



**Kaiser Foundation Health Plan  
of Washington**

**Clinical Review Criteria  
Vertebral Axial Decompression (VAX-D System)**

- Internal Disc Decompression (IDD)
- Spinal System Therapy
- Traction, Spine

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**Criteria**

**For Medicare Members**

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	<a href="#">National Coverage Determination (NCD) for Vertebral Axial Decompression (VAX-D) (160.16)</a> <i>This service is not covered per Medicare criteria.</i>
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

**For Non-Medicare Members**

Kaiser Permanente has elected to use the Traction, Spine (A-0345) MCG\* for medical necessity determinations. This service is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

\*The MCG manuals are proprietary and cannot be published and/or distributed. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

**If requesting this service, please send the following documentation to support medical necessity:**

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

**Background**

Chronic lower back pain is a major health problem and cause of disability in Western countries. The cause of the persistent pain is not well understood for the majority of patients. It generally occurs without specific damage or signs that can be revealed by imaging or other neurophysiological techniques. It is believed that the pain starts as acute pain of muscle and connective tissue and persists among approximately one third of the patients (Rittweger 2002). Mechanical low back pain may have various causes including degenerative disc disease, degenerative spondylosis, disc herniation, facet arthropathy, and others. Patients with low back pain may also experience reduced lumbar flexibility, reduced flexion-relaxation and static balance. The pain is aggravated by sitting, standing and lifting, which increase axial loading on the spine. Walking may relieve some of the pain, but patients experience more relief by lying down as it unloads the spine and reduces intradiscal pressure (Gose 1998).

Conservative medical care for chronic back pain includes bed rest, steroid injection, anti-inflammatory drugs, muscle relaxants, conventional physiotherapy, exercises, stretching, manipulative techniques, ultrasound treatments, electric stimulation techniques and others. These measures ease the pain for some patients but are ineffective, intolerable, or unsuitable for others. Patients not responding to conservative therapy may be offered conventional or percutaneous surgical procedures such as disc space decompression, epidural blocks, and spinal instrumentation. These interventions play an important role in treating patients with low back pain due to herniated disc and degenerative disc problems. However, surgery may not relieve all the pain, and could permanently disrupt the biomechanical and physiological function of the disc. Moreover, not all patients are candidates for surgery.

Some researchers have found that lumbar traction, if adequately applied, may alleviate many of the conditions that cause low back pain. Conventional traction involves simple mechanical stretch which when applied continuously, or by certain techniques, may lead to paravertebral muscle recruitment and increase the intradiscal pressure (Ramos 1994). This observation led to the continuous development of devices and equipment that would achieve decompression of the lumbar discs at a force that the patients can tolerate without stimulating the reactive reflexes of the lumbar musculature (Gose 1998), i.e. without an increase in the resistance to the applied force.

Several systems for vertebral axial decompression have been introduced including the VAX-D equipment, and the Decompression Reduction Stabilization (DRS) System later developed to the Spina System then the Accu-spina Logic System. According the manufacturer's web site, the latter system provides lumbar decompression, cervical decompression, and high-tension oscillation all in one machine, which is also certified to administer IDD therapy treatments.

The VAX-D applies distraction tensions to the patient's lumbar spine in order to non-surgically decompress the spine and intervertebral discs. The patient lies prone on the VAX table that has a split design and is restrained by holding on to adjustable handgrips with the arms extended above the head to stabilize the shoulder girdle and upper body. Patients are allowed to release the handgrips at any time during the treatment. The upper body lies over a stationary portion, and a special harness designed to apply forces to the lateral pelvic alae is fitted and tightened around the patient and connected to a tensionometer at the caudal end of the table. The distraction- relaxation cycles are automated, and continuous feedback from the tensionometer is captured on a chart printout, which allows the operator to constantly monitor the patient. The therapy consists of an average of 20 sessions comprising 15 cycles of decompression and relaxation. The cycles are characterized by one minute of distraction and one minute of relaxation. The therapeutic range of tension is 50-95 pounds, which is reduced by 10-15 pounds when the patients are asymptomatic, or the symptoms have reached a plateau. The investigators of this technology indicate it for patients with low-back pain associated with herniated discs, or degenerative disc disease, and contraindicate it for patients with cauda equine syndrome, infection, tumor severe osteoporosis, fractures, bilateral pars defect, spondylolisthesis Grade 2, and the presence of surgical hardware (Ramos 2004).

The Spina IDD System is also a non-invasive procedure that provides static intermittent and cyclic distraction forces to relieve the pressure on structures causing chronic neck or lower back pain. The system consists of a table split into two cushions, and a controller unit. The patient is anchored by means of a pelvic harness to the traction connector for the prescribed period of time. The therapy is provided in 20 treatment sessions over a period of 35 days. Each session lasts for approximately 30 minutes.

Both the VAX-D System and the Spina System were cleared by the FDA as Class II Medical devices 510 (k). The technology is being reviewed based on requests for coverage of the Internal Disc Compression Therapy.

