

## Nonsurgical Spinal Decompression Therapy

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### Policy Statement

Optum\* by OptumHealth Care Solutions, LLC considers nonsurgical spinal decompression therapy to be unproven and not medically necessary due to insufficient scientific evidence of efficacy and safety in the treatment of spine-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?*

### Scope

The application of this policy is limited to those services best described by HCPCS code S9090 - Vertebral Axial Decompression, per session.<sup>1</sup> This code applies to any motorized mechanical traction device promoted as providing decompression therapy.<sup>2</sup> 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.

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## Background

### Description of the intervention

Traction therapy has been utilized in the treatment of low back pain for decades. The most recent incarnation of traction therapy is non-surgical spinal decompression therapy (NSSDT); a type of intermittent, dispersed traction using a specialized table and computer designed to apply distractive tension along the axis of the spine.<sup>3,4</sup> Many NSSDT devices are regulated by the FDA as class II medical devices based on substantial equivalence to existing devices.<sup>3</sup> Examples of NSSDT devices include, but may not be limited to:

- Acua-Spina System utilizing Intervertebral Differential Dynamics (IDD Therapy)
- Decompression Reduction Stabilization (DRS) System
- DRX-3000
- DRX9000
- Lordex Traction Unit
- SpineMED Decompression Table
- V DRX 9000
- VAX-D Table

### How the intervention might work

Proponents of nonsurgical spinal decompression therapy (NSSDT) assert this form of traction is unique for being able to reduce the relative pressure measured within intervertebral discs (decompression).<sup>5</sup> The relationship between negative intradiscal pressures and clinical outcomes has not been established.<sup>6</sup> It is also uncertain if any mechanical changes observed in a prone position will be sustained after a patient resumes an upright, weight-bearing posture.<sup>3</sup>

### Intended purpose [Patient selection and treatment protocol]

NSSDT is claimed to provide relief for patients with chronic discogenic low back pain with or without leg pain, which has been unresponsive to conventional therapy for a minimum of six to eight weeks.<sup>7</sup> There are no examination findings (clinical, imaging, or laboratory) that have been shown to differentiate patients who are likely to benefit from traction therapies such as NSSDT.<sup>3</sup>

NSSDT is not designed to treat low back pain due to soft tissue injury, muscle strain or progressive inflammatory conditions. Treatment with NSSDT is generally contraindicated for patients with the following conditions: infection, neoplasm, osteoporosis, bilateral pars defect or Grade 2 spondylolisthesis if unstable, fractures, the presence of surgical hardware in the spine and cauda equina syndrome.<sup>7</sup>

Each session of NSSDT is of 25–45 minute's duration. A complete course of NSSDT ranges from 15–24 sessions, typically over an 8-week time period.<sup>2,7</sup> Additional services may be incorporated as part of a standard treatment approach i.e., thermal applications, electrical stimulation, manual therapy, and active therapeutic procedures.<sup>8</sup>

## Evidence Review

### Criteria for considering studies for the evidence review

Evidence syntheses [systematic reviews, technology reports] and randomized controlled trials (RCTs) [not included in evidence syntheses] of any type of NSSDT were included for the assessment of effectiveness and/or safety. Observational study designs were included if they measured adverse events. Studies describing patient selection were also included. There were no restrictions concerning the types of patients (eg, subacute, chronic low back pain). Trials that reported additional treatment were eligible, provided that NSSDT was the main contrast between the intervention and control groups. In order to be eligible for inclusion, studies needed to report on at least one patient-important outcome eg, pain, function, global improvement, etc.).

### Search Strategy

An updated literature search for the identification of studies and reports was performed by applying the guidance provided by the Cochrane Back Review Group.<sup>9</sup> Electronic searches were conducted using the Ovid platform (MEDLINE, EMBASE, AMED), CINAHL, and Index to Chiropractic Literature. Other resources were searched including the websites of governmental agencies and device manufacturers. Searches for studies in progress were performed in protocol registries eg, [www.clinicalTrials.gov](http://www.clinicalTrials.gov).

