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Notice of Independent Review Decision

DATE: September 26, 2012

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Outpatient Lumbar Revision of Dorsal Column Stimulator, Lead and Generator, Electrode, and Analysis

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

This physician is Board Certified by the American Board of Orthopaedic Surgery with over 40 years of experience.

REVIEW OUTCOME:

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

- 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 each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a male who initially sustained a work-related low back injury and is status post bilateral L5-S1 partial laminectomy and foraminotomy. He subsequently re-injured his back when he was involved in a work-related motor vehicle accident. He subsequently underwent redo bilateral L5-S1 discectomy. The claimant underwent facet joint rhizotomy for continued symptoms. He underwent implantation of permanent spinal cord stimulator, placement of connector, and placement of Itrel-3 pulse generator. He underwent thoracic laminectomy, epidural neurolysis, and replacement of spinal cord stimulator with

resumed TL lead. He was later evaluated by MD for continued low back pain. He was found on EMG to have bilateral chronic L4-L5 radiculopathy. A lumbar CT myelogram demonstrated loss of normal disc density at L5-S1 with narrowed lateral recesses bilaterally with severe encroachment bilaterally as well as evidence of a right pars defect and previous laminectomy defect. He then underwent anterior lumbar discectomy at L5-S1 with partial corpectomy and decompression as well as ALIF of L5-S1, revision of lumbar decompression at right L5-S1, revision of lumbar decompression and facetectomy at left L5-S1, posterolateral fusion at L5-S1, and placement of pedicle screws and internal fixation at L5-S1.

06/15/06: Operative Report POSTOPERATIVE DIAGNOSES: Lumbar disc rupture. SURGICAL PROCEDURE: Left L5, Left S1 foraminal epidural root blocks.

04/20/07: Operative Report. POSTOPERATIVE DIAGNOSES: Lumbar disc protrusion, L5-S1. Base-of-spinous-process fracture, L5. SURGICAL PROCEDURE: Bilateral L5-S1 partial laminectomy/foraminotomy.

09/18/07: Operative Report. POSTOPERATIVE DIAGNOSIS: Lumbar radiculopathy. SURGICAL PROCEDURE: Left L5 and left S1 foraminal epidural root blocks.

11/09/07: Operative Report. POSTOPERATIVE DIAGNOSIS: Recurrent herniated nucleus pulposus, L5-S1. PROCEDURE PERFORMED: Redo bilateral L5-S1 discectomy.

08/13/08: Operative report. POSTOPERATIVE DIAGNOSES: Intractable low back pain. Lumbar facet joint arthropathy. History of prior lumbar laminectomy. OPERATIVE PROCEDURE: Left-sided radiofrequency thermal coagulation of the median branch at L3, L4, L5, the sacral ala, and the S1 posterior neural foramina. Fluoroscopic needle localization for the above.

07/09/09: Operative report. POSTOPERATIVE DIAGNOSIS: Lumbar radiculopathy. PROCEDURE PERFORMED: Bilateral S1 nerve root block.

07/30/09: Operative report. DIAGNOSES: Lumbar stenosis. Lumbar radiculopathy. Lumbar disc protrusion. SURGICAL PROCEDURE: Selective nerve root block, L5. Bilateral foraminal epidural block, L5.

10/08/09: Operative Report. POSTOPERATIVE DIAGNOSIS: Chronic intractable pain. PROCEDURE PERFORMED: Placement of Resume TL spinal cord stimulator trial.

10/13/09: The claimant was seen following spinal cord stimulator trial. It was noted that he had almost complete pain relief from his buttocks down. There was a small area in the middle of his incision where the stimulator was not reaching nor covering. The plan was for revision and implant of permanent stimulator/connector and placement of pulse generator.

10/16/09: Operative Report. POSTOPERATIVE DIAGNOSIS: Chronic intractable pain. Successful spinal cord stimulator trial. PROCEDURE PERFORMED: Revision of spinal cord stimulator, placement of connector and placement of Irel-3 pulse generator.

10/26/09: The claimant was examined by MD who removed sutures from the incision and applied Steri-Strips. His incisions were healed "beautifully." It was noted that he was getting excellent coverage in his back and legs.

10/29/09: Thoracic Spine Two Views/Lumbar Spine Two to Three Views report FINDINGS: There is an epidural stimulator noted in place overlying the posterior elements of the lower thoracic spine. IMPRESSION: Thoracic spine, mild spondylosis. Lumbar spine, mild degenerative disc disease.

