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Notice of Independent Review Decision

November 24, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Outpatient Lumbar SCS IPG Replacement

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

This physician is a Board Certified Anesthesiologist with over 6 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 suffered a work related injury resulting in L5-S1 fusion after failed conservative treatment.

09/03/2014: Office Visit. **HPI:** Matthew is a male with low back pain and right posterior leg pain to his foot. As you recall, he has had prior L5-S1 fusion. Imaging shows that it is solid but he does have L4, L5 central canal and foraminal stenosis. Epidural injections unfortunately have been denied by his insurance. His spinal cord stimulator battery has reached end of life. He is following up next week to see about replacing the spinal cord stimulator battery. Hopefully when this is replaced and the stimulator is reprogrammed he will get improved back and leg pain relief. The following information was documented by the patient: Lowest pain level: 5, Worst pain level: 10, Present pain level: 7, Pain description: aching, constant, burning, cramping, radiating. Chronic Problem List: Low back pain, encounter for long-term use of other medications, thoracic spondylosis w/o myelopathy, sacrolitis, lumbar/thoracic Radiculitis, post laminectomy syndrome, battery failure or complication. Current Medications: Hydrocodone-acetaminophen

10-325 MG Tabs take 1 tab every 4-6 hours as needed for pain max 5 a day.
methocarbamol 500 MG Tabs take 1 tab twice daily as needed for spasms.
Senokot S 8.6-50 MG tabs. Take one to two tabs twice daily. OTC. Cardura 2 MG
Tabs (Doxazosin Mesylate) 1 tab in the morning- Zestoretic Tabs (Lisinopril-
Hydrochlorothiazide Tabs) 1 tab in the morning- Lovastatin Tabs Take 2 tabs
daily- Aleve Tabs (Naproxen Sodium Tabs) Take as needed for swelling. OTC

Physical Exam: Musculoskeletal: Gait is independent but antalgic. Lumbar
forward flexion is restricted to 30° due to the pain. Lumbar extension is
moderately restricted. Straight leg raise on the right is positive, straight leg raise
on the left is negative. Neurologic: No motor deficits in bilateral lower extremities.
Decreased sensation to light touch in an L4-L5 dermatome in the right lower
extremity. Normal sensation to light touch in the left lower extremities.

Diagnosis: Low Back Pain **Impression/Plan:** 1. Chronic low back pain with
radiculopathy and history of lumbar post laminectomy syndrome and some
stenosis at L4-L5. 2. He will follow up for evaluation of his spinal cord stimulator
battery replacement. 3. We will continue medications as directed to reduce pain
and improve function.

09/08/2014: Office Visit. **HPI:** Patient has a work-related injury for which he has
tried and failed conservative medical management and has gone on to have
lumbar spine surgery as well as placement of a spinal cord stimulator. Historically,
his stimulator therapy has provided him with significant relief of his pain. He is
approaching end of battery life. We discussed replacing his internal pulse
generator. Overall, he is quite happy with his stimulation. He complains that the
internal pulse generator is in a position that is just above his waist line and is
irritated by the presence of his belt. He would like to move this internal pulse
generator pocket to a lower position if possible. He also feels that recharging of
his current battery has been an issue. I discussed with him that this should be
improved with placement of a new battery. Finally, he complains of an episode of
significant hyper stimulation with movement of his legs. This occurred while he
was sleeping. We discussed at length the possibility of changing his battery to a
RestoreSensor. I said that this will not be an issue in the future if he wishes to
proceed with such a battery. Risks and benefits of the battery change were
discussed with the patient and he wishes to proceed at this time. He will be
scheduled as soon as preauthorization from his workers' comp has been
authorized. The following information was documented by the patient: Lowest pain
level: 5, Worst pain level: 10, Present pain level: 8, Pain description: aching,
constant, burning, cramping, radiating. **Assessment:** This is a male with ongoing
low back pain after a work-related injury. **Plan:** 1. He is advised to continue his
medical management and therapies as laid out by his last visit 2. I discussed at
length the risks and benefits of a battery replacement. He wishes to proceed.
Additionally, he wishes to change his battery to RestoreSensor rechargeable
battery. 3. We will continue medication as previously directed. 4. He would like to
call should he have any additional questions regarding his battery replacement. 5.
He is advised to return in one month to see me at his scheduled office visit time.
6. All of the patient's questions and concerns were answered prior to leaving. The
patient has been provided with APA's contact information and has been

encouraged to contact us with any questions or concerns before the next follow up visit.

09/23/2014: UR. **Rationale for Denial:** The requesting physician has determined that the patient's SCS battery is nearing the end of its life span. However, before authorization can be granted for SCS IPG replacement, evidence must be provided demonstrating both an objectively measured decrease in the patient's pain levels and an increase in patient function since having received the SCS implant. There is currently no such documentation in the submitted records.

