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Notice of Independent Review Decision

October 21, 2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Left Lumbar Radiofrequency Ablation at L4-L5

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

The Reviewer is a Board Certified Orthopaedic Surgeon with over 42 years of experience.

REVIEW OUTCOME:

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

Overturned (Disagree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

12/19/2012: X-ray L-Spine
12/19/2012: Evaluation
12/21/2012: Evaluation
12/28/2012: Evaluation
01/04/2013: Evaluation
01/11/2013: Evaluation
01/18/2013: Evaluation
02/15/2013: Daily Progress Notes
02/16/2013: Daily Progress Notes
02/21/2013: Daily Progress Notes
02/22/2013: Daily Progress Notes
02/23/2013: Daily Progress Notes
02/26/2013: MRI Lumbar Spine

02/27/2013: Daily Progress Notes
02/28/2013: Daily Progress Notes
03/02/2013: Daily Progress Notes
03/04/2013: Daily Progress Notes
03/06/2013: Daily Progress Notes
03/06/2013: Pain Management Consultation
03/07/2013: Electrodiagnostic Evaluation/EMG-NCS
03/07/2013: Daily Progress Notes
03/11/2013: Daily Progress Notes
05/09/2013: Subsequent Medical Report
06/11/2013: Evaluation
06/11/2013: Manual Muscle Strength Exam Lumbar
06/19/2013: UR regarding Diagnostic Medial Branch Block L4-L5
07/26/2013: Evaluation
08/01/2013: Evaluation
08/05/2013: Notification of surgery
08/08/2013: UR performed
08/20/2013: Orthopedic Report
09/04/2013: UR performed
09/16/2013: Evaluation

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a male who was injured on xx/xx/xx while working. There is no pertinent surgical intervention noted. The claimant's working diagnosis included lumbar disc displacement and lumbar region sprain.

12/19/2012: X-ray L-Spine, Impression: Degenerative disc disease at the L4-5 level. No acute bony abnormality is demonstrated.

12/19/2012: Evaluation. Treatment Plan: Cryotherapy locally for 15 min. Medications: hydrocodone. Chief Complaint: lower back and pelvis pain.

01/11/2013: Evaluation. Chief Complaint: lower back. Feeling worse. Physical therapy 3 times a week for 2 weeks. Using back brace. Findings: Restricted range of motion of the back: Flexion; mid-thigh, Extension: 10/30 degrees. Current medications: hydrocodone.

02/15/2013: Daily Progress Notes. Complaints: Reports of pain to lumbar musculature. Findings: tenderness and restricted range of motion of the lumbar region. Weakness of the lumbar musculature. Plan of treatment: Therapeutic exercises/ Neuromuscular re-education, Manual Therapy. Heat to the lumbar.

02/26/2013: MRI Lumbar Spine without contrast, Impression. 1. At the L4-L5 level, there is disc desiccation, moderate disc space narrowing, moderate bilateral facet arthropathy, and circumferential disc bulge measuring 2 to 3 mm producing effacement of the thecal sac and mild stenosis of the bilateral interal recesses. 2. At the LS/S1 level, there is disc desiccation and a broad-based central disc protrusion extending 1 mm posteriorly producing effacement of the thecal sac.

03/06/2013: Pain Management Consultation. Chief complaint: low back, bilateral lower extremity pain, left. Current medications: hydrocodone , naproxen, flexeril . . Physical Examination: Range of motion of the lumbar spine revealed flexion to less than 30 degrees, extension to 15 degrees with pain at the upper lumbar region. Positive bilateral lumbosacral junction tenderness. Positive bilateral lumbar paraspinal spasms. Impression: 1. Lumbar radiculitis. 2. Lumbar disc displacement. 3. Muscle spasms. Plan: Recommended interlaminar L4-5 lumbar epidural steroid injection under fluoroscopic guidance for relief of low back and leg pain.

03/07/2013: Electrodiagnostic Evaluation/EMG-NCS, Impression: 1. There is electrophysiologic evidence most consistent with active radiculopathy processes involving the left more so than the right S1 nerve root levels.

