VAX-D (Vertebral axial decompression) therapy for chronic low back pain:
Legal Definitions under US Law and the issue of Experimental/Investigational Status

Released June 1, 2005

The vertebral axial decompression (VAX-D) system is a specialized treatment table and computer console designed to apply distractive tension along the spine to decompress herniated or degenerated intervertebral discs, and to alleviate pain and neurological deficits associated with nerve root compression. Indications for the VAX-D are patients with low back pain (Quebec 1,2, or 3) due to disc disease who have not responded appropriately to standard medical therapy.

The question as to the legal and regulatory status of *VAX-D Therapy*® has been asked by providers and third party payors. The therapy has previously been categorized as being *Experimental and Investigational* in nature. This review will provide accurate information about the procedure and it's regulatory status under state and national guidelines.

A recent landmark class action lawsuit against a number of managed care companies (including CIGNA Corporation, Humana, Inc.; Aetna, Inc., Aetna-USHC, Inc.; United Health Care; United Health Group; Prudential Insurance Company of America; Coventry Health Care, Inc.; Health Net, Inc. Humana HealthPlan, Inc.; Pacificare Health Systems, Inc.; Wellpoint Health Networks Inc.; and Anthem Inc.) concluded that these companies engaged in a conspiracy to improperly deny and delay claims, in whole or in part, and/or reduce payment to physicians based upon improper use of definitions of *Experimental and Investigational* status of treatments.

Under the settlement, future questions of medical necessity for services will be decided by the physician and the healthcare companies will use the Food and Drug Administration and the National Institutes of Health definitions of what is considered Experimental and Investigational. The court has determined that the recognized definitions are as follows:

Medically Necessary or **Medical Necessity:** Medically Necessary or Medical Necessity shall mean healthcare services or supplies that a Physician, exercising prudent clinical judgment would provide to a patient for the purpose of evaluation, diagnosing or treating an illness, injury, disease or its symptoms that are:
(a) in accordance with generally accepted standards of medial practice
(b) clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease; and
(c) not primarily for the convenience of the patient or Physician, or other Physician, and 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 patients illness, injury or disease.

For these purposes "generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations, the views of Physicians practicing in relevant clinical areas and any other relevant factors.

Experimental or Investigational Status: The court also enforced the payment of claims that were submitted and denied, in whole or in part, on the grounds that the services or supplies delivered to the healthcare member concerned were determined by the healthcare company to be either Experimental or Investigational in nature, where experimental and investigational shall mean service or supplies that, at the time of delivery to the member were:
(a) neither approved by the U.S. Food and Drug Administration ("FDA") to be lawfully marketed for the use to which they were put, not recognized for the treatment of the particular indication involved in one of the standard reference compendia or in scientific studies published in peer-reviewed national professional medical journals; or
(b) under review of the use to which they were put by an Institutional Review Board of similar entity at a licensed and accredited in-patient facility at which such services or supplies were or were intended to be delivered; or

(c) the subject of an ongoing clinical trial that meets the definition of a Phase I, Phase II or Phase III Clinical Trial as set forth in FDA regulations, regardless of whether the trial is subject to FDA oversight; or (d) not demonstrated, through then existing peer-reviewed literature to be safe and effective for treating or diagnosing the condition or illness for which they were used.

VAX-D Therapy qualifies as a medically necessary procedure under current law and under all of the above definitions; and cannot be qualified as an Experimental or Investigational treatment by managed healthcare companies.

In a letter to Congress in 2004, The Assistant Commissioner for Legislation, Department of Health and Human Services, U.S. Food and Drug Administration recently wrote:

"The VAX-D Therapeutic Table is classified as a Class II device under Title 21, Code of Federal Regulations 890.5900, with the following Intended Use:

The VAX-D Therapeutic Table is designed to relieve pressure on structures that may be causing low back pain. It relieves the pain associated with herniated discs, degenerative disc disease, posterior facet syndrome and radicular pain. It achieves these effects through decompression of intervertebral discs, that is, unloading, due to distraction and positioning.

