

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

Notice of Independent Review Decision

February 19, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Spinal cord stimulator implant

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

Board Certified Pain Management Physician

REVIEW OUTCOME:

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

X Overturned (Disagree)

Medical documentation supports 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.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

- Diagnostics (09/10/08 - 10/14/11)
- Office visits (02/16/11 - 01/06/14)
- Procedure (05/07/13)

- Utilization reviews (01/06/14, 01/23/14)

- Office visits (08/26/13 - 11/21/13)
- Diagnostics (11/18/13)
- Utilization reviews (01/06/14, 01/23/14)

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a female who had a work-related injury in xxxx when her stool rolled back and broke and she fell back and developed a ruptured lumbar disc and tailbone injury.

2008: On July 31, 2008, x-rays of the lumbar spine showed status-post laminectomy, L3-L4 with metallic hardware L2-L5. There was narrowing at L2-L3 and L5-S1 with degenerative disc disease (DDD).

On September 10, 2008, magnetic resonance imaging (MRI) of the lumbar spine was obtained for continued pain in the low back radiating down to the legs. This showed: (1) Postoperative changes of fusion demonstrated from L3 through L5 with bilateral screw and rod fixation. The right neural foramen at L3- L4 was partially obscured by metallic artifact, but might be moderately narrowed. (2) Severe degenerative changes were present at L2-L3 with mild spinal canal stenosis and mild bilateral neural foraminal stenosis. (3) At L4-L5, an osteophyte projected into the left neural foramen without apparent nerve root compromise. (4) At L5-S1, there was at least moderate right neural foraminal stenosis with possible compromise of the exiting right L5 nerve root. There appeared to be a small right sub-articular disc protrusion with lateral recess stenosis, but no apparent compromise of the right S1 nerve root. There was mild left neural foraminal stenosis also present.

2009 – 2010: Records not available.

2011: On February 16, 2011, evaluated the patient for ongoing low back complaints. The patient had a work-related injury in xxxx. Her stool rolled back and broke and she fell back and developed a ruptured lumbar disc and a tailbone injury. She subsequently had two lumbar fusion surgeries, the first one in 2000 and subsequently in 2006, where she initially had improvement. However, since 2007, over the last three years, she indicated that she had some increasing lumbar and paraspinal pain and some right gluteal pain and right proximal leg pain. She used Vicodin and Ultram for breakthrough pain. Examination of the lumbar spine showed tenderness in the lumbar and paraspinal area. The patient had a slight antalgic gait on walking. She had a healed scar from her lumbar surgery. The hallux extensor strength was graded at about 4+ bilaterally. She was also able to appreciate light touch in the lower extremities. diagnosed lumbar pain, lumbar discogenic disorder and post-lumbar laminectomy syndrome and recommended undergoing x-rays of the lumbar spine for further evaluation of lumbar pain. also suggested that the patient might benefit with physical therapy (PT).

On March 21, 2011, x-rays of the lumbar spine showed slight loss of lumbar lordosis with an old compression deformity of about 15% at the L3 vertebral body level. There was pedicle screw/rod fixation between L3-L5 and reduction in disc height at the L2-L3 and L5-S1 levels. There was moderate spondylosis in the mid-to-lower lumbar spine.

On March 21, 2011, reviewed the x-rays of the lumbar spine and recommended continuing conservative measures and PT measures.

On September 14, 2011, noted that the patient was having some increasing lumbar and paraspinal pain and right leg pain. recommended obtaining an MRI of the lumbar spine to ensure no significant stenosis, disc protrusion or other pathology. It was also recommended to evaluate the patient's lumbar radiculopathy and lumbar pain.

On October 14, 2011, MRI of the lumbar spine showed: (1) Stable postoperative fusion at the L3-L4, L4-L5 levels. There was posterior spondylosis and facet arthropathy at L3-L4 creating some bilateral foraminal narrowing at that level. (2) Prominent bilateral posterolateral disc protrusion/osteophyte complexes at L2-L3 most notably on the right with facet arthropathy creating more stenosis with right greater than left-sided L3 nerve root and foraminal encroachment. (3) Disc space narrowing with bilateral posterolateral disc protrusion/herniations at L5-S1 with facet arthropathy creating mild stenosis with right greater than left-sided S1 nerve root and foraminal encroachment.

On November 7, 2011, noted that the patient was still having ongoing lumbar and paraspinal pain as well as some right leg pain and occasionally some left leg pain. diagnosed lumbar pain, lumbar radiculopathy, lumbar herniated nucleus pulposus (HNP), lumbar stenosis and post-lumbar laminectomy syndrome and recommended continuing conservative treatment measures versus that of surgery that were discussed with the patient. He also recommended PT. If the patient continued to be symptomatic then she would need to consider surgical treatment options.

2012: On January 4, 2012, noted that the patient was using Vicodin sparingly for breakthrough pain. reviewed the options of continuing conservative treatment measures versus that of surgery. The patient indicated that she was awaiting another cancer surgery and she wished to continue with conservative treatment measures at that stage.