10/01/2014: Office Visit. **HPI:** Patient reports current medications reduce pain and improve his quality of life by 50%. Recent urine drug screens are consistent. Pill count today is consistent. It is noted he has a spinal cord stimulator implanted in 2008. The battery has reached end of life. His workers' insurance has denied replacement of the battery. The following information was documented by the patient: Lowest pain level: 6, Worst pain level: 10, Present pain level: 6, Pain description: aching, constant, burning, cramping, radiating. **Physical Exam:** Musculoskeletal: Gait is moderately antalgic but independent. Lumbar spine forward flexion is restricted to 30° due to pain. Extension is not painful. Straight leg raise is positive on the right with pain radiating down the posterior leg to the heel. Straight leg raise on the left is negative. Neurologic: No sensory or motor deficits in bilateral lower extremities. **Impression/Plan:** 1. Chronic low back pain with a history of L5-S1 fusion secondary to his workers' compensable injury and then a spinal cord stimulator implant 2008. This effectively reduces pain by 50%. Battery has now reached end of life. I did write a letter of medical necessity for the battery replacement to help reduce his chronic intractable back and leg pain. 2. We will continue current medications as directed since they reduce pain and improve function. He remains on hydrocodone 10/325 mg five a day and methocarbamol 500 mg twice a day. 3. Encouraged him to exercise as he is able to for conditioning and strengthening. 4. I would like to see him in a month.

10/01/2014: Letter of Medical Necessity. is under our care for low back pain related to his on the job injury resulting in a lumbar fusion L5-S1. He continues to have chronic intractable low back pain and radiculopathy in his right posterior and lateral leg to his heel. He had a spinal cord stimulator implanted in 2008 which has helped reduce his back and leg pain by 50. The battery pack for the spinal cord stimulator has reached end of life and needs replacement. Please approve this medically necessary procedure for his chronic intractable back and leg pain.

10/14/2014: UR. **Rationale for Denial:** The recommendation is that the requested revision and replacement of the spinal cord stimulator IPG is not medically necessary. The patient has been recommended for a lumbar spinal cord stimulator pulse generator replacement. This is an appeal of a previous denial in which the reviewer noted that there was no objectively measured decrease in the patient's pain levels or overall improvement in function since receiving the spinal cord stimulator implant that would support replacement. The patient has been followed for ongoing chronic low back pain radiating to the right lower extremity following a prior lumbar fusion at L5-S1. The patient received the spinal cord

stimulator in 2008. The patient has had noted difficulty with pain control and was still utilizing Hydrocodone 5mg daily as well as Methocarbonyl 500mg twice daily. The patient did have difficulty with soma addiction and this medication was discontinued. Average pain levels were 7/10 in intensity. The patient's pain scores ranged from between 5-10/10. The evaluation on 9/08/14 indicated that the patient was overall happy with his stimulator; however, the patient did describe some issues to include the internal pulse generator being irritated by the presence of a belt. The patient was wishing to move the internal generator to a lower position if possible. The patient also described issues with trying to recharge the current battery. The patient also described recent periods of hyper stimulation in the lower extremities. As of this evaluation, the patient was using Hydrocodone 10mg every 4-5 hours at a maximum of 5 per day. Other medications include Methocarbonyl utilized twice daily. The patient's physical exam noted moderate limited ROM in the lumbar spine with a positive right leg raise to the right. No sensory or motor deficits were evident. The letter of medical necessity from FNP dated 10/1/14 indicated the patient had been able to reduce his overall low back and lower extremity pain by 50%. The additional clinical information did not discuss specific functional improvements obtained by the patient in regards to the use of a spinal cord stimulator. Furthermore, there was also no discussion regarding the patient's ongoing requirement for narcotic and muscle relaxer usage given the implantation of the spinal cord stimulator, there would be an expectation of a reduction of cessation of narcotic medication for pain. Without additional information to substantiate the internal pulse generator replacement, this reviewer would not recommend certification for the request at this time.

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

The previous adverse determinations are upheld. This claimant has had no objectively measured decrease in the pain levels or overall improvement in function since receiving the spinal cord stimulator implant that would support replacement. Claimant is post lumbar fusion at L5-S1 and spinal cord stimulator in 2008. Physical exam noted moderate limited ROM in the lumbar spine with a positive right leg raise to the right. No sensory or motor deficits were evident. While the claimant has noted difficulty with pain control with hydrocodone 5mg daily and methocarbonyl 500mg twice daily and 50% improvement in pain scores after stimulator implantation, there are no discussions of specific functional improvements obtained by the patient in regards to the use of a spinal cord stimulator. Additionally, there was also no discussion regarding the patient's ongoing requirement for narcotic and muscle relaxer usage given the implantation of the spinal cord stimulator, there would be an expectation of a reduction of cessation of narcotic medication for pain. Without these key determinants, this request is non-certified at this time. For these reasons, Outpatient Lumbar SCS IPG Replacement is not medically necessary at this time and should be denied.

PER 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, 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](#)) In this sample of workers' compensation recipients, the high procedure cost of SCS was not counterbalanced by lower costs of subsequent care, and SCS was not cost-effective. The benefits and potential cost savings reported in RCTs may not be replicated in workers' comp patients. ([Hollingsworth, 2011](#)) 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)**