### Evidence Extraction

The search identified two systematic reviews.<sup>8,10</sup> Two technology reports were retrieved.<sup>7,11</sup> There were three topically-relevant narrative reviews.<sup>3-5</sup> Primary studies that were previously identified and appraised were included in one or more of the reviews/reports. One new RCT was identified in the updated search.<sup>12</sup> Trial registries showed there are at least two studies in progress that are intended to investigate the effectiveness of different NSSDT devices.

### Evidence Appraisal

The evidence syntheses, systematic reviews and evidence reports, were appraised for methodological quality using the AMSTAR tool.<sup>13</sup> All studies were sufficiently conducted in order to allow for confidence in their conclusions [Table 1].

Table 1. Quality appraisal of evidence syntheses

Appraisal Methods		Quality Appraisal			
Item	Description	MSAC (2001)	Macario (2006)	Jurecki-Tiller (2007)	Wegner (2013)
Was an 'a priori' design provided?	The research question and inclusion criteria should be established before the conduct of the review.	Yes	Yes	Yes	Yes
Was there duplicate study selection and data extraction?	There should be at least two independent data extractors and a consensus procedure for disagreements should be in place.	?	Yes	?	Yes
Was a comprehensive literature search performed?	At least two electronic sources should be searched. The report must include years and databases used (e.g. Central, EMBASE, and MEDLINE). Key words and/or MESH terms must be stated and where feasible the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or experts in the particular field of study, and by reviewing the references in the studies found.	Yes	Yes	Yes	Yes
Was the status of publication (e.g., grey literature) used as an inclusion criterion?	The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc.	Yes	Yes	Yes	Yes
Was a list of studies (included and excluded) provided?	A list of included and excluded studies should be provided.	Included-only	Included-only	Yes	Yes
Were the characteristics of the included studies provided?	In an aggregated form such as a table, data from the original studies should be provided on the participants, interventions and outcomes. The ranges of characteristics in all the studies analyzed e.g. age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported.	Yes	Yes	Yes	Yes
Was the scientific quality of the included studies assessed and documented?	'A priori' methods of assessment should be provided (e.g., for effectiveness studies if the author(s) chose to include only randomized, double-blind, placebo controlled studies, or allocation concealment as inclusion criteria); for other types of studies alternative items will be relevant.	No (narrative appraisal)	Yes (Jadad scale)	Yes (ECRI methodology)	Yes (Cochrane Risk of Bias)
Was the scientific quality of the included studies used appropriately in formulating conclusions?	The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review, and explicitly stated in formulating recommendations.	Yes	Yes	Yes	Yes
Were the methods used to combine the findings of studies appropriate?	For the pooled results, a test should be done to ensure the studies were combinable, to assess their homogeneity (i.e. Chi-squared test for homogeneity, I <sup>2</sup> ). If heterogeneity exists a random effects model should be used and/or the clinical appropriateness of combining should be taken into consideration (i.e. is it sensible to combine?).	N/A	N/A	N/A	N/A
Was the likelihood of publication bias assessed?	An assessment of publication bias should include a combination of graphical aids (e.g., funnel plot, other available tests) and/or statistical tests (e.g., Egger regression test).	No	No	No	No
Was the conflict of interest stated?	Potential sources of support should be clearly acknowledged in both the systematic review and the included studies.	No	Yes	No	Yes

**Summary of the evidence review**

## Effectiveness:

There was consistency in the conclusions of the more comprehensive and higher quality-designed systematic review and governmental reports: the available evidence is too limited in quality and quantity to allow for evidence-informed conclusions regarding the efficacy/effectiveness of NSSDT.

