

Icon Medical Solutions, Inc.

11815 CR 452
Lindale, TX 75771
P 903.749.4272
F 888.663.6614

Notice of Independent Review Decision

DATE: May 23, 2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Outpatient Replacement of Spinal Cord Stimulator Batter Under Fluoroscopy and IV Sedation for the Left Shoulder and Cervical Spine

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 Anesthesiology with secondary practice in Pain Management with 40 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.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

08/30/04: Outpatient Followup
12/26/07: Medical Record Review
06/01/12, 09/28/12, 01/04/13: Followup Visit
01/21/13: Initial Pain Evaluation
01/29/13: Lab Results
02/08/13: X-Ray Cervical Spine 3 Views report
02/22/13: Followup Note
03/06/13: Pre-Authorization Form
03/12/13: UR performed
04/01/13: Followup Note
04/05/13: Pre-Authorization Form
04/05/13: Texas Workers' Compensation Work Status Report
04/05/13: Appeal/Reconsideration Acknowledgment
04/14/13: UR performed
04/29/13: Followup Note
05/10/13: Prospective Review (M2) Response

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a female who sustained a left shoulder rotator cuff injury as well as impingement syndrome when she was injured at work on xx/xx/xx. She is status post arthroscopic shoulder surgery and repeat arthroscopy and acromioclavicular joint resection in 1997. She developed a reflex sympathetic dystrophy in the left upper extremity. She underwent spinal cord stimulator placement followed later by spinal cord stimulator replacement with new leads in 2004 with the addition of a beta-assisted programmable battery.

06/01/12: The claimant was evaluated. She complained of left shoulder pain and restricted range of motion of the left shoulder. She complained of nocturnal pain with left shoulder. She stated that the lead wire/wires in lower back need to be checked, done about 8 years ago, may need new battery or be replaced. On examination, her left shoulder was tender to palpation anteriorly and posteriorly. Range of motion was restricted. She had difficulty bringing hand to head. She was given Lortab and Flexeril. She was to return to the office in 90 days and her work status was restricted.

01/04/13: The claimant was evaluated. She complained of having more pain in the left shoulder, mainly at night. She complained of restricted range of motion in the left shoulder. She stated that she felt like the battery in the spinal cord stimulator may have been decreasing as it did not seem to be working as well. On examination, her left shoulder was tender to palpation anteriorly and posteriorly. Range of motion was restricted. She had difficulty bringing her hand to head. She was referred for reevaluation of her spinal cord stimulator.

01/21/13: The claimant was evaluated. She stated that her stimulator gave her excellent relief but was starting to give her less relief as she was requiring higher and higher discharge amplitudes in order to achieve the same level of relief. She stated that she was getting occasional sharp paroxysms and lateral shoulder coverage rather than the anterior shoulder coverage she was formally receiving. She stated that she had sleep loss and mood irritability and felt that the device had been a "God sent." It was noted that she was receiving Lortab 4 times per day. On examination, she had limited neck range of motion. She had some mild trigger point tenderness over the left trapezius, interscapular, and posterior deltoid regions. She had limited range of motion about the left shoulder with moderate pain on abduction. Internal and external rotation also caused moderate pain. There was mild tenderness at the bicipital groove. **DIAGNOSES:** Chronic left shoulder pain, effectively treated with spinal cord stimulation. Cannot rule out lead migration with battery discharge with over 12 years of effective pain control utilizing this device. Myofascial pain syndrome of the shoulder and upper neck areas. stated that analysis had confirmed that the batter is nearly end of life. He wanted the Medtronic rep to do a final analysis as well as obtain x-rays to determine satisfactory lead placement.

02/08/13: X-ray Cervical Spine 3 Views report. **IMPRESSION:** Neurostimulator tip at C4 level in the posterior midline spinal canal.

02/22/13: stated that stimulator was "close to end of life." He noted that x-rays showed a single quadruple electrode in appropriate place extending from C4 down to C7 in the posterior epidural space in the midline. He stated that with higher requirements of energy, he felt it was apparent that her battery was nearly gone. He noted that the claimant stated that her stimulator had offered her significant reduction in pain, more than 70%. noted that the battery had been in place for over seven years.

03/12/13: UR performed. RATIONALE: There is no documentation of any decreased use of opioids during the time using the spinal cord stimulator, and patient continues to take hydrocodone 10 mg four times per day for many years. There is no documentation/analysis printout demonstrating impending battery failure to justify spinal cord replacement, and x-ray reveals no lead migration to justify lead revision or replacement. There is also no documentation of reprogramming attempt or analysis of current spinal cord stimulator device. Finally, fluoroscopy is not necessary to change spinal cord stimulator battery. All requests are therefore not reasonable or necessary and spinal cord stimulator efficiency is clearly questionable at best.

