



Name of Policy:**Thoracic-Lumbo-Sacral Orthosis with Pneumatics**

Policy #: 006
Category: DME

Latest Review Date: January 2014
Policy Grade: C

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- 1. In accordance with generally accepted standards of medical practice; and*
- 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
- 3. Not primarily for the convenience of the patient, physician or other health care provider; and*
- 4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

Thoracic-lumbo-sacral orthosis (TLSO) with pneumatics consists of a vest with inflatable inserts. Inflation of these expandable inserts and pressure are controlled by the patient. The device is used to unload body weight from the spine onto the iliac crests.

A variety of back supports or braces are designed to offer stabilization and decompression as a conservative treatment for pain related to spinal disc disease and/or joint dysfunctions. For example, HCPCS codes L0450 through L0492 describe a variety of thoracic-lumbo-sacral orthoses (TLSO). An orthotic that includes a pneumatic component has become commercially available, the Orthotrac Pneumatic Vest™ (manufactured by Kinesis Medical, Minneapolis, MN). Orthofix, Inc. acquired Kinesis Medical in 2000.

The pneumatic component is inflated by the patient and is designed to lift the patient's body weight off the spine and relieve intervertebral compression. The orthotic is designed to be worn intermittently throughout the day.

Policy:

Effective for dates of service on or after December 12, 2012:

A thoracic-lumbo-sacral orthosis incorporating pneumatic inflation does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered investigational.

Effective for dates of service prior to December 12, 2012:

Lumbo-Sacral Orthosis with Pneumatics does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational** due to lack of sufficient published peer-reviewed literature to verify criteria.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The Orthofix Company submitted information on April 4, 2001 as a result of a request for the peer-review medical literature to verify efficacy of the Orthotrac™ Pneumatic Vest. The information submitted for review included specific product information and two reports. The first report written April 2000 was titled "Clinical Experience with the Orthotrac™ Pneumatic Vest Providing Ambulatory Spinal Decompression". This was a prospective trial, which examined 314 patients. They wore the vest for a minimum of 20-30 minutes, 2-3 times a day, 5-7 times a week for 4-8 weeks. Results were analyzed for up to an eight-week period of time for

conclusions stating the vest significantly improved overall health perception, physical and social function. (V. Loguidice, et.al)

The second publication submitted was also a report comparing a case study of six different orthopedic procedures for low back pain using MRI to assess ambulatory spinal decompression. This included a 30-year old white male who presented with three level degenerative disc disease at L3-L4, L4-L5 and L5-S1 who was tested using six different orthopedic products to assess the MRI exam and review the impact upon the spine. (“Comparative Case Study of Six Orthopedic Products for Low Back Pain, Using MRI to Assess Ambulatory Spinal Decompression”)

Dallolio reported on a case series of 41 patients with radicular back pain who were treated with an Orthotrac pneumatic lumbar vest, worn for 60 minutes for 3 times a day for 5 weeks. 72% of patients reported symptom improvement. However the lack of a control group limits scientific interpretation. Dallolio also concluded that further multicenter and interdisciplinary studies on a greater number of patients are obviously needed to confirm these preliminary results.

February 2007 Update

There is no new published peer-reviewed literature available to alter the policy statement.

February 2008 Update

Orthofix, Inc. has sponsored a randomized controlled trial comparing the Orthotrac Pneumatic Vest with an EZ form brace. The target enrollment was 150 patients who have been recently diagnosed with radiating leg pain from disc bulge, protrusion or herniation; the completion date with a 52-week follow-up is listed as September 2006. A preliminary report of patients (number unreported) completing the 12 week follow-up was presented in 2003. The patients, who were carefully selected to show relief from spine unloading, showed subjective improvements in lower back and leg pain that were 6-to 8-fold greater (5 to 7 points on a VAS scale) than observed in the group treated with the EZ brace. No recent updates or peer-reviewed publications have been identified. The evidence remains insufficient and the policy statement remains unchanged.

February 2009 Update

There are no new published peer-reviewed articles located that would alter the coverage statement of this policy.

February 2010 Update

A literature search was conducted and no new studies were identified related to the device. The policy statement remains unchanged.

November 2012 Update

The most recent literature search was performed for the period October 2011 through September 2012.

As with any therapy for pain, placebo-controlled trials are particularly important to document the extent of the expected placebo effect and to determine the independent contribution of the therapy itself. While the lack of published studies does not permit scientific conclusions about a pneumatic lumbar orthosis alone or in comparison to other types of back orthoses, it should be

noted that the literature regarding back braces and supports is, in general, of poor quality. A meta-analysis of lumbar support devices reported that there was limited evidence that lumbar supports are more effective than no treatment of low back pain and that it was unclear if lumbar supports are more effective than other interventions for treatment of low back pain.

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January 2014 Update

A literature search was conducted and no new studies were identified related to the device. The policy statement remains unchanged.

Summary

The absence of controlled studies of thoracic-lumbar-sacral orthosis with pneumatics precludes any conclusions regarding effectiveness for the treatment of low back pain.

Key Words:

Orthotrac™; pneumatic vest; ambulatory traction device, lumbo-sacral orthosis, pneumatics, Saunders Lumbar HomeTrac, Saunders Stx, ComforTrac, thoracic-lumbo-sacral orthosis with pneumatics, pneumatic orthosis

Approved by Governing Bodies:

On March 20, 1998, the FDA listed the Orthotrac™ Pneumatic Vest as a class 1 device. This classification does not require submission of clinical data regarding efficacy but only notification of the FDA prior to marketing

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply

FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.

Current Coding:

HCPCS: **E0830** Ambulatory traction device, all types, each

References:

1. Dallolio V. Lumbar spinal decompression with a pneumatic orthosis (Orthotrac): Preliminary study, Acta Neurochir Suppl 2005; 92: 133-7.
2. Loguidice, V. et al. Clinical experience with the Orthotrac™ Pneumatic Vest providing ambulatory spinal decompression, Orthotrac™ Corporation, April 2000.
3. Orthotrac™ Corporation. Comparative case study of six orthopedic products for low back pain, using MRI to assess ambulatory spinal decompression, March 1999, pp. 1-4.
4. Triano JJ, Rogers C, Diederich J. Discopathy with leg pain: a randomized controlled trial of Orthotrac vs EZ brace. Spine J 2003; 3(5):105-6.
5. Triano J. A randomized, controlled trial of treatment for disc herniation with radiating leg pain. Available online at: <http://www.clinicaltrials.gov/ct/show/NCT00220935> Last accessed January 2014.
6. Van Tulder M, Jellema P, van Poppel M et al. Lumbar supports for prevention and treatment of low back pain. Cochrane Database Syst Rev 2000;(3):CD001823.

Policy History:

Medical Review Committee, May 2001

Medical Policy Group, January 2003

Medical Policy Group, February 2004

Medical Policy Group, February 2006 **(1)**

Medical Policy Group, February 2007 **(1)**

Key Points updated, added new equipment to key words as not covered, February 2008 **(1)**

Medical Policy Group, February 2009 **(1)**

Medical Policy Group, February 2010 **(1)** No new studies identified

Medical Policy Group, February 2011 **(1)** Update to Key Points and References

Medical Policy Panel, November 2012

Medical Policy Group, November 2012 **(2)**: Added thoracic pneumatic orthoses to non-covered indications to policy. Title, Descriptions, Key Points, Key Words, and References updated to support policy statement

Medical Policy Administration, December 2012

Available for comment December 12, 2012 through January 26, 2013

Medical Policy Panel, November 2013

Medical Policy Group, January 2014 **(2)** Policy statement unchanged. No new studies identified in literature search.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.