Nonsurgical Spinal Decompression Therapy

Policy Statement

Optum* by OptumHealth Care Solutions, LLC considers nonsurgical spinal decompression therapy to be unproven due to insufficient scientific evidence of efficacy in the treatment of neck, low back and related disorders. This includes any motorized mechanical traction device that is promoted as providing “decompression therapy” e.g., VAX-D, IDD System, DRS, DRX-9000, Accu-Spina, Lordex, Triton-DTS, 3D Active Trac, SRT Decompression Table (Spinal Rejuvenation Table), etc.

Purpose

This policy has been developed as the clinical criterion that describes the position of Optum regarding the efficacy, risks and burdens associated with the use of motorized traction devices for nonsurgical spinal decompression therapy.

Key Policy Questions

1. Is there sufficient research evidence of the efficacy and safety of nonsurgical spinal decompression therapy for the sustained reduction of pain and disability to conclude this intervention is an appropriate therapeutic alternative for a specific patient population?
2. Is there a reasonable expectation that health plan members, who undergo the treatment protocol commonly described in scientific literature for nonsurgical spinal decompression therapy, will not be subjected to significant burdens i.e., frequency/duration, administrative requirements, ease of delivery, costs, etc.?
Summary

This policy has been developed following a structured review of the scientific literature, an assessment of information readily available to health plan members i.e., advertisements, website information and promotional material, and a review of professional and legal documents topical to nonsurgical spinal decompression therapy.

The research evidence concerning nonsurgical spinal decompression therapy is sparse and of very low quality. Any estimate of treatment effect is uncertain. The trade-offs between benefits, and risks and burdens are unclear. It is not clear whether nonsurgical spinal decompression therapy does more good than the burdens placed on health plan members.

There are significant burdens placed upon health plan members due to high out-of-pocket costs, time allocation (frequency and duration) for the in-office delivery of services, and the unsubstantiated/misleading advertisements about the proven effectiveness and safety of nonsurgical spinal decompression therapy. These burdens have been recognized as significant by some professional licensing boards and state justice departments.

Similar conclusions have been reached by a broad range of health care organizations. Professionals and groups, who are proponents of nonsurgical spinal decompression therapy, should pursue further investigation using experimental study designs and rigorous methodologies.

Scope

The application of this policy is limited to those services best described by HCPCS code S9090 - Vertebral Axial Decompression, per session.[1] This code applies to any motorized mechanical traction device promoted as providing decompression therapy.[15] Other decompression therapy devices are viewed as substantially similar to VAX-D. The approach taken is this is a type of therapy not a particular device or brand. [Table 1]

Description

Nonsurgical spinal decompression therapy refers to the use of a device granted FDA 510(k) approval as “equipment, powered traction” to administer a treatment protocol that is centered around a form of intermittent mechanical traction, which consists of a specialized table and computer designed to apply variable force, variable traction/relaxation times, and variable angles of pull (in some devices), to produce distractive tension along the axis of the spine.[2,3]
Background

Introduction
Traction as a treatment option for low back pain and sciatica has existed for many years. Its use has progressed from continuous static traction to intermittent motorized traction. “The most recent incarnation of traction has been a form of intermittent motorized traction commonly referred to as spinal decompression therapy. Developers and manufacturers of the equipment along with clinicians often consider it to be a unique form of traction.”[2]

Proponents of nonsurgical spinal decompression therapy claim it to be a safe and effective alternative to surgical interventions. (see “Websites Accessed” in References section) “A perusal of any trade publication aimed at manual therapy professions will demonstrate intense marketing programs extolling the virtues of this new technology. An 86% success rate is claimed by many manufacturers and passed on to the consumer through individual practitioner's advertising.”[2]

Therapeutic Effect
VAX-D, a spinal decompression motorized traction device, secured 510(k) clearance from the FDA after demonstrating that it was substantially similar to a predicate device (a pelvic traction unit that was marketed prior to implementation of the Medical Device Amendment of 1976). [10] FDA 510(k) clearance does not require evidence of effectiveness in the form of clinical trials prior to registration and marketing.

Proponents of nonsurgical spinal decompression therapy (NSSDT) assert this form of traction is; however, unique for being proven able to reduce the relative pressure measured within intervertebral discs (decompression). [4-6] The evidence typically cited to support this claim is from a study by Ramos, 1994.[7]

An evaluation of this study shows the conclusions are based upon data from only three subjects. These data have been viewed with skepticism by Nachemson, a leading expert in the field of intradiscal pressure measurement. He noted a number of methodological flaws likely to invalidate the results. These included not using a closed transducer system, not taking into account temperature effects, absent hydrostatic conditions (in degenerative discs), and no attempt reported to calibrate negative readings.[8-10]

Even if these flaws were absent, this study is not sufficient to arrive at conclusions about the translation of basic science research into clinical care settings. The author (Ramos) concluded additional study is needed to establish the relationship of negative intradiscal pressures with clinical outcomes. [7]

There were no studies identified that directly compared the effectiveness of NSSDT with surgical interventions. The trend in evidence; however, tends to favor surgery over prolonged conservative treatment in the short-term. Outcomes appear to be similar for all interventions, when considering long-term results (1-2 years) [11-13]

Indirect comparisons of VAX-D therapy with a six week course of physiotherapy and with discectomy were reported in a 2001 technology assessment.[14] At 6 months and 1 year VAX-D therapy provided nominally poorer outcomes compared to physiotherapy. Discectomy had more than twice the response rate at 6 months and 1 year compared to VAX-D therapy outcomes.

The same technology assessment concluded that, “… NSAIDs provide greater relief from pain when compared to the natural course of injury/disease [low back]. There is also sufficient evidence to conclude that physical manipulation is effective in relieving chronic non-specific low back pain. In contrast, there is no evidence regarding the effectiveness of VAX-D therapy in these patients.”[14]
**Patient Selection**
There is a consensus on the general indications for NSSDT. Bulging/herniated discs, degenerated discs, facet syndrome and sciatica are conditions typically mentioned in promotional material and websites. Beyond these basic indications NSSDT has been reported by various sources as clinically indicated for a broader range of conditions. [Table 2] Some of these conditions represent vague or diagnostically elusive entities. Most of these conditions lack any good quality research evidence on the predictive value of NSSDT, appropriate dose and safety.

