APPENDIX to Vertebral Axial Decompression Policy

Prior Authorization Requirements

This service (or procedure) is considered **investigational** in all instances. If you would like to submit additional information please forward to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

Evidence Basis for the Policy

Rationale

A search of the MEDLINE database through October 2011 revealed a limited number of studies evaluating patient outcomes associated with vertebral axial decompression.

In a 1994 study of five patients, Ramos and Martin reported that intradiscal pressure decreased during the treatment period. In 1998, Gose and colleagues reported 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.

Sherry and colleagues (2001) reported 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 were difficult to interpret scientifically.

Ramos (2004) conducted 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 rate in those receiving 10 sessions. The study had

several limitations and deficiencies; it was not randomized, the follow-up time was not stated, and it did not use a validated outcome measure.

A study by Jurecki-Tiller et al., (2007) located in a technology assessment by the Agency for Health Care Research and Quality concluded:

> Currently available evidence is too limited in quality and quantity to allow for the formulation of evidence-based conclusions regarding the efficacy of decompression therapy as a therapy for chronic back pain when compared with other non-surgical treatment options. Of the studies examined for assessment of efficacy, neither included patients over 65 years of age. Adverse event reporting for decompression therapy is infrequent. There was one case report of an enlargement of an existing disc protrusion, and other studies reported worsening of pain in some patients.

A search of the MEDLINE database was conducted through May 2008. The literature indicated continued interest in vertebral axial decompression as a treatment of low back pain. Two small randomized trials (n = 27 and 64) found little to no difference between patients treated with or without mechanical traction (Harte et al., 2007; Fritz et al., 2007). Two recent case series reported symptom improvement in patients with chronic low back pain (Macario al., 2008; Beattie et al., 2008). Due to limitations associated with observational studies of chronic pain, randomized controlled trials were needed to demonstrate efficacy of this treatment. The available scientific evidence did not permit conclusions concerning the effect of this procedure on health outcomes.

2011 Update

Results from a randomized sham-controlled trial of intervertebral axial decompression were published in 2009 (Schimmel et al., 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 (North American Medical Corporation, Marietta, GA) (20 traction sessions during six 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.

A separate study by Apfel et al., (2010) included a six-week treatment for patients with low back pain utilizing the DRX9000™ (Axiom Worldwide, Inc., Tampa, FL). Thirty patients with an average age of 65 participated in the study and received prior and post computerized tomography scans. The study concluded:

> We were able to demonstrate an association between the restoration of disc height and pain relief. The correlation of these variables suggests that pain reduction may be mediated, at least in part, through a restoration of disc height. These results call for a randomized placebo-controlled trial to substantiate the efficacy and elucidate the mechanism of this promising treatment modality.

In 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 to determine if there is an independent effect of active treatment. 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.

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. 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.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement Policy

Type	Number	Description
CPT	None	
HCPC	S9090	Vertebral axial decompression, per session
ICD9 Procedure	None	
ICD9	All Diagnoses	

Type	Number	Description
Diagnosis		
Place of Service	All Places of Service	

Tables

N/A

Definitions

N/A

Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

N/A

Key / Related Searchable Words

- Decompression Reduction Stabilization (DRS) System
- DRX-3000
- SpineMED Decompression Table
- Antalgic-Trak
- Lordex Traction Unit
- Triton DTS

References

- Apfel CC, Cakmakkaya O, Martin W et al. Restoration of disk height through non-surgical spinal decompression is associated with decreased discogenic low back pain: a retrospective cohort study. Bio Medical Centers: Musculoskeletal Disorders. 2010. Retrieved September 26, 2011 from http://www.biomedcentral.com/1471-2474/11/155#IDAALGRO.
- 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.
- Blue Cross Blue Shield Association. Medical Policy Reference Manual, No. 8.03.09 (October 2011).
- 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.

- 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.
- 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.
- Jurecki-Tiller M, Bruening W, Tregear S et al. Agency for Healthcare Research and Quality. Decompression therapy for the treatment of lumbosacral pain. 2007, April 26.
- 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.
- Ramos G, Martin W. Effects of vertebral axial decompression on intradiscal pressure. J Neurosurg. 1994; 81(3):350-3.
- Ramos G. Efficacy of vertebral axial decompression on chronic low back pain: study of dosage regimen. Neurol Res. 2004; 26(3):320-4.
- 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 Dec; (12):1843-50.
- 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

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
6/28/2007	New Policy Adoption	Medical Policy Committee
4/3/2009	BCBSA Medical Policy adoption	Medical Policy Committee
1/6/2012	Policy revision without position change	Medical Policy Committee

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

Click here to view the policy statement for this policy

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