Medical Review Institute of America, Inc.
America's External Review Network

AMENDED REVIEW: September 1, 2010
DATE OF REVIEW: August 31, 2010

IRO Case #:

Description of the services in dispute:

This is a request for a three day inpatient stay for L4-S1 decompression/fusion with instrumentation, harvest iliac bone, EBI bone growth stimulator, posterior lumbar interbody fusion with milled bone prosthesis and intra operative spinal cord monitoring.

A description of the qualifications for each physician or other health care provider who reviewed the decision

This physician reviewer is board certified by the American Board of Orthopedic Surgeons in Orthopedic Surgery and has completed a Fellowship in Spine Surgery. This reviewer is a member of American Academy of Orthopedic Surgeons, North American Spine Society, and the American Medical Association.

Review Outcome

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

Based on ODG guidelines, the request for request for a three day inpatient stay for L4-S1 decompression/fusion with instrumentation, harvest iliac bone, EBI bone growth stimulator, posterior lumbar interbody fusion with milled bone prosthesis and intra operative spinal cord monitoring.

Information provided to the IRO for review

Records Received from the State:

Confirmation of receipt of a request for a review by an independent review organization (IRO), 08/23/10 (5 pages)
Request for review by an independent review organization, 08/20/10 (3 pages)
Notice to, INC, of case assignment, 08/24/10 (1 page)

Records received from the Carrier:

, prospective review response, 08/24/10 (3 pages)
Exhibit 1, Confirmation of receipt of a request for a review by an independent review organization (IRO), 08/23/10 (4 pages)
Exhibit 2, Request for review by an independent review organization, 08/20/10 (3 pages)
Exhibit 3, - denial letter, 07/15/10 (1 page), Pre authorization decision

and rationale, 07/15/10 (1 page), Denial letter, 06/18/10 (1 page), Pre authorization decision and rationale, 06/18/10 (1 page), denial form, 6/18/10 (2 pages), - fax cover page, 06/08/10 (4 pages), - authorization request, undated (1 page), Email from to, 06/15/10 (2 pages), Fax cover sheet from, 06/08/10 (1 page), - patient information form, undated (1 page)
Exhibit 4, - denial letter, 07/15/10 (1 page), Preauthorixation decision
and rationale, 07/15/10 (1 page), denial form, 07/14/10 (2 pages), Fax form from, 07/07/10 (1 page), Orthopedic, Letter from, MD, 07/07/10 (2 pages), patient information form, undated (1 page)
Exhibit 5, - denial letter, 04/16/07 (1 page) Preauthorization decision and rationale, 04/16/07 (1 page), - Preauthorization form,
04/16/07 (1 page), patient information forms, undated (2 page), Orthopedic- fax form, 04/11/07 (1 page), - fax form, 03/26/07 (1 page), Fax confirmation forms, 04/03/07 and 04/11/07 (2 pages)
Exhibit 6, C.S.O.S. Inc.- MRI report, 03/05/07 (2 pages), MRI report, 03/22/10 (2 pages)
Exhibit 7, PA, Prior review, 09/25/06 (4 pages)
Exhibit 8, Prior review, 04/03/07 (4 pages), , MD, Prior review,
04/26/10 (3 pages)
Exhibit 9, Independent medical evaluation, 01/19/07 (9 pages)
Exhibit 10, Texas Department of Insurance- determination form, 10/23/07 (1 page), Report of medical evaluation, undated (1 page), request for designated doctor, 10/03/07 (1 page)
Letter of approval, 12/02/05 (1 page), Evaluation, 10/13/07 (6 pages)
Exhibit 11, Orthopedic- initial evaluation, 02/05/07 (2 pages), Clinic note, 02/21/07 (1 page), evaluation, 03/14/07 (2 pages), initial evaluation, 02/08/10 (2 pages), evaluation, 03/17/10 (1 page)

Patient clinical history [summary]
The patient is a male who sustained an injury on xx/xx/xx when he slipped and fell on a wet floor, landing on his low back. The patient saw Dr. on 02/05/07 with complaints of low back pain that radiates into the left buttock and down the posterior aspect of the left thigh to the knee. Prior treatments include electrical stimulation, heat, non-steroidal anti-inflammatories, Medrol Dosepak, and lumbar epidural steroid injections. The patient reports mild temporary relief. The patient states he has had very mild low back discomfort since the mid-80s, but never complained of leg pain prior to the xx/xx/xx accident. Physical exam reveals restricted lumbar motion. There was no clonus. Sciatic scratch test was positive on the left. The left ankle reflex was mildly suppressed. Radiographs of the lumbar spine demonstrate some age anticipated spondylitic changes and some narrowing at L4-5 and L5-S1. The patient was recommended for MRI of the lumbar spine. MRI of the lumbar spine performed 02/05/07 demonstrated a 3 to 4mm left lateral extrusion of the L3-4 intervertebral disc with annular fissuring resulting in moderate left L3-4 neural foraminal narrowing with exiting left L3 nerve root compression. There was loss of height of the L5-S1 intervertebral disc with an annular disc bulge and a right lateral disc protrusion with L5 marginal osteophyte. There was moderate right L5-S1 neural foraminal narrowing. There was loss of height of the L4-5

intervertebral disc with a mild annular disc bulge and a small broad-based central protrusion mildly flattening the anterior aspect of the thecal sac. There was a mild annular bulge of the L1-2 intervertebral disc. A letter by Dr. dated 03/14/07 states the patient was recommended for decompression and fusion from L4 to the sacrum.

