Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

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<th>Plan: Aetna Better Health</th>
<th>Submission Date: 10/01/2019</th>
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<td>Policy Number: 0569</td>
<td>Effective Date: 08/08/2017</td>
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<tr>
<td>Policy Name: Lumbar Traction Devices</td>
<td>Revision Date: 08/08/2017</td>
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**Type of Submission – Check all that apply:**

- [ ] New Policy
- [ ] Revised Policy*
- [x] Annual Review – No Revisions
- [ ] Statewide PDL

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

**CPB 0569 Lumbar Traction Devices**

Clinical content was last revised on 08/08/2017. No additional non-clinical updates were made by Corporate since the last PARP submission.

Name of Authorized Individual (Please type or print):

Dr. Bernard Lewin, M.D.

Signature of Authorized Individual:
Lumbar Traction Devices

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.*

I. Aetna considers autotraction devices experimental and investigational because there is insufficient evidence to support their clinical value in treating low back pain (LBP) or for other indications.

Note: Brand names of autotraction devices include the Anatomotor, the Arthrotonic stabilizer, the Quantum 400 inter-segmental traction table, and the Spinalator Spinalign massage inter-segmental traction table.

II. Aetna considers home pneumatic lumbar traction devices (e.g., Orthotrac Pneumatic Vest, Saunders Lumbar HomeTrac, Saunders STx, DDS 500 Lumbar Traction) experimental and investigational because they have not been demonstrated to be an effective treatment for LBP or other indications.

III. Aetna considers axial spinal unloading (gravity-dependent traction) devices (e.g., LTX 3000, Triton DTS, and Z-Grav Spinal Decompression Table) experimental and investigational for the treatment of LBP or other indications because their effectiveness has not been established.
See also CPB 0180 - Vertebral Axial Decompression (../100_199/0180.html), CPB 0232 - Back Pain - Non Invasive Treatments (../200_299/0232.html) and CPB 0453 - Cervical Traction Devices (../400_499/0453.html).

Background

Traction is a widely used treatment for low back pain (LBP) and it is often provided in combination with other treatment modalities. Types of traction include mechanical traction, manual traction (unspecific or segmental traction), autotraction, gravity-dependent ("(anti-)gravity") traction, pneumatic traction, continuous traction, and intermittent traction.

The most commonly used traction techniques are manual traction (i.e., the traction is exerted by the therapist, using arms and/or legs of the patient), inverted suspension (i.e., the traction is exerted by gravitational forces, through the body weight of the patient), bed rest traction (i.e., the traction is exerted by a pulley and weights) and motorized traction (i.e., the traction is exerted by a motorized pulley). Lumbar traction uses a harness (with Velcro strapping) that is put around the lower rib cage and around the iliac crest. Duration and level of force exerted through this harness can be varied in a continuous or intermittent mode.

The exact mechanism through which traction might be effective is still unclear. It has been suggested that spinal elongation, through decreasing lordosis and increasing intervertebral space, inhibits pain (nociceptive) impulses, improves mobility, decreases mechanical stress, reduces muscle spasm or spinal nerve root compression (due to osteophytes), releases luxation of a disc or capsule from the zygapophyseal joint, and releases adhesions around the zygapophyseal joint and the annulus fibrosus. So far, the proposed mechanisms have not been supported by sufficient empirical information.

Little is known about the adverse effects of traction. Only a few case reports are available, which suggest that there is some danger for nerve impingement in heavy traction, i.e., lumbar traction forces exceeding 50% of the total body weight. Other risks described for lumbar traction are respiratory constraints due to the traction harness or increased blood pressure during inverted positional traction. Lumbar traction forces below 25% of the total body weight do not seem to increase...
intervertebral distances, and can therefore be regarded as a placebo (sham or low dose) traction. Placebo traction can only be expected to produce relaxation of spinal muscles and modification of the spinal curve.

van der Heijden et al (1995) published a systematic review of 21 papers reporting on 24 randomized controlled trials of traction. The authors concluded that the information of these studies did not allow for clear conclusions about the effectiveness of traction due to methodological flaws in study designs. Most studies were considered to be of poor methodological quality. As this previous review was based on literature published up to and including 1992 and several new randomized controlled trials have been published since, the lead author of the 1995 study is preparing an update for the Cochrane Collaboration.