FDA considers any *other use* as *experimental,* however, FDA does not limit or interfere with the authority of a healthcare practitioner to prescribe or administer any legally marketed device to a patient, for any condition or disease, within the confines of a legitimate health care practitioner-patient relationship. The treatment is not considered *Experimental and Investigational* if used in accordance with its Intended Use.

Clinical trials using unapproved medical (Experimental and Investigational) devices on human subjects are performed under an Investigational Device exemption (IDE)."

History of 'Decompression Therapy' as a recognized treatment: The *'decompression of intervertebral discs'* was initially deemed a 'new Intended Use' by the FDA for the VAX-D Therapeutic Table in 1995. At that time the product literature that identified this use was recalled by manufacturer. The FDA then cleared the device for the new intended use in 1996 and cleared under 510(k) K951622. The device does not have an investigational status.

DETERMINATION OF THE OFFICIAL STATUS OF VAX-D THERAPY

State and national guidelines (developed by the Institute of Medicine, National Library of Medicine, RAND Corporation and the AMA) set out a definition of "evidenced-based" and "peer-reviewed" to mean "based, at a minimum, on a systematic review of literature published in medical journals. Systematic reviews of the literature are standard and essential features of an evidence-based guideline development process, as reflected by the fact that they are required by the National Guidelines Clearinghouse and are included in various guideline-assessment methodologies (AGREE 2001, National Guidelines Clearinghouse 2004)." "Nationally recognized," was taken to mean any one of the following: 1. Accepted by the National Guidelines Clearinghouse; 2. Published in a peer-reviewed medical journal(s); developed, endorsed, or disseminated by an organization based in two or more U.S. states; currently used by one or more U.S state governments; 3. Or in wide use in two or more U.S. States."

REVIEW OF LITERATURE AND EVIDENCE OF VAX-D THERAPY

A systematic review of the published literature was completed to identify relevant studies and reviews. Searches were conducted using the Medline (1966 – May 1, 2005), EMBASE (1980 – May 1, 2005) and HealthSTAR (1975 to May 1, 2005) online databases via Ovid. All available evidence on VAX-D was assessed and classified according to the hierarchy of evidence set out below:

Designation of levels of evidence
I Evidence obtained from a systematic review of all relevant randomized controlled trials
II Evidence obtained from at least one properly designed randomized controlled trial
III-1 Evidence obtained from well-designed pseudo-randomized controlled trials (alternate allocation or some other method)
-2 Evidence obtained from comparative studies with concurrent controls and allocation not randomized (cohort studies), case–control studies or interrupted time series with a control group
-3 Evidence obtained from comparative studies with historical control, two or more single-arm studies or interrupted time series without a parallel control group
IV Evidence obtained from case–series, either post-test or pre-test and post-test

Source: NHMRC, National Health and Medical Research Council, A guide to the development, implementation and evaluation of clinical practice guidelines. NHMRC, 1999. The following peer-reviewed published studies were found:

1. Short And Long-Term Outcomes Following Treatment with the VAX-D Protocol for Patients with Chronic, Activity Limiting Low Back Pain
Beattie PF., Nelson R., Michener L., Cammaratta J., Donely J.
Journal of Orthopaedic & Sports Physical Therapy, Volume 35, Number 1, January 2005

One hundred and eighteen patients treated with the VAX-D Therapy protocol were examined for pain reduction and activity modifications at end of treatment, at thirty (30) days and at one hundred and eighty days (180), using the Roland Morris Questionnaire methods. All subjects exhibited radiological evidence of herniated intervertebral disc at one or more levels, and had significant pain that was refractory to at least two previous non-operative procedures. Statistically significant improvements in pain and activity scores were recorded at short and long term follow-up. This study provides evidence that the VAX-D protocol is associated with improvements in pain and activity-limitation in a sample of patients with unfavorable prognosis for recovery from chronic activity-limiting low back pain.

