular symptoms. Reviewers concluded that the current literature does not support or refute the efficacy or effectiveness of continuous or intermittent traction for pain reduction, improved function or global perceived

effect when compared to placebo traction, tablet or heat or other conservative treatments in patients with chronic neck disorders. Large, well conducted RCTs are needed to first determine the efficacy of traction, then the effectiveness, for individuals with neck disorders with radicular symptoms.

In a 2007 Cochrane Review to determine traction's effectiveness, compared to reference treatments, placebo, sham traction or no treatment for LBP, Clarke et al. included 25 RCTs. (9) Five trials were considered high quality. For patients with mixed symptom patterns (acute, sub-acute and chronic LBP with and without sciatica) there was: strong evidence of no statistically significant difference in outcomes between traction as a single treatment and placebo, sham or no treatment; moderate evidence that traction as a single treatment is no more effective than other treatments; limited evidence of no significant difference in outcomes between a standard physical therapy program with or without continuous traction. For LBP patients with sciatica (with acute, sub-acute or chronic pain), there was conflicting evidence in several comparisons: autotraction compared to placebo, sham or no treatment; other forms of traction compared to other treatments; different forms of traction. In other comparisons, there were no statistically significant differences; the evidence was moderate for continuous or intermittent traction compared to placebo, sham or no treatment, and limited for light versus normal force traction. Reviewers concluded that continuous or intermittent traction as a single treatment for LBP is not likely effective, and that traction for patients with sciatica cannot be judged effective at present either, due to inconsistent results or methodological problems in most studies.

In 2011, Chiu et al. conducted an RCT investigating the efficacy of intermittent cervical traction in the treatment of chronic neck pain over a 12-week period. (10) Seventy-nine patients with chronic neck pain were included. Subjects were randomly assigned to either experimental group (n = 39, mean age = 50.5 ± 9.8) or control group (n = 40, mean age = 48.8 ± 9.1). Experimental group received intermittent cervical traction and control group received infrared irradiation alone; twice a week over a period of six weeks. No significant differences were found between the two groups.

Graham et al. (2013) performed a systematic review of existing literature to establish the evidence-base for recommendations on physical modalities for acute to chronic neck pain. One of the modalities was intermittent traction. Their process included a comprehensive computerized search of several databases from January 2000 to August 2010. Of 103 reviews that were screened for eligibility, 20 reviews were included and 83 were excluded. They found moderate evidence of benefit for intermittent traction; when compared to no treatment or placebo treatment for chronic mechanical neck disorder, neck disorder with radiculopathy or degenerative changes intermittent traction showed reduced pain in the short term. Continuous traction showed no difference compared to placebo for improving pain or function in patients with acute to chronic neck pain in the short term. (11)

Fritz et al. conducted an RCT examining the effectiveness of cervical traction in addition to exercise for specific subgroups of patients with neck pain. (12) 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. Baseline assessment included subgrouping-rule status. The primary outcome measure (Neck Disability Index, scored 0-100) and secondary outcome measure (neck and arm pain intensity) were assessed at 4 weeks, 6 months, and 12 months after enrollment. The primary analyses examined 2-way treatment-by-time interactions. Secondary analyses examined validity of the subgrouping rule by adding 3-way interactions. Eighty-six patients (53.5% female; mean age, 46.9 years) were enrolled in the study. Intention-to-treat analysis found lower Neck Disability Index scores at 6 months in the mechanical traction group compared to the exercise group (mean difference between groups, 13.3; 95% confidence interval: 5.6, 21.0) and over-door traction group (mean difference between groups, 8.1; 95% confidence interval: 0.8, 15.3), and at 12 months in the mechanical traction group compared to the exercise group (mean difference between groups, 9.8; 95% confidence interval: 0.2, 19.4). 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. In their conclusion, the authors stated that adding mechanical traction to a standard exercise program, particularly with an in-clinic, motorized device, for patients with cervical radiculopathy led to greater improvements in disability and neck and arm pain. They stated that further research is needed to identify the most effective nonsurgical treatments for patients with cervical radiculopathy, and whether clinical decision-making can be enhanced by consideration of more narrow subgrouping strategies. They further noted that the study had a higher-than-anticipated loss to follow-up and was likely underpowered for examining the validity of the subgrouping rule.