Traction (manual or mechanical pull on extremities or spine to relieve spasm and pain), when provided by physicians or physical therapists, is typically used in conjunction with therapeutic procedures, not as an isolated treatment. Standard treatment is to provide supervised mechanical traction up to 4 sessions per week.

The American Pain Society/American College of Physicians' clinical practice guideline on non-pharmacological therapies for acute and chronic LBP (Chou and Huffman, 2007) evaluated the benefits and harms of acupuncture, back schools, psychological therapies, exercise therapy, functional restoration, inter-disciplinary therapy, massage, physical therapies (interferential therapy, low-level laser therapy, lumbar supports, shortwave diathermy, superficial heat, traction, transcutaneous electrical nerve stimulation, and ultrasonography), spinal manipulation, and yoga for acute or chronic LBP (with or without leg pain). The authors concluded that therapies with good evidence of moderate efficacy for chronic or subacute LBP are cognitive-behavioral therapy, exercise, spinal manipulation, and inter-disciplinary rehabilitation. For acute LBP, the only therapy with good evidence of efficacy is superficial heat.

**Autotraction**

Autotraction is defined as the use of one's own weight to create the traction force (i.e., the patient determines the traction force). By utilizing positional and gravity assisted traction principles, autotraction can provide multi-plane traction. Brand names of autotraction devices include the Spinalator, Spinalign Massage, Intersegmental Traction Table and the Anatomotor. These are tables with custom-
contoured rollers that deliver consistent pressure and move underneath the patient while they are lying on top of the table. A 3-motor operating system allows for roller elevation, roller travel, as well as roller rotation (clockwise or counter-clockwise).

There are only 2 published randomized clinical studies comparing autotraction to other forms of traction; the results of these studies are conflicting. Telso and Merlo (1993) from Italy reported on a randomized clinical trial comparing conventional passive traction to autotraction. The investigators measured subjective response concerning overall improvement, pain intensity using visual analog scale, qualitative pain severity using the McGill Pain Questionnaire, and pain-related disability using the Oswestry Low Back Pain Disability Score. The favorable response to autotraction was 75% (30 of the 40 patients) versus the 22% (6 of 27 patients) to conventional passive traction (p < 0.001).

A study by Ljunggren et al (1984), however, found no differences in effectiveness between autotraction and manual traction. A total of 49 patients with lumbago-sciatica and prolapsed lumbar intervertebral discs, comparable concerning anamnestic and clinical data were randomized for autotraction and manual traction given by the same therapist for a period of 1 week while strict bed rest was prescribed. A blind overall assessment performed immediately after the traction period, after 2 weeks follow-up training and 3 months after hospitalization showed that the 2 traction modalities are equally efficient. The author concluded that, as treatment for hospitalized patients with lumbar intervertebral disc prolapses, the relatively simple manual traction variety should be preferred, if any.

Another 2 randomized clinical studies compared protocols that included autotraction with conservative management by a primary care physician; the results of these studies are conflicting. Moreover, since these latter 2 studies did not compare autotraction to other forms of manipulation, no conclusions about the comparative efficacy of autotraction can be drawn from them. Blomberg et al (1993, 1994) reported on the results of a controlled, multi-center clinical trial comparing outpatients with acute or subacute LBP who were randomly allocated to either standardized but optimized conventional activating treatment by primary health care teams (n = 53) or specific manual treatment such as manipulation, specific mobilization, muscle stretching, autotraction and cortisone injections (n = 48). The treatment effect was evaluated by standardized telephone interviews 3, 7, 14, 21 and 90 days after the start of treatment. The authors reported that, in the early phase of treatment as well as at the 90 days’ follow-up, the group receiving
manual treatment had significantly less pain, less disability, faster rate of recovery and lower drug consumption than patients receiving conventional treatment, indicating that this type of treatment is superior to conventional treatment.

