Clinical Practice Guideline: **Home Traction Therapy**

Date of Implementation: **December 18, 2015**

Product: **Specialty**

GUIDELINES

American Specialty Health – Specialty (ASH) considers home cervical and lumbar traction devices unproven because they have not been demonstrated to be an effective treatment for cervical or lumbar/pelvic back pain (LBP) or other indications. The literature regarding home traction is inconclusive. There is insufficient evidence in the published, peer-reviewed scientific literature to demonstrate that home traction is an effective treatment. Overall, studies are of low quality with poor methodological quality, small sample sizes, and lack of randomization. Further randomized controlled clinical trials are needed.

ICD-10 Codes and Descriptions That Support Medical Necessity: None

HCPCS Codes and Descriptions Related to This Policy:

HCPCS Code	HCPCS Code Description
E0830	Ambulatory traction device, all types, each
E0840	Traction frame, attached to headboard, cervical traction
E0849	Traction equipment, cervical, free-standing stand/frame, pneumatic, applying traction force to other than mandible
E0850	Traction stand, freestanding, cervical traction
E0855	Cervical traction equipment not requiring additional stand or frame
E0856	Cervical traction device, with inflatable air bladder(s)
E0860	Traction equipment, overdoor, cervical
E0890	Traction frame, attached to footboard, pelvic traction
E0900	Traction stand, freestanding, pelvic traction (e.g., Buck's)
E0941	Gravity assisted traction device, any type
E0942	Cervical head harness/halter
E0944	Pelvic belt/harness/boots

For related information see the *Mechanical Traction (Provided in a Clinic Setting) (CPG 275 – S)* clinical practice guidelines.

DESCRIPTION

For the purpose of this policy, traction is the use of a pulling force to treat muscle and or skeletal disorders of the spine. 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. Traction is a widely used treatment for neck and low back pain and it is typically provided in combination with other treatment modalities and an exercise program. 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 impingement, 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. Treatment plans are usually short-term (less than eight weeks in duration) with treatments 2–3 times per week. The type of traction used depends on the patient's age, weight, and medical condition. It can be provided manually by a therapist or by mechanical means in a clinic setting, and also may be self-administered using portable devices. Types of traction include, but are not limited to mechanical traction, manual traction (performed by clinician), autotraction, gravity-dependent ("anti-gravity") traction, pneumatic traction, continuous traction, and intermittent traction. The suggested mechanisms through which traction might be effective include:

- Biomechanical effects, such as separation of the intervertebral motion segment which may increase intervertebral space, thus decreasing mechanical stress and/or spinal nerve root compression, altering intradiscal pressure, and perhaps reducing intervertebral disc protrusion.
- Neurophysiological effects, such as modulation of nociceptive input in either the ascending or descending pathways, thus silencing ectopic impulse generators.

These two mechanisms probably work in concert to produce clinical effects, including pain reduction, increased mobility, reduced muscle spasm, and nerve root irritation. Ideally, normalization of the neurologic deficit and relief of radicular pain occurs. However, the proposed mechanisms have not been supported by sufficient empirical information.

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. 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.

U.S. Food and Drug Administration (FDA)

Home traction devices are classified as Class I devices by the U.S. Food and Drug Administration (FDA). 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."

BACKGROUND

Home Cervical Traction

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 are generally limited to providing less than 20 pounds of traction. This is the most commonly used device employed in which an individual wears a chin strap harness attached to a counterweight that is suspended over a door using a pulley system. The counterweight pulls the chin harness upwards, extending the neck. Variations of this device using the counterweight and pulley system include frames which attach to a headboard or freestanding units. More recently developed technologies include devices that 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. These newer pneumatic devices are designed to be used in the supine position with the device beneath the head and shoulders and a strap or straps holding the head in place. Patient-controlled pressure valves/pumps or bellows allow the individual to increase the tension, pulling the head away from the body, but it also limits the amount of force transmitted to the user and allows for an immediate release of pressure. They also allow the patient to be positioned in any degree of flexion, neutral or in extension. This extends the neck, stretches the affected muscles, and increases the intervertebral spaces. Pneumatic devices typically can deliver up to 50 pounds of tension, which manufacturers' state more closely mimics traction given within an outpatient setting. It is suggested that these devices manufactured for home use are sufficiently sophisticated that outpatient treatment protocols can confidently be translated to the home setting.

Home traction devices include both traditional over-the-door devices (applied in a sitting position) and more advanced technologies (applied in a supine position), such as the HomeTrac® (Empi, Shoreview, MN) and Pronex® Pneumatic Traction Unit (Glacier Cross Inc., Kalispell, MT). Standard over-the-door traction devices are traditionally limited to delivering 20 pounds or less of traction.

