

IRO NOTICE OF DECISION – WC



Claims Eval

Notice of Independent Review Decision

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October 14, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Trial of Spinal Cord Stimulator

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

American Board of Anesthesiology

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 medical necessity exists for each of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:

7-31-12 MRI of the lumbar spine showed mild circumferential disc bulge at T12-L1 which mildly impresses on the thecal sac. Mild right foraminal disc protrusion at U-2 which produces mild right lateral recess stenosis and mild right neural foraminal narrowing. Mild bilateral Subarticular disc protrusions at L2-3 which mildly impress on the thecal sac and produce mild bilateral lateral recess stenosis. Bilateral facet arthrosis is noted. Mild circumferential disc bulge at L3-4 which mildly impresses on the thecal sac. Bilateral facet arthrosis and mild bilateral neural foraminal narrowing are noted. Mild circumferential disc bulge at L4-5 which mildly impresses on the thecal sac. Bilateral facet arthrosis and moderate bilateral neural foraminal narrowing are noted. Left unilateral sacralization of L5. Moderate left foraminal disc protrusion at L5-S1 which produces marked left neural foraminal narrowing. Bilateral facet arthrosis is noted.

11-18-13 MRI of the lumbar spine showed postsurgical changes within the dorsal lumbosacral soft tissue extending posterior to the left L4-5 facet joints. Left Subarticular disc protrusion at T12-L1 which mildly impresses on the thecal sac. Bilateral facet arthrosis is noted. Circumferential disc bulge at L1-2 which mildly impresses on the thecal sac. Bilateral facet arthrosis is noted. Circumferential disc bulge at L2-3 which mildly impresses on the thecal sac. Bilateral facet arthrosis is noted. Circumferential disc bulge at L3-4 which mildly impresses on the thecal sac. Bilateral facet arthrosis, ligamentum flavum hypertrophy, and mild bilateral neural foraminal narrowing are noted. Grade 1 anterolisthesis of L4. Circumferential disc bulge at L4-5 which mildly impresses on the thecal sac. Bilateral facet arthrosis and moderate bilateral neural foraminal narrowing are noted. Bilateral facet arthrosis and moderate bilateral neural foramina! Narrowing are noted at L5-S1. The postsurgical changes reflecting interval change as compared with the 7-31-12 study. The left Subarticular-foraminal disc protrusion at L5-S1 measures smaller in size as compared with the previous study. The subtle anterolisthesis of L4 was not appreciated on the previous MRI. The remaining disc level changes appear essentially stable as directly compared to the previous MRI.

12-11-13 (Blurred copy). DWC-73: The claimant was returned to work from 12-11-13 through 1-11-14 with restrictions.

1-9-14, the claimant is here today for a follow-up visit. He did see in consultation on 12-11-13. At this time, no further surgical intervention is indicated in the lumbar spine region. He does continue to have lower back pain and has not improved with surgical intervention. He continues on medications which include MS Contin, hydrocodone, and Robaxin. At this office visit, he was provided with a DVD of the spinal cord stimulator to review over the next month. This will be further discussed at his follow-up visit in 4 weeks. The current medication is indicated to decrease pain levels effectively and improve his functional ability as well as quality of life. No indicated adverse effects. He will possibly be undergoing left hip replacement surgery. Diagnosis: Post laminectomy syndrome-lumbar, lumbar facet arthropathy,

spondylolisthesis, and lumbosacral spondylosis without myelopathy. Plan: The claimant was prescribed Robaxin, Norco, and MS Contin.

1-9-14 CESD-Review Test Results.

2-21-14, the claimant presents for a Psychological Evaluation. Diagnosis: Axis I: Pain Disorder with Psychological and Medical Factors. Axis II: None. Axis III: Chronic Pain. Axis IV: Severe. Axis V: GAP = 90. Plan: Overall, this claimant appeared to be psychologically stable, and his psychological testing was largely within normal limits. As a result, the evaluator can provide psychological clearance for long term use of opiates. The evaluator can provide psychological clearance for a spinal cord stimulator without reservations.

