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Notice of Independent Review Decision

DATE: August 20, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Trial Spinal Cord Stimulator

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

The reviewer is certified by the American Board of Orthopaedic Surgery with over 13 years of experience.

REVIEW OUTCOME:

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

Upheld (Agree)

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

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a female who injured her low back on xx/xx/xx. She has undergone lumbar laminectomy, discectomy, foraminotomy and decompression at L5-S1 with a fusion on 08/14/00 revision surgery and posterolateral fusion at L5-S1 on 05/06/02, hardware removal and laminectomy on 09/23/09, and revision surgery with posterolateral fusion at L4-L5 on 02/27/13. Documentation was submitted noting that the claimant has undergone physical therapy, medications, and injections.

03/31/11: Electrodiagnostic findings. ELECTRODIAGNOSTIC IMPRESSION:

The electrodiagnostic findings are consistent with bilateral chronic L5 radiculopathy. CLINICAL IMPRESSION: The clinical symptom complex of chronic lower back pain and bilateral numbness and weakness in the extremities is consistent with the electrodiagnostic findings of bilateral chronic L5 radiculopathies.

05/21/13: The claimant was evaluated. It was noted that she had previously had PLIF, EMG LE, CT Myelogram, injection for hardware block, hardware removal,

and spinal fluid leak repair as well as posterior lumbar interbody intertransverse and a TLIF. She rated her pain as 7/10. She complained of low back pain and pain radiating to the right lower extremity when sitting for too long. She also noted numbness in the right lower extremity. No detailed physical exam was documented. It was noted that she had participated in postop therapy which helped out to some degree. The impression was lumbar spinal stenosis and lumbar disc displacement. The plan was to obtain CT myelogram.

04/10/13: Lumbar myelogram report. IMPRESSION: Fluoroscopic guided lumbar myelogram at the L2-L3 level. There is relative decreased flow of contrast below the L4-L5 disc level. Surgical hardware from L4-S1 is noted. There is minimal circumferential narrowing of the thecal sac at L3-L4.

06/10/13: CT of the lumbar spine post myelogram report. IMPRESSION: Anterior and posterior fusion at L4-L5. There is incomplete incorporation of interbody device and questionable mild subsidence. There is also spondylosis eccentric to the right and narrowing of the traversing right L5 nerve root sleeve. Further facet arthrosis contributes to moderate foraminal narrowing and possible contact of exiting bilateral L4 nerve roots. Anterior and posterior fusion at L5-S1 with incorporation of interbody device and bridging osseous fusion. Posterior spondylotic ridging and hypertrophy of fused facet joints contributes to mild to moderate foraminal narrowing. Disc and facet pathology at L3-L4 with circumferential narrowing of the thecal sac and mild canal stenosis and mild/moderate foraminal narrowing.

06/23/14: The claimant was evaluated for a history of throbbing pain in the lumbar region. She rated the pain as 6-7/10. She complained of swelling. She also had numbness and a sharp pain in both feet. On exam, her gait was antalgic. She had a normal lumbar lordosis. She had a healing posterior lumbar wound. She had tenderness to palpation of the thoracic and lumbar regions. Palpation was painful in the bilateral greater trochanters, SI joints, and buttocks. There was moderate muscle spasm. ROM was limited in rotation with moderate restriction and lateral flexion with moderate restriction. Muscle testing was 3/5 at the bilateral hip flexors, hip extensors, quadriceps, hip abduction, hip adduction, knee extensors, and knee flexion. 2/4 bilateral patella and Achilles reflex. Sensation Lower Leg: L5 left is decreased and L5 right is decreased. SLR was positive bilaterally for leg pain to foot. The plan was to perform LESI for treatment of radicular pain. It was noted that the radiculopathy had been unresponsive to prior physical therapy, NSAIDs, and muscle relaxers. The plan was for only one interlaminar level to be injected under fluoroscopy to help with postop radiculitis.

07/12/13: A note indicated that the recommended lumbar epidural steroid injection had been denied.

08/23/13: The claimant was evaluated for complaints of 6/10 pain in her lumbar region with numbness and tingling radiating bilaterally into her lower extremities. On exam, her gait was antalgic. She had tenderness to palpation in the thoracic and lumbar region. The right greater trochanter, SI joint, and buttock were painful

while the left were pain free. She had moderate muscle spasm. ROM was limited in rotation with moderate restriction and lateral flexion with moderate restriction. Motor testing remained unchanged at 3/5 as well as 2/4 patella and Achilles reflexes. Sensation was decreased in bilateral L5 distribution. SLR was positive on the right for leg pain to foot and positive on the left to back pain only. The plan was to request again LESI. A discussion was also had regarding the option of spinal cord stimulator to help with her chronic back pain and lower extremity symptoms.

12/13/13: LESI operative report. POSTOPERATIVE DIAGNOSIS: Lumbar radiculopathy. PROCEDURES: Lumbar epidural steroid injection. Lumbar lysis of adhesions. Interpretation of lumbar epidurogram. Fluoroscopic localization of needle, lumbar.

01/02/14: The claimant was evaluated. It was noted that she had complication following her LESI for which she had to undergo a blood patch. It was noted that the blood patch helped out initially and helped with her headaches. She had not noticed any change in her low back. She continued to experience back pain that she rated 6/10 with discomfort with side-to-side movements, soreness, and stiffness. She complained of muscle spasms in her low back region. She also complained of lower extremity symptoms that included numbness, tingling, and weakness. On exam, she had tenderness to palpation in her mid-lower lumbar region with decreased range of motion with flexion and extension. She had high levels of pain with right and left lateral bending. SLR elicited leg pain and back pain bilaterally, right side greater than left. She continued to experience diminished sensation along her L5 distribution bilaterally, right side greater than left. Her motor strength was weakened in both lower extremities, mostly in knee flexors and knee extensors as well as extensor hallucis longus. Her gait was slow. She was able to heel-toe walk, walk on toes, and walk on heels with discomfort in her right lower extremity. The impression was status post lumbar fusion at L4-L5 with persistent radiculopathy. The plan was for post-injection PT. She was set up for psychological evaluation prior to consideration of proceeding with spinal cord stimulator trial. Her medications were renewed (listed medications on previous report were Lunesta, Nabumetone, Soma, and Lorcet).

