BlueCross BlueShield of Alabama

Name of Policy:
Vertebral Axial Decompression

Policy #: 484
Category: Therapy

Latest Review Date: October 2014
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

Vertebral axial decompression is a type of lumbar traction that has been investigated as a technique to reduce intradiscal pressure and relieve low back pain.

A pelvic harness is worn by the patient. The specially equipped table on which the patient lies 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 to static lumbar traction techniques. An individual session typically includes 16 cycles of tension, and 10 to 15 daily treatments may be administered. Devices include the VAX-D®, Decompression Reduction Stabilization (DRS®) System, Accu-Spina® System, DRX-3000®, DRX90000®, SpineMED Decompression Table®, Antalgic-Trak®, Lordex® Traction Unit, and Triton® DTS.

Policy:

Effective for dates of service on or after January 1, 2012:

Vertebral axial decompression does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational.**

Blue Cross and Blue Shield of Alabama 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 Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate 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.

Key Points:

Assessment of efficacy for therapeutic interventions involves a determination of whether the intervention improves health outcomes. The optimal study design for a therapeutic intervention is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes, but are prone to biases such as noncomparability of treatment groups, the placebo effect, and variable natural history of the condition. It is recognized that RCTs are extremely important to assess treatments of painful conditions and low back pain in particular, due to the expected placebo effect, the subjective nature of pain assessment in general, and the variable natural history of low back pain that often responds to conservative care.

A literature search through September 15, 2014 revealed a limited number of studies that evaluate patient outcomes associated with vertebral axial decompression. In addition, since a placebo effect may be expected with any treatment that has pain relief as the principal outcome,

randomized trials with validated outcome measures are required to determine if there is an independent effect of active treatment.

Randomized Controlled Trials
Results from a randomized sham-controlled trial of intervertebral axial decompression were published in 2009. Sixty subjects with chronic symptomatic lumbar disc degeneration or bulging disc with no radicular pain and no prior surgical treatment (dynamic stabilization, fusion, or disc replacement) were randomly assigned to a graded activity program with an AccuSPINA device (20 traction sessions during six weeks, reaching >50% body weight) or to a graded activity program with a nontherapeutic level of traction (<10% body weight). In addition to traction, the device provided massage, heat, blue relaxing light, and music during the treatment sessions. Neither patients nor evaluators were informed about the intervention received until after the 14-week follow-up assessment, and intention-to-treat analysis was performed (93% of subjects completed follow-up). Both groups showed improvements in validated outcome measures (visual analog scores for back and leg pain, Oswestry Disability Index, and Short-Form 36), with no differences between the treatment groups. For example, visual analog scores for low back pain decreased from 61 to 32 in the active group and from 53 to 36 in the sham group. Evidence from this recent randomized controlled trial does not support an improvement in health outcomes with vertebral axial decompression.

Sherry and colleagues conducted a randomized trial comparing vertebral axial decompression (using the VAX-D device) 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 difficult to interpret scientifically. In 2007, two small randomized trials (n=27, n=64) found little to no difference between patients treated with or without mechanical traction.

Nonrandomized Comparative Studies
In 2004, Ramos reported a nonrandomized comparison of patients receiving ten sessions versus 20 sessions of vertebral axial decompression treatment. Patients receiving 20 sessions had a response rate of 76% versus a 43% response in those receiving ten sessions. The study has several limitations and deficiencies; it is not randomized, the follow-up time is not stated, and it does not use a validated outcome measure.

Observational Studies
In 1998, Gose and colleagues reported on an uncontrolled case series of 778 patients. Although this study reported improvements in pain, mobility, and activity in the majority of patients, the study did not detail methods of patient identification or collection of data and did not indicate the duration of treatment success. Finally, the study was uncontrolled.

In a 1994 study of five patients, Ramos and Martin reported that intradiscal pressure decreased during the treatment period. Two case series in 2008 reported symptom improvement in patients with chronic low back pain. Due to limitations associated with observational studies of chronic pain, randomized controlled trials are needed to demonstrate efficacy of this treatment.

Summary of Evidence
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, randomized trials with 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. Therefore, treatment with vertebral axial decompression is considered investigational.

Practice Guidelines and Position Statements
No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations
Vertebral axial decompression is not a preventive service.

Key Words:
Vertebral axial decompression, VAX-D, Decompression Reduction Stabilization, System, DRS, Accu-Spina System, DRX-3000, DRX90000, DRX, SpineMED Decompression Table, Antalgic-Trak, Lordex Traction Unit, Triton DTS, Spina System, PDS, ActivTrac, Tru-Trac, Intervertebral Differential Dynamics Therapy

Approved by Governing Bodies:
Several devices used for vertebral axial decompression have received 510(k) marketing clearance from the FDA. According to labeled indications from the FDA, vertebral axial decompression may be used as a treatment modality for patients with incapacitation low back pain and for decompression of the intervertebral discs and facet joints.

Benefit Application:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply.
FEP: FEP does not consider investigational if FDA approved. Claims may be reviewed for medical necessity.
Pre-certification requirements: Not applicable.

Current Coding:
The following CPT code should* NOT *be used to bill for vertebral axial decompression.

CPT Codes:	**97012**	Application of a modality to one or more areas; traction, mechanical

The correct* HCPCS *code should be used to bill for vertebral axial decompression.

HCPCS Codes:	**S9090**	Vertebral axial decompression, per session

References:

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):269-74.
2. 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. Spin 20-07; 32(26):E793-800.
3. 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):186-90.
4. Harte AA, Baster GD, Gracey JH. The effectiveness of motorized lumbar traction in the management of LBP with lumbo sacral nerve root involvement: a feasibility study. BMC Musculoskelet Disord 2007; 8:118.
5. Macario A, Richmond C, Auster M et al. Treatment of 94 outpatients with chronic discogenic low back pain with the DRX9000: a retrospective chart review. Pain Pract 2008; 8(1):11-7.
6. Ramos G. Efficacy of vertebral axial decompression on chronic low back pain: study of dosage regimen. Neurol Res 2004; 26(3):320-4.
7. Ramos G, Martin W. Effects of vertebral axial decompression on intradiscal pressure. J Neurosurg 1994; 81(3):350-3.
8. 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 2009; 18(12)1843-50.
9. 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):780-4.

Policy History:

Medical Policy Panel, October 2011
Medical Policy Group, October 2011 **(2):** New policy
Medical Policy Administration Committee, October 2011
Available for comment October 19 through December 31, 2011
Medial Policy Panel, October 2012
Medical Policy Group, October 2012 **(2):** Literature search through August 2012. Policy unchanged.
Medical Policy Panel, October 2013
Medical Policy Group, December 2013 **(2):** Literature search through August 2013. Policy statement unchanged.
Medical Policy Panel, October 2014
Medical Policy Group, October 2014 **(3)**: 2014 Updates to Description & Key Points; no change in policy statement

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.