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# Kansas City

## Vertebral Axial Decompression

**Policy Number:** 8.03.09

**Last Review:** 11/2013

**Origination:** 11/2005

**Next Review:** 11/2014

### **Policy**

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Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for vertebral axial decompression. This is considered investigational.

### **When Policy Topic is covered**

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Not Applicable

### **When Policy Topic is not covered**

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Vertebral axial decompression is considered **investigational**.

### **Description of Procedure or Service**

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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.

### **Background**

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.

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.

### **Regulatory Status**

Several devices used for vertebral axial decompression have received 510(k) marketing clearance from the U.S. Food and Drug Administration (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.

### **Rationale**

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This policy has been updated periodically using the MEDLINE® database, with the most recent literature update performed through August 22, 2013. These literature searches have identified a limited number of studies that evaluated 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.

## Literature Review

Randomized Controlled Trials. Results from a randomized sham-controlled trial of intervertebral axial decompression were published in 2009. 1) 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). (2) 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. (3, 4)

Non-randomized Comparative Studies. In 2004, Ramos reported a nonrandomized comparison of patients receiving 10 sessions versus 20 sessions of vertebral axial decompression treatment. 5) 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. 6) 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. (7) Two case series in 2008 reported symptom improvement in patients with chronic low back pain. (8, 9) Due to limitations associated with observational studies of chronic pain, randomized controlled trials are needed to demonstrate efficacy of this treatment.

## 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.

## Medical National Coverage

Medicare has issued a national non-coverage policy for vertebral axial decompression. (10)

## References

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#### **Billing Coding/Physician Documentation Information**

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<b>64722</b>	Decompression; unspecified nerve(s) (specify)
<b>97012</b>	Application of a modality to one or more areas; traction, mechanical
<b>S9090</b>	Vertebral axial decompression, per session

#### **Additional Policy Key Words**

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IDD

#### **Policy Implementation/Update Information**

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11/1/05	New policy added to the medical section.
11/1/06	No policy statement changes.
11/1/07	No policy statement changes.
11/1/08	No policy statement changes.
11/1/09	No policy statement changes.
11/1/10	No policy statement changes.
11/1/11	No policy statement changes.
11/1/12	No policy statement changes.
11/1/13	No policy statement changes.

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