11/23/09: The claimant was reevaluated by MD who noted that the lower two electrodes in his spinal cord stimulator had come out of his epidural space. The upper two were within the space, and he was still getting good coverage, particularly into his left leg. The claimant stated that he had no pain in his legs and that he was using the stimulator on a regular basis with satisfaction. ASSESSMENT/PLAN: At this point, there is no need to do a stimulator revision. He will call me if the stimulator stops functioning and covers his painful area. There is a small area in the lower part of his lumbar incision, which hurts with trigger points. I am going to put him on a Lidoderm patch to see if he can use that twice a day.

11/30/09: A note by MD indicated that the claimant called stating that his stimulator was not covering his leg pain as well as previously. ASSESSMENT/PLAN: I am strongly suggesting an outpatient procedure to replace the existing stimulator. He does not need a new stimulator nor does he require further surgical intervention other than to have the stimulator in the epidural space and reanchored. He is also having trigger-point pain in the mid portion of his incision, which we will treat with an office block on Friday.

12/01/09: A note by MD indicated that the claimant wished to have his spinal cord stimulator revised. It was noted that recent x-ray showed the bottom three electrodes to be migrated inferiorly out of the epidural space. Dr recommended replacement of the stimulator in the epidural space and use of a different, more secure anchoring technique.

12/31/09: Operative Report. POSTOPERATIVE DIAGNOSIS: Chronic intractable pain. PROCEDURE PERFORMED: Thoracic laminectomy, epidural neurolysis, and replacement of spinal cord stimulator with resumed TL lead.

01/13/10: The claimant was evaluated by MD for suture removal. He stated that several days prior, he felt a sudden jolt in his back, turned the stimulator off, and his pain had been gone since. X-rays were ordered.

01/15/10: Thoracic Spine Two Views report . FINDINGS: There is an epidural stimulator in place in satisfactory position. IMPRESSION: Mild spondylosis.

02/08/10: Note indicated that review of his x-rays demonstrated the stimulator to be in perfect position. It was noted that he would need programming of the stimulator with the xxxx nurse.

06/08/10: The claimant was evaluated for evaluation of continued back pain. He complained of 8/10 back pain with left leg pain. On physical exam, he had tenderness in the lumbar spine. He had painful decreased lumbar flexion. SLR was positive on the left and negative on the right. He was able to toe and heel walk. He had an exquisitely tender left SI joint with a positive FABER test as well as flamingo test and posterior shear and FABER. His patellar reflexes were 1+ on the left and 2+ on the right. His Achilles reflexes were 2+ on the left and 3+ on the right. He had some motor weakness to the extensor hallucis longus on the left as well as foot evertors. MRI scan dated 12/23/08 demonstrated bulging at L4-L5 and L5-S1 per the report. Dr. planned to review his MRI films before making further recommendations. Lumbar spine x-rays taken at the office demonstrated no fractures and no instability.

08/15/11: Operative Report. POSTOPERATIVE DIAGNOSES: Low back pain. Lumbar radiculopathy. Herniated nucleus pulposus of the lumbar spine. PROCEDURE PERFORMED: Injection of contrast material into the spinal canal for lumbar myelogram procedure. Fluoroscopy. Radiological examination and interpretation of lumbar myelogram.

08/15/11: Lumbar CT Myelogram IMPRESSION: A central disc herniation with intradiscal gas is superimposed on osteophytes and annular disc bulging at L5-S1. The AP dimension of the disc-osteophyte complex at L5-S1 measures 8 mm on the sagittal reformatted image. There is moderate L5-S1 canal stenosis. The L5-S1 neural foramina show severe encroachment due to intervertebral disc height loss, osteophytes, and annular disc bulging. There are remote changes of L5-S1 laminectomy. The left L5 inferior facet appears surgically resected. A right L5 pars defect is noted. No spondylolisthesis at L5-S1 is seen. The lateral recess and neural foramina bilaterally at L5-S1 are mildly encroached secondary to osteophytes and annular disc bulging, but no central canal stenosis is shown. The lateral recesses at L3-L4 are borderline stenotic. The neural foramina at L3-L4 are mildly narrowed secondary to osteophytes and annular disc bulging. The central canal at L3-L4 is low normal. No significant canal or foraminal stenosis is at L1-L2 or L2-L3.