There is a gap in clinical documentation. The patient saw Dr. on 02/08/10 with complaints of severe low back pain that radiates down the left leg to the knee. Physical exam revealed restricted lumbar motion in all planes. There was numbness and tingling in the left thigh to the knee, but not below the knee. The reflexes were diminished in the left patella. The sciatic stretch test was mildly positive. Radiographs of the lumbar spine demonstrated settling at L4-5 and L5-S1. Facet arthrosis was considerable. The patient was assessed with mechanical low back pain with a left leg referred or radicular component. The patient was recommended for MRI of the lumbar spine. MRI of the lumbar spine performed 03/22/10 demonstrated moderate to severe left front-back neural foraminal stenosis secondary to a small disc protrusion with marginal osteophytes and facet arthropathy. This was noted to be stable to slight worse when compared to the previous stud. At L4-5 there was moderate bilateral neural foraminal narrowing. This had mildly progressed since the prior exam. At L5-S1 there was severe right up-down neural foraminal stenosis secondary to marginal osteophytes and facet arthropathy. This had progressed since the prior exam.

A letter by Dr. dated 05/17/10 states the patient had been recommended for a decompression and fusion from L4 to the sacrum. The letter states this procedure had been denied in the past, stating the patient should only require decompression. Dr. opines that a decompression would not completely resolve the patient's pain. A letter by Dr. dated 07/07/10 states that psychological clearance was not necessary as Dr. feels the patient is mentally stable. He opines that a psychological clearance would add to the overall cost, but not yield any specific benefit. Dr. states the substantial spondylotic changes at L4-5 and L5-S1 leading to remarkable settling at L4-5 and L5-S1, as well as the considerable facet arthrosis provide evidence of instability. The request for a three day inpatient stay for L4-S1 decompression/fusion with instrumentation was denied by utilization review on 08/24/10 due to lack of evidence of instability and lack of psychological clearance.

<u>Analysis and explanation of the decision include clinical basis, findings and conclusions used to support the decision.</u>

The clinical documentation does not support the request for a decompression and fusion procedure from L4 to S1. The imaging provided for review indicates the presence of foraminal stenosis due to disc protrusions; however, there is no evidence of any significant degenerative disc disease or disc space collapse at L4-5 or L5-S1. There is no evidence of any motion segment instability at any level of the lumbar spine. Additionally, no psychological evaluation was provided as recommended by current evidence based guidelines. As the clinical documentation does not support medical necessity, the prior denials are upheld.

<u>A description and the source of the screening criteria or other clinical basis used to make the</u>

decision:
Official Disability Guidelines, Online Version, Low Back Chapter

Patient Selection Criteria for Lumbar Spinal Fusion:
For chronic low back problems, fusion should not be considered within the first 6 months of symptoms, except for fracture, dislocation or progressive neurologic loss. Indications for spinal fusion may include: (1) Neural Arch Defect - Spondylolytic spondylolisthesis, congenital neural arch hypoplasia. (2) Segmental Instability (objectively demonstrable) - Excessive motion, as in degenerative spondylolisthesis, surgically induced segmental instability and mechanical intervertebral collapse of the motion segment and advanced degenerative changes after surgical discectomy. [For excessive motion criteria, see AMA Guides, 5th Edition, page 384 (relative angular motion greater than 20 degrees). (Andersson, 2000) (Luers, 2007)] (3) Primary Mechanical Back Pain (i.e., pain aggravated by physical activity)/Functional Spinal Unit Failure/Instability, including one or two level segmental failure with progressive degenerative changes, loss of height, disc loading capability. In cases of workers' compensation, patient outcomes related to fusion may have other confounding variables that may affect overall success of the procedure, which should be considered. There is a lack of support for fusion for mechanical low back pain for subjects with failure to participate effectively in active rehab pre-op, total disability over 6 months, active psych diagnosis, and narcotic dependence. [For spinal instability criteria, see AMA Guides, 5th Edition, page 379 (lumbar inter-segmental movement of more than 4.5 mm). (Andersson, 2000)] (4) Revision Surgery for failed previous operation(s) if significant functional gains are anticipated. Revision surgery for purposes of pain relief must be approached with extreme caution due to the less than 50% success rate reported in medical literature. (5) Infection, Tumor, or Deformity of the lumbosacral spine that cause intractable pain, neurological deficit and/or functional disability. (6) After failure of two discectomies on the same disc, fusion may be an option at the time of the third discectomy, which should also meet the ODG criteria. (See ODG Indications for Surgery -- Discectomy.)

Pre-Operative Surgical Indications Recommended: Pre-operative clinical surgical indications for spinal fusion should include all of the following: (1) All pain generators are identified and treated; & (2) All physical medicine and manual therapy interventions are completed; & (3) X-rays demonstrating spinal instability and/or myelogram, CT-myelogram, or discography (see discography criteria) & MRI demonstrating disc pathology; & (4) Spine pathology limited to two levels; & (5) Psychosocial screen with confounding issues addressed. (6) For any potential fusion surgery, it is recommended that the injured worker refrain from smoking for at least six weeks prior to surgery and during the period of fusion healing. (Colorado, 2001) (BlueCross BlueShield, 2002)