INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee’s specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines® to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
**POLICY DESCRIPTION:**

This policy provides information on spinal unloading devices, which are intended to be used for individuals with chronic low-back pain as a conservative treatment for pain related to spinal disc disease or joint dysfunction. These devices provide a traction-like effect through applied pneumatic pressure, gravitational force, and/or other methods. These systems often are used as an adjunct to pharmacological therapy, chiropractic, and/or physical therapy modalities, such as electrical stimulation, ultrasound, massage, cryotherapy, and home exercise.

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**COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:**

Spinal Unloading Devices are considered EXPERIMENTAL AND/OR INVESTIGATIONAL for the treatment of any condition, including but not limited to low back pain and scoliosis, due to inadequate evidence of safety and/or efficacy, in published peer-reviewed literature.  Well designed studies are needed to support the use of any spinal unloading devices and to establish long-term improved patient outcomes.

Devices include (but are not limited to):

- Quantitative muscle testing and treatment devices (e.g., MedX, Isostation B-200, Cybex, KinCom, and Biodex)
- Vertebral axial decompression therapy and devices (e.g., Vax-D, DRX, DRX2000, DRX3000, DRX5000, DRX9000, DRS, Accu-Spina™ System, Intervertebral Differential Dynamics (IDD) Therapy®, Tru Track 401 Traction, Lordex Power Traction Device, Spinerx IDM)
- Patient-operated, spinal unloading devices (e.g., LTX 3000™, Orthotrac™ Pneumatic Vest)

**Clinical Considerations:**

**Contraindications:**

- Cord compression
- Spinal infection
- Acute back pain
- Uncontrolled hypertension
- Severe respiratory disease
- Aortic aneurysm
- Rheumatoid arthritis
- Abdominal hernia
- Hiatal hernia
- Active peptic ulcers
- Severe hemorrhoids

**Other conditions that might preclude full participation of the patient in a program:**

- Leg weakness that prevents sitting or standing without assistance
- Severe osteoporosis
- Morbid obesity
- Pain increase during a trial
- Pregnancy beyond the first trimester
- Pulmonary dysfunction where breathing is compromised by weight bearing at the rib cage
- Rheumatoid arthritis reducing strength or dexterity in hands or fingers
- Rib pathology, or recent injury to rib cage
- Cardiac or cardiovascular conditions
- Recent spinal or abdominal surgery

Spinal unloading devices are not recommended for use in heavy lifting.

Possible complications: No complications associated with use of spinal unloading devices have been reported in the reviewed literature.

BACKGROUND:

Low back pain affects up to 80% of adults in the United States at some time in their lives and is the second leading cause of work absences, with direct and indirect treatment costs exceeding $50 billion each year. Treatment for low back pain traditionally starts with conservative, noninvasive, low-cost measures involving physical therapy, exercises, analgesics, and nonsteroidal anti-inflammatory drugs (NSAIDs). Alternative and less well-accepted noninvasive treatment options include: chiropractic manipulation, transcutaneous electrical nerve stimulation (TENS), thermal techniques, spinal orthotic devices, and traction.

The use of traction for the treatment of low back pain is controversial. The theory underlying the use of traction for treatment of low back pain is that decreased load-bearing at the affected site will reduce associated pain and promote healing of injured tissues. Other putative benefits of traction include: reduction of spinal curvature, rupture of adhesions, tightening of spinal ligaments, and mobilization of hypomobile joints (Letchuman and Deusinger, 1993). Traction can be applied to the lumbar spine with therapist-operated devices that apply active distracting forces to the back. Alternatively, some spinal unloading devices may be operated by the patient in a home setting. Patient-operated home devices use gravity-dependent spinal unloading or pneumatic pressure-dependent shifting of weight off the lower back and onto the hips.

Generally, the use of spinal unloading devices is proposed as a method of treatment for persons with subacute or chronic low back pain and who have failed either standard medical or surgical therapy.

