Protocol

Vertebral Axial Decompression

(80309)

Medical Benefit		**Effective Date**: 04/15/08	**Next Review Date**: 03/19
Preauthorization	No	**Review Dates**: 09/07, 09/08, 09/09, 05/10, 03/11, 03/12, 03/13, 03/14, 03/15, 03/16, 03/17, 03/18	

This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With chronic lumbar pain	Interventions of interest are: • Vertebral axial decompression	Comparators of interest are: • Standard conservative therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

Description

Vertebral axial decompression applies traction to the vertebral column to reduce intradiscal pressure and, in doing so, potentially relieves low back pain associated with herniated lumbar discs or degenerative lumbar disc disease.

Summary of Evidence

For individuals who have chronic lumbar pain who receive vertebral axial decompression, the evidence includes randomized controlled trials. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Evidence for the efficacy of vertebral axial decompression on health outcomes is limited. Because a placebo effect may be expected with any treatment that has pain relief as the principal outcome, RCTs with sham controls and validated outcome measures are required. The only sham-controlled randomized trial published to date did not show a benefit of vertebral axial decompression compared with the control group. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy

Vertebral axial decompression is considered **investigational**.

Background

Vertebral axial decompression (also referred to as mechanized spinal distraction therapy) is used as traction therapy to treat chronic low back pain. Specific devices available are described in the Regulatory Status section.

In general, during treatment, the patient wears a pelvic harness and lies prone on a specially equipped table. The table is slowly extended, and a distraction force is applied via the pelvic harness until the desired tension is reached, followed by a gradual decrease of the tension. The cyclic nature of the treatment allows the patient to withstand stronger distraction forces compared with static lumbar traction techniques. An individual session typically includes 15 cycles of tension, and 10 to 15 daily treatments may be administered.

Regulatory Status

Several devices used for vertebral axial decompression have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Devices include the VAX-D®, Decompression Reduction Stabilization (DRS®) System, Accu-SPINA® System, DRX-3000®, DRX9000®, SpineMED Decompression Table®, Antalgic-Trak®, Lordex® Traction Unit, and Triton® DTS. According to labeled indications from the FDA, vertebral axial decompression may be used as a treatment modality for patients with incapacitating low back pain and for decompression of the intervertebral discs and facet joints. FDA product code: ITH.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Schimmel JJ, de Kleuver M, Horsting PP, et al. No effect of traction in patients with low back pain: a single centre, single blind, randomized controlled trial of Intervertebral Differential Dynamics Therapy. Eur Spine J. Dec 2009; 18(12):1843-1850. PMID 19484433
2. Isner-Horobeti ME, Dufour SP, Schaeffer M, et al. High-force versus low-force lumbar traction in acute lumbar sciatica due to disc herniation: a preliminary randomized trial. J Manipulative Physiol Ther. Nov - Dec 2016; 39(9):645-654. PMID 27838140
3. Sherry E, Kitchener P, Smart R. A prospective randomized controlled study of VAX-D and TENS for the treatment of chronic low back pain. Neurol Res. Oct 2001; 23(7):780-784. PMID 11680522
4. Fritz JM, Lindsay W, Matheson JW, et al. Is there a subgroup of patients with low back pain likely to benefit from mechanical traction? Results of a randomized clinical trial and subgrouping analysis. Spine. 2007; 32(26):E793-800. PMID 18091473
5. Harte AA, Baxter GD, Gracey JH. The effectiveness of motorised lumbar traction in the management of LBP with lumbo sacral nerve root involvement: a feasibility study. BMC Musculoskelet Disord. 2007; 8:118. PMID 18047650

6. Centers for Medicare and Medicaid Services. National Coverage Decision for Vertebral Axial Decompression (VAX-D) (160.16). 1997; https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=124&ncdver=1&DocID=160.16&ncd_id=160.16&ncd_version=1&basket=ncd*3a%24160.16*3a%241*3a%24Vertebral+Axial+Decompression+(VAX-D)&bc=gAAAAAgAAAAAAA%3d%3d&. Accessed March 7, 2017.