Anthem

Medical Policy

Subject: Mechanized Spinal Distraction Therapy
Document #: SURG.00008
Status: Reviewed

Publish Date: 09/27/2023
Last Review Date: 08/10/2023

Description/Scope

This document addresses the use of mechanized spinal distraction therapy. There are many devices currently available that are used for this therapy, including, but not limited to the Vertebral Axial Decompression (VAX-D®) Therapeutic Table, the Decompression Reduction Stabilization DRS® System and the Accu-Spina System™ IDD Therapy.

Position Statement

Investigational and Not Medically Necessary:

Use of mechanized spinal distraction therapy, including, but not limited to, the VAX-D® Therapeutic Table, the Decompression Reduction Stabilization DRS® System, and Accu-Spina System™ IDD Therapy, is considered **investigational and not medically necessary** for the treatment of low back pain or any other condition.

Rationale

Mechanized spinal distraction therapy has been proposed as a treatment for back pain. While large case series of the use of vertebral axial decompression in individuals with low back pain have reported improvements in pain, mobility and activity in the majority of study subjects, these studies were uncontrolled. For pain therapies, controlled studies are particularly relevant in order to eliminate the possibility of a significant placebo effect. Sherry and colleagues (2001) conducted a randomized trial comparing VAX-D with transcutaneous electrical nerve stimulation (TENS). While a 68% success rate was associated with VAX-D compared to a 0% success rate associated with TENS therapy, without a true placebo control the results are suspect. A more recent study by Beattie and associates evaluated the use of the VAX-D device on a case series of 296 individuals (2008). While this study reports significant benefits in terms of pain improvement and results on the Roland-Morris Disability Questionnaire (RMDQ), there are significant methodological flaws in the study, including lack of a control group and significant loss to follow-up (19.6% at 180 days). The authors of this study conclude, “Causal relationships between these outcomes and the intervention cannot be made. Further study is needed using randomized comparison groups.”

A small double-blind randomized clinical trial (RCT) involving 17 subjects with acute lumbar sciatica secondary to disc herniation was reported by Isner-Horobeti and colleagues (2016). Subjects were assigned to either high-force mechanical traction at 50% body weight (LT50, n=8) or to low force mechanical traction at 10% body weight (LT10, n=9). Treatment was applied to both groups for 10 sessions over a 2-week period. Study evaluations were undertaken at baseline and at 7, 14, and 28 days. Outcome measures included radicular pain as measured on a 10-point visual analogue scale (VAS), lumbo-pelvic-hip complex motion (finger-to-toe test), lumbar-spine mobility (Schöber-Macrae test), nerve root compression (straight-leg-raising test), disability (EIFEL score), drug consumption, and overall evaluation. The authors reported that significant ($p<0.05$) improvements were observed in the LT50 and LT10 groups, respectively, between day 0 and day 14 (end of treatment) for VAS (-44% and -36%, respectively), EIFEL score (-43% and -28%, respectively) and overall patient evaluation (+3.1 and +2.0 points, respectively). Additionally, between baseline and day 14, the LT50 group had additional improvements in the finger-to-toe test (-42%), the straight-leg-raising test (+58), and drug consumption (-50%). The treatment effect was found to be independent of medication levels. From day 14 through day 28, only the LT10 group improved ($p<0.05$) in VAS (-52%) and EIFEL scores (-46%). The authors reported that mechanical lumbar traction “reduced radicular pain and functional impairment and improved well-being regardless of the traction force group to which they were assigned.” While the results are promising, there are many methodological issues with this study, including small population, lack of a standard of care comparison group, and short duration of follow-up.

There is insufficient evidence in the peer-reviewed medical literature to support the use of any method of mechanized spinal distraction therapy for the treatment of back pain or other spine conditions. The few studies showing a semblance of efficacy have not demonstrated that mechanized spinal distraction therapy is as beneficial as any established alternative or leads to improved net health outcomes.

Background/Overview

Low back pain is a common problem affecting approximately 90% of adults in the United States at some point in their lives. Etiologies are related primarily to various musculoskeletal problems, mostly muscle strain and degenerative disease of the vertebral joints. Standard therapy includes use of analgesic medications, a balanced rest program, exercises, physical therapy, and ergonomic counseling. Alternative therapies include various forms of manipulation, massage, injections, traction, TENS, percutaneous electrical nerve stimulation, acupuncture, and other techniques. Selected cases may require surgical intervention to reduce pressure on nerves or the spinal cord.

Mechanized spinal distraction devices utilize computer controlled mechanical tables to apply distractive tension, or stretching, along the spinal axis. They are designed to provide gradual, controlled distraction along the spinal axis, based on the theory that reducing pressure in the intervertebral discs and/or intervertebral joint spaces will relieve back pain. There are several mechanized spinal distraction devices which have United States Food and Drug Administration (FDA) clearance to market through the FDA’s 510k process. These devices are proposed as nonoperative treatment options for the relief of back pain associated with disc protrusion, disc herniation, degenerative disc disease, facet syndrome, or radiculopathy. The devices are designed to apply static, intermittent, and cycling distraction tension forces to the spine and relieve pressure on structures that cause back pain.

During the therapy, the individual wears a pelvic harness and is positioned on a table which restricts torso movement in some fashion. Each end of the table is then slowly moved in opposing directions to apply a distraction force to the individual’s back. This is then followed by a gradual decrease of tension. The individual is subjected to several cycles of this distraction and release, which enables the individual to withstand stronger distraction forces compared to static spinal traction. Each session averages 30 minutes in duration and includes 15 decompression relaxation cycles. The number of sessions varies depending on the severity of underlying conditions

but typically involves one session each day for 20 days.

