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Notice of Independent Review Decision

DATE OF REVIEW: MARCH 28, 2011

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Permanent Dual Read Spinal Cord Stimulator Lumbar 63650 x 2 Outpt

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

This physician is a Board Certified Orthopedic Surgeon.

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 or not medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

On August 3, 2010 claimant underwent an MRI of the lower spine without contrast. The result of the MRI was 1.) 6.1cm cyst to the upper pole of the right kidney. Correlation with renal ultrasound is recommended, 2.) Findings are suggestive of small spinal canal throughout, secondary to congenital spinal stenosis. The AP diameter measures approximately 9 mm throughout. 3.) Desiccation of the disc with 4mm postero-central disc protruding at L5-S1, bilateral foraminal stenosis left more than right. Status post left laminectomy.

On September 15, 2010 claimant had an office visit with MD. States that the claimant is being seen for postlaminectomy syndrome, lumbar region. The pain radiates to the left hip(s), lateral thigh(s), lateral lower leg(s), and foot (feet) to and myalgias the left foot dorsal surface. Claimant characterizes it as moderate in intensity and the current episode of pain started XX/XX/XXXX. Associated symptoms include stiffness, paravertebral muscle spasm, radicular left leg pain and numbness in the foot (feet) to the left foot toes 1st – 4th digits. ROS musculoskeletal is positive for back pain, limb pain (left leg pain). Current problems as noted are bulging lumbar disc, lumbar spinal stenosis, lumbar spondylarthritis, post laminectomy syndrome, lumbar region. General exam for musculoskeletal: digits/nails: no clubbing, cyanosis or evidence of ischemia or infection, normal gait, no laxity or subluxation of any joints. In the back exam palpation elicited pain over the left and right lumbar paraspinal muscles, no palpable muscle spasm. Range of motion showed limited active ROM with extension (to 20 degrees) and flexion (to 45 degrees). Deep Tendon reflexes ¼ left patellar, 2/4 right patellar, 2/4 left Achilles, 2/4 right Achilles. Muscle strength 4/5 left 5/5 right quadriceps, 5/5 left iliopsoas, 5/5 left and 5/5 right hip adduction, 4/5 left and 5/5 right tibialis anterior.

On October 11, 2010 claimant was seen for an outpatient follow up visit from a left L5 and left S1 transforaminal epidural steroid injection with epidurogram (records not available for review) by MD. Medications were reviewed and updated claimant presented with a current VAS of 3-4 peak VAS 9-10. But that claimant's pain is not that severe at this time. Claimant stated that he had not had pain relief since the injection and was now starting to have pain in both ankles and he is also having numbness in his small toes. States that pain is primarily in the lower lumbar spine. The pain radiates to the left hip(s), lateral thigh (s), lateral lower leg (s), left, and to both feet. Claimant characterized it as constant, severe, aching, and numbing. Associated symptoms include stiffness, paravertebral muscle spasm, radicular left leg pain and numbness to both feet laterally, toes 1st through 4th digits and 5th digit. ROS Musculoskeletal is positive for back pain, limb pain (left leg pain) and myalgias. Exam shows no changes in musculoskeletal.

Plan of Care from Physical Therapy today dated 10/18/2010

November 9, 2010 claimant was seen for an outpatient follow up visit with MD at claimant request chief complaint states that the claimant is able to complete activities of daily living without any assistance and presents with a current VAS of 4-5. Claimant states that he is not a surgical candidate with Dr. and he would like to know what the next treatment step available. No changes noted within examination notes as compared with October 11, 2010 follow up visit. Conversation notes state that there was an option of starting therapy with a neurostimulator and states that the procedure and the trial phase were discussed in great detail. The claimant would be a candidate for this treatment due to the scar tissue that is present with the past surgery. The claimant would need to be evaluated by a psychologist for clearance for a permanent implant.

On November 11, 2010 a referral was sent to Ph.D. for psychological evaluation.

On November 24, 2010 claimant had psychological evaluation completed by Ph.D. and the recommendation was: there are no counter indications for his (the claimant's) involvement in implantable spinal cord stimulation.

On February 7, 2011, M.D. performed a utilization review on the claimant. Rationale: The claimant reported to have obtained 80% percent relief from a spinal cord stimulator trial. The aforementioned trial was not validated in a formal procedural report. While the trial conferred adequate pain relief there was no documentation of medication reduction or functional improvement following the trial. There was no objective evidence of failure with adequate non-interventional care, including medications, ESIs, and PT. In consideration of the foregoing issues and the reference guidelines, the medical necessity of the requested permanent spinal cord stimulator placement has not been fully established.

On March 3, 2011, M.D. performed a utilization review on the claimant. Rationale: Based on the clinical information submitted for this review and using the evidence based peer-reviewed guidelines.

PATIENT CLINICAL HISTORY:

Past medical history includes hypertension, lumbar spine surgery XXXX, and femoral artery bypass XXXX.

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

Based on the reviewed information, the spinal cord stimulator is not indicated in this claimant; therefore, the previous decisions are upheld. According to ODG criteria, a spinal cord stimulator is indicated when there is no alternative therapy for neuropathic pain. According to Dr. report, there was no evidence of failure of adequate non-interventional care such as ESI's and PT. The claimant only underwent one ESI. At this point, he is a candidate for a second and third steroid injection.

In addition, the pain generator has not been fully identified. The claimant's MRI documents disc dessication with bilateral foraminal stenosis at L5-S1 with associated congenital stenosis. However, the examination of Dr. (Sept 2010) documents 1/4 patellar reflex, indicating a potential problem of the L4 nerve root. An EMG/NC study would clarify which nerve roots are affected.

The claimant may require a L5-S1 fusion to address the disc dessication at this level. He may also require decompression to address the congenital stenosis. A discogram would be required prior to surgery to confirm L5-S1 as a back pain generator.

If the claimant fails this type of revision operation, then he falls into the category of "failed back surgery." Only at this point, would a spinal cord stimulator be appropriate.

Per the ODG:

Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated. See the [Pain Chapter](#) for *Indications for stimulator implantation*. There is some evidence supporting the use of Spinal Cord Stimulation (SCS) for Failed Back Surgery Syndrome (FBSS) and other selected 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 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](#))

Recent research: 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, i.e. 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](#)) For average hospital LOS if criteria are met, see [Hospital length of stay](#) (LOS).

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)