Devices that are used in the home and allow greater traction force include the HomeTrac and Pronex cervical traction devices. The Pronex is a patient-controlled, pneumatic traction device that is used in a supine position. The device cradles a reclining patient's head and neck between two soft foam cushions. An air-inflated bellows between the cushions provides up to 20 pounds of continuously adjustable traction. The Pronex II is a newer device capable of delivering greater than 20 pounds of force. The HomeTrac may provide up to 50 pounds of traction force at a 15° angle. Traction forces are directed at the occiput, preventing undue pressure on the Temporomandibular joint (TMJ). The device has an adjustable extension foot that allows additional traction angles of 20° and 25°. The patient can immediately release the traction force by using a pressure release valve.

Both HomeTrac and Pronex are operated by a patient-controlled, hand-held pump. Manufacturers and therapists propose that these devices maintain the normal cervical lordosis, resulting in uniform traction posteriorly and anteriorly across the vertebral disc, in comparison to other devices, which occlude the anterior disc space for temporary relief posteriorly. The manufacturers suggest that the use of these devices in a home setting allows treatment comparable to that provided in an outpatient setting and may provide more continuous pain relief. These devices can be used to deliver a traction force that avoids TMJ force and allows patients control of their own comfort level.

There are cervical traction devices that may be used with ambulation. They may also be referred to as a cervical support brace. The device consists of an inflatable collar that is inflated with attached bulb pumps. Cervical traction equipment that does not prevent ambulation during use has not been shown to be effective and is considered not medically necessary as a treatment for musculoskeletal and/or neurological conditions. Scientific evidence supporting the efficacy of this device is lacking. Examples of these devices include but are not limited to:

- Pneu-trac® Traction Collar (Trulife, Poulsbo, WA)
- TracCollar® (BodySport®, Ft. Worth, Texas)

Home Lumbar Traction

Lumbar traction is used to treat low back pain, often in conjunction with other treatment modalities. The traction may be applied intermittently, using any of several methods to treat conditions of the spine, in either an outpatient setting or in a home setting. Typically, these modalities are used short term. The duration of the exerted force applied may be intermittent or continuous throughout a treatment session. Generally, during lumbar traction a harness is attached around the pelvis (to deliver a caudal pull), and the upper body is stabilized with a chest harness or voluntary arm force (for the cephalad pull) (Wieting et al., 2013). In some cases, 70–150 pounds of pull are required to distract lumbar vertebrae (Wieting et al., 2013).

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. Devices may include the use of a table, vest, weights, gravity, or pneumatic devices. Several available home lumbar traction devices that are not pulley and weight systems may apply increased traction forces (greater than 20 pounds). This type of device is designed to provide traction (stretching) to the lumbar region (low back). Examples include Saunders Lumbar Home Traction© (DJO Global Inc., Vista, CA) and Lo-Bak TRAX™ (Allstar Products Group, Hawthorne NY).

The Back Bubble® **(**Back Bubble, Solana Beach, CA) is an inflatable lumbar traction device that is suspended from a door and connects with a buoyancy spring to an inflatable body harness which encircles and suspends the patient in air-cushioned weightlessness. The manufacturer's website states that the patient's own body weight will provide a gentle stretch which relaxes the lower back. There is insufficient evidence in the medical literature regarding the efficacy of inflatable traction devices in the treatment of back pain.

EVIDENCE REVIEW

Cervical Traction

There is very little published evidence on home cervical traction for neck pain and the existing studies are uncontrolled and of poor quality. Overall, the quality of the body of evidence is very low, and is insufficient in the published, peer-reviewed scientific literature for drawing conclusions about the efficacy and safety of home cervical traction.

Cai et al. (2011) completed a study with the purpose of identifying neck pain patients who would demonstrate a short-term improvement from the home-based mechanical cervical traction (HMCT) approach. In order to separate the responders from the non-responders, three different outcome criteria were used which were considered clinically important: reduction of pain intensity, global rating of perceived improvement and improvement of Neck Disability Index (NDI). All patients were given HMCT treatment for 2 weeks. The traction method was standardized, with written instructions about the use of a simplified over-the-door traction suspension and a standard adjustable cervical halter. The traction force was determined by 10–15% of the subject's body weight. Patients were instructed to pull the pulley string to generate traction force, until the determined traction force was reached. The traction force generator is designed to generate 0.5 kg of traction force per pull from the patient, and to self-lock at the end of each pull. This design allowed the patient to generate traction force independently, and the force to be sustained by the device itself. Patients were also instructed to use a mirror to read the force meter in order to confirm that the determined traction force had been reached. In general, patients were instructed to

generate a traction force that should be "moderate to moderately strong" without increasing symptoms. The patients were told to use the traction device for 20 minutes a day for 2 weeks, reinforced by a treatment diary, in which they recorded both the compliant sessions and missed sessions. All 103 participants completed the treatment with overall high compliance to the treatment program. The mean compliance rate was 91.0% according to participant's response, which was considered a "courtesy" answer by the investigators and therefore was not entered into the statistical analysis. Several limitations were present for this study: no control group, heterogeneous sample given the wide range of episode duration (from acute to chronic), lack of diagnoses clarity (non-specific vs. cervical radiculopathy), lack of compliance rate formally monitored and analyzed, 60% unknown variance, short duration of study creating lack of generalizability, traction force of 10-15% may be considered too much or too little given there is a lack of agreement about the force that should be used in clinical practice, and lastly, the small sample size. Four predictors have been identified for predicting responders to short-term HMCT. The prediction model in this study suggested that having 3 of 4 predictors increased the probability of the treatment success. These predictors included Fear-Avoidance Beliefs Questionnaire- Work Subscale (FABQW) score < 13, pre-intervention Numerical Pain Scale (NPS) ≥ 7/10, pain below shoulder present, and positive cervical distraction test.