Wegner et al. (2013) updated a Cochrane review that was first published in 1995, and then updated in 2006. (13) The objective was to assess the effects of traction compared to placebo, sham traction, reference treatments, and no treatment in people with lower back pain. Investigators reviewed the evidence on the effect of traction on pain intensity, ability to perform normal daily activities, overall improvement and return to work among people with LBP in the acute (less than four weeks' duration), subacute (from four to 12 weeks' duration) or chronic (more than 12 weeks' duration) phase. Some patients also had sciatica. They examined the effects of traction immediately after the traction session, in the short-term (up to three months after traction) and in the long-term (around one year after traction). The review included 32 studies and 2762 people with LBP. Most studies included a similar population of people with LBP with and without sciatica. The majority of studies included people with acute, subacute and chronic LBP. Most studies reported follow-up of one to 16 weeks, and a limited number of studies reported long-term follow-up of six months to one year. The included studies show that traction as a single treatment or in combination with physiotherapy is no more effective in treating LBP than sham treatment, physiotherapy without traction or other treatment methods including exercise, laser, ultrasound and corsets. These conclusions are valid for people with and without sciatica. There was no difference regarding the type of traction (manual or mechanical). Side effects were reported in seven of the 32 studies and included increased pain, aggravation of neurological signs and subsequent surgery. Four studies reported that there were no side effects. The remaining studies did not mention side effects. The quality of the evidence ranged from very low to moderate. There was a scarcity of high-

quality studies, especially those that distinguished between people with different symptom patterns (with and without sciatica, with pain of different duration).

In 2015, Bagheripour et al. conducted a double-blind pilot study of 20 women with mild to moderate osteoarthrosis evaluating over-the-door home cervical traction unit in combination with routine physical therapy compared to physical therapy alone. (14) Pain, level of disability, and drug consumption were evaluated before and after 10 sessions of intervention. Patients in both groups showed a significant decrease in pain intensity and disability level ($p<0.05$). Despite the greater improvement in pain levels and disability in the experimental group compared to the controls, the differences were not significant ($p>0.05$). No significant differences were found in terms of drugs consumption within and between the groups at the end of the treatment ($p>0.05$). The results revealed that applying sustained traction using an over-the-door home cervical traction unit was not significantly superior to the routine physical therapy and ergonomic training to manage symptoms including neck pain and disability in a small group of mild to moderate cervical osteoarthrosis patients.

Colombo et al. (2020) conducted a systematic literature review with meta-analysis of randomized controlled trials (RCTs) that compared the effectiveness of cervical traction therapy in reducing pain to other treatment modalities for cervical radicular syndrome (CRS). 81 studies were assessed and seven RCTs (589 participants) were included in the systematic review, of which, six were used for meta-analysis. The authors concluded that cervical traction appears to be superior to other conservative treatments when combined with these other treatments, with mechanical traction and continuous delivery providing better pain relief than manual traction and intermittent delivery. The meta-analysis demonstrated a low quality of evidence. Many of the studies had a high risk of bias because of a lack of blinding, inconsistent outcome reporting, inappropriate methods for randomization, and unacceptable drop-out rates. Other limitations included the lack of investigation of other functional outcomes (such as activities of daily living or adverse events), only including publications in English and including a wide variety of control groups. Future studies are needed to evaluate head-to-head comparisons of active versus passive interventions, other therapeutic interventions for CRS and study designs to minimize for biases. (15)

