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Notice of Independent Review Decision

DATE OF REVIEW: 02/06/2012

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Surgery with hospital stay as well as DME (durable medical equipment) x2 CPT Codes 22612, 22630, 63047, 63710, 22851, 22840, 63048, 20930, L0637 and E0748.

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

Board Certified Orthopedic Spine Surgeon

REVIEW OUTCOME

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

<input checked="" type="checkbox"/>	Upheld	(Agree)
<input type="checkbox"/>	Overtaken	(Disagree)
<input type="checkbox"/>	Partially Overtaken	(Agree in part/Disagree in part)

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

A request for functional restoration program dated 01/11/2012, clinical notes dated 01/12/2012, 12/21/2011, 12/25/2011, 10/04/2011, 08/18/2011, 08/06/2011, 08/03/2011, work conditioning utilization review certification dated 12/09/2011, clinical notes dated 05/20/2011, clinical notes dated 04/08/2011, report of injury to an employee dated xx/xx/xx, lab report from Corp dated 07/09/2011, handwritten clinical note dated 07/18/2011, copy of electrodiagnostic study dated 11/15/2011, clinical note dated 06/30/2011, clinical note dated 07/05/2011, clinical note dated 07/14/2011, repeat clinical note dated 07/14/2011, clinical note dated 07/28/2011, clinical noted dated 08/25/2011, clinical note dated 10/25/2011, and clinical note dated 11/15/2011.

Additional medical records submitted include lab report dated 07/09/2011, handwritten note dated 07/18/2011, electrodiagnostic study dated 11/15/2011, clinical notes dated 06/30/2011, 07/05/2011, and copy of 07/14/2011 clinical note, clinical note dated 07/28/2011, clinical noted dated 08/25/2011, and clinical note dated 10/25/2011, and clinical note dated 11/15/2011

PATIENT CLINICAL HISTORY [SUMMARY]:

This patient is a male with a reported date of injury of xx/xx/xx. At that time, he stated he was loading a counter top on a trailer and the floor fell through and he struck his left knee and jammed his back. On xx/xx/xx, this patient was seen in clinic. At that time, he complained of pain to his back, both hips and

left knee. Pain was rated at 7/10. He denies previous back injury but does state that he has had previous surgery on his left knee. Examination of the lumbar spine showed bilateral paraspinal muscle spasms and tenderness of the upper, middle and lower lumbar spine. There was tenderness at both S1 areas, with the right side being greater than the left. Flexion, extension and bending were compromised secondary to pain. Reflexes were normal and there were no radicular or other neurological findings. X-rays of the thoracic spine demonstrated moderate to severe degenerative changes. On 05/13/2011, this patient had MRI of the lumbar spine. This exam showed disc desiccation of the lower lumbar spine and facet arthropathy changes. There was a 7 mm broadbased midline and paramedian, right greater than left, protruding disc herniation at L5-S1, and contact with the right S1 nerve root and compressing and partially displacing it. On 08/23/2011, this patient underwent psychological evaluation. Barriers to recovery included an inability to work, fear of re-injury, anxiety regarding recovery, and frustration and anger regarding his injury. On 11/21/2011, this patient was seen in clinic. At that time, he continued to have low back pain with radiation in to both hips. He had tried physical therapy and work conditioning and epidural steroid injections. Physical exam showed this patient had trouble heel and toe walking. He had trouble performing a single leg heel raise. Otherwise, he was neurologically intact. Flexion/extension views of the lumbar spine showed degenerative disc disease most notable at L5-S1 segment. A previous MRI demonstrated a disc herniation in contact with the traversing S1 nerve root with Mobic endplate changes at the L5-S1 interval. An EMG had been performed. On 01/12/2012, this patient returned to clinic. At that time, he reported pain being 5/10 to 9/10. Pain was 10/10 on that date. Medications were hydrocodone, Lexapro and gout medicine. Examination of the lumbar spine showed no muscle spasms noted but he did have left-sided S1 tenderness. Reflexes were 3+ at both the right and left knee. Reflexes were 1+ at the right and left ankles. Straight leg raise in the sitting or recumbent position did not cause discomfort. There was no radicular pain or other neurological findings. He was able to touch his toes. He was able to squat with some difficulty as well as drop on his toes and heels with some difficulty. Overall impression was disc desiccation of the lower lumbar spine, facet arthropathic change, and a 7 mm broadbased midline and paramedian-protruding disc at L5-S1. It was stated that his condition has improved compared to last evaluation.

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

The initial review performed on 12/09/2011, indicates that this was an adverse determination. The rationale was not provided. The subsequent appeal determination dated 12/19/2011 indicated that there was an adverse determination and that the basis for this was that the decompression of the L5-S1 level may be indicated. There was no evidence of spondylolisthesis or motion segment instability that would support the need for instrumented fusion. Even if fusion were indicated, it is noted that stem cell autologous transplantation is under study per ODG. Also, there was no need for bone growth stimulator as the proposed procedure is a one-level fusion and the patient did not smoke or have other increased risk factors for non-union. This reviewer is in agreement as that the medical records failed to demonstrate significant spondylolisthesis for the proposed fusion, and the use of a bone growth stimulator is not considered reasonable as this was considered a one-level fusion, and there is lack of long-term evidence indicating the efficacy and safety of stem cell autologous transplantation.

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

 X **ODG-OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**

REFERENCES:

Official Disability Guidelines, Low Back Chapter, Online Version.
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, with 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. Spinal instability criteria includes 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.)

Patient Selection Criteria for Lumbar Spinal Fusion:

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.

Stem cell autologous transplantation

Under study. See the Knee Chapter for more information and references. Stem cell therapy has been used for osteoarthritis, rheumatoid arthritis, spinal injury, degenerative joint disease, autoimmune diseases, systemic lupus erythematosus, cerebral palsy, critical limb ischemia, diabetes type 2, heart failure, multiple sclerosis, and other conditions. Adult stem cells are harvested from many areas of the body, including the bone marrow, fat and peripheral blood, and they are purified and reintroduced back in the patient. According to the theory, stem cells isolated from a patient (i.e. from the bone marrow or fat) have the ability to become different cell types (i.e. nerve cells, liver cells, heart cells and cartilage cells), and they are capable of "homing in" on and repairing damaged tissue. At present, research on intervertebral disc regeneration is at the stage of animal studies, but studies have been conducted on regenerating

intervertebral discs. Done as an alternative to fusion for lumbar intervertebral disc instability, this study, for the first time, performed therapeutic intervertebral disc regeneration therapy in patients and obtained favorable findings. (Yoshikawa, 2010) In a small pilot study in patients with chronic back pain diagnosed with lumbar disc degeneration and treated with autologous expanded bone marrow mesenchymal stem cells injected into the nucleus pulposus area, outcomes compared favorably with the results of other procedures such as spinal fusion or total disc replacement. (Orozco, 2011)