HOME TRACTION THERAPY

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INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced. The terms of the federal, state or contractual requirements for benefit plan coverage may differ greatly from the standard benefit plan upon which this Medical Policy is based. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage supersedes this Medical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the contractual requirements for 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 federal, state or contractual requirements for benefit coverage.

COVERAGE RATIONALE

Home traction therapy is unproven and not medically necessary for treating low back and neck disorders with or without radiculopathy.

The majority of studies are office based with mixed results. The quality of peer reviewed studies for home traction are limited as well to conclude that it is effective in the management of neck or low back pain or that it improves health outcomes. The indications for clinical application, patient selection criteria, risks, and comparison to alternative technologies have not been established for home traction therapy.

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 federal, state or contractual requirements 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.
**DESCRIPTION OF SERVICES**

Traction is the act of drawing or pulling and relates to forces applied to the body to stretch a given part or to separate 2 or more parts. Traction is intended for patients with musculoskeletal or neurological impairments of the spine; the objective is to relieve pain, relax muscle spasms, and decompress spinal structures. The type of traction used depends on the patient’s age, weight and medical condition. Treatment plans are usually short-term (less than eight weeks in duration) with treatments 2-3 times per week.

Cervical and lumbar traction have been utilized to treat many causes of spine-related pain including radiculopathy secondary to herniated disc, narrowing of the intervertebral foramen, degenerative changes resulting in nerve root encroachment, and spondylolisthesis. Beyond these broad clinical indications, the particular characteristics of patient subgroups that are likely to benefit from home traction do not appear to have been identified in clinical studies.

Patient-operated spinal unloading devices for the lower back are intended as conservative treatment of subacute and chronic low back pain for patients who have not improved with standard medical therapy or who have failed surgical therapy. These devices provide a traction-like effect by shifting weightbearing off the lower back and onto the hips. Spinal unloading devices for the cervical (neck) region may be administered by various techniques ranging from pneumatic traction utilizing supine mechanical motorized cervical traction to seated cervical traction using an over-the-door pulley support with attached weights to relieve pain in the neck region due to neck muscle spasm or nerve root compression.

Home traction units generally provide sustained (static) or intermittent distractive forces. Various cervical traction devices are available for use in a home setting including over-the-door pulley systems, pneumatic (inflatable) neck traction devices, rigid or foam collars, and mechanical traction systems. Some devices intended primarily for home use are limited in comparison to those usually available in supervised outpatient settings. Traction forces used in the clinic setting commonly reach between 20 and 50 pounds. The traditional over-the-door traction units (applied in a supine position) are generally limited to providing less than 20 pounds of traction. More recently developed technologies devices that are used in the supine position, do not cause pressure to the temporomandibular joint, and reportedly provide cervical traction in the home using forces comparable to those in the outpatient setting.

Some of the most commonly used lumbar traction techniques are not suited for home use. Manual traction (distractive force is exerted by and under the control of the clinician) and motorized traction (distractive force is exerted by a motorized pulley) are not practical for home application. There are also questions about the ability of lumbar traction some devices designed for home use to achieve the magnitude of distractive force (80-120 lbs or ≥50% of body weight) necessary to increase intervertebral joint space. (Saunders, 1995)

Devices may include the use of a table, vest, weights, gravity or pneumatic devices.