Some examples of these devices include, but are not limited to the Saunders Home Traction Device, Orthotrac Pneumatic Vest, DDS 500, and the LTX 3000 Lumbar Rehabilitation System.

LTX 3000:
The LTX 3000 is a gravity-dependent axial spinal unloading device. Unloading occurs as a result of the downward force provided by the body mass of the patient. Proper training in adjustment and use of the device is required for safe use in the home. The LTX 3000 is often used as part of rehabilitation programs, such as the Low Back Rehabilitation Program, the ReSpond Program, and more recently the LIFEBACK™ Spine Programs. These programs may be used by patients who have reached maximum therapeutic benefit of physical therapy or chiropractic care and whose pain limits activities of exercise and/or work. Recommended use of the device is 3-4 times a day for sessions of 10-15 minutes for 2-3 months.

Orthotrac Pneumatic Vest:
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, spondylolysis, etc). The pneumatic vest is intended to be worn 2-3 times a day for 30-60 minutes each session. It is a spinal decompression orthotic designed to offload and stabilize the lower back, using air pressure to provide support. When worn, the device applies a decompressive force to the spine, transferring the weight from the upper torso to the hips, preventing compression and aggravation of the lower back. The amount of force on the spine is controlled by the patient through a manual inflation device, with pressure prescribed to offload approximately 50% of the patient’s weight. The patient can deflate the device to reduce pressure at any time. It is proposed that use of the device alleviates pain and improves function and quality of life.

Saunders Devices:
The Saunders Lumbar Traction Device and the Saunders Lumbar Hometrac Deluxe also utilize apply pneumatic pressure in an effort to shift weight bearing. The patient lies supine on a friction-free track with specially designed air cylinders that apply the traction force. Utilizing pelvic belts, force is applied via a hand held pump, actively separating the lower half of the treatment surface, which actually moves.

REGULATORY STATUS:

1. U.S. FOOD AND DRUG ADMINISTRATION (FDA):
   Classification of devices by the FDA proposed for the treatment of back pain varies. Some have received approval through the FDA as isokinetic testing and evaluation systems (e.g., Isostation, Cybex Systems, KinCom, Biodex Systems) and others as powered/mechanical traction devices (e.g., VAX-D, DRS, AccuSpina System). According to the FDA, an isokinetic testing and evaluation system is a rehabilitative exercise device intended for medical purposes, such as to measure, evaluate, and increase the strength of muscles and the range of motion of joints. Powered traction devices consist of powered devices intended for medical purposes for use in conjunction with traction accessories, such as belts and harnesses, to exert therapeutic pulling forces on the person’s body. These devices are regulated by the FDA as Class II devices.
   The LTX 3000™ (Spinal Designs International, Minneapolis, MN) and Orthotrac™ Pneumatic Vest are regulated as Class I devices by the FDA (FDA, 2001a; FDA, 2001b). The Orthotrac™ Pneumatic Vest was patented by Kinesis Medical, Inc. (Minneapolis, MN), which was acquired by Orthofix, Inc. (Huntersville, NC) on August 31, 2000.

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS): CMS does not have a specific national policy regarding Medicare coverage of the LTX 3000 or Orthotrac spinal unloading devices. However, a closely related therapy, vertebral axial decompression (VAX-D), is not covered by Medicare; CMS states that there is insufficient data to support the benefits of this technique. (CMS, 2001).

3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS): Minnesota DHS does not have a policy statement regarding spinal uploading devices in its Provider Manual or other specific provider references.
CLINICAL EVIDENCE:

SUMMARY:
Several noninvasive treatments for back pain, which include quantitative muscle testing and therapy, vertebral axial decompression, and patient-operated spinal unloading devices, have emerged; however, there are few well-designed controlled clinical trials available to support improved clinical outcomes when these treatments are compared to standard equipment used for rehabilitation and physical therapy. The few published studies have had methodological flaws, such as lack of blinding, self-reported outcomes, small populations, and short-term follow-up. There is insufficient evidence in the published, peer-reviewed scientific literature to demonstrate that any of these mechanical devices used for the treatment of back pain are as effective as, or more effective, than standard established methods of treatment.