05/09/2013: Subsequent Medical Report. The LESI was denied by the carrier. Stated that his work is not heavy, however, at times he stand for prolonged periods and that is increased his back pain. Clinical Findings: Examination of the lumbar spine reveals tenderness of the lumbar paraspinals bilaterally. Lumbar ranges of motion are restricted with pain. Straight left raise test is positive. There is decreased sensation of the bilateral lower extremities. Examination of the right hip revealed tenderness of the right hip joint at the lateral aspect upon palpation. Right hip ranges of motion provoke pain. Faber test provokes pain. Treatment plan: Evaluation. Medications: Hydrocodone, Naproxen, Keto. DME: Patient stated EMS unit helps with pain, recommended patient to continue using the EMS unit. Work with restrictions. Follow up in four weeks.

06/11/2013: Evaluation. Chief complaint: History of pain in the lumbar region. Plan: Lumbar: Patient continued to have primarily axial back pain. There was paravertebral tenderness with normal motor and sensory exam. Straight leg raises did not cause radicular pain, just some back pain. Conservative treatment including physical therapy, NSAID's and muscle relaxers has been tried with little or no effect. Going to examine no more than two levels. The patient was advised to refrain from taking pain relievers for 4-hours prior to the procedure. No surgical procedure is currently anticipated for the lumbar spine, but successful pain relief with medical branch block will result in a recommendation for radiofrequency rhizotomy. Will proceed with the MBB at his left L4 and Left L5 region.

07/26/2013: Evaluation. Patient presented for a lumbar medial branch block. He stated his pain level was 7/10 with numbness in left leg. Physical Exam: The gait is antalgic and compensated. Tenderness of the spinous and lumbar. Moderate restriction in rotation and lateral flexion. 5/5 strength and 2/4 lower extremity reflexes. Sensation intact. Straight left raise positive bilaterally for back pain only. Procedures: Pre-Operative Diagnosis; Lumbar facet strain/syndrome. Procedures: 1. Lumbar medial branch block L4 facet nerve left. 2. Lumbar medial branch block L5 facet nerve. 3. Fluoroscopic localization needle, lumbar. Plan: Lumbar: Patient had 80% relief of pain on the left. Stated that although the left side of his back typically hurts, after the medical branch block, his left side felt

much improved and he now has mostly right sided pain. This suggests that he has pain from his right side facets as well. Will proceed with left L4-L5 facet nerve medial branch rhizotomy, and then follow up with the MBB on the right.

08/01/2013: Evaluation. Patient stated his pain level was 4/10. He did state he had relief from the medial branch block. Physical Exam: There was tenderness to the spinous process and lumbar. Mild spasm. ROM was moderately restricted in rotation and lateral flexion. Strength 5/5, Reflexes 2/4 bilaterally. Sensation intact. Straight left raise positive bilaterally for back pain only. Plan: Patient had 80% relief of pain on the left. Stated that although the left side of his back typically hurts, after the medial branch block, his left side felt much improved and he now has mostly right sided pain. This suggests that he has pain from his right side facets as well. Will proceed with left L4-L5 facet nerve medial branch rhizotomy, and then follow up with the MBB on the right.

08/08/2013: UR performed. Rationale for Denial: The requested procedure is currently under study and is not considered medically necessary. Without peer-to-peer review, the request cannot be considered medically necessary based on the documentation presented for review.

08/20/2013: Orthopedic Report. reviewed the denial letter regarding the recommended radio frequency ablation to his lumbar spine that was performed by. After reading the rationale of noncertification, copied and pasted the ODG section regarding radio frequency ablation of the lumbar spine. gave no reason why the patient should not undergo the radio frequency ablation. The patient's physical examination revealed axial mechanical back pain in nature with no lower extremity symptoms. The patient had a diagnostic medial branch block to the left side of his lumbar spine, which gave him 8-% relief and decreased his pain tremendously. At that point, we were considering the radio frequency ablation to his lumbar spine to treat his axial mechanical back pain in nature. stated that the patient's physical examination revealed axial mechanical back pain with no lower extremity radiculopathy. He stated an EMG/NCV dated March 7, 2013 showed some radiculopathy process involving the left greater than right S1 nerve root. Physical examination did not reveal radiculopathy. opined that the patient does meet indications to proceed with a radio frequency ablation.