Definitions

Degenerative disc disease: A condition where intervertebral discs degenerate as a natural part of the aging process. The discs of some people degenerate much more quickly and profoundly than others.

Herniated disc: Sometimes referred to as a 'slipped', 'ruptured', or 'torn' disc. This occurs when the outer portion of the disc (annulus) weakens and allows the inner core (nucleus pulposus) to bulge out or extrude, sometimes compressing nearby nerve roots.

Spinal stenosis: A condition caused by the narrowing of the space in the spinal vertebrae that surrounds and protects the spinal cord. This condition may result in pressure on the spinal cord and/or nerve roots and may cause back pain as well as pain in the legs and or arms. This disorder is more common after the age of 50, although it can occur in younger people.

Spondylolisthesis: A condition in which a vertebra in the spine slips out of the proper position onto the vertebra below it, potentially causing nerve compression. There are three main types of spondylolisthesis: congenital, isthmic (resulting from stress fractures of spondylolysis) and degenerative, which is the most common cause. Traumatic, post-surgical, and pathological (osteoporosis, tumor) causes also occur, though less commonly.

Spondylolysis: A specific defect in the connection between vertebrae which results from weakness in the section of the facet joints called the pars interarticularis. It can lead to small stress fractures and is most common in people younger than 26 and often related to sports and hyperextension of the spine. Exact cause of the weakness is unknown.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure codes, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

97039	Unlisted modality [when specified as vertebral axial decompression] Note: there is no specific CPT code for spinal distraction therapy

HCPCS

S9090	Vertebral axial decompression, per session

ICD-10 Diagnosis

	All diagnoses

References

Peer Reviewed Publications:

1. Beattie PF, Nelson RM, Michener LA, et al. Outcomes after a prone lumbar traction protocol for patients with activity-limiting low back pain: a prospective case series study. Arch Phys Med Rehabil. 2008; 89(2):269-274.
2. Gose EE, Naguszewski WK, Naguszewski RK. Vertebral axial decompression therapy for pain associated with herniated or degenerated discs or facet syndrome: an outcome study. Neurol Res. 1998; 20(3):186-190.
3. 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. 2016; 39(9):645-654.
4. Naguszewski WK, Naguszewski RK, Gose EE. Dermatomal somatosensory evoked potential demonstration of nerve root decompression after VAX-D therapy. Neurol Res. 2001; 23(7):706-714.
5. Ramos G, Martin W. Effects of vertebral axial decompression on intradiscal pressure. J Neurosurg. 1994; 81(3):350-353.
6. Shealy CN, Borgmeyer V. Decompression, reduction, and stabilization of the lumbar spine: a cost-effective treatment for lumbosacral pain. Am J Pain Manage. 1997; 7(2):63-65.
7. 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. 2001; 23(7):780-784.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Agency for Healthcare Research and Quality. Decompression therapy for the treatment of lumbosacral pain. Technology Assessment Report. 2007 April. Available at: https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id47TA.pdf. Accessed on May 23, 2023.
2. Centers for Medicare and Medicaid Services. National Coverage Determination: Vertebral Axial Decompression (VAX-D). NCD #160.16. Effective April 15, 1997. Available at: http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd. Accessed on May 23, 2023.

Websites for Additional Information

1. National Institute of Neurological Disorders and Stroke. Back Pain Information Page. Last Modified March 8, 2023. Available at: https://www.ninds.nih.gov/health-information/disorders/back-pain?search-term=back%20pain. Accessed on May 23, 2023.

Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Description/Scope, Rationale and References sections.
Reviewed	08/11/2022	MPTAC review. Updated Rationale and References sections.
Reviewed	08/12/2021	MPTAC review. Updated Background/Overview, References, and Index sections.
Reviewed	08/13/2020	MPTAC review. Updated Rationale section.
Reviewed	08/22/2019	MPTAC review. Updated Rationale and Background/Overview sections.
Reviewed	09/13/2018	MPTAC review. Updated Description/Scope, Rationale, Background/Overview, and Index sections. Title changed.
Reviewed	11/02/2017	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Rationale and References sections.
Reviewed	11/03/2016	MPTAC review. Updated References section.
Reviewed	11/05/2015	MPTAC review. Removed ICD-9 codes from Coding section.
Reviewed	11/13/2014	MPTAC review.
Reviewed	11/14/2013	MPTAC review. Deleted device names from title.
Reviewed	11/08/2012	MPTAC review.
Reviewed	11/17/2011	MPTAC review.
Reviewed	11/18/2010	MPTAC review.
Reviewed	11/19/2009	MPTAC review.
Reviewed	11/20/2008	MPTAC review. Updated Index section.
Revised	11/29/2007	MPTAC review. Added “or any other condition” to investigational/not medically necessary section. The phrase “investigational/not medically necessary” was clarified to read “investigational and not medically necessary.” Updated rationale and Reference sections.
Reviewed	05/17/2007	MPTAC review. Updated Index section.
	11/29/2006	Added DRX9000 to index section.
Reviewed	06/08/2006	MPTAC review.
	11/22/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Revised	07/14/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.	06/16/2003	SURG.00008	Mechanized Spinal Distraction Therapy for Low Back Pain (VAX-D® Therapy, DRS® System)
WellPoint Health Networks, Inc.	04/28/2005	2.07.05	Vertebral Axial Decompression

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Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.