Seferlis (1998) also compared a program that included autotraction to conventional management, but unlike Blomberg, found no differences in effectiveness. A total of 180 patients sick-listed less than 2 weeks for LBP with or without sciatica, 95 men and 85 women aged 19 to 64 years, were randomized to 3 groups: (i) an intensive training program (I), (ii) a manual therapy program that included autotraction (R1), or (iii) standard treatment by a general practitioner (R2). The intensive training program (I) (n = 60) consisted of small groups, muscle training and general condition training, strength and co-ordination, abdominal, gluteal, paraspinal, shoulder and lower extremity muscles, 3 times per week, for 8 weeks. The manual therapy program (R1) (n = 60) consisted of autotraction, manipulation of lumbar facet joint and sacroiliac joint, mobilization, muscle energy technique, stretching, and coordination training, with number of sessions decided by the physiotherapist. The general practitioner program (R2) (n = 60) included standard treatment, rest, sick leave, drug prescription, postural advice, and back school or physiotherapy for patients failing to recover. No significant differences were found between the 3 groups in pain intensity, functional status after 1, 3 and 12 months. No significant differences were found between the 3 groups in number of days off of work due to back pain; median (range) number of days off work due to back pain after 1 year was: (I) 23 (5-365), (R1) 28 (4-365), (R2) 30 (4-365). Subjective satisfaction with treatment was significantly better with intensive training (I) and manual therapy (R1) than with standard treatment (R2); mean (SD) satisfaction on a 5 point scale after 1, 3, and 12 months was: (I) 4.3 (0.8), 4.4 (0.6), 4.1 (1.1); (R1) 4.4 (0.8), 4.5 (0.6), 4.3 (0.9); (R2) 3.4 (1.2), 3.5 (1.1), 3.6 (1.2). However, mean number of treatment sessions was least for standard treatment; mean number of treatment sessions for each of the groups was: (I) 18, (R1) 10, (R2) 4.

A Cochrane review on traction for LBP with or without sciatica (Clarke et al, 2007) found that while there was moderate evidence that autotraction was more effective than mechanical traction for global improvement in patients with sciatica, these studies had methodological limitations and inconsistent results.

Because the clinical evidence is limited and conflicting, no conclusions can be drawn about the efficacy of autotraction, or about its effectiveness in comparison to other forms of traction.
Home Traction

The Norwegian Centre for Health Technology Assessment (2001) completed an assessment, "Treatment of Lumbar Disc Herniation", that concluded that traction of patients with lumbar disc herniation has "no effect." The Swedish Council on Technology Assessment reviewed the literature on treatments of back pain and concluded that there is in fact, "moderate evidence against" the use of traction in back pain (Nachemson et al, 2000). Birkmeyer and Weinstein (1999) concluded that lumbar traction for back pain is an outmoded technology that has "fallen out of favor".

van der Heijden and colleagues (1995) reviewed the literature on traction for back pain, and concluded that "the available RCTs do not allow clear conclusions to be drawn about the effectiveness of cervical or lumbar traction." A Prodigy Clinical Practice Recommendation (SCHIN, 2001) states, based on the literature, that "[t]raction does not appear to be effective for low back pain or radiculopathy."

According to the AHCPR Clinical Practice Guideline on Acute Low Back Pain in Adults (Bigos et al., 1994), the evidence does not demonstrate traction to be effective in treatment of patients with acute LBP.