2. Efficacy of Vertebral Axial Decompression (VAX-D) on Chronic Low Back Pain: A Study of Dosage Regimen
Ramos G., MD,
Journal of Neurological Research, Volume 26, April 2004

Prospective study comparing one group of patients who received an average course of treatment consisting of 18 daily sessions and another group received half that number. Seventy-six percent of the higher dosage group achieved remission of low back pain compared to forty-three percent of the lower dosage group. Chi-square analysis revealed that the differences in response in the two dosage groups were statistically significant at a $P < .0001$.

3. Effects of Vertebral Axial Decompression On Intradiscal Pressure.
Ramos G., MD, Martin W., MD,
Journal of Neurosurgery 81: 350-353, 1994

The results of this prospective study indicate that it is possible to lower pressure in the nucleus pulposus of herniated lumbar discs to levels significantly below 0 mm Hg when distraction tension is applied according to the VAX-D protocol.

4. A Prospective Randomized Controlled Study of VAX-D and TENS for the Treatment of Chronic Low Back Pain
Sherry E., MD FRACS, Kitchener P., MB, BS FRANZCR, Smart R., MB, Ch.B
Journal of Neurological Research Volume 23, No 7, October 2001

A prospective comparison of VAX-D therapy with TENS for low back pain with associated leg pain caused by lumbar disc herniation. Statistical analysis established that the success rate with VAX-D was significantly higher than the control group. At the end of VAX-D therapy 68% (15/22) of patients were successfully treated, and six months after VAX-D therapy was completed the success rate was 27%

(6/22). No patients were successfully treated with the TENS protocol.

5. Vertebral Axial Decompression Therapy for Pain Associated with Herniated or Degenerated Discs or Facet Syndrome: An Outcome Study
Gose E., Ph.D, Naguszewski W., MD, Naguszewski R., MD,
Journal of Neurological Research, Volume 20, No 3, April 1998.

Retrospective before-and-after comparison of VAX-D therapy in 778 patients with herniated or degenerated disc or facet syndrome with or without leg pain. At the end of VAX-D therapy 72% (437/611) of herniated patients, 72% (106/147) of degenerative disc patients, and 68% (13/19) facet syndrome patients were successfully treated.

6. Dermatosomal Somatosensory Evoked Potential Demonstration of Nerve Root Decompression After VAX-D Therapy
Naguszewski W., MD, Naguszewski R., MD, Gose E., Ph.D
Journal of Neurological Research Vol 23, No 7, October 2001

This study demonstrated that patients suffering from chronic low back pain and radiculopathy had multiple nerve root abnormalities based on abnormal DSSEPs, many of which would not be predicted radiographically. Successful treatment by VAX-D therapy resulted in clinical reduction in pain and improved DSSEP waveforms suggesting that nerve root decompression is occurring at multiple levels.

7. The Effects of Vertebral Axial Decompression On Sensory Nerve Dysfunction In Patients with Low Back Pain and Radiculopathy
Tilaro F., MD, Miskovich D. MD
Canadian Journal of Clinical Medicine Vol. 6, No 1, January 1999

Retrospective before-and-after comparison of VAX-D therapy in patients with radiculopathy. The results after therapy were as follows: 14/22 nerves (64%) returned to normal function, 6/22 (27%) improved, 1/22 (4.5%) had no improvement and 1/22 (4.5%) showed deterioration. The average neurometer grade before therapy was 6.36 and after therapy 2.09 (a score of zero indicates normal function). Overall improvement was 67% ($p<0.05$).

8. An Overview of Vertebral Axial Decompression
Tilaro F., MD
Canadian Journal of Clinical Medicine Vol. 5, No 1, January 1998

Research review of several VAX-D studies (published, unpublished and in-progress).

9. VAX-D Reduces Chronic Discogenic Low Back Pain- 4 year Study
Odell R., MD. Ph.D, Boudreau D. DO
Anesthesiology News, Volume 29, Number 3 , March 2003

Retrospective before-and-after comparison of VAX-D therapy in patients with acute and chronic pain with herniated or degenerated disc with or without leg pain. Four years after a single course of VAX-D therapy the response rate was 56% (ie, 19/34 patients who received treatment had >50% improvement in VAS pain score). Of the 23 patients who responded, 52% had a pain level of zero, 91% were able to resume their normal daily activities, and 87% were either working or were retired without having back pain as the cause for retirement.'

