IRO Express Inc.

An Independent Review Organization
2131 N. Collins, #433409
Arlington, TX 76011
Phone: (817) 349-6420
Fax: (817) 549-0310
Email: resolutions.manager@iroexpress.com

NOTICE OF INDEPENDENT REVIEW DECISION

DATE NOTICE SENT TO ALL PARTIES:
Sep/13/2012

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Lateral Interbody Fusion @ L3-4, L4-5 with Minimally Invasive Pedicle screw, additional level; insert Spine Fixation Device, apply Spine Prosthetic Device, Fixation L3 to L5 with K2M Hardware, spinal Bone Allograft, apply Spine Prosthetic Device, graft repair of Spine Defect, Inpatient Hospitalization: 4 days

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

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

[X] Upheld (Agree)

[ ] Overturned (Disagree)

[ ] Partially Overturned (Agree in part/Disagree in part)

Provide a description of the review outcome that clearly states whether medical necessity exists for <u>each</u> health care service in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:
ODG - Official Disability Guidelines & Treatment Guidelines
Hand written clinical notes 10/22/01-06/26/02
Laboratory reports dated 04/06/05
FCE dated 10/09/01
Clinical notes 08/23/2000
Lumbar Discography dated 09/28/2000
Clinical notes 11/22/2000-12/20/2000
Radiographs of Lumbar Spine dated 01/24/01
Operative Report and Hospital Course notes dated 01/30/01
Clinical notes 07/30/01-08/27/01
Clinical notes dated 09/18/01
Clinical note dated 12/14/01
MRI of Lumbar Spine dated 01/24/02

Clinical notes 02/11/02-07/10/02
Designated doctor evaluation dated 09/24/02
Clinical notes 03/15/04
Operative Report dated 06/17/04
Clinical notes 09/29/04-03/30/05
Operative Report and Hospital Course notes dated 04/05/05
Discharge Summary dated 04/06/05
Clinical notes 04/13/05-11/28/05
Electrodiagnostic studies dated 01/12/06
MRI of Lumbar Spine dated 02/01/06
Clinical notes dated 03/27/06
Procedure Report dated 05/11/06
Clinical notes 05/17/06, 06/21/06
Operative Report dated 06/27/06
Clinical notes 07/05/06
Clinical note 08/07/06
Clinical notes 11/05/06-02/14/07
Clinical note from 04/02/07
MRI of Lumbar Spine dated 04/26/07
Clinical notes 05/14/07-08/29/07
Electrodiagnostic studies dated 09/28/07
Clinical notes 07/07/10-10/03/07
MRI of Lumbar Spine dated 07/28/10
Clinical notes 08/04/10
Clinical note 11/01/10
Electrodiagnostic studies dated 11/29/10
Clinical note 11/29/10
Clinical notes 12/22/10
Manual muscle testing and range of motion evaluation dated 01/07/11
Clinical note 01/07/11, 02/09/11
Clinical notes 02/21/11
Clinical note 03/08/11, 04/15/11
Clinical notes 04/25/11-05/04/11
Clinical note 07/15/11
Clinical note 07/18/11-07/16/12
MRI of Lumbar Spine dated 05/17/12

PATIENT CLINICAL HISTORY [SUMMARY]:
The patient is a female who sustained an injury and is status post lumbar fusion at L5-S1 on 01/30/01. The patient also underwent right sacroiliac joint fusion in 2005 and symptomatic hardware removal of the lumbar spine in 2006. The patient has been followed for continuing long term chronic low back pain radiating primarily through the right lower extremity. Previous electrodiagnostic studies have revealed a chronic L5-S1 radiculopathy. The patient has been using medications to include Flexeril and Vicodin as well as Motrin. The patient began reporting numbness and pain in the left buttock and left lower extremity in January of 2011. Pain management notes indicate the patient did not discuss any spinal cord stimulator trial. There was a noted smoking history of 1 pack per day for approximately 6 months in 2011. Pain management notes indicated the patient was going to consider a spinal cord stimulator trial. The patient returned to Dr. with complaints of severe low back pain, more severe to the right than the left. Physical examination on 07/18/11 reported positive straight leg raise to the right. Repeat MRI studies were recommended; however, this was not completed until 05/17/12. The MRI study revealed postoperative changes at L5-S1 to include spinal infusion and prior laminectomies. At L3-4, there was advanced loss of the disc signal with ligamentous thickening and mild to moderate facet changes. No canal stenosis was noted. At L4-5 there was loss of disc signal and moderate loss of disc height. A 2mm disc bulge was noted along with moderately advanced facet changes. No significant canal stenosis was noted and there was mild compromise to the lateral recesses. The patient was placed on Neurontin 900mg QD on 05/23/12. This did not improve the patient’s symptoms and the patient continued to report severe low back pain. The most recent evaluation stated

that the patient would reasonably benefit from a lumbar fusion at L3-4 and L4-5 with removal of preexisting hardware. The patient was prescribed Tramadol 50mg, Neurontin 300mg, and Flexeril 10mg this visit. The request for L3-4 and L4-5 fusion was denied by Utilization Review on 06/26/12 as there were no flexion extension films or psychological evaluation. The request was again denied on by Utilization Review on 08/08/12 as clinical literature did not support the use of lumbar fusion for chronic low back pain in the absence of canal stenosis or severe spinal listhesis.

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

The request for a lumbar fusion at L3-4, L4-5 with a 4 day inpatient stay along with the requested hardware would not be recommended as medically necessary based on the clinical documentation provided for review. The patient has had a long history of chronic low back pain that was not addressed with prior fusions at L5-S1 or the right sacroiliac joint. The patient has not significantly improved with pain management to include medications. The most recent MRI of the lumbar spine did reveal some degenerative disc changes at L3-4 and L4-5; however, there was no significant canal stenosis or unstable spondylolisthesis that would support the use of lumbar fusion in the clinical study of chronic low back pain. Clinical literature does indicate that outcomes from a lumbar fusion solely for chronic low back pain without spondylolisthesis or canal stenosis have poor outcomes. Given the patient's lack of response to prior surgical interventions, an updated psychological evaluation would warranted to rule out any confounding issues that would further the patient's progress with treatment. As the clinical documentation provided for review does not meet guideline recommendations for requested medical procedures, medical necessity would not be established and the prior denials would be upheld.

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

[ ] ACOEM-AMERICA 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

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

[ ] MERCY CENTER CONSENSUS CONFERENCE GUIDELINES

[ ] MILLIMAN CARE GUIDELINES

[X] 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)