Cigna Medical Coverage Policy

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Subject  Home Traction Devices: Cervical and Lumbar

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Physical Therapy

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Coverage Policy

Cigna does not cover home cervical and/or lumbar traction devices for any indication because they are considered experimental, investigational or unproven.

General Background

Traction is the act of drawing or pulling and relates to forces applied to the body to stretch a given part or to separate two or more parts. Traction is used for treatment of disorders of cervical or lumbar spine with the goal of relieving pain in, or originating from, those areas (Wieting, et al., 2013). 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. Traction has not been proven effective for lasting relief of pain. Usual endpoints to treatment plans are pain relief, return to normal range of motion, and return to work, but a demonstrated lack of symptom improvement and the inability of the patient to continue with treatment may also be an endpoint to ongoing therapy.

Home Cervical Traction

Cervical traction is noninvasive traction that is used to stretch the soft tissues of the neck and to separate the spinal joint structures in order to relieve neck pain. Constant traction results in tiring of the muscles, allowing the strain to rest on the joints. It is theorized that this results in a widening of the joint spaces, promoting pain relief. Cervical traction employs a free weight and pulley system or a mechanical motorized device, often involving a head or chin sling to allow pull in a cephalad direction. Mechanical motorized devices are easily applied but require patient attendance and, therefore, are most often used in an outpatient clinic setting. Traction forces used in a clinic setting typically reach between 20 and 50 pounds of force. Cervical traction may be used in a home setting as an alternative to or in addition to outpatient rehabilitation.
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 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.

Cervical Traction Device—Cervical Collar with Inflatable Air Bladder

Home traction devices include those that are used in a sitting position (e.g., traditional over-the-door devices) or in a supine position. 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)

Literature Review: 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.

Graham et al. (2008) published a Cochrane review that 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 authors reviewed seven randomized controlled trials with 958 participants. 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. Graham et al. found no evidence from that clearly supports or refutes the use of either continuous or intermittent traction for neck disorders.

Graham et al. (2006) conducted a systematic review of randomized controlled trials to assess whether mechanical traction, either alone or in combination with other treatments, improves pain, function/disability, patient satisfaction and global perceived effect in adults with mechanical neck disorders. Of the ten studies included in the review, it was noted that one study was of high quality. The review revealed low-quality trials for mechanical neck disorders, and demonstrated evidence of benefit that favored intermittent traction for pain reduction. Regarding continuous traction, the review indicated no significant difference for defined outcomes. The reviewers concluded that “inconclusive evidence for continuous and intermittent traction exists due to trial methodological quality. Two clinical conclusions may be drawn, one favoring intermittent traction and the other
not supporting the use of continuous traction. Attention to research design flaws and description of traction characteristics is needed” (Graham, et al., 2006).

Two small retrospective studies indicated there was moderate relief with cervical traction (Olivo and Dulebohn, 2002; Swezey, et al., 1999). The studies were limited by the retrospective design, small sample size and lack of a comparison group.

**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. Various techniques have been reported to widen or decompress disc spaces, unload the vertebrae, decrease disc protrusion or muscle spasm, separate the vertebrae, or lengthen and stabilize the spine. The duration of the exerted force applied may be intermittent or continuous throughout a treatment session. The exact mechanism through which traction is effective is unclear, and little is known about any adverse effects it may have (van Tulder, et al., 2004).

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).

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 may be indicated when use of a standard home device has been unsuccessful. The Saunders HomeTrac and Saunnder STx (Empi, Shoreview, MN) are compact home lumbar traction devices, which manufacturers claim can apply up to 200 pounds of home traction force. Manufacturers propose that the device 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. It is suggested that, when using these devices, the patient can be positioned so that the lumbar curve is in any degree of flexion, neutral or in extension. Each of these devices has both 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.

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.

**Literature Review:**

Wegner et al (2013) published and update to a 2007 Cochrane review (Clark, 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 that 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.

Thoomes et al. (2013) conducted a systematic review is to assess the effectiveness of conservative treatments for patients with cervical radiculopathy. Eleven randomized controlled studies were included with conservative treatments such as oral medication, physiotherapy, manual therapy, spinal manipulation, bed rest, cervical collar, or traction. The review found that there is low-level evidence that a collar is no more effective than physiotherapy at short-term follow-up and very low-level evidence that a collar is no more effective than traction;
there is low-level evidence that traction is no more effective than placebo traction and very low level-evidence that intermittent traction is no more effective than continuous traction.

van Middelkoop et al. (2011) conducted a systematic review of randomized controlled trials to determine the effectiveness of various physical and rehabilitation interventions including traction for chronic non-specific low back pain. The review found one study of 42 patients that involved traction. The study had a high risk of bias, compared motorized traction treatment plus standard physiotherapy with standard physiotherapy only. No statistically significant differences were found on pain intensity, disability, and recovery at post-treatment and after three months follow-up between both intervention groups. The authors concluded that further research is encouraged to identify the effectiveness of the interventions, including traction and that there appeared to be insufficient data to draw firm conclusion on the clinical effect of traction.