Wegner, et al (2013) concluded, "...that traction either alone or in combination with other treatments, has little or no impact on pain intensity, functional status, global improvement and return to work among people with LBP. There is only limited-quality evidence from studies with small sample sizes and moderate to high risk of bias. The effects shown by these studies are small and are not clinically relevant."<sup>8</sup>

An earlier systematic review determined the efficacy of spinal decompression achieved with motorized traction for chronic discogenic low back pain remains unproved.<sup>10</sup> The authors commented on the need for more rigorous studies with better randomization, more complete control groups, uniform selection criteria, evidence-based diagnostic measures, and standardized outcome measures are needed to identify the best responders to this conservative intervention.

In a 2007 evidence synthesis the Agency for Healthcare Research and Quality (AHRQ) found the body of evidence for NSSDT for chronic low back pain was insufficient to answer questions on its effectiveness: when compared to other commonly used therapies; with different patient characteristics; on work disability; and pain relief (magnitude of effect and durability).<sup>11</sup>

The Australian Medical Services Advisory Committee (MSAC) published a technology assessment on a NSSDT (VAX-D) for low back pain in 2001.<sup>7</sup> This report concluded there was only limited evidence of the effectiveness of VAX-D therapy in one patient group (patients with radiculopathy or radicular pain associated with herniated disc). There is no good quality evidence of the effectiveness of VAX-D therapy in other patient groups (degenerative discogenic radiculopathy and nonspecific low back pain). Overall, it appears that VAX-D therapy provides short-term symptomatic relief from nerve root compression for patients with radiculopathy or radicular pain associated with herniated disc. There is no evidence; however, that VAX-D therapy provides longer term relief or cure of nerve root compression for patients with radiculopathy or radicular pain associated with herniated disc.

A RCT that was not included in any of the appraised evidence syntheses investigated the effectiveness of NSSDT as a treatment for individuals diagnosed with lumbar disc herniation.<sup>12</sup> After 15 sessions of NSSDT, there were no significant differences compared to an active control group in patient-reported outcomes (pain and function) or changes in disc morphology (thickness of herniation, disc height). This trial was judged to have a high risk of bias (attrition and selection bias) [Table 2].

**Table 2. Risk of Bias** (limitations in study design or implementation)

Bias Domain	Source of Bias	Demirel <sup>12</sup>	Rationale
Selection	1. Was the method of randomization adequate?	Yes	Sealed envelopes
Selection	2. Was the treatment allocation concealed?	Yes	Executed by an independent researcher
Performance	3. Was the patient blinded to the intervention?	No	
Performance	4. Was the care provider blinded to the intervention?	No	
Detection	5. Was the outcome assessor blinded to the intervention?	Yes	
Attrition	6. Was the drop-out rate described and acceptable?	No	50% drop-out rate in each group
Attrition	7. Were all randomized participants analyzed in the group to which they were allocated?	No	Drop-out participants were not included in the analysis
Reporting	8. Are reports of the study free of suggestion of selective outcome reporting?	No	The conclusion in the abstract selectively reported only intra-group outcomes.
Selection	9. Were the groups similar at baseline regarding the most important prognostic indicators?	No	Significant differences between groups regarding the distribution of herniation segments and type of herniation (Table 3)
Performance	10. Were co-interventions avoided or similar?	Unclear	Not discussed in the study
Performance	11. Was the compliance acceptable in all groups?	Unclear	
Detection	12. Was the timing of the outcome assessment in all groups similar?	Yes	
<b>Judgment</b>		<b>High RoB</b>	<b>Primarily due to the risk of attrition and selection bias</b>

Key: RoB = risk of bias

Interpretation:

- Low RoB = sources of bias are unlikely to seriously alter the results
- High RoB = bias may alter the results seriously

Sources:

Higgins JPT, Altman DG, Gøtzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *BMJ* 2011;343:d5928  
 Furlan AD, Malmivaara A, Chou R, et al. 2015 updated method guideline for systematic reviews in the Cochrane Back and Neck Group. *Spine* 2015;40(21):1660-73.