**Treatment Protocol**
The treatment protocols recommended by device manufacturers range from 15-20 sessions @ 25-45 minutes per session.[15] Additional services may be incorporated as part of a standard treatment approach i.e., thermal applications, electrical stimulation, manual therapy, and active therapeutic procedures.

The published frequency of sessions and duration of care are variable. Daily treatment sessions were scheduled in separate studies by Shealy and Ramos.[16,17] A number of studies evaluated did not describe the precise scheduled frequency and/or duration of the care program.[18-21]

There was only a single study that sought to assess for a dose-response effect.[17] The validity and confidence in this study were confounded by very serious methodological flaws (lack of baseline characteristics, unstated selection criteria for group assignment, probability of attention bias, timing of follow-up varied by group, and no long-term follow-up) and an absence of clinical significance reporting within the study results.

**Literature Review**
A structured literature search and qualitative review using a broadly adopted appraisal methodology, Grading of Recommendations, Assessment, Development and Evaluation (GRADE), was conducted by a clinical work group.[22] Biomedical databases searched included Medline and Mantis. Consumer search engines (Google, Yahoo, etc.), hand-searched documents, non-indexed documents and texts were included in the search strategy. Randomized controlled trials (RCT), cohort and case series studies were subjected to formal quality appraisal. Two RCTs, one cohort and eight case series were identified for quality profiling. [Table 3] Case studies and opinion papers were not included in the formal quality appraisal. [Table 4]

*Pain* (a critical outcome variable) was assessed in nine of the eleven studies that were formally evaluated. [Table 5] The other critical outcome variable, *Disability*, was assessed in six of the eleven studies. **All of these studies were rated as being of “Very Low” (any estimate of effect is very uncertain) quality.** [Table 6]

All of the studies presented with serious or very serious methodological limitations. Common limitations included the unorthodox use of validated outcome instruments (e.g., using a only a single component of the ten section Oswestry Questionnaire), the use of nonstandard and unvalidated outcome measures, lack of baseline subject data, lack of assessor blinding, use of co-interventions, insufficient follow-up and failure to include all subjects in analyses.

The confidence in the results of all of the studies was decreased due to varying degrees of sparse and/or imprecise data i.e., small study populations, statistical and/or clinical significance of results not calculated, and follow-up data not reported. None of the studies discussed the occurrence of adverse events.

Most of the studies demonstrated either inconsistency in the direction of effect and/or directness. Important inconsistencies included results where an expected placebo effect in the control group did not occur, and when outcome variables (pain, disability, ADL) did not fully correlate with imaging (MRI) or physiologic testing (SSEP). The directness of several studies was considered to be uncertain when the critical outcomes

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(pain, disability) were not explicitly measured i.e., neural tissue tension signs measured via a pain scale, or disability measured via self-report of functional capacity.

The overall quality rating was also impacted by a general lack of rigorous statistical analysis. Clinically significant results were identified in only four of eleven studies. The magnitude of treatment effect was not calculated in any relevant study.

The probability of reporting bias is another factor in determining a quality rating of the evidence. Confidence in the estimates of effects of four of the eleven studies was decreased due to a reasonable probability of publication bias i.e., study author was a shareholder in a company that delivers the intervention, or the study was published without undergoing any peer-review process.

Consequently, the strength of recommendation upon which the policy statement is based is termed “weak” due to the lack of quality evidence and uncertainty about the balance of benefits vs. risks and burdens. Further research may have an important impact in the confidence in the estimate of effect and may change this policy. [Table 7]

**What are the Conclusions of Others?**

In addition to the work group’s review of the scientific literature, seven review articles and technology assessments conducted by others were identified. [Table 8] The conclusions of these reviews parallel the current literature appraisal findings. Spinal decompression therapy is of unproved efficacy due to insufficient evidence, methodological problems and inconsistent results.

CMS Medicare policy does not provide coverage for nonsurgical spinal decompression traction devices.[23] The Centers for Medicare & Medicaid Services recently requested that the Agency for Healthcare Research and Quality (AHRQ) commission an evidence-based technology assessment to assist in updating the 1997 national coverage policy. The AHRQ report, “Decompression Therapy for the Treatment of Lumbosacral Pain” concluded the current evidence regarding the efficacy of decompression therapy is too limited in quality and quantity to allow for evidence-based conclusions. Adverse event reporting for decompression therapy was viewed as infrequent.[24]

Other health care organizations have evaluated the evidence-basis for nonsurgical spinal decompression therapy and adopted policies and position statements. [Table 9] The definitive trend in the policies of health care organizations is that nonsurgical spinal decompression therapy is unproven, investigational and experimental.

**Burdens and Risks**

**Safety:**

“Detailed evidence on the safety and complication rates of the VAX-D table is lacking.”[14] None of the studies evaluated by the work group reported on the occurrence or non-occurrence of adverse events. A single case report of a sudden, severe exacerbation of radicular pain during a VAX-D therapy session is the only published literature describing a complication with NSSDT.[25] While causality cannot be determined by a case report, the fact that symptoms dramatically worsened during the treatment session suggests the NSSDT was the proximate cause of the patient’s deterioration. The association between therapy and exacerbation is further strengthened by the before/after MRI studies, which showed a marked progression of the previously imaged disc herniation.

**Cost:**

There were no formal cost-analyses of NSSDT found in published literature. The cost of a typical treatment protocol (20 sessions) for NSSDT reportedly ranges from $4,000 to $5,000.[10,26] The cost of a single NSSDT session in 1998 had been estimated to range from $175 to $215.[10] In contrast, motorized mechanical traction per session costs typically fall into the $10 to $20 range.