8-11-14, the claimant is here today for a follow-up visit. He has a history of low back surgery. He is complaining of ongoing chronic low back pain and muscle spasms. He did undergo a psychological evaluation and is pending approval to proceed with a spinal cord stimulator. He currently takes Robaxin 750 mg b.i.d. t.i.d., and Norco 10/325 mg b.i.d. p.r.n. break through pain, Lyrica 100 mg bid, and MS Contin 60 mg q.12 hours and reports no side effects or adverse reactions. The evaluator will discontinue his Norco 10-325 and had Ultram 50 mg one to 2 tablets bid. to see if this helps provide relief. He additionally takes MS Contin 60mg q12 hours. He does report that the MS Contin does not seem to be lasting therefore he takes the Norco for breakthrough. He is having some issues with sleep and therefore the evaluator will prescribe him Lunesta 3 mg q.h.s. He did undergo a total hip replacement on 3-31-14. He has completed physical therapy. He continues to use a cane to help him walk. The evaluator will place a request for his spinal cord stimulator. will check on this as well. The evaluator will refill his medication and see him back in the office in approximately 4 weeks for follow-up and re-examination. Diagnosis: Lumbar displacement, chronic pain syndrome, muscle spasm, post laminectomy syndrome, lumbar neuritis/radiculitis, backache nos. Plan: The claimant was prescribed Ultram, Robaxin, Lyrica, and Lunesta. Use TENS unit 3-4 times per day in each area.

8-12-14 Pre-Certification Request.

8-15-14, pre-authorization: The request is for trial of spinal cord stimulator. The evaluator recommend an adverse determination. The non-certification disclaimer was issued.

8-18-14 Utilization Review Determination: Request: Trial of spinal cord stimulator is not medically necessary. The evaluator reported that examination did not report focal neurological deficits on the lower extremity examination.

9-8-14 Pre-Certification Request.

9-8-14, "This letter is in regard. We are in receipt of peer review report from unnamed physician. Letter dated 8/18/14 indicating spinal cord stimulator trial is not medically necessary. Letter indicated that "there is no report regarding other attempted medication for neuropathic pain". The patient has tried Neurontin and is currently on Lyrica 100 mg b.i.d. Additionally, You letter indicated "there is also no report regarding trials of epidural steroid injections for suspected radiculopathy". It should be noted that the patient did undergo some epidural steroid injections with no benefit and has completed physical therapy with no significant benefit. The injections were done on his own since her care would not approve the injections. Additionally. He reported indicated that "examination did not report focal neurological defects on the lower extremity examination". Examination did reveal left lower extremity radicular symptoms of pain, numbness, and tingling. He does have motor weakness in the left lower extremity with muscle atrophy. He does have symptoms of "feeling like a burning copper wire" down the lower extremity. There is motor weakness in the left lower extremity as compared to the right. Additionally it should be noted that he has to use a cane and/or a walker to walk do to motor weakness. He currently takes MS Contin 60 mg q.12 hours, Ultram 50 mg one to 2 tablets b.i.d., Robaxin 750 mg b.i.d., Lyrica 100 mg b.i.d., and Lunesta 3 mg q.h.s. We are attempting a spinal cord stimulator trial to see if we can reduce his oral medication on his opioids and narcotic medications. We would like to undergo a spinal cord stimulator trial to see how it as before attempting a permanent implant. Please review the requested procedure and updated office visit notes dated 9/8/14 for her a spinal cord stimulator trial. Please have this request reviewed by an anesthesiologist who performs invasive pain management 100% of the time, just like me."

9-10-14 has received a request for reconsideration (appeal) of an adverse utilization review determination related to the above named individual. The clinical documentation available at the time of the initial utilization review request and any additional information submitted with the request for reconsideration will be provided to the practitioner conducting the appeal review. Appealed treatment/service request: implant neuroelectrodes. The appeal Peer Reviewer will contact you to afford an opportunity to provide additional documentation and/or participate in a peer-to-peer discussion of the treatment request.

