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Notice of Independent Review Decision

MEDICAL RECORD REVIEW:

DATE OF REVIEW: 05/09/2011

IRO CASE #:

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

This case was reviewed by a Pain Management (Board Certified) Doctor, Licensed in Texas and Board Certified. The reviewer has signed a certification statement stating that no known conflicts of interest exist between the reviewer and the injured employee, the injured employee's employer, the injured employee's insurance carrier, the utilization review agent (URA), any of the treating doctors or other health care providers who provided care to the injured employee, or the URA or insurance carrier health care providers who reviewed the case for a decision regarding medical necessity before referral to the IRO. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Neurostimulator implant (63688, 63660, 63650, 63685, 95970)

REVIEW OUTCOME

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be: Upheld (Agree)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the medical records and prior reviews the patient is a male employee who sustained an industrial injury to the left lower extremity on xx/xx/xx when a joint coupling fell onto him and crushed his foot. He has undergone multiple surgeries for multiple fractures of the toes of the left foot. He developed CRPS type I. Treatment has included an implanted peripheral nerve stimulator (PNS) in the lower extremity and a spinal cord stimulator (SCS) implanted in the thoracic region. Peer review dated January 27, 2009 (as cited) indicated the SCS was not functioning properly.

Handwritten and partly illegible visit note of October 5, 2009 indicate the patient's PNS never had full stimulation and didn't cover the pain. More recently he had a SCS implanted with periods of successful coverage of his pain. However, he has also had

episodes of shocks, recently three weeks ago, quite sudden and severe from the left ankle to the back and more recently from the left ankle to the neck and all up and down the spine. This happened once before and required replacement of the IPG and one lead. The charger is in a Velcro cover over the IPG. Unable to reprogram. The remote reads, "recharge soon."

Visit notes of February 15, 2010 indicate the left leg still hurts. He is status post a crush injury to the left foot. He is having severe

uncovered pain in the middle 3 toes of the left foot. He is having bizarre episodes of shock-like pain on stimulation of the back that occurs while sitting or lying down. Consider retrograde lead placement to provide direct stimulation of left L5 nerve roots and use new splitter to existing dual leads. The company will be called and informed of the bizarre sensations.

Visit notes of April 13, 2010 state SCS still hurting with back and leg pains and left foot pain which ranges from 7-10/10. If he turns of the stimulator the pain is much worse. He is constantly being shocked with certain motions such as just moving around in his chair. He even gets shocked when not moving and when asleep. Assessment is CRPS Type 1 with inadequate pain relief from SCS. Plan is epidural Dilaudid infusion.

Visit notes of November 9, 2010 indicate his pain continues. He has a history of a crush injury which developed into CRPS Type II. He charges his SCS daily so the irregular functioning is not due to improper charging of the IPG. He complains of severe low back pain with frequent episodes throughout the day. These are very painful and worse than any benefit he has since using the IPG. The IPG is in the left lower quadrant (illegible) for lumbar. IPG is in (illegible) left and high for the PNS. He has a minimal effective painful SCS. Plan is to remove the painful SCS system at the first of the year.

The most current treatment notes are dated February 28, 2011. He has a crush injury to the left foot and CRPS Type II. Original treatment was implantation of a PNS in 1999, which is only partially helpful. He otherwise has a more recent SCS implant, Boston Scientific, rechargeable that turns out to be a failure based on patient's inability to recharge the SCS IPG. The Medtronic Synergy System for PNS IPG was implanted at the anterior left thigh in 1999 at least 10 years ago. Major problem is severe low back pain associated with the SCS IPG and anchoring in the mid lumbar region. Patient cannot sit back normally. He has to sit with the left and middle portion of his spine off the seat back. On examination, the patient was extremely painful with palpation over the anchoring site. Plan is to remove the painful SCS (illegible).

On March 9, 2011 request was made to revise and replace the patient's Medtronic nerve stimulator.

Request for neurostimulator implant was considered in review on March 14, 2011 with recommendation for non-certification. Per a peer review of January 2009 the SCS was not functioning properly. The handwritten progress notes are difficult to interpret. A note of October 5, 2009 states the patient underwent SCS implantation and has periods of successful coverage, but has also had episodes of sudden shocking. A note of February 28, 2011 indicates the stimulator has been a failure because the patient is unable to charge the unit. He is extremely painful to palpation over the anchoring site. Rationale for denial states there is insufficient clinical information provided to support this request. He currently has a SCS implanted and the records indicate this has been a failure. There is no comprehensive assessment of the patient's objective, functional response to the unit when it was working properly to establish efficacy of treatment and support stimulator implant. A peer discussion was attempted but not realized.