09/04/2013: UR performed. Rationale for Denial: According to evidence based guidelines, facet joint radiofrequency neurotomy is under study. Conflicting evidence is available as to the efficacy of this procedure. Treatment requires a diagnosis of facet joint pain using a medial branch block. The criteria for the use of diagnostic blocks for facet "mediated" pain includes one set of diagnostic medial branch blocks with a response of at least 70 percent pain reduction. The pain response should be approximately 2 hours of Lidocaine. In this case, while it is appreciated that the patient is reported to have received 80 percent pain relief following a medial branch block, the records do not establish that the pain relief was sustained for at least 2 hours, as specified by evidence based guidelines to consider proceeding with a radiofrequency neurotomy procedure. The appeal request for Left Lumbar Radiofrequency Ablation at L4-L5 is not certified.

09/16/2013: Orthopedic Report. Patient stated his was an 8/10 with radiating pain into right hip to right thigh. Patient had a medial branch block on 7/26 with improvement. Patient stated he has been doing physical therapy for 2 sessions. Medications: Flexeril 5mg, Naproxen Sodium 550 mg, Lorcet 10-650. Plan: Lumbar: He had 80% relief of pain on the left. Stated that although the left side of his back typically hurts, after the medial branch block, his left side feels much improved and he now has mostly right side pain. This suggests that he has pain from his right sided facets as well. Will proceed with left L4-L5 facet nerve medial branch rhizotomy, and then follow that up with MBB on the right. Insurance carrier has denied the request twice.

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

The previous adverse determinations are overturned. The Official Disability Guidelines are ambivalent on this procedure. Although the procedure may be under study there are studies to support this procedure. The ablation rhizotomy is indicated since the claimant did have relief following the medial branch block on 7/26/13. The request is for only one joint level and the claimant is undergoing physical therapy in conjunction with the procedure. The procedure will likely afford relief for at least 6 months. Therefore, the request for Left Lumbar Radiofrequency Ablation at L4-L5 is found to be medically necessary.

PER ODG:

Facet joint radiofrequency neurotomy

Under study. Conflicting evidence is available as to the efficacy of this procedure and approval of treatment should be made on a case-by-case basis (only 3 RCTs with one suggesting pain benefit without functional gains, potential benefit if used to reduce narcotics). Studies have not demonstrated improved function. Also called Facet rhizotomy, Radiofrequency medial branch neurotomy, or Radiofrequency ablation (RFA), this is a type of injection procedure in which a heat lesion is created on specific nerves to interrupt pain signals to the brain, with a medial branch neurotomy affecting the nerves carrying pain from the facet joints.

Current research: Multiple placebo-controlled trials have been completed on this topic, but these studies all had potential clinical methodologic flaws including the use of non-controlled diagnostic blocks and potential discrepancies in technique of lesioning from that which is currently recommended. ([Hooten, 2005](#)) ([van Kleef, 1999](#)) ([Boswell, 2005](#)) ([Leclaire, 2001](#)) ([Van Kleef, 1999](#)) ([Gallagher, 1994](#)) ([van Wijk, 2005](#)) A recent small RCT found that the percutaneous radiofrequency neurotomy treatment group showed statistically significant improvement not only in back and leg pain but also back and hip movement as well as the sacro-iliac joint test. There was significant improvement in quality of life variables, global perception of improvement, and generalized pain. But RF neurotomy was not a total treatment, and it provided relief for only one component of the patients' pain. ([Nath, 2008](#)) *Observational Trials:* One observational trial found 60% of patients received 90% relief at 12 months and 87% had 60% pain relief. The authors used confirmatory blocks with 80% pain relief. ([Dreyfuss, 2000](#)) Clinical audits have reported pain relief in almost 70% of patients at 6 months. ([Gofeld, 2007](#))

