

DATE OF REVIEW: 03/20/07

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

The service under dispute is a Dynesys Percutaneous Screw L3-5 posterior fusion with 2 day inpatient stay.

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

The reviewer is a Doctor of Osteopathy who is Board Certified in Orthopedic Surgery and has greater than 10 years of experience in this field.

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 in its entirety.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

The following documents were received and reviewed from the carrier and from the treating doctor.

Records from Carrier:

- Letter: 3/6/2007.
- Letters: 10/18 and 11/8/2006.
- Reports: 5/1/2006 to 1/4/2007.
- MD, Discogram: 8/18/2006.
- StandUp MRI, MRI: 5/22/2006.
- MD, ESI: 6/28/2006.
- Facet Injection: 9/13/2006.
- ODG Low Back: No date.
- Schwarzenbach et al: Posterior Dynamic Stabilization, ORTHO Clin N Am36 (2005)363-372.

Dynamic Stabilization Devices, ORTHO Clin N Am35
(2004)43-56.

Atty, Letter: 2-27-2007.

Texas Department of Insurance, Letters: 2/27 and 3/1/2007.

Letters: 1/10 and 1/26/2007.

Records from the treating doctor include the following (in addition to any previously mentioned records):

DO, Reports: 5/1/2006-7/18/06

MD, reports 8/4/06-1/4/07

MD ESI report

PATIENT CLINICAL HISTORY [SUMMARY]:

This male injured his low back when he was lifting a light pole to take off the lamp head and developed low back pain. Patient's pain is worse at night and with coughing, standing, walking, and physical activity. Pain is relieved by rest and with the application of heat/cold.

Physical Examination revealed restricted lumbar range of motion and flexion/extension, tenderness at L4-5 and 5-S1, right sciatic notch tender, straight leg raise positive on the right at 40 degrees, contralateral positive at 60 degrees, motor test 5/5 and patient can walk on toes and heel. Patient has a prior history of a lumbar laminectomy at L5-S1 in 1981.

MRI of 05/22/2006 revealed narrowing at L3-4 and L4-5. There was mild foraminal stenosis bilaterally at L5-S1 with a moderately advanced narrowing of the disc space with a broad based right paracentral disc protrusion of 7mm migrating inferiorly compressing and displacing the right S1 nerve root. Lumbar spine X-rays reveal vacuum phenomenon at L4-5, marked narrowing at L5-S1, and slight narrowing at L3-4. Lumbar discogram on 08/18/2006 revealed concordant pain at L3-4 and 4-5. At the L5-S1 level there was a degenerated disc with no reproduction of pain. Treatment has been conservative with chiropractic care, physical therapy, ESIs, and facet injections. The conservative care has given only temporary relief.

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

This male had a prior laminectomy at L5-S1. Patient had a new injury to his back resulting in low back pain radiating down the right leg. The MRI revealed a displaced HNP on the right displacing the S1 nerve root. Patient's discogram revealed concordant pain at L3-4 and 4-5.

According to the Guidelines of ODG, Dynesys is not recommended because it is an investigational device currently limited by Federal Law to investigational use in the USA. The review of literature reveals a lack of published data for dynamic stabilization procedure. A closer look into the Dynesys System clarifies that introduction of the spacers between the pedicle screws leads to loss of lordosis of the segment. Although soft stabilization seems promising, one should take a cautious approach to any new implant system. An implant for fusion only has to serve a temporary stabilization until fusion has taken place; on the other hand, a soft stabilization system has to provide stability throughout its life. Implant loosening following fusion surgery is common in the presence of pseudoarthrosis. After soft stabilization, the implant has to stay anchored to the bone despite allowing movement. This sounds like a daunting task according to MD.

According to Drs, in 1994 Dubois and colleagues, for the first time, implanted a pedicle screw-based system with elastic, flexible connections, named DYNESYS (dynamic neutralization system for the spine.)

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**
SCHWARZENBACH, BERLEMANN, STOLL & DUBOIS: POSTERIOR DYNAMIC STABILIZATION SYSTEMS: DYNESYS, ORTHOP CLIN N AM 36 (2005) 363-372.

SENGUPTA: DYNAMIC STABILIZATION DEVICES IN THE TREATMENT OF LOW BACK PAIN. ORTHOP CLIN N AM 35 (2004) 43-56.

MULHOLLAND & SENGUPTA: RATIONALE, PRINCIPLES, AND EXPERIMENTAL EVALUATION OF THE CONCEPT OF SOFT STABILIZATION. EUR SPINE J 2002 (SUPPL 2): S198-205.

STOLL, DUBOIS & SCHWARZENBACH: THE DYNAMIC NEUTRALIZATION SYSTEM FOR THE SPINE: A MULTI-CENTER STUDY OF A NOVEL NON-FUSION SYSTEM. EUR SPINE J 2002; 11(SUPPL 2): S170-178.
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**