9-12-14, appeal: The request is for trial of spinal cord stimulator. An adverse determination is recommended. The non-certification disclaimer was provided. He noted the documentation in this case does not support that treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) have been tried and failed, or that the pain is neuropathic in nature; i.e., resulting from actual damage to the peripheral nerves. Common indications include, but are not limited, to failed back syndrome, complex regional pain syndrome (i.e., reflex sympathetic dystrophy), arachnoiditis, radiculopathies, phantom limb/stump pain, and peripheral neuropathy. The documentation indicates the patient was cleared by psychological evaluation for this procedure in February 2014; however since that time the patient

has undergone total hip replacement. It would appear the patient is still recovering from hip surgery. Medical necessity has not been established for this request based on the available information. Therefore, the request for trial of spinal cord stimulator is recommended for adverse determination. Reference: Official Disability Guidelines.

9-15-14 Utilization Review Determination: Request: Trial of spinal cord stimulator is recommended for adverse determination.

9-24-14 Request Form: Request for a Review by an Independent Review Organization.

9-25-14 Fax coversheet; from: Utilization management.

9-26-14 Fax coversheet; to: Claims Eval; from: Utilization management.

9-26-14 Fax coversheet; to: Claims Eval.

9-26-14 In accordance with Article 21.58A of the Texas Insurance Code, we are providing a copy of the following: Any medical records of the enrollee that are relevant to the review. Any documents used by the plan in making the determination. A copy of the notifications sent to the enrollee by the Utilization Review Agent notifying them of the adverse determination and the resolution of the appeal. Any documentation and written documentation submitted to the Utilization Review Agent in support of the appeal. A list of each physician or health care provider who has provided care to the enrollee and who may have medical records relevant to the review-Please see attached copy of the "Company Request for IRO" form.

9-26-14 Fax coversheet.

9-26-14 Notice to Claims Eval of Case Assignment.

9-26-14 Notice to Utilization Review Agent of Assignment to Independent Review Organization.

9-26-14 Fax coversheet.

Independent Review Portal IRO Request Details.

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

The claimant meets the criteria for a SCS trial. Based on the records provided, he has the diagnosis, failed back surgery, has tried multiple different therapies, and has been cleared for the procedure by a psychologist. Therefore, based on the records provided, the Trial of Spinal Cord Stimulator is reasonable and medically necessary.

ODG 2014 SCS: Recommended only for selected patients with Complex Regional Pain Syndrome (CRPS) Type I. For use in failed back surgery syndrome (FBSS), see the Low Back Chapter. More trials are needed to confirm whether SCS is an effective treatment for certain types of chronic pain. (Mailis-Gagnon-Cochrane, 2004) (BlueCross BlueShield, 2004) See Complete list of SCS References. This supporting evidence is significantly supplemented and enhanced when combined with the individually based observational evidence gained through an individual trial prior to implant. This individually based observational evidence should be used to demonstrate effectiveness and to determine appropriate subsequent treatment. (Sundaraj, 2005) 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. (Furlan-Cochrane, 2004) CRPS patients implanted with SCS reported pain relief of at least 50% over a median follow-up period of 33 months. (Taylor, 2006) SCS appears to be an effective therapy in the management of patients with CRPS. (Kemler, 2004) (Kemler, 2000) Recently published 5-year data from this study showed that change in pain intensity was not significantly different between the SCS plus PT group and the PT alone group, but in the subgroup analysis of implanted SCS patients, the change in pain intensity between the two groups approached statistical significance in favor of SCS, and 95% of patients with an implant would repeat the treatment for the same result. A thorough understanding of these results including the merits of intention-to-treat and as-treated forms of analysis as they relate to this therapy (where trial stimulation may result in a large drop-out rate) should be undertaken prior to definitive conclusions being made. (Kemler, 2008) Permanent pain relief in CRPS-I can be attained under long-term SCS therapy combined with physical therapy. (Harke, 2005) 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) See also Psychological evaluations (SCS) in the Stress & Other Mental Conditions Chapter.

Indications for stimulator implantation:

- Complex Regional Pain Syndrome (CRPS) when all of the following are present:
 - (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).

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)