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Notice of Independent Review Decision

DATE: November 12, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

SCS Implant 63650 63685 95971 72275 77003

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 male who injured his low back while working on xx/xx/xx.

09/05/13: The claimant was evaluated for pain. It was noted that his low back pain was much improved since his revision fusion. He denied neurologic bowel or bladder changes. He was still working with restrictions. On exam, he had minimal pain with ROM of the lumbar spine. Negative straight leg raise. Tenderness over hamstrings on the right. Assessment was post-revision fusion at L4-L5, doing well. Post-laminectomy syndrome with complex regional pain. It was noted that he had 50% improvement in his low back pain from revision fusion. He still had leg pain which had been present since his first surgery and was noted to be a complex regional pain syndrome. recommended a spinal cord stimulator trial. noted that much of his problems were neuropathic pain due to his first surgery.

03/17/14: The claimant was evaluated for possible spinal cord stimulator trial. He complained of low back pain and right lower extremity pain since a motor vehicle accident in xxxx. He underwent fusion at L4-L5 and L5-S1 in 2008. He reported

no relief of his low back and right lower extremity symptoms following that surgery. He had hardware removal in 2010 with no improvement in pain following the surgery. He reported having two motor vehicle accidents in xxxx. He later underwent a single level revision at L4-L5. He reported significant relief in low back pain following that surgery but had persistent right lower extremity symptoms. He complained of persistent right lower extremity pain and numbness and tingling in his right buttock, lateral anterior thigh, and right lateral lower leg and right medial foot. On exam, strength was 4+ at the psoas, quadriceps, tibialis anterior; 4 at the EHL/peroneus and gastro-soleus on the right and 5 on the left. He had diminished sensation to the right lower extremity along the medial dorsal foot, anterior lower leg, and lateral thigh. He was scheduled for an MRI and psychiatric evaluation for consideration of spinal cord stimulator trial.

03/26/14: MRI Lumbar Spine without Contrast report. IMPRESSION: At L4-L5, there has been laminectomy with partial discectomy and interbody fusion as well as posterior fusion with pedicle screws. This is unchanged from the most recent study. There is a right-sided extradural T1 and T2 hypointense structure in the right lateral recess at L4-L5. This is 6 x 6 x approximately 6 mm. This was not visible or was smaller on the previous study in December 2012. This appears unchanged from May 2012 however and therefore may represent a recurrent protrusion. There is metallic artifact in this region but this study was designed to minimize metallic artifact. I recommend obtaining post-contrasted scans with sagittal and axial T1-weighted scans. No fat-suppressed scans should be performed, only post-contrasted scans without fat suppression due to the metallic artifact in this region. Post-contrasted scans may help differentiate enhancing granulation tissue from non-enhancing scar tissue or fibrosis or recurrent protrusion in the right lateral recess. This is at L4-L5. Moderate facet arthropathy and bilateral neural foraminal narrowing at L3-L4 described above. There is no canal stenosis but there is neural foraminal narrowing. This is unchanged. would be happy to discuss these findings with the referring clinician at your convenience. Note that there is bilateral paraspinous muscle edema, possibly from postoperative changes which is stable.

05/21/14: EMG/NCS BLE. IMPRESSION: Chronic, inactive, right L4 and bilateral L5 radiculopathies. No evidence of a distal lower extremity peripheral neuropathy.

06/02/14: A note indicates that he was waiting for the claimant to submit to him a CD from his myelogram. He stated that he was still having pain in his leg.

06/12/14: CT Myelogram Lumbar Spine with Intrathecal Contrast report. IMPRESSION: Postoperative changes of lower lumbar fusion as detailed above. Multilevel lumbar spondylosis. Mild central spinal canal narrowing at L3-L4. Multilevel neural foraminal stenosis. Findings are similar to the prior MRI of 03/26/14. The prior MRI showed soft tissue density such as disc protrusion or scarring/fibrosis indenting the right anterolateral thecal sac in the region of the subarticular recess at the right L4-L5 level. This is also visualized on the myelogram but is mildly less conspicuous. This may be mildly decreased in size

compared to the MRI or the difference may relate to technical limitations due to artifact in this region.

06/27/14: A note states the claimant is a "rather huge gentleman. For his size, he has got a narrow spinal canal." He was noted to be fused successfully at L4-L5 and L5-S1 with calcification of the abdominal aorta and the conus at T12-L1. The transcription report notes "Ample posterior space that is epidural space. We can clearly go ahead and do a SCS trial."