On March 14, 2012, evaluated the patient for low back pain, right-sided lower buttock and upper right posterior leg pain since the injury. She had undergone two previous surgeries that were both apparently targeting the L3-L4 and L4-L5 levels. The first surgery was in 2000. One or more of those fusions did not take and she ultimately underwent a second surgery in 2006 when himself was indisposed because he had back surgery. fusion was successful at achieving segmental stability there and the patient entered into relatively pain free interval until about 2008 when her low back pain began to escalate. diagnosed lumbar pain, drug dependence narcotic for pain control, adjacent lumbar segment DZ after fusion L3-L4 and L4-L5, chronic postoperative pain not elsewhere classified. prescribed Norco, vitamin D, oxybutynin, venlafaxine, calcium, Trazodone, Norco and glimepiride. felt that the patient might ultimately be a candidate for Botox therapy, but while she was undergoing her treatment for her breast cancer, felt that she really wanted was just stability of her symptom control.

On August 6, 2012, evaluated the patient for ongoing low back pain. The patient had been a very active person for the last three months with all of the increased activities and demands on her physically that she was going through for treatment of her breast cancer. She was all the time on her feet moving around and going here and there at medical centers though was taking a toll on her chronic back issues which were her work related problems. She had experienced an increase in her symptoms as a result of that and reported that her pain medicine was not effective at relieving her symptoms as it was previously. prescribed Norco, oxybutynin, venlafaxine, calcium, Trazodone, glimepiride and vitamin D capsules. The potency of the patient's pain medication was increased to help her with her increased symptom burden from the chronic back issues.

On October 30, 2012, evaluated the patient for ongoing low back pain. MRI of the lumbar spine that was done in May 2012 was reviewed that showed stenosis of a moderate degree at L2-L3 above the fusion. There was also stenosis found within her fusion, but it was called mild, so likely than leg symptoms and her posture was coming from the stenosis that was found at L2-L3 right above the fusion. prescribed Norco, oxybutynin, venlafaxine, calcium, Trazodone, glimepiride and vitamin D capsule and recommended starting PT. The patient did not want to consider any further injections. She had many in the past which did not give her any relief of her pain and she also had to struggle with her blood sugar with them.

2013: On March 13, 2013, evaluated the patient for back pain. The patient was never able to do PT. The insurance carrier would not cover it. Obviously, one of those options was to consider surgery. Surgery was denied to her previously before. She was reporting itching to her hydrocodone, but it was one particular brand that seemed to be bothering her. recommended trying some oxycodone as a replacement. He introduced the concept of a spinal cord stimulator (SCS) to the patient. He refilled Percocet, oxybutynin, venlafaxine, calcium, Trazodone, glimepiride, Herceptin-Solr, vitamin D and exemestane.

On April 4, 2013, performed an initial behavioral health evaluation. The patient had a score of 18 regarding her Beck Anxiety Inventory (BAI) indicating moderate symptoms of anxiety. Her Beck Depression Inventory II (BDI-II) score was 20 indicating symptoms of depression. The diagnosis was pain disorder associated with both psychological factors and the general medical condition and adjustment disorder with mixed anxiety and depressed mood, chronic. Based on the data from the clinical interview, medical records and the test results, there was no evidence of factors that would indicate negative outcome to an invasive medical technique and the patient would be an appropriate candidate for SCS trial. If her depression and/or anxiety should increase in intensity, a referral for individual psychotherapy was recommended to enhance her coping skills to manage her pain.

On April 10, 2013, evaluated the patient for ongoing low back pain. refilled the medications and recommended SCS trial.

On May 7, 2013, performed anteroposterior and lateral thoracolumbar x-ray with interpretation, fluoroscopy for needle localization of the T12-L1 thoracolumbar epidural plane bilaterally, percutaneous fluoroscopic needle localization of the T12-L1 thoracolumbar epidural plane bilaterally, insertion of dual Octrode SCS trial electrode array through the T12-L1 epidural needles up to the top of the vertebral body segment in the posterior epidural space and establishment of SCS trial parameters utilizing the dual Octrode array.

On May 13, 2013, noted that the patient's pain was about 80% reduced with a SCS trial. She had only taken three pain pills through the whole time. There were no findings or signs of infection. Electrodes were removed. refilled the medications.

On May 20, 2013 noted that the patient continued to report about and 85% net reduction in her painful symptoms. She was also able to dramatically reduce her pain medication need to a total of three tablets during her entire period. The trial was pretty straightforward and obviously had had a very positive effect. Her leg symptom coverage was absolutely 100% optimal. Her low back pain was not completely covered during the stimulator trial and getting a little better back coverage than during the trial itself should be tried. had also talked about a paddle electrode versus percutaneous electrodes. refilled the medications to include Norco, oxybutynin, venlafaxine, calcium, Trazodone, glimepiride, vitamin D capsules, Herceptin, exemestane and recommended MRI of the thoracic spine without contrast to know whether the thoracic canal was adequately sized to accommodate a paddle electrode.

