

CALIGRA MANAGEMENT, LLC
1201 ELKFORD LANE
JUSTIN, TX 76247
817-726-3015 (phone)
888-501-0299 (fax)

Notice of Independent Review Decision

October 29, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Spinal cord stimulator trial

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

Orthopedic Physician

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

Upheld (Agree)

Medical documentation **does not support** the medical necessity of the health care services in dispute.

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 patient is a female who sustained an injury to her back in xxxx. She had L4-L5, L5-S1 fusion.

No records available through February 19, 2013.

On March 19, 2013, saw the patient for back pain. It was noted that the patient sustained an injury to her back on xx/xx/xx, resulting in back pain and L4-L5, L5-S1 fusion surgery. The patient was well after the surgery but she was experiencing recurrent pain in the last couple of years. She had crepitus in her back and was sent two years ago who recommended further diagnosis. The patient was trying to manage with Tylenol and ibuprofen. She was doing exercises and was on full duty work. She underwent extensive conservative treatment before the surgery. The patient was told that the sciatic nerve might be nicked. Medical history was remarkable of high blood pressure, stomach ulcer

and kidney stones. Past surgical history was remarkable of shoulder surgery in 1995 and elbow surgery in 1997. Examination of the back revealed difficulty in a full, upright position when getting out of the chair, painful, restricted lumbar range of motion (ROM) at flexion at 25 degree and extension at 50 degree. X-rays of the lumbar spine showed solid fusion at L4-L5 and L5-S1 and some degenerative changes and instability on flexion-extension at L3 for above her fusion. diagnosed low back pain, old L4-L5, L5-S1 fusion and transitional syndrome at L3-L4. He prescribed Mobic and Ultram and recommended physical therapy (PT).

On April 30, 2013, the patient underwent PT evaluation and was recommended therapy two visits a week for four weeks with modalities to include active assistive ROM, aerobic conditioning, and functional activities, active assistive ROM, aerobic conditioning, and functional activity

On May 7, 2013, saw the patient for the back pain. He stated that the patient had just started PT. She stated that Ultram helped her but it was giving her headache when it wore off. Meloxicam might be helpful, she could not take Vicodin. diagnosed low back pain and hypertension and prescribed Pentazocine-acetaminophen. A nutrition handout was given to the patient.

On May 30, 2013, noted the patient had been in PT. She had a lot of trigger points causing spasms and left groin pain mostly on the low back. Codeine was helpful without side effects. Examination of the lumbar spine revealed tenderness in the paravertebral muscles bilaterally, painful and restricted lumbar ROM with flexion at 75 degree and extension at 25 degree. Fortin Finger test, Yeoman's test and Faber test were positive to the right and left. Sacroiliac (SI) joint examination revealed femoral thrust and Gaenslen's positive on the left. diagnosed low back pain, previous L4-L5, L5-S1 fusion with a transitional syndrome and SI joint instability. had ordered SI joint injection on the left for diagnostic and therapeutic purposes as the patient had met criteria as having at least three provocative tests for SI dysfunction which was common sequelae to a lumbar fusion.

On June 11, 2013, performed a left SI joint injection with corticosteroid.

On July 9, 2013, saw the patient after SI joint injection and noted that the pain level was decreased from 6/10 to 3/10 and then to 1/10. The patient stated that she was doing well and walking better and faster, she did not have to prop up or unload her back at the grocery store or doing chores. The work was much better and she could get up and down much easier. Examination of the lumbar spine revealed positive Fortin finger test to the right and left. diagnosed low back pain and SI joint dysfunction and opined that if the patient would be getting continuous benefit from the injection then rhizotomy might be considered.

On July 23, 2013, noted the pain level at 1-2/10. Certain activities were increasing her pain but still she was better. Examination of the lumbar spine revealed positive Fortin finger test, Yeoman's test and Faber test to the right and left. recommended follow-up after rhizotomy.

On August 28, 2013, a physical medicine/rehab specialist, evaluated the patient for the rhizotomy. Examination of the lower back revealed bilateral tenderness over the SI joints and positive Patrick's and Stork maneuver bilaterally. diagnosed low back pain and SI joint dysfunction, history of lumbar fusion and no radiculopathy and left L5, S1, S2 and S3 cooled RF. The patient was to continue home exercise program (HEP) and medications.

On November 27, 2013, noted that SI joint radiofrequency ablation was denied. Examination of the lower back revealed bilateral tenderness over the SI joints and positive Patrick's and Stork maneuver bilaterally and bilateral tenderness over the left sided para spinals. There was a long middle incision scar. diagnosed low back pain and sacroiliac joint dysfunction, history of lumbar fusion, no radiculopathy and chronic lumbar paraspinal myofascial pain. He referred the patient for the possible lumbar Botox injection and advised to continue HEP and medications. opined that the only other intervention was a spinal cord stimulator (SCS).

On December 12, 2013, saw the patient for chronic low back pain. The patient appeared to have taut/spastic lumbar paraspinal muscles that might be contributing to her pain. recommended a trial of Botox injections.

2014: On March 6, 2014, noted that the Botox injections were denied. recommended trying Zanaflex for muscle pain and to help her rest at night. The patient was to follow-up.