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Malter et al (1996) concluded that for carefully selected patients with herniated discs, surgical discectomy is a cost-effective treatment when compared to ongoing conservative medical treatment.[27] The Medical Services Advisory Committee (2001) used this evidence to conclude that it is likely discectomy is more cost-effective than VAX-D therapy for patients with herniated discs, who are suited for surgery {since VAX-D therapy is no better (and may be worse) than standard conservative treatment}.[14]

It is likely and reasonable to anticipate patients’ expectations that services rendered by participating healthcare providers will be covered by their insurance.[15] Since most carriers do not cover this service, health plan members bear the full burden of costs. In some instances, health plan members report having to pay up to $3,500 up front before receiving treatment.[15,28]

There is anecdotal information found on website blogs that corroborates assertions of adverse events, anxiety about costs, up-front payment requirements, unexpected debt, and undue pressure to continue treatment sessions.[29]

Consumer Marketing:
Advertising claims concerning NSSDT have been the subject of several state licensing boards. The some of the wording in advertisements to both the public and health care practitioners has been deemed unfair, deceptive and misleading. The Alabama State Board of Chiropractic Examiners specifically reminded practitioners to “be very careful” when making claims about Decompression Therapy.[30] Similarly, the Maryland Board of Chiropractic Examiners specifically cited Spinal Decompression units when reminding health care providers, “…that their advertisements do not violate aforementioned advertising regulations.”[31] The Minnesota Board of Chiropractic Examiners, while not taking a formal position, has posted a notice on its website concerning a number of inquiries received about decompression therapy.[32]

After soliciting information and conducting an internal review of NSSDT the Oregon Board of Chiropractic Examiners adopted five additional policy statements regarding advertising of nonsurgical spinal decompression therapy in May 2007.[33,34] These policies require that advertising claims must be supported by credible evidence, meet statutory standards when implying or claiming ‘superiority’ of treatment, appropriately contrast NSSDT with other kinds of chiropractic treatment (not just drugs or surgery), and avoid misbranding or misleading statements regarding the term “FDA approved”. [34]

Concerns about misleading and unsubstantiated advertising have been the subject of at least two investigations by state attorney generals. After admitting he could not substantiate advertising claims directed at the public, a chiropractor was found guilty of false advertising in a California State Superior Court ruling.[35] The Oregon Department of Justice recently filed a settlement agreement to resolve allegations of deceptive advertisements used by Oregon chiropractors.[36] The news release from the attorney general, Hardy Meyers, reminds consumers to, “…be wary of unrealistic health claims that lack adequate substantiation; even those made by Oregon medical professionals.”

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Coded Information

Note: The Current Procedural Terminology (CPT) codes listed in this policy may not be all inclusive and are for reference purposes only. The listing of a service code in this policy does not imply that the service described by the code is a covered or non-covered health service. Coverage is determined by the member’s benefit document.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S9090</td>
<td>Vertebral Axial Decompression, per session; {most accurately describes services for the application of spinal decompression motorized traction devices}</td>
</tr>
<tr>
<td>64722</td>
<td>Decompression; unspecified nerves {a surgical code}</td>
</tr>
<tr>
<td>97012</td>
<td>Application of a modality, traction, mechanical</td>
</tr>
<tr>
<td>90901</td>
<td>Biofeedback training by any modality</td>
</tr>
<tr>
<td>97112</td>
<td>Therapeutic procedure, one or more areas, each 15 minutes</td>
</tr>
<tr>
<td>97530</td>
<td>Therapeutic activities, direct (one-on-one) patient contact by provider</td>
</tr>
<tr>
<td>97140</td>
<td>Manual therapy techniques, each 15 minutes</td>
</tr>
</tbody>
</table>

References

2. Daniel DW. Non-surgical spinal decompression therapy: does the scientific literature support efficacy claims made in the advertising media? *Chiropractic & Osteopathy* 2007; 15:7; [http://www.chiroandosteo.com/content/15/1/7](http://www.chiroandosteo.com/content/15/1/7)

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15. Vogenitz W. Special investigative report: Misleading coding advice causes financial troubles, liabilities for unsuspecting anesthesia, pain offices. *Anesthesia & Pain Coder’s Pink Sheet* 2005; December: Rockville, MD


20. Gose EE, et al. Vertebral axial decompression therapy for pain associated with herniated or degenerated discs or facet syndrome: An outcome study *Neurological Research* 1998;20:186-190


28. Internal communication records. *OptumHealth Care Solutions, Inc.*


32. Decompression Therapy. *Minnesota Board of Chiropractic Examiners*, Fall/Winter 2006: [http://www.chiroboard.state.mn.us/newsletter%202006%20Fall%20winter.pdf](http://www.chiroboard.state.mn.us/newsletter%202006%20Fall%20winter.pdf)


35. People v. Tony L. Hoang Chiropractic Inc. - Civil Complaint. Case No. M79192; Final Judgment May 5, 2006: *Superior Court of the State of California in the County of Monterey*: [http://www.mm-chiroboard.state.mn.us/Forms/Decompression%20Therapy%20Court%20Case.pdf](http://www.mm-chiroboard.state.mn.us/Forms/Decompression%20Therapy%20Court%20Case.pdf)

Quality-Reviewed Studies

- Eyerman EL. MRI evidence of nonsurgical, mechanical reduction, rehydration and repair of the herniated lumbar disc. (Also published as, “Simple pelvic traction gives inconsistent relief to herniated disc suffers”) *Journal of Neurological Imaging* 1998;8(2)
- Gose EE, et al. Vertebral axial decompression therapy for pain associated with herniated or degenerated discs or facet syndrome: An outcome study *Neurological Research* 1998;20:186-190

Websites Accessed

http://www.vaxd.com/
http://www.vaxd.net/index.html
https://axiomworldwide.com/DRX9000.aspx
http://www.iddtherapy.com/
http://www.spinaprogram.com/howitworks.html
http://www.444disc.com/
http://www.thediscover.com/
http://www.orthopedictechreview.com/issues/mayjun05/pg08.htm
http://www.spinaldecompressiontherapy.com/
http://www.cerhealthsciences.com/?gclid=CMHm19j3vY0CFRImWAod-GbvLQ
http://www.healthquest.lcdtherapy.com/
http://www.dunskyrehab.com/
http://www.american спинал.com/
http://www.vaxd.com/Pages/ClinicalResearch/StudiesPublications.html
http://www.medspinecare.com/Newsletter.aspx
http://www.disc-ease.info/table.html