Handwritten appeal letter dated April 4, 2011 notes students are used for calls and do not understand the protocols regarding peer review calls. In any case, the situation is complex and requires discussion with a provider well acquainted with spinal cord stimulation. Here's the situation: He has a partially helpful PNS in his left leg and with a now 10-year-old IPG implanted in the mid anterior left thigh. This IPG site is well tolerated with no pain, but it is only partially helpful for his crush injury residual pain at the left foot with CRPS type II. The next part of the situation is as follows: He has failed further conservative management including PT, lumbar sympathetic blocks and medications. We decided on a trial SCS dual lead which was done on May 22, 2008. The patient returned five day later stating 100% pain relief even though the last day a lead moved. He still showed great excitement at the prospect of an implanted SCS. Over the ensuing two years, he has had variable results with a lot of the problems having to do with his lack of any understanding regarding how to change the charger and how to charge the rechargeable IPB battery. Other than that problem, he has a severe sensitivity that is exquisitely painful in the IPG pocket site. With the severely painful IPG site in the left upper flank, he can't sit straight and has to constantly lean forward toward the right side. What is being proposed is that he has removed what bothers him so much, the SCS IPG battery. Then, we want to convert both dual leads of the SCS system to Medtronic. These can then be connected to a bifurcated extension and connected to the Medtronic IPG in his left thigh. This would alleviate the misunderstanding regarding recharging the SCS (Medtronic is non-rechargeable). This would also eliminate the severely painful IPG battery site in his left upper flank. Assessment is chronic pain syndrome LLE status post a crush injury with Type I CRPS of the LLE and poorly malfunctioning and painful IPG neurostimulator/SCS. Plan is to remove the painful malfunctioning Boston Scientific SCS/IPG and implant a dual lead Medtronic lead and use bifurcated extension to connect to a Medtronic non-rechargeable IPG in the left thigh so he can run both the SC and the PNS off one IPG without pain.

Request for reconsideration neurostimulator implant was considered in review on April 14, 2011 with recommendation for non-certification. Letter of appeal dated 04/04/11 indicates the requesting provider is proposing removal of the SCS battery pack and the flank and complex rerouting of the lead to the battery pack in the left thigh. A peer discussion was attempted but not realized. The patient has a history of chronic regional pain syndrome Type 2. He has a history of peripheral nerve stimulator implant as well as SCS implant. His current SCS hardware is causing lower back pain. Additionally, the patient does not understand how to manage the rechargeable SCS battery pack of these spinal cord stimulators. The physician has requested removal of the SCS battery pack and complex rerouting to connect the SCS to the battery pack in the left thigh. It is unclear from the documentation submitted for review why a standard removal of the current battery pack and replacement with a non-rechargeable battery pack would not be appropriate. It is unclear why complex rerouting is necessary in this case. Without additional clinical information, the medical necessity cannot be established.

Request was made for an IRO.

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

ODG: Spinal cord stimulation devices are recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated, for specific conditions indicated below (Failed Back Surgery Syndrome and Complex Regional Pain Syndrome Type I) and following a successful temporary trial. As batteries for both rechargeable and non-rechargeable systems are nearing end of life, there are both early replacement indicators and end of service notifications. Typical life may be 8-9 years for rechargeable batteries, but this depends on the unit. In addition, the physician programmer can be used to interrogate the implanted device and determine the estimated remaining battery life.

First level denial rationale states, there is insufficient clinical information provided to support this request. He currently has a SCS implanted and the records indicate this has been a failure. There is no comprehensive assessment of the patient's objective, functional response to the unit when it was working properly to establish efficacy of treatment and support stimulator implant.

Second level denial rationale states, the physician has requested removal of the SCS battery pack and complex rerouting to connect the SCS to the battery pack in the left thigh. It is unclear from the documentation submitted for review why a standard removal of the current battery pack and replacement with a non-rechargeable battery pack would not be appropriate. It is unclear why complex rerouting is necessary in this case. Without additional clinical information, the medical necessity cannot be established.

The provider's appeal notes good pain relief with the stimulator trial of 2008 even though a lead moved. The patient subsequently had variable results with a lot of the problems having to do with his lack of any understanding regarding how to change the charger and how to charge the rechargeable IPB battery. He has a severe sensitivity that is exquisitely painful in the IPG pocket site. With the severely painful IPG site in the left upper flank, he can't sit straight and has to constantly lean forward toward the right side. What is being proposed is that he has removed what bothers him so much, the SCS IPG battery. Then both the dual leads of the SCS system to Medtronic. Per the provider, these can then be connected to a bifurcated extension and connected to the Medtronic IPG in his left thigh. This would alleviate the misunderstanding regarding recharging the SCS (Medtronic is non-rechargeable). This would also eliminate the severely painful IPG battery site in his left upper flank.

However, the second level denial rationale has merit. The current plan to remove the Boston Scientific SCS/IPG and implant dual lead Medtronic leads and use bifurcated extension to connect to a Medtronic non-rechargeable IPG in the left thigh so he can run both the SCS and the PNS off one IPG is overly complicated. It remains unclear from the documentation submitted for review why a standard removal of the current battery pack and replacement and relocation would not be appropriate. It is unclear why complex rerouting is necessary in this case or why the left upper flank battery site could not be relocated. A less complex revision should be considered for this patient. The medical necessity of the current revision plan is not supported.

Therefore, my recommendation is to agree with the previous non-certification for Neurostimulator implant (63688, 63660, 63650, 63685, 95970).

The IRO's decision is consistent with the following guidelines:

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

The Official Disability Guidelines 04-29-2011 - Spinal Cord Stimulators:

Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated, for specific conditions indicated below, and following a successful temporary trial. Although there is limited evidence in favor of Spinal Cord Stimulators (SCS) for Failed Back Surgery Syndrome (FBSS) and Complex Regional Pain Syndrome (CRPS) Type I, more trials are needed to confirm whether SCS is an effective treatment for certain types of chronic pain.

Battery Life for SCS: As batteries for both rechargeable and non-rechargeable systems are nearing end of life, there are both early replacement indicators and end of service notifications. Typical life may be 8-9 years for rechargeable batteries, but this depends on the unit. In addition, the physician programmer can be used to interrogate the implanted device and determine the estimated remaining battery life.

Indications for stimulator implantation:

- ? 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)

For average hospital LOS if criteria are met, see Hospital length of stay (LOS).