Fritz et al. (2014) completed an RCT that examined the effectiveness of cervical traction in addition to exercise for specific subgroups of patients with neck pain. Eighty-six patients with neck pain and signs of radiculopathy were randomized to one of three groups: exercise, exercise with mechanical traction, or exercise with over-the-door traction. All patients were scheduled to receive 10 individual physical therapy sessions over a 4-week treatment. The primary outcome measure was the Neck Disability Index (NDI) and secondary outcome measure was neck and arm pain intensity. Assessment periods were at 4 weeks, 6 months, and 12 months. Intention-to-treat analysis found lower NDI scores at six months in the mechanical traction group compared to the exercise group and over-the-door traction group, and at 12 months in the mechanical traction group compared to the exercise group. Secondary outcomes favored mechanical traction. Limitations of the study existed with several patients crossing over to a different treatment group during the first four weeks and differences in baseline characteristics at the outset of the study between groups (i.e., duration of symptoms).

The NASS clinical guideline for the diagnosis and treatment of cervical radiculopathy from degenerative disorders (Bono, et al., 2011) lists Question 10: What is the role of ancillary treatments such as bracing, traction, electrical stimulation, acupuncture, and transcutaneous electrical nerve stimulation in the treatment of cervical radiculopathy from degenerative disorders? Ozone injections, 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. Such modalities may

be considered recognizing that no improvement relative to the natural history of cervical radiculopathy has been demonstrated (Work Group Consensus Statement).

Lumbar Traction

There is a lack of/insufficient evidence in the published, peer-reviewed scientific literature to demonstrate that home traction is effective in the treatment of lumbar spine disorders including low back pain. In general, studies have been of poor methodological quality, with small sample sizes and lack of randomization and only include mechanical traction devices used in the clinical setting. Further randomized controlled clinical trials are needed assessing effectiveness of home traction devices.

The American Physical Therapy Association (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 traction for patients with low back pain. There is moderate evidence that clinicians should not utilize intermittent or static lumbar traction for reducing symptoms in patients with chronic low back pain."

The North American Spine Society (NASS) clinical guideline for the diagnosis and treatment of lumbar disc herniation with radiculopathy (Kreiner, et al., 2014) lists Question 9: what is the role of traction (manual or mechanical) in the treatment of lumbar disc herniation with radiculopathy? There is insufficient evidence to make a recommendation for or against the use of traction in the treatment of lumbar disc herniation with radiculopathy. Grade of recommendation: I (insufficient evidence). The NASS clinical guideline for the diagnosis and treatment of degenerative lumbar spinal stenosis (Kreiner, et al., 2013) lists Question 12: What is the role of ancillary treatments such as bracing, traction, electrical stimulation, and transcutaneous electrical stimulation (TENS) in the treatment of lumbar spinal stenosis? There is insufficient evidence to make a recommendation for or against traction, electrical stimulation, or transcutaneous electrical stimulation for the treatment of patients with lumbar spinal stenosis. Grade of Recommendation: I (insufficient evidence).

PRACTITIONER SCOPE AND TRAINING

Practitioners should practice only in the areas in which they are competent based on their education, training, and experience. Levels of education, experience, and proficiency may vary among individual practitioners. It is ethically and legally incumbent on a practitioner to determine where they have the knowledge and skills necessary to perform such services and whether the services are within their scope of practice.

It is best practice for the practitioner to appropriately render services to a member only if they are trained, equally skilled, and adequately competent to deliver a service compared to others trained to perform the same procedure. If the service would be most competently delivered by another health care practitioner who has more skill and training, it would be best practice to refer the member to the more expert practitioner.

Best practice can be defined as a clinical, scientific, or professional technique, method, or process that is typically evidence-based and consensus driven and is recognized by a majority of professionals in a particular field as more effective at delivering a particular outcome than any other practice (Joint Commission International Accreditation Standards for Hospitals, 2020).

Depending on the practitioner's scope of practice, training, and experience, a member's condition and/or symptoms during examination or the course of treatment may indicate the need for referral to another practitioner or even emergency care. In such cases it is prudent for the practitioner to refer the member for appropriate co-management (e.g., to their primary care physician) or if immediate emergency care is warranted, to contact 911 as appropriate. See the *Managing Medical Emergencies (CPG 159 – S)* clinical practice guideline for information.

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