



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject Home Traction Devices:
Cervical and Lumbar**

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Hyperlink to Related Coverage Policies

- Chiropractic Care
- Mechanical Devices for the Treatment of Back Pain
- Physical Therapy

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2010 CIGNA

Coverage Policy

Coverage for cervical and lumbar traction devices is subject to the terms, conditions and limitations of the applicable benefit plan's Durable Medical Equipment (DME) benefit and schedule of copayments. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage. Under many benefit plans, coverage for DME is limited to the lowest-cost alternative.

If coverage for cervical and lumbar traction devices is available, the following conditions of coverage apply.

CIGNA covers standard home cervical traction (i.e., over-the-door) capable of delivering up to and including 20 pounds of traction force as medically necessary for the treatment of musculoskeletal and/or neurological conditions for which traction is clinically appropriate.

CIGNA covers a home cervical traction device that is not an over-the door device and is capable of delivering greater than 20 pounds of traction force as medically necessary for the treatment of a musculoskeletal or neurological condition for which traction is clinically appropriate when there is failure, contraindication, or intolerance to a reasonable trial of over-the-door home cervical traction.

CIGNA covers a home lumbar traction device as medically necessary for the treatment of a musculoskeletal or neurological condition for which traction is clinically appropriate.

CIGNA does not cover the following devices because each is considered experimental, investigational or unproven:

- cervical collar with inflatable air bladder (HCPCS code E0856)
 - inflatable lumbar traction devices
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General Background

Traction is the use of a pulling force to treat muscle and skeletal disorders. It may be applied to the arms, legs, neck, back or pelvis for treatment of fractures, dislocations, muscle spasms and other muscular disorders. It employs weights, counterweights and pulleys to provide a force that gradually stretches the spine to a normal position. The type of traction used depends on the patient's age, weight and medical condition. The use of traction requires training and experience, since incorrect application may cause harm. 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. While traction therapy may provide short-term pain relief, that is secondary to its primary goal of returning the patient to a functioning level to aid in recovery. Typically, traction is used as part of an ongoing comprehensive rehabilitation treatment program to improve activity levels, mobility and overall function.

There are two main types of traction: skin traction and skeletal traction. Skin traction is a noninvasive method that involves the indirect attachment of weights to the skin, providing a counterforce. This type of traction, which is usually preferred for conditions requiring temporary traction or light pulling force, is usually applied in an outpatient or home setting. Skeletal traction is employed when greater pulling force is required or for treatment of a body part that cannot be treated by skin traction. Skeletal traction involves weight usually greater than 25 pounds and requires the insertion of tongs, pins or screws directly into the bone for the application of weight. This type of traction is an invasive procedure and is performed under anesthesia, most often in an inpatient setting. Once the hardware is surgically in place, pulleys and weights are attached to provide proper pull and alignment to the affected body part.

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."

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. 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. Care must be exercised when instructing the patient in the proper use of the device; it should be applied in the position of maximal pain relief and should not result in discomfort. 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. To prevent irritation of the temporomandibular joint (TMJ), they require appropriate session duration and fitting of the head halter (Canale, 2008). The head halter fits under the chin. As force is transmitted through the chin strap to the teeth, the TMJ becomes a weight-bearing structure, which may potentially cause the joint to deteriorate.

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: While studies specifically evaluating the types of cervical traction are lacking, cervical traction in general is supported in the literature as safe and effective for short-term pain reduction. It has been accepted as a standard of care for short-term treatment of neck pain.

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).

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.

A retrospective study of 58 outpatients was conducted for the purpose of determining the efficacy of home cervical traction (Swezey, et al., 1999). The study found that a brief, over-the-door home cervical traction modality provided symptomatic relief in 85% of the patients with mild to moderately severe neck pain. This study was limited by retrospective design, sample size and lack of comparison to established standards, thus no conclusions can be drawn from these findings.

Professional Societies/Organizations: 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.

Home Lumbar Traction

Lumbar traction is widely 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) (Weiting, et al., 2008). In some cases, 70–150 pounds of pull are required to distract lumbar vertebrae (Weiting, et al., 2008).

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 Saunder 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.

Literature Review: 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 (less than four weeks duration), subacute (four to 12 weeks) or chronic (more than 12 weeks) 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. **Level of evidence: 1**

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]." **Level of evidence: 1**

The Swedish Council on Technology Assessment in Healthcare reviewed evidence on treatments of low back pain and concluded: (1) that limited evidence suggests that traction is effective in treating acute low back problems, and (2) that the evidence strongly shows traction to be ineffective in relieving chronic back pain (Nachemson, et al., 2000).

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. Despite the poor evidence, traction remains a recommended short-term therapy for the initial treatment of back pain.

Inflatable Lumbar Traction Device—Back Bubble

The Back Bubble[®] (Back Bubble, Solana Beach, CA) is a 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.

Summary

Cervical home traction has been used to treat various orthopedic, musculoskeletal or neurological impairments and is considered a standard of care. Cervical traction in general is supported in the literature as safe and effective for short-term pain reduction. The literature regarding lumbar traction is inconclusive regarding this treatment used in conjunction with other therapies or as a sole modality; however, this treatment may be considered a standard of care for treatment of back pain. There is insufficient evidence in the published peer-reviewed medical literature to support the efficacy of the cervical collar with inflatable air bladder and inflatable lumbar traction devices (e.g., Back Bubble).

Coding/Billing Information

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

Covered when medically necessary:

CPT[®]* Codes	Description
	No specific codes

HCPCS Codes	Description
E0840	Traction frame, attached to headboard, cervical traction
E0849	Traction frame, 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
E0860	Traction equipment, overdoor, cervical

ICD-9-CM Diagnosis Codes	Description
524.60	Temporomandibular joint disorders, unspecified
721.0	Cervical spondylosis without myelopathy
721.1	Cervical spondylosis with myelopathy
721.3	Lumbosacral spondylosis without myelopathy
721.42	Lumbosacral spondylosis with myelopathy, lumbar region
722.0	Displacement of cervical intervertebral disc without myelopathy
722.10	Displacement of lumbar intervertebral disc without myelopathy
722.52	Degeneration of lumbar or lumbosacral intervertebral disc
723.1	Cervicalgia
724.02	Spinal stenosis of lumbar region
724.2	Lumbago

Experimental/Investigational/Unproven/Not Covered:

HCPCS Codes	Description
E0830	Ambulatory traction device, all types, each
E0856	Cervical traction device, cervical collar with inflatable air bladder

ICD-9-CM Diagnosis Codes	Description
	All Codes

***Current Procedural Terminology (CPT®) ©2010 American Medical Association: Chicago, IL.**

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	12/15/2007	0265	Home Traction Devices: Cervical and and Lumbar Traction
Great-West Healthcare	3/12/2007	05.284.02	Traction, Cervical, for Home Use

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.