In 2021, Xiao et al. conducted a single center randomized controlled trial evaluating the efficacy of a traction exercise neck brace (TENB) for the treatment of cervical spondylotic radiculopathy. (16) The study included 40 adults aged 21–51 years with CSR who were randomly assigned to either the treatment group (N = 20) that received cervical traction with TENB for 30 minutes at home twice a day for 4 weeks or to the control group (N = 20) who received jaw-occipital belt traction (JOBT) for vertical traction while sitting in a chair in the hospital. The authors reported that, after treatment, visual analogue scale (VAS) scores in the TENB group decreased from 6.10 to 2.45 and neck disability index (NDI) scores decreased from 22.05 to 9.60 which were lower scores than those in the control group that only received JOBT. The study also reported that the curvature of the cervical vertebra, which were evaluated using the method of Borden and cervical curvature index (CCI), improved significantly more in the TENB group than in the JOBT group. The study concluded that TENB treatment significantly improved the curvature of the

cervical spine and increased the size of the intervertebral foramen which reduced the symptoms of CSR. Results were promising but further studies are needed. Limitations of the study include the small sample size, the narrow age range of the participants and the single center design.

UpToDate

A review from December 2023 stated that, "There is no evidence that traction is beneficial for acute low back pain. A 2013 systematic review including 32 randomized trials of traction for low back pain (with or without sciatica) concluded that traction provides no benefits." (17)

Summary of Evidence

For individuals who have cervical neck pain or lumbar back pain who receive home traction treatment(s), the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant outcomes are symptoms, function, disability, patient satisfaction, and quality of life. In general, studies have not demonstrated that home traction is an effective treatment, and have been of poor methodological quality, with small sample sizes and a lack of randomization. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

North American Spine Society (NASS)

The NASS evidence-based clinical guideline (Kreiner et al., 2020) for diagnosis and treatment of low back pain indicated that traction is not recommended as it provides no clinically significant improvement in pain or function in patients with subacute or chronic low back pain. (18)

The NASS evidence-based clinical guideline for the diagnosis and treatment of cervical radiculopathy from degenerative disorders (Bono et al., 2010) notes that regarding the role of traction in the treatment of cervical radiculopathy from degenerative disorders, that cervical halter traction and combinations of medications, physical therapy, injections, and traction have been associated with improvements in patient reported pain in uncontrolled case series. (19) They note that such modalities may be considered, recognizing that no improvement relative to the natural history of cervical radiculopathy has been demonstrated.

The NASS evidence-based clinical guideline for diagnosis and treatment of lumbar disc herniation with radiculopathy (Kreiner et al., 2013) notes that there is insufficient evidence to make a recommendation for or against the use of traction in the treatment of lumbar disc herniation with radiculopathy. (20)

American College of Physicians

The American College of Physicians (ACP) Clinical Practice Guideline on Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain (Qaseem et al., 2017) provides treatment guidance based on the efficacy, comparative effectiveness, and safety of noninvasive pharmacologic and non-pharmacologic treatments for acute (<4 weeks), subacute (4 to 12 weeks) and chronic (>12 weeks) low back pain. (21) Nonpharmacologic interventions evaluated

were numerous. For acute or subacute low back pain, the evidence was deemed insufficient to determine the effectiveness of traction. For chronic low back pain, low quality evidence showed no clear differences between types of active treatments (e.g., traction, spinal manipulation, etc…) for pain or function.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov did not identify any ongoing or unpublished trials that would likely influence this policy.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	None
HCPCS Codes	E0840, E0849, E0850, E0855, E0856, E0860, E0890, E0900, E0920, E0930, E0941, E0942, E0944, E0946, E0947, E0948

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/31/2025	Document became inactive.
02/15/2025	Reviewed. No changes.
03/15/2024	Document updated with literature review. Coverage unchanged. References 1, 15 and 16 added; others updated.
04/01/2023	Reviewed. No changes.
10/15/2022	Document updated with literature review. Coverage unchanged. References 13 and 14 added.
09/01/2021	Reviewed. No changes.
11/15/2020	Document updated with literature review. Coverage unchanged. Reference 16 added.
10/15/2019	Reviewed. No changes.
12/15/2018	Document updated with literature review. Coverage unchanged. References 13-15 were added; some references removed.
02/15/2016	Reviewed. No changes.
06/01/2015	Document updated with literature review. Coverage unchanged.
07/01/2014	Reviewed. No changes.
10/15/2013	Literature reviewed. Coverage unchanged.
05/15/2007	Document updated with literature review. Coverage unchanged.
11/01/2005	New medical document. Traction devices for use in the home are considered experimental, investigational and unproven.