Vertebral Axial Decompression

Policy #  00135
Original Effective Date:  08/06/2001
Current Effective Date:  12/16/2015

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 is a type of lumbar traction that has been investigated as a technique to reduce intradiscal pressure and relieve low back pain associated with herniated lumbar discs or degenerative lumbar disc disease.

Vertebral axial decompression is a type of lumbar traction in which 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 15 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®‡, DRX9000®‡, SpineMED Decompression Table®‡, Antalgic-Trak®‡, Lordex®‡ Traction Unit, and Triton®‡ DTS.

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
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 incapacitating low back pain and for decompression of the intervertebral discs and facet joints.

Centers for Medicare and Medicaid Services (CMS)
Medicare has issued a national non-coverage policy for vertebral axial decompression.

Rationale/Source
This policy has been updated periodically using the MEDLINE® database. The most recent literature review was performed through September 15, 2014.

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.

The literature searches for this policy have identified a limited number of studies that evaluated patient outcomes associated with vertebral axial decompression. In addition, 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 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 6 weeks, reaching >50% body weight) or to a graded activity program with a non-therapeutic 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, 2 small randomized trials (n=27, n=64) found little to no difference between patients treated with or without mechanical traction.

Non-randomized Comparative Studies
In 2004, Ramos reported a nonrandomized comparison of patients receiving 10 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 10 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 5 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.

Ongoing and Unpublished Clinical Trials
An online search of www.ClinicalTrials.gov did not identify ongoing clinical trials related to vertebral axial decompression.

Summary
Evidence for the efficacy of vertebral axial decompression on health outcomes is limited. 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. The only sham-controlled randomized trial published to date did not show a benefit of vertebral axial decompression compared to the control group. Therefore, treatment with vertebral axial decompression is considered investigational.

References
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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
12/16/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 12/2016

Coding
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<td>ICD-9 Diagnosis</td>
<td>All related diagnoses</td>
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*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. 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:
   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.

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