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Review Articles & Technology Assessments

- Daniel DW. Non-surgical spinal decompression therapy: does the scientific literature support efficacy claims made in the advertising media? *Chiropractic & Osteopathy* 2007; 15:7; [http://www.chiroandosteo.com/content/15/1/7](http://www.chiroandosteo.com/content/15/1/7)

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Table 6: Summary of Quality Assessment of Studies (Disability)
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### What are the Coding Policies/Positions of Other Organizations?  
**Table 1**

<table>
<thead>
<tr>
<th>Organization</th>
<th>Coding Requirements</th>
<th>Devices Represented by Coding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centers for Medicare and Medicaid Services (CMS)</td>
<td>97799 (Unlisted physical medicine / rehabilitation service or procedure) with GY* modifier; and enter “VAX-D” in box 19 of claim form</td>
<td>VAX-D, MedX, Spina System, DRS System</td>
</tr>
<tr>
<td>AmeriHealth</td>
<td>S9090</td>
<td>VAX-D, DRS System, 3D Active Trac</td>
</tr>
<tr>
<td>Blue Cross and Blue Shield of North Carolina</td>
<td>S9090</td>
<td>VAX-D, DRX 9000, DRS System</td>
</tr>
<tr>
<td>CIGNA HealthCare</td>
<td>S9090</td>
<td>VAX-D, Lordex, DRX, DRX 2000, Tru Trac 401, DRX 3000, DRX 5000, DRX 9000, SpineRx LDM</td>
</tr>
<tr>
<td>UnitedHealthcare / Oxford</td>
<td>S9090</td>
<td>IDD Therapy, VAX-D, Accu-Spina System, DRS System</td>
</tr>
<tr>
<td>Blue Cross and Blue Shield of Tennessee</td>
<td>S9090</td>
<td>VAX-D</td>
</tr>
<tr>
<td>CIGNA/Medicare</td>
<td>97012 + GY modifier</td>
<td>Accu-Spina Device, DRS, DRX 9000, IDD Therapy</td>
</tr>
<tr>
<td>Blue Cross and Blue Shield of Wisconsin</td>
<td>S9090</td>
<td>VAX-D, Lordex, SpineMed</td>
</tr>
<tr>
<td>Regence</td>
<td>S9090</td>
<td>VAX-D, IDD Therapy, Accu-Spina System, DRS, Spine Med</td>
</tr>
<tr>
<td>Independence Blue Cross</td>
<td>S9090</td>
<td>3D ActiveTrac, VAX-D, DRS System</td>
</tr>
<tr>
<td>Humana</td>
<td>S9090</td>
<td>DRX 9000, Spina System, VAX-D, Lordex</td>
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Conditions for which spinal decompression therapy has been recommended

Table 2

<table>
<thead>
<tr>
<th>Conditions</th>
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</thead>
<tbody>
<tr>
<td>Bulging or herniated discs</td>
</tr>
<tr>
<td>Degenerative disc disease</td>
</tr>
<tr>
<td>Posterior facet syndrome</td>
</tr>
<tr>
<td>Sciatica</td>
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<tr>
<td>Acute or chronic back pain</td>
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<tr>
<td>Low back pain due to disc disease for patients who have not responded</td>
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<tr>
<td>appropriately to standard medical therapy</td>
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<tr>
<td>Neuromusculoskeletal conditions not suited for surgery but who have</td>
</tr>
<tr>
<td>reached maximum medical improvement with conservative therapies</td>
</tr>
<tr>
<td>Subligamentous disc hernias</td>
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<tr>
<td>Facet arthrosis</td>
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<tr>
<td>Lumbar radiculopathy</td>
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<tr>
<td>Foraminal stenosis</td>
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<tr>
<td>Extruded herniated discs</td>
</tr>
<tr>
<td>Decreased spinal mobility</td>
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<tr>
<td>Neck and shoulder pain</td>
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<tr>
<td>Low back pain</td>
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<tr>
<td>Other afflictions associated with back and neck pain</td>
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<tr>
<td>Arthritis</td>
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<tr>
<td>Spinal Stenosis</td>
</tr>
<tr>
<td>Failed Back Surgery/Post Surgical Pain Syndrome</td>
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<tr>
<td>Low back pain and/or leg pain/numbness</td>
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<tr>
<td>Neck pain and/or arm pain/numbness</td>
</tr>
</tbody>
</table>

Recommendations obtained from literature review and survey of websites
(see references section of policy document)
## Clinical Studies Meeting Selection Criteria for Quality Appraisal  
### Table 3