Systematic reviews: When compiled into systematic reviews, the evidence has been found to be conflicting for a short-term effect ([Niemisto-Cochrane, 2003](#)) ([Niemisto-Cochrane, 2006](#)) and moderate to strong for a long-term effect when compared to a placebo. ([Geurts, 2001](#)) ([Boswell, 2005](#)) The latter systematic review failed to distinguish results between lumbar and cervical patients. A critical nonsystematic review by Slipman et al. reported "sparse evidence" to support use in the lumbar region ([Slipman, 2003](#)) and the ICSI did not feel the current scientific evidence allowed for a conclusion on the subject. ([ICSI, 2005](#)) Boswell et al have recently published a systematic review that included several new observational studies that came to

the conclusion that the evidence for neurotomy was moderate (Level III) for long-term relief of cervical and lumbar facet joint pain. This conclusion was based on the standard techniques used in the United States. ([Boswell2, 2007](#)) Interventional strategies, such as prolotherapy, botulinum toxin injections, radiofrequency denervation, and intradiskal electrothermal therapy, are not supported by convincing, consistent evidence of benefit from randomized trials. ([Chou, 2008](#))

Technique: There are several techniques. ([Gofeld2, 2007](#)) The North American technique uses tangential insertion of a curve-tipped cannula parallel to the nerves. There is a long learning curve and results vary among operators. The European technique relies on radiologic appearance. Potential technical flaws include inadequate exposure of the tip to the target nerve and generation of a lesion that is too small to ablate the nerve. There is also an Australian technique.

Factors associated with failed treatment: These include increased pain with hyperextension and axial rotation (facet loading), longer duration of pain and disability, significant opioid dependence, and history of back surgery.

Factors associated with success: Pain above the knee (upper leg or groin); paraspinal tenderness. ([Cohen2, 2007](#))

Duration of pain relief: One retrospective analysis has determined that the mean duration of relief is approximately 10-12 months (range 4-19 months). Subsequent procedures may not be as successful (possibly secondary to technical failure or progression of spinal degeneration). ([Schofferman, 2004](#)) In a more recent study 68.4% of patients reported good to excellent pain relief at 6 months and showed consistent results with the above findings. ([Gofeld, 2007](#))

Complications: Potential side effects include painful cutaneous dysesthesias, increased pain due to neuritis or neurogenic inflammation, and cutaneous hyperesthesia. Neuritis is the most frequent complication (5% incidence). ([Boswell, 2005](#)) ([Boswell2, 2007](#)) ([Cohen, 2007](#)) The clinician must be aware of the risk of developing a deafferentation centralized pain syndrome as a complication of this and other neuroablative procedures. This procedure is commonly used to provide a window of pain relief allowing for participation in active therapy. ([Washington, 2005](#)) ([Manchikanti, 2003](#)) See also [Facet joint diagnostic blocks](#) (injections); [Facet joint pain, signs & symptoms](#); [Facet joint medial branch blocks](#) (therapeutic injections); [Facet joint intra-articular injections](#) (therapeutic blocks). Also see [Neck Chapter](#) and [Pain Chapter](#).

Criteria for use of facet joint radiofrequency neurotomy:

(1) Treatment requires a diagnosis of facet joint pain using a medial branch block as described above. See [Facet joint diagnostic blocks](#) (injections).

(2) While repeat neurotomies may be required, they should not occur at an interval of less than 6 months from the first procedure. A neurotomy should not be repeated unless duration of relief from the first procedure is documented for at least 12 weeks at $\geq 50\%$ relief. The current literature does not support that the procedure is successful without sustained pain relief (generally of at least 6 months duration). No more than 3 procedures should be performed in a year's period.

(3) Approval of repeat neurotomies depends on variables such as evidence of adequate diagnostic blocks, documented improvement in VAS score, decreased medications and documented improvement in function.

(4) No more than two joint levels are to be performed at one time.

(5) If different regions require neural blockade, these should be performed at intervals of no sooner than one week, and preferably 2 weeks for most blocks.

(6) There should be evidence of a formal plan of additional evidence-based conservative care in addition to facet joint therapy.

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 (PROVIDE A DESCRIPTION)**
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**