In addition to the above, the following study has been found and is pending publication:

10. An Industry Based, Retrospective, Cost Analysis of Vertebral Axial Decompression (VAX-D) VS. Surgery For Lumbar Disc Disease: 10 Case Studies
David C. Duncan, MD, Don Keenan, SPHR, Ph.D.
Sinclair Oil Corporation Study, Tulsa Oklahoma

This study demonstrated cost benefits to oil refinery employees while maintaining an overall competitive health care package; reducing pain, suffering, and absenteeism. The "costs" data for this paper was derived from a five (5) year study involving 10 employee case files from a small petrochemical refinery.

Overall, it appears that VAX-D therapy provides symptomatic relief from chronic lumbar back pain and nerve root compression. There has been one prospective randomized controlled trial on VAX-D that is classified as level II evidence. The remaining evidence relating to VAX-D therapy is from non-randomized studies level III-2, and from case–series studies which correspond to level IV evidence.

EVIDENCE OF U.S. STATE / GOVERNMENT TREATMENT APPROVAL

As noted in the definition of a "Nationally Recognized" service, an example demonstrative of U.S. State Government authorization of VAX-D treatment (and payment schedule) is as follows: Alaska Medicaid has sent a notification to all outpatient therapy providers regarding revisions to the Alaska Medical Payment System, published on June 9, 2000 that applies to VAX-D Treatment for Medicaid patients in that State. First Health Service Corporation is the billing service agency for the State of Alaska. Not only has a unique code been officially designated for VAX-D Therapy, but also a reasonable reimbursement rate has been established (calculated using the RBRVS) that reflects the current rate being charged in other states.

Prior authorization is not required. The number of treatment sessions depends on the professional judgment and expertise of the practitioner.

VAX-D also qualifies a 'National Recognized' treatment (by definition) as it is currently in use in the following U.S. States (must be utilized in 2 or more states):

Alabama	Kansas	New York	Washington
Alaska	Kentucky	Ohio	Wisconsin
Arizona	Louisiana	Oklahoma	
California	Maryland	Pennsylvania	
Connecticut	Michigan	Rhode Island	
Florida	Minnesota	South Carolina	
Georgia	Mississippi	North Carolina	
Hawaii	Missouri	Tennessee	
Illinois	Nevada	Texas	
Indiana	New Jersey	Utah	

The determination that VAX-D treatment for chronic low back pain is not 'Experimental and Investigational' has been made utilizing the recognized evidence discussed:

1. Department of Health and Human Services, U.S. Food and Drug Administration position is that VAX-D therapy is not considered Experimental and Investigational.

2. A comprehensive review of the literature reveals that clinical studies with recognized levels of evidence have been published in peer-reviewed medical journals as proof that VAX-D is a valid treatment for low back pain.

3. VAX-D qualifies as being 'Nationally Recognized' under current U.S. guidelines.

4. VAX-D is currently used by one U.S state government(s).

5. VAX-D is in wide use in thirty-two or more U.S. states.

The majority of VAX-D services are now being provided by medical specialists (68% of clinics) in the following fields: Neurological Surgery, Orthopedic Surgery, Anesthesia and Pain Management, Physiatry, and Occupational Medicine. Many of the orthopedic and pain management physicians in the VAX-D community have treated thousands of difficult back pain patients using this methodology with success rates paralleling those in the published research.

This Status explanation applies only to VAX-D tables manufactured by VAX-D Medical Technologies, LLC. VAX-D's device utilizes a unique and patented logarithmic curve and has not licensed the technology to any other firm claiming "equivalency" under an FDA 510K.

Given the VAX-D Studies and Research listed above, versus the body of research indicating that static or cycling traction is ineffective, a careful review of "equivalent" device's mechanism of action is in order, and in particular, a review of published research that was conducted using that manufacturer's device.