## Medical Technology Assessment Committee(MTAC)

### *Internal Disc Decompression Therapy in the Treatment of Pain from Spinal Disc Problems*

#### **06/09/1999: MTAC REVIEW**

**Evidence Conclusion:** The published scientific evidence reporting clinical outcomes from VaxD treatment consists of a case series of 778 patients diagnosed with herniated or degenerated lumbar discs or facet syndrome. This study reports improvements in pain, mobility, activity and satisfaction following treatment. The validity of these results are uninterpretable however because no statistical analysis was reported and no information on the length and completeness of patient follow up was presented. Another small retrospective case series of 17 patients reports some changes in sensory nerve function as measured by a Current Perception Threshold neurometer following VaxD but the relationship between these changes and clinical improvement is unclear. The published evidence is not sufficient to determine if the benefits of Vax-D outweigh the harms of treatment. No studies which compare benefits and harms of Vax-D to the natural history of disc related low back pain have been published. Data from the large case series was obtained from 22 medical centers in the US. However, a lack of statistical analysis of this data

does not permit conclusions to be made regarding the effect of Vax-D on back pain. The best published evidence is insufficient to demonstrate that Vax-D is effective and therefore Vax-D does not represent an efficient use of healthcare resources.

**Articles:** Gose, EA, et al, Neurological Research, 1998, 20:186-190 See [Evidence Table](#).

The use of internal disc decompression therapy in the treatment of pain from spinal disc problems does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

## 02/06/2006: MTAC REVIEW

### Internal Disc Decompression Therapy in the Treatment of Pain from Spinal Disc Problems

**Evidence Conclusion:** The literature search did not reveal any published studies on the IDD Therapy or the Spina System. The latter received FDA Clearance, in July 2000 based on its equivalence to the vertebral axial decompression device (VAX-D). There was one randomized trial and few case series published on the VAX-D. The RCT and a large series were critically reviewed. Sherry et al randomized 44 patients, 18-65 years old, with chronic low-back pain to receive either vertebral axial decompression (VAX-D) or transcutaneous electrical nerve stimulation (TENS) therapy. The primary outcome was the difference in proportion of successfully treated patients in the two treatment groups. Success of treatment was defined as 50% decrease in pain on the visual analogue scale and improvement in disability. The trial was small, poorly randomized, un-blinded, and had a high dropout rate. The authors did not conduct an intention to treat analysis but calculated their results on data for patients who completed therapy and follow-up, and concluded that VAX-D therapy was associated with a significant reduction in pain and disability. They compared the therapy to TENS, which seems to have a negative effect. A recent Cochrane Systematic Review (Khadiolkar 2005) of published RCTs evaluating the effect of TENS on lower back pain, showed that the efficacy of TENS therapy was limited and inconsistent. Gose et al, reported the results of 778 patients with low back pain who had received at least 10 sessions of VAX-D therapy in 22 centers in the USA. The primary outcome was reduction in pain, improvement in mobility, ability to walk and sit, and patient satisfaction with the treatment. The study was only observational and had no control or comparison group. Moreover, all outcomes were subjective, and apparently there was no extended follow-up after the end of treatment. Overall, the results show that the treatment was successful among 71% of cases, with treatment success defined as a reduction in pain to 0 or 1 on a 0-5 scale. In conclusion, the current literature does not provide sufficient evidence to recommend the use of the VAX-D therapy, or the Spina System for the management of chronic low back pain. Larger, multi-center randomized controlled trials are needed to determine the effectiveness and long-term net health outcomes of the therapy. The published scientific evidence reporting clinical outcomes from VaxD treatment consists of a case series of 778 patients diagnosed with herniated or degenerated lumbar discs or facet syndrome. This study reports improvements in pain, mobility, activity and satisfaction following treatment. The validity of these results is uninterpretable however because no statistical analysis was reported and no information on the length and completeness of patient follow up was presented. Another small retrospective case series of 17 patients reports some changes in sensory nerve function as measured by a Current Perception Threshold neurometer following VaxD but the relationship between these changes and clinical improvement is unclear.

**Articles:** The search yielded 20 articles several of which were not related to the devices. Four studies on the vertebral axial decompression therapy using the VAX-D device were identified. One was an RCT comparing it to TENS, and the other three were case series with patient sizes varying from 5 to 778 patients. The RCT and the largest case series were selected for critical appraisal. No articles on the Spina System were identified. *The following articles were critically appraised:* Sherry E, Kitchener P, and Smart R. A prospective randomized controlled study of VAX-D and TENS for the treatment of chronic low back pain. *Neurol Res* 2001; 53:780-784. [See Evidence Table](#). Gose EE, Naguszewski WK, and Naguszewski RK. Vertebral axis decompression therapy for pain associated with herniated or degenerated discs or facet syndrome: An outcome study. *Neurol Res* 1998; 20:186-190. [See Evidence Table](#).

The use of internal disc decompression therapy in the treatment of pain from spinal disc problems does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

## Applicable Codes

### Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
S9090	Vertebral axial decompression, per session

**\*Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

\*\*To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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Date Created	Date Reviewed	Date Last Revised
12/1998	04/04/2011 <sup>MDCRPC</sup> , 02/07/2012 <sup>MDCRPC</sup> , 12/04/2012 <sup>MDCRPC</sup> , 10/01/2013 <sup>MPC</sup> , 08/05/2014 <sup>MPC</sup> , 06/02/2015 <sup>MPC</sup> , 04/05/2016 <sup>MPC</sup> , 02/07/2017 <sup>MPC</sup> , 12/05/2017 <sup>MPC</sup> , 11/06/2018 <sup>MPC</sup> , 11/05/2019 <sup>MPC</sup> , 11/03/2020 <sup>MPC</sup> , 11/02/2021 <sup>MPC</sup> , 11/01/2022 <sup>MPC</sup> , 11/07/2023 <sup>MPC</sup>	08/05/2014

<sup>MDCRPC</sup> Medical Director Clinical Review and Policy Committee  
<sup>MPC</sup> Medical Policy Committee

Revision History	Description