11/18/11: Operative Report. POSTOPERATIVE DIAGNOSES: Herniated nucleus pulposus of L5-S1. Neurogenic Claudication. PROCEDURES PERFORMED: Anterior lumbar discectomy at L5-S1 with partial corpectomy and decompression. ALIF of L5-S1 using STALIF 13 mm 12-degree cage. Preparation and application of interbody device, L5-S1. Anterior lumbar instrumentation, L5 and S1. Harvest of local bone graft from partial corpectomy with preparation on the back table and application. Use of intraoperative microscopic magnification and light intensification through assistant

decompression. Cell Saver. Neurological monitoring.

11/18/11: Operative Report. POSTOPERATIVE DIAGNOSES: Herniated nucleus pulposus L5-S1. Neurogenic claudication. PROCEDURES PERFORMED: Revision lumbar decompression, L5-S1 right. Reversion lumbar decompression and facetectomy, L5-S1 left. Use of intraoperative microscopic magnification and light intensification for decompression. Posterolateral effusion, L5-S1. Placement of pedicle screws internal fixation, L5-S1. Harvesting of local bone graft with processing and grafting. Placement of an amniotic membrane adhesion barrier over the dura. Placement of external bone graft stimulator. Cell saver. Intraoperative neuromonitoring.

01/20/12: The claimant was reevaluated by MD who noted that he had been doing physical therapy. It was noted that he was still getting some burning sensation to the tops of his feet, but he differentiated that from the leg pain he was having preoperatively. He also stated that he had not had much back pain since the surgery. On physical exam, his incisions were well healed. He was wearing a back brace. He had intact sensation, although there were paresthesias along L5 on the left. His EHL was improving but still weak. SLR were negative. The plan was to continue with additional physical therapy.

06/12/12: The claimant was reevaluated by MD. He continued to experience lower extremity symptoms that included numbness, tingling, and weakness. He stated that he used his spinal cord stimulator, which gave him good result in his lower extremities. He stated that until recently, he noticed malfunctioning of the spinal cord stimulator. He was interested in getting that evaluated. His low back pain was rated at 2/10. On physical exam, there was tenderness on the mid-lower lumbar region and decreased range of motion with flexion and extension. SLR were mildly positive on the left and negative on the right. Motor strength was weak on the left when compared to the right, mostly in the EHL. He had some paresthesias along his L5 distribution on the left. DISCUSSION PLAN: The patient was advised of various home exercises and stretching to help with his range of motion and help with strengthening. The above patient is set up with xxxx rep to evaluate and run diagnostics on his spinal cord stimulator. The patient's medications will be renewed as they come due. These medications are medically necessary to treat the symptoms naturally resulting from this compensable injury.

07/27/12: The claimant was reevaluated by MD. He stated that he recently had an increase in his back pain. He stated that the pain was worse in the morning, but was often relieved by a bowel movement. It was noted that he had a dorsal column stimulator, which was still in his spine, and he stated that there were certain types of motions that he could do that would recreate a shock that ran up and down his spine and into his left leg. He stated that the dorsal column stimulator was revised on 12/31/09 and at that time, one of the wires was spliced. He stated that prior to that revision surgery, he was not having this "shock thing." However, since that revision surgery, he continued to get this intermittent shock with certain types of positions of his spine. It was noted that it severely limited his

ability to move into certain positions because he was afraid of receiving the very intense and painful shock. On physical exam, he had a well-healed surgical incision. He had decreased lumbar range of motion. His lower extremity motor strength and sensation were intact. PLAN OF TREATMENT: The patient has a dorsal column stimulator which otherwise is helpful except for the occasional intense and painful shocks that he gets with various positions. The patient states it feels like a loose wire and that certain positions cause very intense electrical shock. I believe this could be corrected with revising the stimulator and generator to ensure that whatever faulty component is in there is removed. When the patient returns for his next visit, we can get x-rays of the thoracic spine so that when we revise his dorsal column stimulator, we can place it in the same level. As stated earlier, the patient's current stimulator position is working well, all except for the occasional and sporadic intense shocks that he has been getting. X-rays

08/20/12: UR performed. RATIONALE: The request for a revision of the spinal cord stimulator is not clinically warranted at this time. There is no objective documentation indicating that the claimant's spinal cord stimulator, lead and generator are not working properly. The claimant has had subjective supports of symptoms; however, there is no objective documentation or input from the spinal cord stimulator technician or diagnostic evidence of failure and the request cannot be certified at this time.