04/01/13: The claimant was evaluated who noted that they programmed her stimulator on this day and it was recommended that she have replacement of the spinal cord stimulator and battery with a primary cell. They did reanalyze her on this day with the assistance of the Medtronic representative. did not turn her battery off as she did not use her stimulator while she was driving. The note indicates that "she was reporting more than 70% up to 90% relief of her left shoulder and arm pain, placed by another doctor well over 10 years ago." She used her stimulator off and on with excellent result, which noted "kept her medications minimal, allowing her to be more functional, active, and continue working." He stated that they were going to "replace her with a primary batter cell." He also stated that they would do analysis of her stimulator intraoperative. Her use of amplitude was 2 volts. Medtronic neurostimulation printout was submitted.

04/15/13: UR performed. RATIONALE: The records indicate that the unit was queried and reprogrammed on 04/01/13. There was no indication of impending battery failure. Although indicates that the unit provides 70-90% pain relief and she uses only occasional hydrocodone, this does not match the reports. For example, his note of 04/05/13 stated that she had constant pain and had restricted shoulder range of motion which was worse. Medication records indicate she is taking four hydrocodone 10 mg tabs per day. I do not consider the request reasonable or necessary. There is no evidence of impending battery failure. The changing of the battery does not require fluoroscopy. Also the actual benefit from the device is not clear. There appears to be varying belief as to how much benefit is delivered.

04/29/13: The claimant was evaluated. noted that the claimant continued to have to raise the amplitude of her spinal cord stimulator as she had "been determined

by the Medtronic representative and as by my clinic experience that her battery is near end of life.” noted that on this day (04/29/13), she had to raise her amplitude up to 4 volts to even feel the stimulation in her left shoulder, which was double what it was just two months ago. It was noted that she was getting good coverage in her left shoulder and arm. Her intake urinalysis was negative for illicit drug use. It was noted that she was increasing her medicine to “2 weak narcotics at night as well as a benzodiazepine.” It was noted that she was “nearly off these medicines completely prior to coming to us.” noted that this was secondary to her battery being nearly expired. It was noted that good location of the stimulation paresthesia was noted on this day. Medtronic neurostimulator printout was submitted.

05/10/13: Prospective Review (M2) Response. notes that the claimant has undergone extensive treatment including diagnostic studies, left shoulder injection, left shoulder arthroscopy in April 2007 with a repeat arthroscopy and acromioclavicular joint resection in July 2007, physical therapy programs, use of TENS unit rental, and trigger point injections. She underwent spinal cord stimulator implant in October 1999. notes that the Physician Advisor reported that the records indicate that the unit was queried and reprogrammed on 04/01/13 and there was no indication of impending battery failure. He concluded that the request was not supported at this time.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION: The previous adverse decisions are upheld. First, the claimant has a multi-year history of continuous, and at times high dose, narcotic usage. This alone suggests the spinal cord stimulator has not been working for all of those years at the efficiency to which it was intended, or that she has not received benefits from the stimulator. In addition, the stimulator leads have been checked, have not migrated, and are in the proper position as of 02/08/13 as indicated by three views of cervical x-rays interpreted. On 04/01/13, her stimulator was programmed as reported when he evaluated her on that day. During this programming, there was no indication of impending battery failure. Despite the comments that “it has been working well”, she has continued to have multiple invasive treatments since 2007, including a variety of injections and arthroscopic surgeries. Thus one questions the need for the stimulator as a pain controlling device. Lastly, from the retrospective review of the medical records, the spinal cord stimulator was apparently placed to treat complex regional pain syndrome (reflex sympathetic dystrophy). Yet, the descriptions of the present symptoms and signs do not appear to be a resurgence of the reflex sympathetic dystrophy. Instead, they appear to be those of the exigencies of life, including the development of painful symptoms of arthritis with a decrease in the range of motion and pain on performing clinical evaluations. Therefore, the request for Outpatient Replacement of Spinal Cord Stimulator Batter Under Fluoroscopy and IV Sedation for the Left Shoulder and Cervical Spine does not meet the ODG criteria and is not medically necessary.

ODG:

| | |
|-------------------------------|--|
| Spinal cord stimulators (SCS) | <p><i>Battery Life for SCS:</i> As batteries for both rechargeable and nonrechargeable 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. (Restore, 2011)</p> <p>Indications for stimulator implantation:</p> <ul style="list-style-type: none">• • 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) <p>For average hospital LOS if criteria are met, see Hospital length of stay (LOS).</p> |
|-------------------------------|--|

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)**