### Safety:

Detailed evidence on the safety and complication rates of the NSSDT is lacking.<sup>7,11</sup> Information regarding the range and incidence of adverse effects that occur during NSSDT is limited. Complications that have been reported with NSSDT include:

- The development of a sharp burning, radiating pain during therapy
- Stress to the shoulder girdle and rotator cuff muscles, and
- Overstretching of the soft tissues of the back.

None of the available studies describing NSSDT report the incidence of these or any other adverse effects, or the patient drop-out rate associated with adverse effects. Anecdotal evidence from the applicant states that 10 per cent of patients are not able to tolerate the positioning of the table or the distractive pressures and discontinue therapy.<sup>7</sup>

One case report described a patient who developed a sudden, severe exacerbation of pain during a VAX-D treatment session.<sup>14</sup> A MRI showed a marked enlargement of a disc protrusion, requiring an urgent microdiscectomy.

### Coding 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.

Code	Description
S9090	Vertebral Axial Decompression, per session; { most accurately describes services for the application of spinal decompression motorized traction devices }
	Other CPT codes that have been associated with the use of nonsurgical spinal decompression therapy are:
64722	Decompression; unspecified nerves { a surgical code }
97012	Application of a modality, traction, mechanical
90901	Biofeedback training by any modality
97112	Therapeutic procedure, one or more areas, each 15 minutes
97530	Therapeutic activities, direct (one-on-one) patient contact by provider
97140	Manual therapy techniques, each 15 minutes

### References

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## Policy History/Revision Information

Date	Action/Description
10/11/2007	Original effective date
4/10/2008	Annual review and approval completed
11/11/2008	Policy updated: re-branded - OptumHealth Care Solutions – Physical Health; renumbered (462 to 473)
1/15/2009	Policy reformatted
4/30/2009	Annual review and approval completed
4/08/2010	Annual review and approval completed
10/26/2010	Policy rebranded to “OptumHealth Care Solutions, Inc. (OptumHealth)”
4/07/2011	Annual review and approval completed
4/19/2012	Annual review and approval completed
4/18/2013	Annual review and approval completed
4/17/2014	Annual review and approval completed; Policy rebranded “Optum* by OptumHealth Care Solutions, Inc.”
4/16/2015	Annual review and approval completed
4/21/2016	Annual review and approval completed
4/20/2017	Annual review and approval completed; Legal entity name changed from “OptumHealth Care Solutions, Inc.” to “OptumHealth Care Solutions, LLC.”
4/26/2018	Annual review and approval completed; Policy Background, Evidence Review and References were revised
4/25/2019	Annual review and approval completed; Evidence Review and References were updated
4/23/2020	Annual review and approval completed; No new evidence was identified that supports a change to the policy statement

## Contact Information

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

The services described in Optum\* by OptumHealth Care Solutions, LLC policies are subject to the terms, conditions and limitations of the Member's contract or certificate. Optum reserves the right, in its sole discretion, to modify policies as necessary without prior written notice unless otherwise required by Optum's administrative procedures.

Certain internal policies may not be applicable to self-funded members and certain insured products. Refer to the member's Summary Plan Description (SPD) or Certificate of Coverage (COC) to determine whether coverage is provided or if there are any exclusions or benefit limitations applicable to any of these policies. If there is a difference between any policy and the member's SPD or COC, the member's SPD or COC will govern.



## **PLAIN LANGUAGE SUMMARY**

### ***Nonsurgical Spinal Decompression Therapy***

#### **Utilization Management Policy # 473**

*Plain Language Summaries* are a service provided by *Optum*<sup>\*</sup> by *OptumHealth Care Solutions, LLC* to help patients better understand the complicated and often mystifying language of modern healthcare.

Plain Language Summaries are presented to supplement the associated clinical policy or guideline. These summaries are not a substitute for advice from your own healthcare provider.

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

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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 (pain killers, 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?**

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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. 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.

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### What did the work group find?

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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?

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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?

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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.