**CLINICAL EVIDENCE**

“Parameters that must be considered when traction is chosen as a treatment intervention include the magnitude and direction of the applied force, the duration of force application, and the frequency of traction treatments” (Michlovitz and Nolan, 2005). There are good data on the forces necessary to produce distraction sufficient to increase intervertebral disc spacing. However, the recommended duration of traction force varies widely in literature (Pellechcia, 1994). The frequency of traction ranges from several times per day for up to 2 weeks for acute disorders to 2-3 times a week for ≥3 weeks for chronic conditions. These parameters have largely been scripted from anecdotal judgments. The absence of formal clinical evidence on traction treatment parameters suggests, “A careful reassessment of the effectiveness of the traction intervention should occur after every treatment session” (Michlovitz and Nolan, 2005).
Traction, when applied at home, presents with additional factors that may influence clinical effectiveness and the risk of adverse events. The absence of professional supervision decreases confidence that the appropriate amount of force will be consistently applied and the desired angle of pull will be maintained. It is suggested that certain devices manufactured for home use are sufficiently sophisticated that outpatient treatment protocols can confidently be translated to the home setting. Certain devices have a patient-controlled pressure valve that limits the amount of force transmitted to the user and a hand-held pump for immediate release of pressure. They also allow the patient to be positioned in any degree of flexion, neutral or in extension. Another consideration that has the potential to affect treatment response is patient compliance with home-based traction. While there is emerging evidence about the factors associated with poor compliance with home-based care, there has been little study on effective remediation strategies (Jack, 2010).

**Lumbar Traction**

A Cochrane systematic review was conducted for the purpose of determining the effectiveness of traction in the management of low back pain with or without sciatica (Clarke, et al., 2007). The study included randomized controlled trials involving traction to treat acute, subacute or chronic nonspecific low-back pain with or without sciatica. The review included 25 studies. The studies included 2206 patients with 1045 receiving traction. Five of these trials were considered high quality. The authors concluded that traction is probably not effective, and traction as single treatment for low back pain is not supported by the studies. In addition, the authors note that future research on traction for patients with low back pain should distinguish between symptom pattern and duration and should be carried out according to the highest methodological standards.

Wegner et al (2013) published an update to a 2007 Cochrane review (Clarke, et al., 2007) that assessed the effects of traction compared to placebo, sham traction, reference treatments and no treatment in people with low back pain (LBP). The review included 32 randomized controlled trials with 2,762 participants involving traction to treat acute (less than four weeks' duration), subacute (four to 12 weeks' duration) or chronic (more than 12 weeks' duration) non-specific LBP with or without sciatica. The review found for individuals 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. The review noted that 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. Regarding chronic LBP without sciatica, the review found that there was moderate-quality evidence that traction probably makes little or no difference in pain intensity when compared with sham treatment. The authors concluded that the findings indicate 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 review found that there is only limited-quality evidence from studies with small sample sizes and moderate to high risk of bias and that the effects shown by these studies are small and not clinically relevant.

A study by Janke et al. (1997) suggests that the LTX 3000T device is effective in producing distraction of the lumbar vertebrae, and increasing the lumbar intervertebral disc spaces. However, the duration of the effect has not been determined and there is controversy as to whether this biomechanical effect translates into long-term relief of symptoms or improvement in function. While data provided by the device manufacturers suggest that both the LTX 3000 and the Orthotrac vest may have some beneficial effect, none of the studies were controlled, blinded, or had undergone peer review, so the outcomes may have been subject to substantial bias. In addition, the LTX 3000T was used in conjunction with a comprehensive back rehabilitation program; the possible benefit of the traction device cannot be separated from the effects of exercise, education, and participation in a program that provided support and supervision by healthcare professionals. Other studies have demonstrated the value of education and exercise programs in reducing the occurrence of low back pain, and it may be these components, rather than the LTX 3000T traction-inducing device, that are responsible for the reported beneficial effects.

Dallolio (2005) completed a preliminary study using the Orthotrac vest on 41 patients with radicular pain due to degenerative discopathy and stenosis. The results indicate that 78% of the patients showed significant subjective and clinical improvement with subsequent better quality of life. This was not a randomized controlled trial and the measurement system use to report improvement was not documented. The author concludes that the system gives effective spinal decompression but further studies are needed to confirm the preliminary results.