Clarke et al. (2006) conducted a systematic review of 24 randomized controlled trials to determine if traction is more effective than reference treatments, placebo/sham traction or no treatment for low back pain. Five of the trials were considered high quality. Regarding low back pain with sciatica, the review found conflicting evidence in several of the comparisons, including: autotraction compared to placebo, sham, or no treatment; other forms of traction compared to other treatments; and different forms of traction. The authors concluded that for patients with low back pain, who may or may not have sciatica, the present evidence is that traction, as a single treatment, is no more effective than placebo, sham, no treatment, or other treatments. Regarding patients who do have sciatica, the evidence is inconsistent. The conclusion noted that, "However, because high quality studies within the field are scarce, because many are underpowered, and because traction often is supplied in combination with other treatment modalities, the literature allows no firm negative conclusion that traction, in a generalized sense, is not an effective treatment for patients with LBP [low back pain]."

Evidence in the scientific literature is inconsistent regarding the effectiveness of the use of traction in the treatment of low back pain (Maher, 2004; Borman, 2003; Harte, et al., 2003). 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 are classified as Class I devices by the U.S. Food and Drug Administration (FDA). The FDA has described these devices as: “A nonpowered 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.”

**Professional Societies/Organizations**

**American Physical Therapy Association (APTA):**

American Physical Therapy Association (APTA) published clinical practice guidelines regarding low back pain (Delitto, et al., 2013). The guidelines note, “There is conflicting evidence for the efficacy of intermittent lumbar traction for patients with low back pain. There is preliminary evidence that a subgroup of patients with signs of nerve root compression along with peripheral symptoms or a positive crossed straight leg raise will benefit from intermittent lumbar traction in the prone position. There is moderate evidence that clinicians should not utilize intermittent or static lumbar traction for reducing symptoms in patients with acute or subacute, nonradicular low back pain or patients with chronic low back pain. (Recommendation based on conflicting evidence*)

*conflicting evidence: Higher-quality studies conducted on this topic disagree with respect to their conclusions. The recommendation is based on these conflicting studies.

American Physical Therapy Association (APTA) published clinical practice guidelines regarding neck pain (Childs, et al., 2008). The guidelines include the recommendation regarding cervical traction:

Clinicians should consider the use of mechanical intermittent cervical traction, combined with other interventions such as manual therapy and strengthening exercises, for reducing pain and disability in patients with neck and neck-related arm pain. (Based on moderate evidence**).

**Moderate evidence: a single high-quality randomized controlled trial or a preponderance of level II studies support the recommendation.
Level II evidence: evidence obtained from lesser-quality randomized controlled trials, prospective studies, or diagnostic studies (e.g., improper randomization, no blinding, <80% follow-up).

**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).

**North American Spine Society:** 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).

**Washington State Department of Labor:** 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.

**Use Outside of the US**
National Institute for Health and Clinical Excellence (NICE): NICE published guidelines for early management of persistent non-specific low back pain (2009). Regarding the use of traction, it is noted, “Do not offer traction.”

**Summary**
Home traction is used to treat various orthopedic, musculoskeletal or neurological impairments. The literature regarding home traction is inconclusive regarding this treatment used in conjunction with other therapies or as a sole modality. There is insufficient evidence in the published, peer-reviewed scientific literature to demonstrate that home traction is effective in the treatment of lumber and cervical disorders.

**Coding/Billing Information**

**Note:** 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

**Experimental/Investigational/Unproven/Not Covered:**

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<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>E0830</td>
<td>Ambulatory traction device, all types, each</td>
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<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>
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<tr>
<td>E0855</td>
<td>Cervical traction equipment not requiring additional stand or frame</td>
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<tr>
<td>E0856</td>
<td>Cervical traction device, cervical collar with inflatable air bladder</td>
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<tr>
<td>E0860</td>
<td>Traction equipment, overdoor, cervical</td>
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<table>
<thead>
<tr>
<th>ICD-9-CM Diagnosis Codes</th>
<th>Description</th>
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References