Several additional systematic evidence reviews have been published more recently that have reached these same conclusions about the lack of adequate evidence of lumbar traction for back pain (e.g., Harte et al, 2003; Vroomen et al, 2000; Philadelphia Panel, 2001; Clarke et al, 2007; McIntosh and Hall, 2007). A Cochrane review on traction for LBP with or without sciatica (Clarke et al, 2007) noted that various types of traction are used in the treatment of patients with LBP, often in conjunction with other treatments. These investigators concluded that that traction is probably not effective. Neither continuous nor intermittent traction by itself was more effective in improving pain, disability or work absence than placebo, sham, or other treatments for patients with a mixed duration of LBP, with or without sciatica. They also noted that while there was moderate evidence that autotraction was more effective than mechanical traction for global improvement in patients with sciatica, these studies had methodological limitations and inconsistent results.

Spinal Unloading Devices

http://www.aetna.com/cpb/medical/data/500_599/0569.html
Spinal unloading devices provide a traction-like effect in an effort to shift weight-bearing off the lower back and onto the hips. The method used to shift weight-bearing varies from device to device. Some devices (e.g., LTX 3000) utilize gravitational force provided by the body mass of the individual. Other devices (e.g., Orthotrac Pneumatic Vest, STx -- Saunders Lumbar Traction Device, Saunders Lumbar Hometrac Deluxe) utilize applied pneumatic pressure in an effort to shift weight-bearing.

The DDS 500 Lumbar Traction is described as having a unique and patented spinal air-traction design that provides traction and support as opposed to just support. The manufacturer states that the DDS 500 acts to provide traction between the lower part of the rib cage and the upper part of the hip creating weight-bearing forces away from the lower back and reduces the pressure in the lumbar spine (spinal decompression). The unique quality that DDS 500 offers is the use of vertically expandable columns to provide a secure mechanical support and as well as spinal decompression for the lumbar vertebrae. The manufacturer states that it converts to a soft LSO and provides greater flexibility.

These devices were cleared by the Food and Drug Administration based on a 510 (k) premarket notification, so that the manufacturer was not required to submit the evidence of effectiveness that would be required to support a premarket approval application.

Falkenberg and associates (2001) examined the surface electromyographic (EMG) changes during axial spinal unloading using the LTX 3000 in normal subjects to determine the optimal time for effective traction. Hales et al (2002) reported on the short-term effect of LTX3000 on spinal curvature. Janke et al (1997) and Podien and Iaizzo (1998) have reported on the biomechanical and physiologic changes during axial spinal unloading the LTX 3000. However, there is a lack of evidence regarding the clinical value of LTX 3000 in improving clinical outcomes (reduction in pain and disability, improvements in function) in patients with LBP.

There are a lack of published peer-reviewed studies that have specifically evaluated the safety and effectiveness of the Saunders Lumbar HomeTrac or Saunders STx (The Saunders Group, Chaska, MN) home pneumatic traction devices for back pain. In addition, there is a lack of well-designed studies comparing the safety and effectiveness of the Saunders Lumbar HomeTrac or Saunders STx with lumbar traction provided by a physical therapist. Well-designed
controlled clinical studies demonstrating reductions in pain and disability and improvements in function are especially important in evaluating pain interventions because of the susceptibility of this symptom to placebo effects. One is unable to determine from uncontrolled observations whether any noted improvements are due to the application of home lumbar traction, the impact of any other interventions that the patient was concurrently receiving, or the waxing and waning natural history of chronic back pain.

The Orthotrac™ Pneumatic Vest (Orthofix, Inc., McKinney, TX) is an inflatable pneumatic vest that has been promoted for use in relieving back pain from a variety of causes (e.g., herniated disc, spinal stenosis, facet syndrome, spondylolysthesis, etc). The Orthotrac was evaluated in a study of 41 patients with radicular pain due to degenerative discopathy (Dallolio, 2005). The investigator reported that, after 5 weeks, 32 patients (78 %) have showed improvements on a SF-36 inventory, and all patients referred a decrease or disappearance of radicular pain. The investigator concluded, however, that “further multicenter and interdisciplinary studies on a greater number of patients are obviously needed to confirm these preliminary results.” The primary limitations of this study was the uncontrolled nature of this study, its short duration, and the subjective endpoints.