APPLICABLE CODES:

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

<table>
<thead>
<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>E0941</td>
<td>Gravity assisted traction device, any type</td>
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<tr>
<td>E1399</td>
<td>Durable medical equipment, miscellaneous</td>
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<tr>
<td>S9090</td>
<td>Vertebral axial decompression, per session</td>
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<tr>
<th>ICD-9 ® Codes</th>
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<tr>
<td>719.48</td>
<td>Facet and zygapophyseal joint pain</td>
</tr>
<tr>
<td>722.10</td>
<td>Intervertebral disc displacement without myelopathy</td>
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<tr>
<td>722.52</td>
<td>Degeneration of lumbar or lumbosacral intervertebral disc</td>
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<td>722.72</td>
<td>Intervertebral disc disorder, thoracic</td>
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<td>Lumbar disorder</td>
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<td>724.2</td>
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<td>724.3</td>
<td>Sciatica</td>
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<td>724.4</td>
<td>Thoracic or lumbosacral neuritis or radiculitis</td>
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<td>737.30</td>
<td>Scoliosis (and kyphoscoliosis), idiopathic</td>
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<td>846.x*</td>
<td>Sprains and strains of sacroiliac region</td>
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<td>847.2</td>
<td>Lumbar strain/sprain</td>
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<td>H16.00-H16.9</td>
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<td>H17.00-H17.9</td>
<td>Corneal scars and opacities</td>
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<td>H18.0-H18.069</td>
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<td>H18.10-H18.13</td>
<td>Bullous keratopathy</td>
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<td>H18.20-H18.239</td>
<td>Other and unspecified corneal edema</td>
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<td>H18.461-H18.469</td>
<td>Peripheral corneal degeneration</td>
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H18.50  Unspecified hereditary corneal dystrophies
H18.51  Endothelial corneal dystrophy
H18.59  Other hereditary corneal dystrophies
H18.601-H18.609 Keratoconus
H18.70-H18.799 Other and unspecified corneal deformity
H21.551-H24.559 Recession of chamber angle
H25.89  Other age-related cataract
H40.001-H40.9 Glaucome
Q11.2  Microphthalmos
Q12.0-Q12.9 Congenital lens malformations
Q13.0-Q13.5 Congenital malformations of anterior segment of eye
Q15.0  Congenital glaucoma
T85.398 Other mechanical complication of other ocular prosthetic devices, implants and grafts
T86.890-T86.899 Complication of other transplanted tissue
T86.90-T86.99 Complications of unspecified transplanted organ and tissue
Z48.810 Encounter for surgical aftercare following surgery on the sense organs

CPT® Codes

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<tr>
<td>97012</td>
<td>Application of a modality to 1 or more areas; traction, mechanical</td>
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<td>64999</td>
<td>Unlisted procedure, nervous system</td>
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<tr>
<td>97039</td>
<td>Unlisted modality (specify type and time if constant attendance)</td>
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<tr>
<td>97139</td>
<td>Unlisted therapeutic procedure (specify)</td>
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CPT® is a registered trademark of the American Medical Association.

REFERENCES:

32. Spinal Designs International. The Low Back Rehabilitation Program™. Outcomes Data System and Physician’s


**Policy History:**

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<tr>
<td>06/27/2013</td>
<td>Reviewed and approved by the Quality Improvement Advisory and Credentialing Council (QIACC).</td>
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<td>11/15/2013</td>
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| 07/01/2015 | Policy Update:  
  • Added applicable ICD-10 codes to the Coding Section. The list of codes may not be all-inclusive and does not denote coverage.  
  • Policy identification number updated to 2015M0027A. |