09/04/12: UR performed. RATIONALE: The request for reconsideration for outpatient lumbar revisions of dorsal column stimulator, lead and generator, electrode, and analysis is not clinically warranted. The request remains not certified as no solid objective documentation of failure of the spinal cord stimulator or lead placement has been documented thus far. No documentation from the technician has been provided other than subjective reports of shock like symptoms documented on physical examination; therefore, the request for reconsideration for outpatient lumbar revision of dorsal column stimulator, lead and generator, electrode, and analysis is not certified.

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

The previous adverse decisions are upheld. I would agree with the outcome of the other reviewers that there is no objective evidence that the spinal column stimulator is out of place or not working properly to warrant adjustment, revision, etc. I think that further surgery at this time is not indicated. Therefore, the request for Outpatient Lumbar Revision of Dorsal Column Stimulator, Lead and Generator, Electrode, and Analysis is not medically necessary and is non-certified.

ODG:

<p>Spinal cord stimulation (SCS) LHL602 REV 05/12</p>	<p>Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated. See the Pain Chapter for <i>Indications for stimulator implantation</i>. There is some evidence supporting the use of Spinal Cord Stimulation (SCS) for Failed Back Surgery Syndrome (FBSS) and other selected</p>
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chronic pain conditions. Spinal Cord Stimulation is a treatment that has been used for more than 30 years, but only in the past five years has it met with widespread acceptance and recognition by the medical community. In the first decade after its introduction, SCS was extensively practiced and applied to a wide spectrum of pain

	<p>diagnoses, probably indiscriminately. The results at follow-up were poor and the method soon fell in disrepute. In the last decade there has been growing awareness that SCS is a reasonably effective therapy for many patients suffering from neuropathic pain for which there is no alternative therapy. There are several reasons for this development, the principal one being that the indications have been more clearly identified. The enhanced design of electrodes, leads, and receivers/stimulators has substantially decreased the incidence of re-operations for device failure. Further, the introduction of the percutaneous electrode implantation has enabled trial stimulation, which is now commonly recognized as an indispensable step in assessing whether the treatment is appropriate for individual patients. These implantable devices have a very high initial cost relative to conventional medical management (CMM); however, over the lifetime of the carefully selected patient, SCS may lead to cost-saving and more health gain relative to CMM for FBSS. See the Pain Chapter for complete list of references. Fair evidence supports the use of spinal cord stimulation in failed back surgery syndrome, those with persistent radiculopathy after surgery, according to the recently released joint American College of Physicians/ American Pain Society guideline recommendations on surgery and interventional treatments. (Chou, 2008) The National Institute for Health and Clinical Excellence (NICE) of the UK just completed their Final Appraisal Determination (FAD) of the medical evidence on spinal cord stimulation (SCS), concluding that SCS is recommended as a treatment option for adults with failed back surgery syndrome lasting at least 6 months despite appropriate conventional medical management. (NICE, 2008)</p> <p><i>Recent research:</i> New 24-month data is available from a study randomizing 100 failed back surgery syndrome patients to receive spinal cord stimulation (SCS) plus conventional medical management (CMM) or CMM alone. At 24 months, the primary outcome was achieved by 37% randomized to SCS versus 2% to conventional medical management (CMM), and by 47% of patients who received SCS as final treatment versus 7% for CMM. All 100 patients in the study had undergone at least one previous anatomically successful spine surgery for a herniated disk but continued to experience moderate to severe pain in one or both legs, and to a lesser degree in the back, at least six months later. Conventional medical therapies included oral medications, nerve blocks, steroid injections, physical and psychological therapy and/or chiropractic care. (Kumar, 2008) There is fair evidence that spinal cord stimulation is moderately effective for failed back surgery syndrome with persistent radiculopathy, though device-related complications are common. (Chou3, 2009) A nonrandomized, prospective cohort study in workers comp patients with chronic back and leg pain after spine surgery, ie failed back surgery syndrome (FBSS), found no significant difference in pain, disability, or opioid use between patients that received (at least a trial of) SCS, care at a pain clinic, or neither (usual care) at 12 and 24 months. Only 25% of SCS patients in this study received psychological screening prior to the trial, whereas ODG recommends psychological screening prior to all SCS implantations. Because few patients in any group in this study achieved success at any follow-up, the authors suggested that no treatment has a substantial impact on average in this patient group. (Turner, 2010)</p> <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)**