BlueCross BlueShield
of Alabama

<u>Name of Blue Advantage Policy:</u>
Thoracic-Lumbo-Sacral Orthosis with Pneumatics

Policy #: 006
Latest Review Date: December 2021
Category: DME

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*

    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat a **thoracic-lumbo-sacral orthosis incorporating pneumatic inflation** as a **non-covered benefit** and as **investigational**.

Blue Advantage 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 Advantage administers benefits based on the members' contract and 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.

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.

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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, specifically off the lumbar spine. The orthotic is designed to be worn intermittently throughout the day.

KEY POINTS:

Literature review completed December 2021.

Summary of Evidence

The absence of controlled studies of thoracic-lumbar-sacral orthosis with pneumatics precludes any conclusions regarding effectiveness for the treatment of low back pain. The evidence is insufficient to determine the effects of the technology on health outcomes.

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.

CURRENT CODING:

HCPCS

E0830	Ambulatory traction device, all types, each

REFERENCES:

1. Dallolio V. Lumbar spinal decompression with a pneumatic orthesis (Orthotrac): Preliminary study, Acta Neurochir Suppl 2005; 92: 133-7. Accessed December 2020.
2. IOM (Institute of Medicine). 2011. Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press.
3. Loguidice, V. et al. Clinical experience with the Orthotrac™ Pneumatic Vest providing ambulatory spinal decompression, Orthotrac™ Corporation, April 2000.
4. 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. 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: //www.clinicaltrials.gov/ct/show/NCT00220935. 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.
6. 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.
7. 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:

Adopted for Blue Advantage, March 2005
Available for comment May 1-June 14, 2005
Medical Policy Group, February 2006
Medical Policy Group, February 2008
Medical Policy Group, February 2009
Medical Policy Group, February 2010
Medical Policy Group, February 2011
Medical Policy Group, November 2011
Medical Policy Group, November 2012
Available for comment December 12, 2012 through January 26, 2013
Medical Policy Group, January 2014
Medical Policy Group, June 2015
Medical Policy Group, June 2019
Medical Policy Group, December 2020
Medical Policy Group, November 2021: Reviewed by consensus. Updates to Key Points and References added. No new published peer-reviewed literature available that would alter the coverage statement in this policy.

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.