<table>
<thead>
<tr>
<th>Author</th>
<th>Date</th>
<th>Study Design</th>
<th>Population and Setting</th>
<th>Interventions &amp; Schedule</th>
<th>Outcome Variables</th>
<th>Follow-up Assessments</th>
</tr>
</thead>
</table>
| Shealy (1997)   |            | Randomized Controlled Trial | • 39 adult subjects  
• 23 with ruptured discs documented by MRI  
• Symptoms <1 year  
• With and without sciatica  
• 16 diagnosed with facet arthrosis  
• Symptoms >1 year  
• With and without sciatica | Experimental Group:  
• Decompression (DRS System)  
• Ice pack  
• EMS [20 daily treatments; 30 minutes each]  
• TENS [At home during awake hours]  
• Supervised exercise [3 sessions]  
Control Group:  
• Mechanical traction using same schedule and co-interventions as the experimental group | Patient self-report of pain relief:  
• Excellent  
• Good  
• Poor | Re-evaluation 5-8 weeks after entering program |
| Sherry (2001)   |            | Randomized Controlled Trial | • 44 subjects  
• 18 - 65 years  
• Symptoms > 3 months duration  
• LBP with leg pain  
• Herniated or protruded disc confirmed by MRI or CT scan  
• Multi-clinic settings | Experimental Group:  
• Decompression (VAX-D) Therapy [24 treatments over eight weeks; 30 minutes each]  
Control Group:  
• TENS using same schedule as the experimental group | Pain: Visual Analogue Scale (VAS)  
Disability: Self-nominated rating scale (1 to 4) | Re-evaluation performed at end of treatment program.  
Successfully treated patients to be f/u 6 months after treatment (not reported in this study) |
| Ramos (2004)    |            | Cohort                | • 142 subjects  
• 15 - 76 years  
• Average symptom duration = 10 months  
• Discogenic disorder confirmed by MRI or CT scan  
• Private medical clinic  
• Patients referred for neurosurgical evaluation | Decompression (VAX-D) Therapy  
• Group I = 20 daily sessions  
• Group II = 10 daily sessions [30-45 minutes per session] | Pain: 0 to 10 scale  
ADL: 0 to 5 scale  
Disability: return to work | Re-evaluation performed at end of treatment program. |
| Eyerman (1998)  |            | Case Series           | • 20 subjects  
• 26 - 74 years  
• Lumbar radiculopathy confirmed by clinical exam and EMG  
• Received at least 4 weeks of nonsurgical treatment  
• Setting: not described | Decompression (DRS System)  
• 18 patients received 20 sessions over 4-5 weeks  
• 2 patients received 40 sessions in 10 weeks  
• All sessions were 30 minutes in duration | Measured improvement in local or general disc herniation size  
• Pain: VAS  
• Lumbar mobility  
• Neurological exam results | Re-evaluations performed during and at end of the treatment program. |

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<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Case Series Details</th>
<th>Treatments</th>
<th>Disability/Outcome Measures</th>
<th>Re-evaluation Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lauerman (2002)</td>
<td>Case Series</td>
<td>50 subjects 23 - 77 years  Chronic (&gt;3-months) lumbar radiculopathy  Setting: not described</td>
<td>Decompression (DRS System)  Physical therapy: education and exercise  Treatment duration was up to six weeks  Average number of sessions was 7.08 [treatment protocols varied based on clinical findings]</td>
<td>ADL: Functional ability evaluated by each patient  Neural Tension Signs: rated by individual patients  Functional Range of Motion: rating scheme not described</td>
<td>Follow up measurement periods were not described</td>
</tr>
<tr>
<td>Gionis (2003)</td>
<td>Case Series</td>
<td>229 adult subjects  Symptoms associated with herniated and degenerative disc disease that had been ongoing for at least 4 weeks  Diagnoses confirmed by MRI  Setting: not described</td>
<td>Spinal decompression therapy (unit type and/or manufacturer were not described)  Lumbar support belt  Nonsteroidal medication  Ice  Interferential therapy  [20 sessions over six weeks; 45 minutes per decompression session]</td>
<td>Oswestry Disability Questionnaire  Pain: question and scale used within the Oswestry  Physical Measures: Modified physical exam</td>
<td>Re-evaluations performed: 2 weeks 4 weeks 6 weeks 90 days after end of treatment program</td>
</tr>
<tr>
<td>Gose (1998)</td>
<td>Case Series</td>
<td>778 cases  Data were collected from 22 medical centers  Patients who received at least 10 sessions and had a diagnosis of herniated disc, degenerative disc or facet syndrome</td>
<td>Decompression (VAX-D) Therapy  Average number of sessions:  Facet syndrome = 17  Degenerative disc desease = 19  Other diagnoses = 20 [duration and time per session were not described]  Other modalities and medications were recorded but not described in the study.</td>
<td>Oswestry Disability Questionnaire  Pain: question and scale used within the Oswestry  Mobility limitation: 0-3 scale  ADL: 0-3 scale</td>
<td>Re-evaluations were performed: At the mid-point of the treatment schedule  At the end of the treatment program</td>
</tr>
<tr>
<td>Tilaro (1999)</td>
<td>Case Series</td>
<td>17 subjects  Average age was 40.8 years  Average symptom duration was 17.2 months  Sciatica and positive SLR  Clinically correlated imaging studies</td>
<td>Decompression (VAX-D) Therapy  3-5 sessions per week  Average 23 sessions [time per session was not described]</td>
<td>Sensory Testing: CPT Neurometer (current perception threshold testing)</td>
<td>Re-evaluation performed at end of treatment program.</td>
</tr>
</tbody>
</table>

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### Utilization Management Policy

<table>
<thead>
<tr>
<th>Study</th>
<th>Case Series</th>
<th>Subjects</th>
<th>Age</th>
<th>Pain Assessment</th>
<th>Re-evaluation</th>
<th>Diagnosis</th>
<th>Therapy Sessions</th>
<th>Overall Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shealy (2005)</td>
<td>Case Series</td>
<td>33 subjects</td>
<td>Mean age: 73.49 (SD: 6.87)</td>
<td>Decompression (IDD Therapy)</td>
<td>At the end of treatment program (4-6 weeks)</td>
<td>Patients with LBP, with/without previous other treatments</td>
<td>20 sessions</td>
<td>4-6 weeks duration</td>
</tr>
<tr>
<td>Naguszewski (2001)</td>
<td>Case Series</td>
<td>7 subjects</td>
<td>Age range: 23-56 years</td>
<td>Decompression (VAX-D) Therapy</td>
<td>At 1 year post-treatment</td>
<td>Subacute and chronic LBP with referred leg pain</td>
<td>10 to 35 sessions</td>
<td>[time per session and overall duration of care program were not described]</td>
</tr>
</tbody>
</table>
Utilization Management Policy

Studies Excluded From Quality Appraisal

Table 4

<table>
<thead>
<tr>
<th>Study/Source</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case reports [1,2]</td>
<td>Do not meet the minimum criteria for evidence profiling</td>
</tr>
<tr>
<td>News releases/articles/advertisements [3-5]</td>
<td>Do not meet the minimum criteria for evidence profiling</td>
</tr>
<tr>
<td>Commentaries/presentations [6, 7]</td>
<td>Do not meet the minimum criteria for evidence profiling</td>
</tr>
<tr>
<td>Citations that did not yield any search results</td>
<td>Study has not been published as cited</td>
</tr>
<tr>
<td>[8]</td>
<td></td>
</tr>
<tr>
<td>Basic science research [9]</td>
<td>Clinical application yet to be established</td>
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</tbody>
</table>

2. Edwards JD, Vaughn CS. Actual Case Studies From Our Office. [http://www.444disc.com/cases.htm](http://www.444disc.com/cases.htm); accessed July 2007

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Summary of Quality Assessment of Studies

**Key Question:** Is there sufficient research evidence of the efficacy and safety of spinal decompression devices for the sustained reduction of pain and disability to conclude this intervention is an appropriate therapeutic alternative for a specific patient population?