On March 31, 2014, noted that the Botox injections were denied. The patient had low back pain especially on the left in the left posterior thigh. She was utilizing Tylenol, Mobic, Flexeril and Zanaflex. Examination of the back revealed difficulty in a full, upright position when getting out of the chair. The gait was slow and purposeful. There was bilateral tenderness over the para vertebral muscles with bilateral spasms, painful and restricted lumbar ROM with painful flexion at 25 degree, extension at 5 degree, lateral bending to the right and left was painful at 15. Seated slumped straight leg raise (SLR) caused pain and pulling sensation in the back but no radicular complaints. diagnosed chronic low back pain with muscle spasms and SI joint dysfunction and prescribed Robaxin. opined that the patient was the candidate for a spinal stimulator.

On July 21, 2014, noted the patient continued to have sharp right low back pain. She could not get comfortable sleep. She stated that Robaxin was not helpful and started Codeine. renewed Tylenol, prescribed Zanaflex and Mobic and referred the patient for consideration of the SCS.

On August 6, 2014, performed an independent medical evaluation (IME) and rendered the following opinions: (1) The patient was treated reasonably with medications. She was functional and working well with her low-dose narcotics. There was no evidence of any monitoring of her drug status. (2) The patient was being seen occasionally for maintenance of her medications. Invasive treatment

was not necessary. (3) The patient should be seen every six months to maintain her on the medication. Meloxicam should be replaced with over-the-counter (OTC) anti-inflammatories. If not already present, there was a need for drug monitoring program and a narcotic agreement. At the current time, there was no indication for the treatment other than maintenance of her medications. The patient should be seen once every four to six months by the treating provider. There was no indication for invasion treatment such as epidural injections or facet joint injections. She was a not candidate for a spinal cord stimulator. (4) She would only need x-rays or diagnostic testing if her symptoms change from the current time. She would not need durable medical equipment (DME). (5) Given the decision at the time to proceed with surgery continued treatment was reasonable and necessary. (5) There was no indication for treatment other than maintenance of her medications. There was no indication for invasive treatment such as epidural injections or facet joint injections. (6) It would appear that the patient had a contusion and was treated for a hypothetical aggravation of the pre-existing degenerative changes. (7) The patient was merely suffering from the sequela of the surgery that was performed as a result of the occupational injury.

On August 20, 2014, saw the patient for the moderate-to-severe, chronic back pain and leg pain located on the left side. The patient had difficulty in sitting for long periods of time and she had noted some overall improvement in symptoms when standing, walking around and staying active. Examination of the back revealed difficulty in a full, upright position when getting out of the chair and old scars were seen on the spine. There was bilateral tenderness over the paravertebral muscles, painful and restricted lumbar ROM with painful flexion at 25 degree, extension at 25 degree. diagnosed chronic low back pain, post laminectomy syndrome and SI joint dysfunction, prior lumbar fusion. He recommended SCS and referred the patient for the presurgical psychological screening evaluation and subsequent SCS trial implantation.

Per utilization review dated September 11, 2014, the request for SCS trial was denied with the following rationale: *"There was no documented psychological evaluation that details whether the patient is an appropriate candidate or not for the spinal cord stimulator. Also the patient had a previous independent medical evaluation that mentioned the patient was not a candidate for the spinal cord stimulator as spinal cord stimulators were indicated for the patients with failed back syndrome when symptoms are primarily lower extremity pain and in this case the patient's symptoms were reportedly 90% axial and she would be unlikely to receive any improvement with a spinal cord stimulator. There was also no clear detail provided whether other lower levels of treatment have been attempted such as addressing of the patient's pain coping skills. Therefore, this request is not medically reasonable or necessary."*

On September 17, 2014, a psychologist, evaluated the patient for the low back pain and left leg pain. The pain level was at 4/10. He stated that based on this presurgical psychological screening the patient was clear for the stimulator with a fair to good prognosis for the pain reduction and functional improvement.

Per reconsideration review dated September 25, 2014, the request for SCS trial was denied with the following rationale: *“The patient had had lower back pain (LBP) for a long time and had a successful fusion from L4-S1, which would relieve mechanical pain. The reported indicated that most of her pain was LBP and not radicular pain. Also, she had SI joint dysfunction and had an SI joint injection with 80% relief. About 25% of back pain has the SI joint generator. With this history, SI joint needs to be addressed and it may be that the fusion of the SI joint would relieve much of the pain. This could be done percutaneously and the spinal cord stimulator will not relieve her non radicular symptoms. Therefore, the request for trial spinal cord stimulator was non -certified as it was medically necessary and appropriate.”*

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

The requested spinal cord stimulator trial cannot be recommended as medically necessary based on the information reviewed. Spinal cord stimulator trials are often performed in patients after failed lumbar fusion when they have neuropathic pain complaints as their primary issue. The records clearly suggest that this claimant has a predominance of back pain as opposed to lower extremity pain. The records also indicate that the claimant had significant relief of symptoms (80%) following a previous sacroiliac joint injection. The records, therefore, do not seem to support a spinal cord stimulator trial based on the specific indications noted within Official Disability Guidelines. If the claimant had a predominance of lower extremity symptoms and failed to have significant relief with a previous sacroiliac joint injection, a spinal cord stimulator could be supported. The records, however, simply do not support a spinal cord stimulator trial based on the information reviewed.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES Official Disability Guidelines (19th annual edition) & ODG Treatment in Workers' Comp (12th annual edition), 2014

Low Back Chapter

Spinal Cord Stimulator

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. (Hollingworth, 2011)

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