



3250 W. Pleasant Run, Suite 125 Lancaster, TX 75146-1069
Ph 972-825-7231 Fax 975-274-9022

Notice of Independent Review Decision

DATE OF REVIEW: 9-21-2011

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

The item in dispute is the prospective medical necessity of kinetic activities/DRX 9000 x 1 week.

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION

The reviewer is a Medical Doctor who is board certified in Physical Medicine and Rehabilitation. The reviewer has been practicing for greater than 10 years.

REVIEW OUTCOME

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

- Upheld (Agree)
 Overturned (Disagree)
 Partially Overturned (Agree in part/Disagree in part)

The reviewer agrees with the previous adverse determination regarding the kinetic activities/DRX 9000 x 1 week

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Records were received and reviewed from the following parties:

These records consist of the following:

- Clinic Office Visits. 2010/12/24 through 2011/8/31.
- 2011/01/25: Neurometer Test.

- 2011/01/27: through 2011/01/27: Summary Progress Note pertaining to physical therapy.
- 2011/02/11: Utilization Review Referral requesting kinetic activities, EMS attended, (DRX), neuromuscular reeducation.
- 2011/02/24: Medical Clinic Medical Notes and Doctor's Orders
- 2011/03/09: MRI Lumbar Spine
- 2011/04/18: Utilization Review Referral requesting kinetic activities, EMS attended (DRX), neuromuscular reeducation.
- 2011/04/21: Notification of Adverse Determination.
- 2011/07/15: Utilization Review Referral requesting kinetic activities, EMS attended (DRX), neuromuscular reeducation.
- 2011/08/22: Notification of Reconsideration Determination
- 2011/09/01: Notice of Assignment of Independent Review Organization and accompanying denials/reviews and paperwork.
- 2011/08/31: Request for a Review by an Independent Review Organization.
- 2011/08/31: Narrative Report Submitted by, M.D.

PATIENT CLINICAL HISTORY [SUMMARY]:

Worker sustained injuries to the lower back xx/xx/xxxx. According to a narrative report by Dr. the worker was injured while lifting 450-lb from the ground. After six weeks of treatment with medications and physical therapy he returned to work.

The worker was seen at Clinic 12/24/2010 complaining of aggravation of the lower back. Dr. diagnosed lumbar strain and sciatica. Treatment included medications and physical therapy. Therapy commenced in mid-January, 2011 after authorization was secured. On the follow-up visit 2/3/2011 the pain level had improved but there was persistent numbness in the left big toe. The worker was released to full duty. On 2/4/2011 the worker complained of pain in the legs and numbness in the left big toe. Lumbar DRX treatment was requested. From March 10 through March 21, 2011 the therapy included DRX treatments, massage and heat application.

On the follow-up visit April 13, more DRX treatments were requested to finish the planned program of 18 sessions. The requested treatments were non-authorized April 21, 2011.

On the follow-up visit June 28, 2011 the worker complained of unresolved lower back pain that became more severe after he had traveled for work. He stated that he was able to continue working at full duty. Prescriptions were written for Lortab and naproxen and for a lumbar support.

On the follow-up visit July 26, 2011 the back pain had increased and was interfering with sleep. The worker continued working without restrictions. DRX treatments were again requested. Prescriptions were written for Flexeril and Lortab.

The requested DRX treatment was non-authorized August 22, 2011.

On the follow-up visit August 31, 2011 the pain had increased to level 8/10. Dr. submitted a narrative report summarizing the initial injury, initial objective findings, test results, treatment, diagnosis and recommendations.