**Critical Outcome Variable:** Pain (using various scales assessed at variable time periods)

<table>
<thead>
<tr>
<th>Author</th>
<th>Design</th>
<th>Quality</th>
<th>Consistency</th>
<th>Directness</th>
<th>Other Modifying Factors</th>
<th>Clinical Significance / Magnitude of Effect</th>
<th>Adverse Events</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shealy</td>
<td>RCT</td>
<td>very serious limitations</td>
<td>no important inconsistency</td>
<td>N/A</td>
<td>sparse data; probability of reporting bias</td>
<td>insufficient data</td>
<td>not addressed</td>
<td>Very low</td>
</tr>
<tr>
<td>Sherry</td>
<td>RCT</td>
<td>serious limitations</td>
<td>important inconsistencies</td>
<td>N/A</td>
<td>sparse and imprecise data; probability of reporting bias</td>
<td>clinically significant improvement (4.14 scale points); treatment effect not calculated</td>
<td>not addressed</td>
<td>Very low</td>
</tr>
<tr>
<td>Ramos</td>
<td>Cohort</td>
<td>very serious limitations</td>
<td>no important inconsistency</td>
<td>N/A</td>
<td>sparse data</td>
<td>clinical significance of results not calculated</td>
<td>not addressed</td>
<td>Very low</td>
</tr>
<tr>
<td>Eyerman</td>
<td>Case Series</td>
<td>serious limitations</td>
<td>important inconsistencies</td>
<td>some uncertainty</td>
<td>sparse data</td>
<td>insufficient data</td>
<td>not addressed</td>
<td>Very low</td>
</tr>
<tr>
<td>Gundersen</td>
<td>Case Series</td>
<td>serious limitations</td>
<td>important inconsistencies</td>
<td>N/A</td>
<td>imprecise and sparse data</td>
<td>insufficient data</td>
<td>not addressed</td>
<td>Very low</td>
</tr>
<tr>
<td>Gionis</td>
<td>Case Series</td>
<td>very serious limitations</td>
<td></td>
<td>N/A</td>
<td>sparse data</td>
<td>clinical significance of results not calculated</td>
<td>not addressed</td>
<td>Very low</td>
</tr>
<tr>
<td>Gose</td>
<td>Case Series</td>
<td>very serious limitations</td>
<td>no important inconsistency</td>
<td>N/A</td>
<td>sparse data</td>
<td>statistical &amp; clinical significance of results not calculated</td>
<td>not addressed</td>
<td>Very low</td>
</tr>
<tr>
<td>Shealy</td>
<td>Case Series</td>
<td>serious limitations</td>
<td>N/A</td>
<td>some uncertainty</td>
<td>sparse data; probability of reporting bias</td>
<td>clinically significant improvement (4.46 scale points) at last session; improvement maintained at 1 year</td>
<td>not addressed</td>
<td>Very low</td>
</tr>
<tr>
<td>Naguszewski</td>
<td>Case Series</td>
<td>serious limitations</td>
<td>important inconsistencies</td>
<td>N/A</td>
<td>sparse data</td>
<td>clinically significant improvement (4.43 scale points)</td>
<td>not addressed</td>
<td>Very low</td>
</tr>
</tbody>
</table>

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Summary of Quality Assessment of Studies

**Key Question:** Is there sufficient research evidence of the efficacy and safety of spinal decompression devices for the sustained reduction of pain and disability to conclude this intervention is an appropriate therapeutic alternative for a specific patient population?

---

**Critical Outcome Variable:** Disability or ADL (using various scales assessed at variable time periods)

<table>
<thead>
<tr>
<th>Author</th>
<th>Design</th>
<th>Quality</th>
<th>Consistency</th>
<th>Directness</th>
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<th>Adverse Events</th>
<th>Rating</th>
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<tbody>
<tr>
<td>Sherry</td>
<td>RCT</td>
<td>serious limitations</td>
<td>important inconsistencies</td>
<td>N/A</td>
<td>sparse and imprecise data; probability of reporting bias</td>
<td>insufficient data; treatment effect not calculated</td>
<td>not addressed</td>
<td>Very low</td>
</tr>
<tr>
<td>Ramos</td>
<td>Cohort</td>
<td>very serious limitations</td>
<td>no important inconsistency</td>
<td>N/A</td>
<td>sparse data</td>
<td>insufficient data; treatment effect not calculated</td>
<td>not addressed</td>
<td>Very low</td>
</tr>
<tr>
<td>Gundersen</td>
<td>Case Series</td>
<td>serious limitations</td>
<td>important inconsistencies</td>
<td>N/A</td>
<td>imprecise and sparse data</td>
<td>clinically significant improvement in means of Oswestry (17.72%) and NDI (10%)</td>
<td>not addressed</td>
<td>Very low</td>
</tr>
<tr>
<td>Lauerman</td>
<td>Case Series</td>
<td>very serious limitations</td>
<td>N/A</td>
<td>some uncertainty</td>
<td>imprecise and sparse data; probability of reporting bias</td>
<td>insufficient data</td>
<td>not addressed</td>
<td>Very low</td>
</tr>
<tr>
<td>Gionis</td>
<td>Case Series</td>
<td>very serious limitations</td>
<td>N/A</td>
<td>some uncertainty</td>
<td>sparse data</td>
<td>insufficient data</td>
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</tr>
<tr>
<td>Gose</td>
<td>Case Series</td>
<td>very serious limitations</td>
<td>no important inconsistency</td>
<td>N/A</td>
<td>sparse data</td>
<td>insufficient data</td>
<td>not addressed</td>
<td>Very low</td>
</tr>
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Strength of Recommendation

