



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Thoracic-Lumbo-Sacral Orthosis with Pneumatics

Policy # 00117

Original Effective Date: 08/26/2002

Current Effective Date: 05/22/2013

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers thoracic-lumbo-sacral orthosis incorporating pneumatic inflation to be **investigational**.*

Background/Overview

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 dysfunction. For example, HCPCS codes L0450 through L0492 describe a variety of TLSO. An orthotic that includes a pneumatic component has become commercially available, the Orthotrac Pneumatic Vest™† (manufactured by Kinesis Medical, Minneapolis, Minn.). 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

According to the manufacturer, the device is considered a Class I device by the FDA. This classification does not require submission of clinical data regarding efficacy but only notification of the FDA prior to marketing.

Rationale/Source

This policy was originally created in 2002 and was updated regularly with searches of the MEDLINE database. The most recent literature search was performed for the period January 2011 through September 2011. Following is a summary of the key literature to date.

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



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Thoracic-Lumbo-Sacral Orthosis with Pneumatics

Policy # 00117

Original Effective Date: 08/26/2002

Current Effective Date: 05/22/2013

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.

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 had been recently diagnosed with radiating leg pain from disc bulge, protrusion, or herniation. The study is listed as completed as of October 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 visual analogue scale) than observed in the group treated with the EZ brace. No further reports of this trial were found in literature searches through September 2011.

In 2005, 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, three times a day, for five weeks. A total of 72% of patients reported symptom improvement. However, the lack of a control group limits scientific interpretation.

Summary

The absence of controlled studies of thoracic-lumbo-sacral orthosis with pneumatics precludes any conclusions regarding effectiveness for the treatment of low back pain; the device is considered investigational.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Thoracic-Lumbo-Sacral Orthosis with Pneumatics", 1.03.03, 11:2012.
2. 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.
3. 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 September, 2011.
4. Triano J, 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. Dallolio V. Lumbar spinal decompression with a pneumatic orthosis (Orthotrac): preliminary study. *Acta Neurochir Suppl* 2005; 92:133-7.

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines (BCBSLAMPCG) are obtained from Current Procedural Terminology (CPT®)†, copyright 2012 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of

©2013 Blue Cross and Blue Shield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Thoracic-Lumbo-Sacral Orthosis with Pneumatics

Policy # 00117
 Original Effective Date: 08/26/2002
 Current Effective Date: 05/22/2013

Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No code
HCPCS	E0830
ICD-9 Diagnosis	All relevant diagnoses
ICD-9 Procedure	No code

Policy History

Original Effective Date: 08/26/2002
 Current Effective Date: 05/22/2013

06/20/2002 Medical Policy Committee review
 08/26/2002 Managed Care Advisory Council approval
 12/07/2004 Medical Director review
 12/14/2004 Medical Policy Committee review. Formal revision. Coverage eligibility unchanged.
 01/31/2005 Managed Care Advisory Council approval
 07/07/2006 Format revision including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
 05/02/2007 Medical Director review
 05/23/2007 Medical Policy Committee approval. Coverage eligibility unchanged. Additional information added to FDA and or other governmental regulatory approval and rationale/source.
 05/07/2009 Medical Director review
 05/20/2009 Medical Policy Committee approval. No change to coverage.
 06/03/2010 Medical Policy Committee approval
 06/16/2010 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
 05/05/2011 Medical Policy Committee review
 05/18/2011 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
 05/03/2012 Medical Policy Committee review
 05/16/2012 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
 05/02/2013 Medical Policy Committee review
 05/22/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
 Next Scheduled Review Date: 05/2014

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Thoracic-Lumbo-Sacral Orthosis with Pneumatics

Policy # 00117

Original Effective Date: 08/26/2002

Current Effective Date: 05/22/2013

of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.