Diagnostic studies included 2011/01/25 Graphic Display of Neurometer test result and 2011/03/09 MRI Lumbar Spine Without Contrast, M.D. The results revealed:

- Disc dehydration at the L3-4, L4-5 and LS-S1 levels with remaining lumbar discs adequately hydrated.
- DM spaces and vertebral body heights are adequately maintained at each level. Previously identified disc pathology at the T11-12 level is not as clearly seen on current study, but is suggested on TPI-weighted sagittal image #6 measuring approximately 2 mm pressing on the thecal sac at the midline. No disc pathology is demonstrated at the T12-L1 level. The bone marrow is within normal limits,
- L1-2: There is again minimal posterior 1-2 mm disc protrusion pressing on the thecal sac with no neural foraminal narrowing.
- L2-3: Posterior 1-2 mm disc protrusion presses on the thecal sac with no neural foraminal narrowing.
- L3-4: Signal intensity abnormality measuring up to 7 mm over an 11 mm transverse base presses on the right anterior thecal sac suggestive of potential epidural fibrosis and there was enhancement in this location on previous study. This finding is superimposed on a posterior 1-2 mm disc protrusion pressing on the thecal sac. Further evaluation with post-contrast imaging may be useful to evaluate disc versus epidural fibrosis, if clinically indicated.
- L4-5: Posterior 2-3 mm disc protrusion/herniation presses on the thecal sac narrowing the medial aspect of the right more than the left neural foramen contacting the nerve root in the right, but not the left neural foramen as before. No definitive epidural fibrosis is suggested with previous study suggesting 1-2 mm thickness epidural fibrosis along the posterior left paracentral aspect of the disc. Further evaluation with post-contrast imaging may be useful, if clinically indicated.
- L5-S1: Posterior 3-4 mm disc protrusion/herniation presses on the thecal sac and narrows the medial aspect of the neural foramen bilaterally contacting the nerve root in the neural foramen on each side as seen previously.
- S1-2: There is no disc bulge, herniation or neural foraminal narrowing. The conus terminates at the T12-L1 level and is within normal limits. No facet disease or spinal stenosis is seen at any lumbar level.
- **CONCLUSION:** Disc pathology is seen at multiple lumbar levels as described and also suggested to some degree at the T11-12 level with somewhat prominent S1-2 interspace consistent with partial lumbarization of the S1 segment. There is mid signal intensity abnormality along the right paracentral aspect of the L4 disc consistent with previously identified epidural fibrosis on prior study of 07/24/03. Previously identified epidural fibrosis along the left paracentral aspect of the L4-5 disc space is not identified by this exam. Clinical correlation is recommended.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION.

Based on the records submitted for review, the procedure as requested is not recommended at this time.

BASIS FOR THE DECISION

- The worker is entitled to treatment for problems related to the work injury. The pain and radicular symptoms have persisted for more than six months, meeting the criteria for a diagnosis of chronic pain as defined in the ODG Integrated Treatment/Disability Duration Guidelines, Pain (Chronic), (updated 09/19/11).
- According to the ODG Guidelines, Low Back - Lumbar & Thoracic (Acute & Chronic), (updated 08/04/11), DRX (traction) is not recommended.
- The DRX treatments were focused at the L5 level which may or may not correlate with the anatomic level corresponding with the symptoms of numbness in the left big toe and the findings on the Neurometer test. The MRI showed lumbarization of the S1 vertebra with nerve root contact by the disc on the left side at the L5-S1 level but not at the L4-L5 level.

References:

ODG -TWC

ODG Treatment

Integrated Treatment/Disability Duration Guidelines

Low Back - Lumbar & Thoracic (Acute & Chronic)

(updated 08/04/11)

DRX® (traction)

Not recommended. Another brand of powered traction device similar to VAX-D. The DRX 9000 is provided by Axiom Worldwide, Tampa, FL. See Powered traction devices. See also Traction. A retrospective chart review (with no controls) provided preliminary data that chronic LBP may improve with DRX 9000 spinal decompression, but concluded that randomized double-blind trials are needed to measure the efficacy of such systems. (Macario, 2008) Macario A, Richmond C, Auster M, Pergolizzi JV. Treatment of 94 outpatients with chronic discogenic low back pain with the DRX9000: a retrospective chart review. Pain Pract. 2008 Mar;8(1):11-7.