<table>
<thead>
<tr>
<th>Quality of Evidence</th>
<th>Benefits</th>
<th>Baseline Risks and Burdens</th>
<th>Translation</th>
<th>Strength of Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Low</td>
<td>It is uncertain if nonsurgical spinal decompression therapy provides additional benefit beyond that typically achieved by more well-established therapeutic interventions.</td>
<td>There is uncertainty about the estimates of risk associated with nonsurgical spinal decompression therapy. There are significant inherent burdens (direct costs to the member, expectations of results and time commitment) associated with the use of nonsurgical spinal decompression therapy.</td>
<td>There is uncertainty about translating the evidence into clinical practice settings. Factors likely to impact the effect (i.e., patient selection criteria, optimal dose and frequency) have not been sufficiently investigated.</td>
<td>WEAK: There is uncertainty about the trade-offs between benefits and risks/burdens. It is not clear whether nonsurgical spinal decompression therapy does more good than the burdens placed on health plan members. Other alternatives may be equally or more reasonable.</td>
</tr>
</tbody>
</table>

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### What are the Conclusions of Literature Reviews and Technology Assessments?  
**Table 8**

<table>
<thead>
<tr>
<th>Author/Date</th>
<th>Type</th>
<th>Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Macario (2006)</td>
<td>Systematic Review</td>
<td>The data suggest the efficacy of spinal decompression achieved with motorized traction for chronic discogenic low back pain remains unproved. Scientifically more rigorous studies with better randomization, control groups, and standardized outcome measures are needed to overcome the limitations of past studies.</td>
</tr>
<tr>
<td>Martin (2005)</td>
<td>Systematic Review</td>
<td>To date there is no evidence that the VAX-D system is effective in treating chronic LBP associated with herniated disc, degenerative disc, posterior facet syndrome, sciatica or radiculopathy.</td>
</tr>
<tr>
<td>Medical Services Advisory Committee (2001)</td>
<td>Systematic Review</td>
<td>Detailed evidence on the safety and complication rates of the VAX-D table is lacking. For patients with radiculopathy or radicular pain associated with a herniated intervertebral disc, there is some evidence to suggest that surgical discectomy is more effective than VAX-D therapy at relieving pain in the short to medium term. No comparisons can be made between these two therapies in this patient group over the long term. For other patient groups i.e., radiculopathy/radicular pain associated with degenerative intervertebral discs, and patients with nonspecific LBP, there is insufficient evidence to make any conclusions regarding the relative effectiveness of VAX-D therapy.</td>
</tr>
<tr>
<td>Daniel (2007)</td>
<td>Narrative Review</td>
<td>There is very limited evidence in the scientific literature to support the effectiveness of nonsurgical spinal decompression therapy. This intervention has never been compared to exercise, spinal manipulation, standard medical care or other less expensive conservative treatment options, which have an ample body of research demonstrating efficacy. Considering the cost-benefit relationship, many better researched and less expensive treatment options are available to the clinician</td>
</tr>
<tr>
<td>Clarke (2006)</td>
<td>Systematic Review</td>
<td>Based upon the current evidence, intermittent or continuous traction as a single treatment for LBP cannot be recommended for mixed groups of patients with LBP with and without sciatica. Neither can traction be recommended for patients with sciatica because of inconsistent results and methodological problems in most of the studies involved. To have more conclusive evidence regarding VAX-D replication of studies would be required, using adequate numbers of patients and methods that limit the possibility of bias.</td>
</tr>
<tr>
<td>Jurecki-Tiller (2007)</td>
<td>Technology Assessment</td>
<td>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…Adverse event reporting for decompression therapy is infrequent.</td>
</tr>
<tr>
<td>Wang (1999)</td>
<td>Technology Assessment</td>
<td>As a treatment, VAX-D has not been established as more or less beneficial than other forms of traction.</td>
</tr>
</tbody>
</table>

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### What are the Policies/Positions of Other Organizations?  
**Table 9**