01/20/14: The claimant underwent psychiatric assessment, who opined that there were no psychosocial barriers to recovery, and no evidence of secondary gain from a psychological standpoint. She was found to be psychologically intact and cleared for spinal cord stimulator surgery.

02/26/14: The claimant was evaluated for chronic back pain and lower extremity radiculopathy. She rated her pain as 6/10 with constant pain, discomfort with side-to-side movements, soreness, and stiffness. She had right lower extremity numbness, tingling, and weakness. Her exam remained unchanged from 01/02/14 with a note being made that she noted right hip, thigh, and right knee pain. The plan was to proceed with spinal cord stimulator trial.

04/09/14: The claimant was evaluated for persistent back pain and lower extremity radiculopathy. made note that the claimant had undergone psychological assessment and clearance. He also noted that she underwent lumbar epidural steroid injection on 12/13/13 with some relief of her lower extremity symptoms that was only temporary. She had been in post-injection PT as well. She continued to be symptomatic and was recently prescribed Lyrica to help with her lower extremity symptoms. She presented with low back pain rated at 5/10 with constant pain, discomfort with various movements. She had bilateral lower extremity numbness, tingling, and weakness. On exam, she had tenderness upon palpation in her mid-lower lumbar region with decreased range of motion with flexion and extension and pain with right and left lateral bending. SLR elicited leg pain and back pain, right side greater than left. She noted right hip, right thigh, and right buttock pain. She had diminished sensation along her L5 distribution with weakness noted in knee flexors and knee extensors as well as extensor hallucis longus. The plan was to resubmit for spinal cord trial. Her mediations were reviewed, and she was to continue with Lyrica to help with her persistent lower extremity radiculopathy.

06/04/14: The claimant was evaluated for continued back pain rated at 4/10. She continued to note increased pain with increased activity as well as lower extremity numbness, tingling, and weakness. On exam, she had tenderness upon palpation in her lumbar spine with decreased range of motion with flexion and extension and pain with right and left lateral bending. SLR elicited leg pain and back pain, right side greater than left. She noted right hip, right thigh, and right buttock pain. She had diminished sensation along her L5 distribution bilaterally with weakness noted in knee flexors and knee extensors as well as extensor hallucis longus. The plan was to continue with spinal cord stimulator trial, currently awaiting approval.

06/17/14: UR. RATIONALE: There is no mention or documentation of the patient having other lower levels of care that have been done, particularly addressing the patient's pain coping skill issues. There is also no mention of any plans for significant medication weaning and discontinuation if a spinal cord stimulator is done. Therefore, this request is not medically reasonable or necessary.

07/14/14: UR. RATIONALE: The first criteria for this procedure includes "symptoms are primarily lower extremity radicular pain." Clearly documented in the last visits, the patient's major complaint was low back. Complaints in the legs seem to be mostly that of numbness, tingling, and weakness but no indication of pain. Based on this, I recommend adverse determination.

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

The previous adverse decisions are upheld. The Official Disability Guidelines (ODG) supports spinal cord stimulators for patients with persistent lower extremity radicular pain following failed spinal surgery. The claimant's primary issue is pain in the lower back. recent office notes (01/2/14, 04/9/14, 06/4/14) indicate

complaints of lower extremity numbness, tingling, and weakness. The record does not clearly state that the claimant has lower extremity radicular pain. Therefore, the request for Trial Spinal Cord Stimulator is not medically necessary based on the records reviewed as the ODG criteria have not been met.

ODG:

<p>Spinal cord stimulators (SCS)</p>	<p>Indications for stimulator implantation:</p> <ul style="list-style-type: none"> • Failed back syndrome (persistent pain in patients who have undergone at least one previous back operation and are not candidates for repeat surgery), when all of the following are present: (1) symptoms are primarily lower extremity radicular pain; there has been limited response to non-interventional care (e.g. neuroleptic agents, analgesics, injections, physical therapy, etc.); (2) psychological clearance indicates realistic expectations and clearance for the procedure; (3) there is no current evidence of substance abuse issues; (4) there are no contraindications to a trial; (5) Permanent placement requires evidence of 50% pain relief and medication reduction or functional improvement after temporary trial. Estimates are in the range of 40-60% success rate 5 years after surgery. Neurostimulation is generally considered to be ineffective in treating nociceptive pain. The procedure should be employed with more caution in the cervical region than in the thoracic or lumbar due to potential complications and limited literature evidence. • Complex Regional Pain Syndrome (CRPS)/Reflex sympathetic dystrophy (RSD), 70-90% success rate, at 14 to 41 months after surgery. (Note: This is a controversial diagnosis.) • Post amputation pain (phantom limb pain), 68% success rate (Deer, 2001) • Post herpetic neuralgia, 90% success rate (Deer, 2001) • Spinal cord injury dysesthesias (pain in lower extremities associated with spinal cord injury) • Pain associated with multiple sclerosis • Peripheral vascular disease (insufficient blood flow to the lower extremity, causing pain and placing it at risk for amputation), 80% success at avoiding the need for amputation when the initial implant trial was successful. The data is also very strong for angina. (Flotte, 2004) <p>For average hospital LOS if criteria are met, see Hospital length of stay (LOS).</p>
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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)**