

SENT VIA EMAIL OR FAX ON
Aug/24/2011

IRO Express Inc.

An Independent Review Organization

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NOTICE OF INDEPENDENT REVIEW DECISION

DATE OF REVIEW:

Aug/24/2011

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

L5/S1 prodisc with 3 day LOS

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

Board Certified Orthopedic Surgery

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)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

OD Guidelines

1. Cover sheet and working documents
2. Clinic note 04/28/08
3. MRI lumbar spine dated 07/26/10
4. Progress notes 07/26/10-05/17/11
5. Procedure report lumbar epidural steroid injection with fluoroscopy dated 09/30/10
6. Procedure note lumbar epidural steroid injection with sedation dated 11/15/10
7. Radiographic report lumbar spine AP and lateral flexion / extension dated 01/31/11
8. Behavioral medicine evaluation dated 02/23/11
9. Preauthorization determination L5-S1 ProDisc with 3 days LOS dated 05/27/11
10. Preauthorization determination appeal request L5-S1 ProDisc with 3 days LOS dated 06/27/11

PATIENT CLINICAL HISTORY SUMMARY

The injured employee is a male whose date of injury is xx/xx/xxxx. He reportedly injured his back. The injured employee complains of severe back pain and posterior thigh pain. MRI of the lumbar spine dated 07/26/10 revealed small facet joint effusions at L1-2 through L5-S1 indicative of acute facet joint irritation and lumbar facet syndrome. There were 1mm broad disc bulges at L3-4 and L4-5. At L5-S1 there is a broad 4mm disc protrusion with mild bilateral neural foraminal narrowing. The injured employee has been treated conservatively with physical therapy, medications, and epidural steroid injections times two which provided minimal relief for less than a week. Physical examination reported the injured employee to be

5'11" tall and 240 pounds. There is tenderness at L5-S1. Flexion is 30 degrees and extension is 10 degrees with more pain on extension than flexion. Sensory exam is intact. He has a decreased Achilles tendon reflex on the right at trace and 2+ on the left. Patellar reflexes are equal. He may have some decreased EHL on the right at 5-/5 and on the left it is 5/5. There is some decreased plantar flexion on the right at 4/5 and on the left 5/5. Sitting root test is positive, right greater than left. One level lumbar discogram at L5-S1 dated 05/04/11 reported the disc was abnormal and degenerative and pressurization produced severe concordant pain.

A pre-authorization review dated 05/27/11 determined the request for L5-S1 ProDisc with three day length of stay to be non-certified as medically necessary. The review noted that the injured employee complained of low back pain with radiation of pain into the lower extremities. Evidence based guidelines do not recommend a ProDisc/disc prosthesis as the procedure remains investigational in nature. There is insufficient evidence in current clinical literature that establishes the efficacy of lumbar artificial disc replacement over standard surgical procedures to address discogenic pain such as lumbar fusion. Additionally there is no evidence on MRI studies of any significant degenerative disc disease, disc space collapse, severe spondylolisthesis, or motion segment instability which would indicate the need for artificial disc replacement at L5-S1. Given the investigational nature of the requested treatment, the request does not meet guideline recommendations.

A pre-authorization review dated 06/27/11 determined the appeal request for L5-S1 ProDisc with three day length of stay to be non-certified as medically necessary. The review noted MRI studies submitted for review indicate the injured employee has evidence of a 4mm disc protrusion at L5-S1 with mild bilateral neural foraminal narrowing and no canal stenosis. The injured employee complains of persistent low back pain and despite physical therapy and two epidural steroid injections. Official Disability Guidelines do not recommend artificial disc replacement of the lumbar spine. In addition the proposed surgery is only FDA approved for patients with lumbosacral degenerative disc disease at one level L3-S1 who have failed at least six months of conservative management. The imaging studies submitted for review fail to indicate that the injured employee has severe degenerative disc disease at the L5-S1 level to warrant the surgery.

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

Based on the clinical information provided, the proposed L5-S1 ProDisc with three day LOS is not indicated as medically necessary. The injured employee sustained an injury to the low back on xx/xx/xxxx. His condition was refractory to conservative care including medications, physical therapy, TENS unit, and epidural steroid injections. MRI of lumbar spine revealed a 4 mm disc protrusion at L5-S1 with mild bilateral neural foraminal narrowing but no canal stenosis. There is no evidence of nerve root compression. The injured employee underwent a one level discogram at L5-S1, but no control level was documented. As noted on previous reviews, current evidence based guidelines do not support total disc arthroplasty for the lumbar spine. Guidelines note that other than spinal fusion there are no direct comparison studies, and artificial disc outcomes of lumbar spine are about the same as lumbar fusion, but neither results have demonstrated superiority compared with recommended treatments including nonoperative care. Total disc replacement has been approved by FDA for use of lumbar spine for one level degenerative disc disease L3-S1, but the approval required long term studies to establish safety and efficacy. These studies have not been finalized, and as such, the procedure remains investigational and unproven.

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

MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

ODG-OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES