Vertebral Axial Decompression

Policy # 00135
Original Effective Date: 08/06/2001
Current Effective Date: 08/09/2021

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 vertebral axial decompression to be **investigational.***

Background/Overview

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 FDA or Other Governmental Regulatory Approval 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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. Examples of these 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.

Rationale/Source

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 with chronic lumbar pain who receive vertebral axial decompression, the evidence includes randomized controlled trials (RCTs). 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, RCT s 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 that the technology results in an improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

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Medicare National Coverage
In 1997, Medicare issued a national noncoverage policy (160.16) for vertebral axial decompression.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in March 2021 did not identify any ongoing or unpublished trials that would likely influence this review.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Vertebral Axial Decompression", 8.03.09, May 2021.
2. Peloza J. Non-Surgical Treatments for Lower Back Pain. Spine-health. https://www.spine-health.com/conditions/lower-back-pain/non-surgical-treatments-lower-back-pain. Updated April 20, 2017.
3. 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): 1843-50. PMID 19484433
4. 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 2016; 39(9): 645-654. PMID 27838140
5. 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): 780-4. PMID 11680522
6. 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 (Phila Pa 1976). Dec 15 2007; 32(26): E793-800. PMID 18091473
7. 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. Nov 29 2007; 8: 118. PMID 18047650
8. Centers for Medicare & Medicaid Services. National Coverage Decision (NCD) for Vertebral Axial Decompression (VAX-D) (160.16). 1997; https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=124&KeyWord=vertebral%20axial%20decompress&KeyWordLookUp=Title&KeyWordSearchType=Exact&bc=CAAAAAAAAAAA.

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07/19/2001	Medical Policy Committee review
08/06/2001	Managed Care Advisory Council approval
07/15/2003	Medical Policy Committee review
08/25/2003	Managed Care Advisory Council approval
12/07/2004	Medical Director review
12/21/2004	Medical Policy Committee review. Format revision. No substance change to policy.
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.
04/04/2007	Medical Director review
04/18/2007	Medical Policy Committee approval. No change to coverage eligibility.
04/02/2009	Medical Director review
04/15/2009	Medical Policy Committee approval. No change to coverage eligibility.
04/08/2010	Medical Director review
04/21/2010	Medical Policy Committee approval. No change to coverage eligibility.
04/07/2011	Medical Policy Committee review
04/13/2011	Medical Policy Implementation Committee approval. No change to coverage eligibility.
04/12/2012	Medical Policy Committee review
04/25/2012	Medical Policy Implementation Committee approval. No change to coverage eligibility.
05/02/2013	Medical Policy Committee review
05/22/2013	Medical Policy Implementation Committee approval. No change to coverage eligibility.
08/07/2014	Medical Policy Committee review
08/20/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
12/03/2015	Medical Policy Committee review

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12/16/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/01/2016	Medical Policy Committee review
12/21/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
12/07/2017	Medical Policy Committee review
12/20/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/06/2018	Medical Policy Committee review
12/19/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/05/2019	Medical Policy Committee review
12/11/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/02/2020	Medical Policy Committee review
07/08/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/01/2021	Medical Policy Committee review
07/14/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 07/2022

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2020 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.

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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 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 codes
HCPCS	S9090
ICD-10 Diagnosis	All related diagnoses

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

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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: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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.