07/21/14: The claimant was evaluated with complains of low back pain and stabbing and burning in the right thigh greater than back pain. He continued to take Norco 7.5 mg, methocarbamol, and Flexeril 10 mg. It was noted that he had lost 30 pounds in the last month "without trying and without dietary or activity change." His weight was 220 pounds and height 70 inches. He was instructed to call his PCP due to weight loss, family history of cancer, and personal history of smoking. He was to undergo psychiatric evaluation for SCS trial.

07/28/14: The claimant underwent psychological evaluation who concluded he was a good psychological candidate for spinal cord stimulator.

09/30/14: Operative report. POSTOPERATIVE DIAGNOSIS: "Failed back surgery syndrome on multiply operated low back x 4 with the patient experience having fused L4 to L5 to the sacrum, 360; serious and significant exogenous obesity; low back pain and right lumbar radicular syndrome buttock and right leg pain felt worst. Note, also on a positive note lost 15 pounds." PROCEDURE: Percutaneous placement of a 45 cm Medtronic 8-contact compact array lead introduced T12-L1 left of midline and advanced to the midline slightly to the right T8 and below. Epidurography; fluoroscopic interpretation no radiologist in attendance. Concerned about stenosis. Epidural anesthesia. Intraoperative trial. Complex programming x 1.

10/06/14: The claimant was evaluated for temporary spinal cord stimulator lead removal. He was noted to have a sinus infection. He denied any infection of the lead implant site. The temporary SCS was to be evaluated by Medtronic on this date. He indicated some reduction of this leg pain with ambulation but it was not a significant change. With standing, the leg still felt like fire. He had decreased his hydrocodone use from 4-5 per day down to 3 per day and had been relying upon the stimulator. On exam, he sounded congested. He was ambulating well. "change the program and have the patient stands for 20 min, as this is typically his pain provoking position." He reported continued "fire down his leg." It was noted that he would like to "speak with someone tomorrow regarding if his pain actually worsens now that the stimulators to be removed." The lead was removed with no evidence of infection or drainage. His hydrocodone was renewed. He was to follow up in four weeks. It was noted that was to call the patient the following day regarding if he wished to proceed with a stimulator implant or not. He was to call his for treatment of sinus infection.

(Date not listed): UR RATIONALE: According to ODG, there was no documentation of the patient having undergone psychological evaluation prior to requesting his spinal cord implantation. Furthermore, there was no indication that the previous spinal cord stimulator trial was providing the patient with positive effects from its use. Peer to peer contact was not successful. Therefore, although the patient has had ongoing complaints of low back pain, without having a clear identification that the spinal cord stimulator trial was effective in reducing the patient's pain and improving his functional ability, that the patient has undergone a psychological evaluation to address any confounding issues, and that the patient's potential infection had been cleared, which could affect the patient's overall pathology, the request cannot be supported at this time, and is non-certified.

(Date not listed): UR. RATIONALE: This male was injured on xx/xx/xx. He has undergone four prior back surgeries – the last of which consisted of a revision L5-S1 fusion. A psychological evaluation was performed on 07/28/14 for the proposed spinal cord stimulator. It was deemed that he was psychologically a good candidate. There was no documentation, however, of a successful spinal cord stimulator trial. Without such, the placement of the formal stimulator cannot be approved. If there is diminished symptomatology, a permanent replacement would be appropriate.

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

The previous adverse decisions are upheld. The patient does not require a permanent spinal cord stimulator (SCS). According to ODG, the trial SCS should provide at least 50% pain relief before considering a permanent device. The medical records indicate that the trial SCS resulted in mild reduction in leg pain for this claimant. Based on his experience with the trial SCS, it is unlikely that a permanent device will provide him with significant pain relief. Therefore, the request for SCS Implant 63650 63685 95971 72275 77003 is not medically necessary.

ODG:

<p>Spinal cord stimulators (SCS)</p>	<p>Indications for stimulator implantation:</p> <ul style="list-style-type: none"> • Complex Regional Pain Syndrome (CRPS) when all of the following are present: <ol style="list-style-type: none"> (1) There has been limited response to non-interventional care; (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. • For use in failed back surgery syndrome (FBSS), see the Low Back Chapter. • For average hospital LOS if criteria are met, see Hospital length of stay (LOS).
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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)**