<table>
<thead>
<tr>
<th>Organization</th>
<th>Policy Information</th>
<th>Position</th>
</tr>
</thead>
</table>
| Centers for Medicare and Medicaid Services (CMS) | • NCD for Vertebral Axial Decompression (VAX-D)  
  • # 160.16  
  • Accessed July 2007   | There is insufficient scientific data to support the benefits of this technique. Therefore, VAX-D is not covered by Medicare.                                                                                     |
| Blue Cross of California            | • Mechanized Spinal Distraction Therapy for Low Back Pain  
  • # SURG.00008  
  • Accessed July 2007   | Use of mechanized spinal distraction therapy, including, but not limited to, the VAX-D® Therapeutic Table, the Decompression Reduction Stabilization DRS® System, and Accu-Spina System™ IDD Therapy, is considered investigational/not medically necessary in all cases for the treatment of low back pain. |
| The Regence Group (Blue Cross / Blue Shield) | • Vertebral Axial Decompression  
  • # 45  
  • Accessed July 2007   | Vertebral axial decompression is considered investigational.                                                                                                                                                 |
| CIGNA HealthCare                    | • Mechanical Devices for the Treatment of Back Pain  
  • # 01410  
  • Accessed July 2007   | Spinal unloading devices are considered experimental, investigational or unproven.                                                                                                                           |
| UNICARE                             | • Mechanized Spinal Distraction Therapy for Low Back Pain  
  • # SURG.00008  
  • Accessed July 2007   | Use of mechanized spinal distraction therapy, including, but not limited to, the VAX-D® Therapeutic Table, the Decompression Reduction Stabilization DRS® System, and Accu-Spina System™ IDD Therapy, is considered investigational/not medically necessary in all cases for the treatment of low back pain. |
| UnitedHealthcare                    | • Spinal Unloading Treatment for Low Back Pain  
  • # 2005T0365C  
  • Accessed July 2007   | The use of a spinal unloading device is unproven for low back pain due to inadequate clinical evidence of safety and/or efficacy in published peer-reviewed medical literature. This includes axial spinal distraction, spinal decompression, vertebral axial decompression therapy and pneumatic vests. |
| Aetna                               | • Vertebral Axial Decompression Therapy  
  • # 0180  
  • Accessed July 2007   | Vertebral axial decompression (e.g., by means of the VAX-D Table, DRX9000, the DRS System, the Alpha-Spina System, the Lordex Lumbar Spine System, or the Internal Disc Decompression (IDD) Therapy) is considered to be experimental and investigational. Currently, there is no adequate scientific evidence that proves that vertebral axial decompression is an effective adjunct to conservative therapy for back pain. In addition, vertebral axial decompression devices have not been adequately studied as alternatives to back surgery. |
| ASHA                                | • Axial Decompression Therapy  
  • # 83  
  • Accessed July 2007   | Axial decompression therapy is experimental or investigational because further studies or clinical trials are necessary to determine its dose, its safety, its efficacy, or its efficacy as compared with the currently accepted professional standard means of treatment. Detailed evidence on the safety and complication rates of the device is lacking. |
| Humana                              | • Vertebral Decompression Therapy  
  • Accessed July 2007   | Vertebral decompression therapy is considered experimental/investigational as it is not identified as widely used and generally accepted for and other proposed use as reported in nationally recognized peer-reviewed medical literature. |
| MSAC (Australia)                    | • Vertebral Axial Decompression Therapy for Chronic Low Back Pain  
  • # 1012  
  • Accessed July 2007   | As there is currently insufficient evidence pertaining to the effectiveness of VAX-D therapy, public funding should not be supported at this time for this procedure. |

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Policy History/Revision Information

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
</tr>
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<tbody>
<tr>
<td>10/11/2007</td>
<td>Original effective date</td>
</tr>
<tr>
<td>4/10/2008</td>
<td>Annual review and approval completed</td>
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<tr>
<td>11/11/2008</td>
<td>Policy updated: re-branded - OptumHealth Care Solutions – Physical Health; renumbered (462 to 473)</td>
</tr>
<tr>
<td>1/15/2009</td>
<td>Policy reformatted</td>
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<tr>
<td>4/30/2009</td>
<td>Annual review and approval completed</td>
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<tr>
<td>4/08/2010</td>
<td>Annual review and approval completed</td>
</tr>
<tr>
<td>10/26/2010</td>
<td>Policy rebranded to “OptumHealth Care Solutions, Inc. (OptumHealth)”</td>
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<tr>
<td>4/07/2011</td>
<td>Annual review and approval completed</td>
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<td>4/19/2012</td>
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<td>4/18/2013</td>
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<tr>
<td>4/17/2014</td>
<td>Annual review and approval completed; Policy rebranded “Optum* by OptumHealth Care Solutions, Inc.”</td>
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<tr>
<td>4/16/2015</td>
<td>Annual review and approval completed</td>
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<td>4/21/2016</td>
<td>Annual review and approval completed</td>
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<tr>
<td>4/20/2017</td>
<td>Annual review and approval completed; Legal entity name changed from “OptumHealth Care Solutions, Inc.” to “OptumHealth Care Solutions, LLC.”</td>
</tr>
</tbody>
</table>

Contact Information

Please forward any commentary or feedback on Optum utilization management policies to: policy.inquiry@optumhealth.com with the word “Policy” in the subject line.

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Plain Language Summary

Nonsurgical Spinal Decompression Therapy

What is nonsurgical spinal decompression therapy and what is known about it so far?

Spinal pain is a common problem. Traditional treatments that are helpful for some patients with neck, mid, and low back pain include, physical therapy, manipulation, exercise, and drugs (painkillers, anti-inflammatory drugs, and muscle relaxants). Nonsurgical spinal decompression therapy is a possible alternative treatment for spinal pain.

Nonsurgical spinal decompression therapy is a type of computer-aided motorized traction that has been promoted as being able to reduce the pressure on spinal nerves (decompression), which is something that has not been demonstrated to occur with conventional mechanical traction. There is disagreement about the research that has been used as the reference to support this claim. In part, this is due to the study having evaluated the results of only three subjects.

There is a lack of research concerning the safety of nonsurgical spinal decompression therapy. It is uncertain if this therapy helps more than traditional treatments. Most healthcare organizations exclude nonsurgical spinal decompression therapy from benefit coverage.

How was nonsurgical spinal decompression therapy evaluated?

A work group of clinicians was assigned to review the available research. The internet was searched for policies, guidelines and articles about nonsurgical spinal decompression therapy.

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The work group independently examined the research using a broadly accepted method. Possible ratings were high, moderate, low, or very low quality.

Before it was approved, the policy was presented to a series of committees that included independent health care practitioners.

What did the work group find?

The marketing claims made about the benefits and safety of nonsurgical spinal decompression therapy are not supported by research. The research quality was rated as very low. It was not possible to make a determination that nonsurgical spinal decompression therapy provided more benefit or less risk, when compared to generally accepted and safe treatments including traditional spinal manipulation. The vast majority of other healthcare companies and governmental agencies appear to have reached similar conclusions.

What were the limitations of the information?

The research on spinal nonsurgical spinal decompression therapy is limited. All of the studies considered suitable for evaluation were of very low quality. Accordingly, any conclusions about the results were uncertain. Only two studies were designed to evaluate the benefits of nonsurgical spinal decompression therapy vs. other treatments. Some of the studies were conducted by individuals with financial interests in the results.

What are the conclusions?

Nonsurgical spinal decompression therapy is viewed as unproven. Further research is needed before nonsurgical spinal decompression therapy can be considered an established treatment option for any spinal conditions.