Hahne et al (2010) determined the effectiveness and adverse effects of conservative treatments for people who have lumbar disc herniation with associated radiculopathy (LDHR). These investigators searched 10 computer databases for trials published in English between 1971 and 2008. Trials focusing on people with referred leg symptoms and radiological confirmation of a lumbar disc herniation were included if at least 1 group received a conservative and non-injection treatment. A total of 18 trials involving 1,671 participants were included. Seven (39 %) trials were considered of high quality. Meta-analysis on 2 high-quality trials revealed that advice is less effective than microdiscectomy surgery at short-term follow-up, but equally effective at long-term follow-up. Individual high-quality trials provided moderate evidence that stabilization exercises are more effective than no treatment, that manipulation is more effective than sham manipulation for people with acute symptoms and an intact anulus, and that no difference exists among traction, laser, and ultrasound. One trial showed some additional benefit from adding mechanical traction to medication and electrotherapy methods. Adverse events were associated with traction (anxiety, fainting, lower limb weakness, and pain) and ibuprofen (gastrointestinal events). The authors concluded that advice is less effective than microdiscectomy in the short-term but
equally effective in the long-term for individuals who have LDHR. Moderate
evidence favors stabilization exercises over no treatment, manipulation over sham
manipulation, and the addition of mechanical traction to medication and
electrotherapy. There was no difference among traction, laser, and ultrasound.
Adverse events were associated with traction and ibuprofen. They stated that
additional high-quality trials would allow firmer conclusions regarding adverse
effects and effectiveness.

The North American Spine Society's clinical practice guideline on "Diagnosis and
treatment of degenerative lumbar spinal stenosis" (2011) noted that there is
insufficient evidence to make a recommendation for or against traction, electrical
stimulation or transcutaneous electrical nerve stimulation for the treatment of
patients with lumbar spinal stenosis. Moreover, the Work Loss Data Institute's
clinical practice guideline on "Low back - lumbar & thoracic (acute &
chronic)" (2011) listed DRX® (traction), Powered traction devices/Lordex®/vertebral
axial decompression (VAX-D®), and Traction/IDD therapy (intervertebral disc
decompression) as interventions/procedures that were considered, but are not
recommended.

CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification
purposes. Codes requiring a 7th character are represented by "+":

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>Other CPT codes related to the CPB:</td>
<td></td>
</tr>
<tr>
<td>97012</td>
<td>Application of a modality to one or more areas; traction, mechanical</td>
</tr>
<tr>
<td>97140</td>
<td>Manual therapy techniques (e.g., mobilization/manipulation, manual lymphatic drainage, manual traction), one or more regions, each 15 minutes</td>
</tr>
<tr>
<td>HCPCS codes not covered for indications listed in the CPB:</td>
<td></td>
</tr>
<tr>
<td>Z-Grav Spinal Decompression table - no specific code:</td>
<td></td>
</tr>
<tr>
<td>E0830</td>
<td>Ambulatory traction device, all types, each</td>
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</table>
ICD-10 codes not covered for indications listed in the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>L0631</td>
<td>Lumbar-sacral orthosis, sagittal control, with rigid anterior and posterior panels, posterior extends from sacrococcygeal junction to T-9 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise</td>
</tr>
<tr>
<td>S9090</td>
<td>Vertebral axial decompression, per session [Triton DTS]</td>
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The above policy is based on the following references:


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Amendment to
Aetna Clinical Policy Bulletin Number: 0569 Lumbar
Traction Devices

The following code is covered under the Pennsylvania Medical Assistance Program and will be considered on case by case basis:

L0631 Lumbo-sacral orthosis