**Cervical Traction**

Fritz et al. (2014) reported on a randomized controlled trial of 86 patients that compared exercise with mechanical traction during treatment sessions or exercise with over-door traction provided during treatment session and at home. 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. All patients were scheduled to receive 10 individual physical therapy sessions over a 4-week treatment. The primary outcome measure was Neck Disability Index and secondary outcome measure was neck and arm pain intensity-assessment was performed at four weeks, six months,
There is conflicting evidence for the efficacy of intermittent lumbar tractions for patients with low back pain. The APTA has published a clinical practice guideline regarding low back pain (Delitto, et al., 2013). The guideline reported, “There is conflicting evidence for the efficacy of intermittent lumbar tractions for patients with low back pain. There is unproven conclusion.”

Ongoing Studies

No registered ongoing studies using home cervical or lumbar traction for treatment of neck and/or back pain were identified on the ClinicalTrials.gov online database, which is sponsored by the National Institutes of Health.

The clinical evidence was reviewed on April 20, 2017 with no additional information identified that would change the unproven conclusion.

Professionals Societies

American Physical Therapy Association (APTA)

The APTA published a clinical practice guideline regarding low back pain (Delitto, et al., 2013). The guideline reported, “There is conflicting evidence for the efficacy of intermittent lumbar tractions for patients with low back pain. There is unproven conclusion.”

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moderate evidence that clinicians should not utilize intermittent or static lumbar traction for reducing symptoms in patients with chronic low back pain.”

**North American Spine Society (NASS)**

The NASS evidence-based clinical guideline for the diagnosis and treatment of cervical radiculopathy from degenerative disorders 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. They note that such modalities may be considered recognizing that no improvement relative to the natural history of cervical radiculopathy has been demonstrated (Bono et al., 2010).

The NASS evidence-based clinical guideline (Kriener et al., 2011) for diagnosis and treatment of lumbar disc herniation with radiculopathy 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.

**Washington State Department of Labor and Industries**

The Washington State Department of Labor and Industries conducted a technology assessment in 2002 and concluded that there is insufficient scientific evidence to indicate whether Pronex and HomeTrac cervical traction devices result in better or worse outcomes than over-the-door traction units.

**American College of Physicians and American Pain Society**

A joint clinical practice guideline from the American College of Physicians and the American Pain Society for the diagnosis and treatment of low back pain notes that intermittent or continuous traction in patients with or without sciatica have not been proven effective for chronic low back pain (Chou, et al., 2007b).

The literature regarding home traction is inconclusive. There is insufficient evidence in the published, peer-reviewed scientific literature to demonstrate that home traction is effective treatment. In general, studies have been of poor methodological quality, with small sample sizes and lack of randomization. Further randomized controlled clinical trials are needed.

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

Home traction devices, or non-powered orthopedic traction, are classified as Class I devices. There are numerous FDA-registered traction devices including foam or rigid collars, and over-the-door pulley, pneumatic, or mechanical systems. The devices are exempt from the premarket notification procedures. Additional information is available at: [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=888.5850](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=888.5850). (Accessed April 20, 2017)

**Note:** Orthotrac Pneumatic Vest is no longer available for sale as of January 1, 2009.

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

Medicare covers traction equipment under the Durable Medical Equipment benefit, when criteria are met. See the National Coverage Determination (NCD) for [Durable Medical Equipment Reference List (280.1)](http://www.cms.gov/Medicare/DurableMedicalEquipment/Downloads/2801.pdf).

Local Coverage Determinations (LCDs) specifically for home traction therapy do not exist at this time. However, Medicare does have LCDs that address cervical traction; see the LCDs for [Cervical Traction Devices](http://www.cms.gov/medicare-coverage-database/details/nca-coverage-detail.aspx?N = 72957). (Accessed March 10, 2017)

**REFERENCES**


Cai C, Ming G, Ng LY. Development of a clinical prediction rule to identify patients with neck pain who are likely to benefit from home-based mechanical cervical traction. Eur Spine J. 2011;20(6):912-922


POLICY HISTORY/REVISION INFORMATION

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<td>• Updated supporting information to reflect the most current clinical evidence and references; no change to coverage rationale or list of applicable codes</td>
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