BENEFIT CONSIDERATIONS

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee’s specific plan document to determine benefit coverage.
**COVERAGE RATIONALE**

Home traction therapy is unproven and not medically necessary for the treatment of 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 Current Procedural Terminology (CPT®) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit 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 claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0830</td>
<td>Ambulatory traction device, all types, each</td>
</tr>
<tr>
<td>E0840</td>
<td>Traction frame, attached to headboard, cervical traction</td>
</tr>
<tr>
<td>E0849</td>
<td>Traction equipment, cervical, free-standing stand/frame, pneumatic, applying traction force to other than mandible</td>
</tr>
<tr>
<td>E0850</td>
<td>Traction stand, freestanding, cervical traction</td>
</tr>
<tr>
<td>E0855</td>
<td>Cervical traction equipment not requiring additional stand or frame</td>
</tr>
<tr>
<td>E0856</td>
<td>Cervical traction device, cervical collar with inflatable air bladder</td>
</tr>
<tr>
<td>E0860</td>
<td>Traction equipment, overdoor, cervical</td>
</tr>
<tr>
<td>E0941</td>
<td>Gravity assisted traction device, any type</td>
</tr>
</tbody>
</table>

**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, such as the LTX 3000, various pneumatic vests and the Saunders Lumbar HomeTrac, 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 include the Pronex® and Saunders HomeTrac® devices 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) The Saunders HomeTrac® and Saunders STx® are home lumbar traction devices that according to the manufacturer can apply up to 200 pounds of home traction force. The device reportedly mimics the traction offered in a clinical setting by providing a friction-free split surface that actively moves, enabling vertebral separation by inducing a pulling force.

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. (Pellecchia, 1994; Harris, 1977). 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 re-assessment 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 can 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)

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 for drawing conclusions about the efficacy and safety of home cervical traction.

**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 (Clark, 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.

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**
In a prospective case series, Cai et al. (2011) evaluated potential prognostic variables and the validity of a clinical prediction rule for improvement in spondylosis neck pain after home cervical traction in 103 consecutive patients with cervical pain. The patients used a traction device with an adjustable cervical halter with a traction force equaling 10% to 15% of their body weight. They were instructed to pull the rope of the pulley system until the determined traction force was reached. The patients were instructed to perform 2 traction treatments for 20 minutes daily for 2 weeks, reinforced by a treatment diary. Standard physical examination of the cervical spine was conducted before intervention. Data on the Numerical Pain Scale (NPS) score, Neck Disability Index (NDI), Fear-Avoidance Beliefs Questionnaire (FABQ) scores, and a global rating of perceived improvement were collected before and after treatment. A positive treatment response was defined as 50% improvement between pre- and post treatment of NPS or NDI, or rated as *much improved or completely recovered* in the global rating scheme. Forty-seven patients had a positive response to home cervical traction, while 56 did not. This study is limited by its short-term follow-up and lack of controls.

Young et al. (2009) conducted a randomized controlled trial of 81 patients with cervical radiculopathy. The patients received manual therapy, exercise, and intermittent cervical traction or they received manual therapy, exercise, and sham intermittent cervical traction. The results
suggested that the addition of mechanical cervical traction to a multimodal treatment program of manual therapy and exercise yields no significant additional benefit to pain, function, or disability in patients with cervical radiculopathy.

A Cochrane review of 7 randomized controlled trials (n=958) by Graham et al. (2008) assessed the effects of mechanical traction for neck disorders. Outcomes included pain, function, disability, global perceived effect, patient satisfaction, and quality of life measures. The review found no statistically significant difference between continuous traction and placebo traction in reducing pain or improving function for chronic neck disorders with radicular symptoms. The authors concluded that there was no evidence to clearly support or refute the use of either continuous or intermittent traction for neck disorders. Further studies are needed to assess the safety and efficacy of traction for neck disorders.

Olivero and Dulebohn (2002) conducted a retrospective review of 81 patients receiving halter cervical traction for the treatment of cervical radiculopathy. All patients experienced at least 6 weeks of symptoms before undergoing a trial of traction that consisted of wearing a cervical collar and home-based halter cervical traction: 8 to 12 pounds, applied for 15 minutes, 3 times a day for 3 to 6 weeks. Sixty-three (78%) of 81 patients responded to therapeutic traction, experiencing significant or total pain relief, 3 could not tolerate the traction, and traction failed in 15 patients. Three of the 63 patients who responded to traction therapy, suffered recurrence of their symptoms and required surgery. The authors concluded that 75% of patients with at least a 6 week history of cervical radiculopathy will benefit from home-based halter traction therapy. The study is limited by small sample size and lack of a comparison group.

Swezey et al. (1999) reported that a brief (3-5 min), over-the-door home cervical traction modality provided symptomatic relief in 81% of the patients with mild to moderately severe (Grade 3) cervical spondylosis syndromes. Five patients discontinued treatment after reporting transient symptom aggravation with traction. No serious or sustained adverse events were recorded. The author noted that prospective, randomized assessment of cervical traction for this and other methods is needed.

Case series reports have evaluated the relationship between the separation of the vertebral bodies and the amount of traction force and angle of rope pull. Colachis et al. (1965) found that the mean angle of distraction changed based on weight (traction force) and angle of pull. Fater et al. (2008) found that neither seated nor supine cervical traction with the neck in 15 degrees of flexion was effective in increasing anterior vertebral separation.

Two additional case reports evaluated the use of cervical traction and the impact on temporomandibular joint (TMJ) disorders. Frankel et al. (1964) found that the use of cervical traction increased TMJ symptoms. Franks (1967) found similar results due to pressure on the temporomandibular joint especially in patients predisposed to osteoarthritic changes.

A clinical trial is now completed to assess the effectiveness of adding mechanical traction to standard physical therapy treatments for patients with low back pain. No study results have been posted since last updated in January 2013. Additional information (NCT00942227) is available at: http://clinicaltrials.gov/ct2/show/NCT00942227?term=NCT00942227&rank=1. Accessed April 21, 2014.

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.

Professional Societies/Organizations: 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 tractions 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) 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 (NASS, 2010).

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.

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.

The clinical evidence was reviewed in May 2014 with no additional information identified that would change the conclusion.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Home traction devices, or non-powered orthopedic traction, are classified as Class I devices. These devices consists of a rigid frame with non-powered traction accessories, such as cords, pulleys, or weights, and that is intended to apply a therapeutic pulling force to the skeletal system. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=888.5850. Accessed April 23, 2014.

Devices include (but are not limited to):
- Hometrac
- Pronex
- Saunder 3D ActiveTrac
- Spinex
- Easy-Trax™

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

Additional products
- Dynatron 900, Back Bubble

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare covers traction equipment under the Durable Medical Equipment benefit, when criteria are met. Refer to the NCD for Durable Medical Equipment Reference List (280.1).
Local Coverage Determinations (LCDs) for home traction therapy do not exist at this time. However, Medicare does have LCDs that address cervical traction. Refer to the LCDs for **Cervical Traction Devices**.

(Accessed April 23, 2014)

**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

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
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<tbody>
<tr>
<td>08/01/2014</td>
<td>• Reorganized policy content</td>
</tr>
<tr>
<td></td>
<td>• Added benefit considerations language for Essential Health Benefits for Individual and Small Group plans to indicate:</td>
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<td>• Updated coverage rationale; added language to indicate the unproven services are “not medically necessary”</td>
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<tr>
<td></td>
<td>• Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references</td>
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