Traction

Not recommended using powered traction devices, but home-based patient controlled gravity traction may be a noninvasive conservative option, if used as an adjunct to a program of evidence-based conservative care to achieve functional restoration. As a sole treatment, traction has not been proved effective for lasting relief in the treatment of low back pain. Traction is the use of force that separates the joint surfaces and elongates the surrounding soft tissues. (Beurskens, 1997) (Tulder, 2002) (van der Heijden, 1995) (van Tulder, 2000) (Borman, 2003) (Assendelft-Cochrane, 2004) (Harte, 2003) (Clarke, 2006) (Clarke, 2007) (Chou, 2007) The evidence suggests that any form of traction may not be effective. Neither continuous nor intermittent traction by itself was more effective in improving pain, disability or

work absence than placebo, sham or other treatments for patients with a mixed duration of LBP, with or without sciatica. There was moderate evidence that autotractor (patient controlled) was more effective than mechanical traction (motorized pulley) for global improvement in this population. (Clarke-Cochrane, 2005) Traction has not been shown to improve symptoms for patients with or without sciatica. (Kinkade, 2007) The evidence is moderate for home based patient controlled traction compared to placebo. (Clarke, 2007) A clinical prediction rule with four variables (non-involvement of manual work, low level fear-avoidance beliefs, no neurological deficit and age above 30 years) was identified. The presence of all four variables (positive likelihood ratio = 9.36) increased the probability of response rate with mechanical lumbar traction from 19.4 to 69.2%. (Cai, 2009) See also Powered traction devices; Vertebral axial decompression (VAX-D); IDD therapy (intervertebral disc decompression); & Orthrotrac vest.

Not recommended. While there are some limited promising studies, the evidence in support of powered traction devices in general, and specifically vertebral axial decompression, is insufficient to support its use in low back injuries. Vertebral axial decompression for treatment of low back injuries is not recommended. VAX-D therapy may also have risks, including the potential to cause sudden deterioration requiring urgent surgical intervention. Decompression therapy is intended to create negative pressure on the spine, so that the vertebrae are elongated, pressure is taken off the roots of the nerve, and a disk herniation may be pulled back into place. Decompression therapy is generally performed using a specially designed computerized mechanical table that separates in the middle. The above information applies to other brands of powered traction devices as well, including DRX and Lordex. Although the American Medical Association (AMA), FDA and Centers for Medicare and Medicaid Services (CMS) all consider decompression therapy to be a form of traction, the manufacturers of these devices consider them different from traction devices. (Sherry, 2001) (Gose, 1998) (Colorado, 2001) (Deen, 2003) (Ramos, 2004) (Humana, 2004) (BlueCross BlueShield, 2004) (Martin, 2005) (Clarke, 2007) (Chou, 2007) The evidence suggests that any form of traction is probably not effective. Neither continuous nor intermittent traction by itself was more effective in improving pain, disability or work absence than placebo, sham or other treatments for patients with a mixed duration of LBP, with or without sciatica. There was moderate evidence that autotractor (patient controlled) was more effective than mechanical traction (motorized pulley) for global improvement in this population. (Clarke-Cochrane, 2005) The efficacy of spinal decompression achieved with motorized traction for chronic discogenic low back pain remains unproved. (Macario, 2006) The most recent incarnation of traction therapy is non-surgical spinal decompression therapy which can cost over \$100,000. This form of therapy has been heavily marketed to manual therapy professions and subsequently to the consumer. Only limited evidence is available to warrant the routine use of this therapy, particularly when many other well investigated, less expensive alternatives are available. (Daniel, 2007) The recent AHRQ review concluded that 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. (Jurecki-Tiller-AHRQ, 2007) A recent case series study (with no control) found that an 8-week course of prone lumbar traction (using VAX-D) was associated with improvements in pain intensity, but said that causal relationships between these outcomes and the intervention should not be made until further

study is performed using randomized comparison groups. It should also be noted that this study excluded patients involved in litigation and those receiving workers' compensation. (Beattie, 2008) A retrospective chart review (with no controls) provided preliminary data that chronic LBP may improve with DRX9000 spinal decompression, but concluded that randomized double-blind trials are needed to measure the efficacy of such systems. (Macario, 2008) This RCT concluded that adding IDD Therapy to a standard graded activity program has been shown not to be effective. (Schimmel, 2009) See also Traction.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN
- INTERQUAL CRITERIA
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
- MILLIMAN CARE GUIDELINES
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS
- TEXAS TACADA GUIDELINES
- TMF SCREENING CRITERIA MANUAL
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME

FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)