On June 14, 2013 evaluated the patient for ongoing low back pain complaints. felt that the patient would require revision posterior spinal surgery based on instability at the L2-L3 level caused by adjacent segment degeneration and based on excessive movement on flexion extension radiographs. The judicious use of anti-inflammatory drugs was also discussed. At computerized tomography (CT) myelogram of the spine would be necessary. The patient was to contact PT clinic for choice to set up physical therapy evaluation.

On August 26, 2013 evaluated the patient for ongoing low back pain. reviewed the patient's thoracic MRI and discovered that the patient had pretty significant issues at L2-L3 which was right above where she had had her previous surgeries. She had a pretty bad case of adjacent segment syndrome there had suggested the patient that he could fix it for her. The patient was a little taken aback by suggesting further surgery. advised the patient was just being thorough by looking at the thoracic MRI adjacent segment below in the lumbar spine and offering her his opinion about what he could do to help her. was in no way telling her that she was not a candidate for a stimulator. However, the need for a stimulator which was in its entirety a palliative tool only could potentially go away if she had that area of instability corrected. That made a lot of sense, he discussed it with the patient and the patient understood it as well. The patient needed more time to reconsider the surgery.

On September 23, 2013, evaluated the patient for ongoing low back pain and right leg pain. The patient stated that she was still not at the point where she was ready to make a big decision about her back surgically, however. She felt that a little more time would be helpful. recommended contemplating stimulator implant in the patient, but felt that he could fix her back. The patient had some lingering concerns that another surgery would not be approved which was a legitimate concern particularly in a worker's compensation patient. The patient could be cured by the surgery of her problems that would be a better way to go than a palliative solution like the stimulator. She might not need the stimulator if the surgery goes well. refilled medications.

On October 21, 2013 discussed with the patient about whether she was a better candidate for the stimulator which was palliative tool for control of her pain or whether she should consider offer to investigate the possibility of curing her back problem by extending her fusion up to L2-L3. The patient said that she was really not interested in more surgery on her spine. It was just too hard on her and she was not sure she had it in her to get through another big surgery. Additionally, the patient was not at all confident that her workers compensation carrier would even pay for another surgery, even if she was interested in having it done. was going to write a letter asking him to reconsider the patient for the stimulator implant. refilled medications to include Norco, oxybutynin, venlafaxine, calcium, Trazodone, glimepiride, vitamin D, Herceptin and exemestane.

On November 18, 2013, the patient was evaluated for ongoing back pain and shoulder complaints. The handwritten reports are illegible.

On November 18, 2013, cervical, thoracic and lumbar myelogram was performed. The findings showed status post fusion at C4 through C7 and L3 through L5. Spondylosis was scattered throughout.

On November 18, 2013, computerized tomography (CT) scan of the cervical spine showed: (1) Neural foraminal stenosis from C2-C3 through C7-T1. (2) Status post anterior cervical discectomy and fusion (ACDF) from C4 through C7. Interbody fusion had occurred at C4-C5 and C5-C6. (3) Right thyroid lobe lesions for which correlation with sonography was suggested.

On November 18, 2013, CT scan of the thoracic spine showed status post bariatric surgery. There was scoliotic curvature demonstrating concavity to the right centered at T3-T4 and to the left at T6-T7. Some atelectatic changes were evident in the lung bases.

On November 18, 2013, CT scan of the lumbar spine showed: (1) Status post fusion from L3 through L5. Bony fusion had occurred at both levels. There was some involvement of the right lateral recess at the L3-L4 level.

On November 21, 2013 evaluated the patient for ongoing severe low back complaints rated at 9/10 which was continuous and worsening. That pain affected her daily life by waking her at night interfering with work. She described her pain

as increased with activity, work and exercise. It improved with medications, rest, heat and SCS trial that she felt was successful. She complained of right greater than left numbness, tingling and burning of her leg. She had undergone previous epidural steroid injections (ESIs), epidurals and above-mentioned surgery and PT. Examination of the lumbar spine showed obvious flat back deformity. There was pain to palpation in the midline from the lower thoracic spine to the sacrum. There was marked paraspinal muscle spasm of the lumbosacral junction. The patient demonstrated restricted uncomfortable ROM on flexion and extension and lateral bending. Extension was found to be very provocative. The patient had markedly kyphotic uncomfortable gait. reviewed the thoracic spine myelogram and also lumbar CT myelogram. The thoracic spine findings were as follows: (1) Scoliotic curvature. Status post bariatric surgery. The lumbar spine findings were as follows: (1) Status post fusion from L3 through L5. Bony fusion had occurred at both levels. There was some involvement of the right lateral recess at the L3-L4 level. (2) There was disc pathology with facet hypertrophy at L2-L3 and L5-S1 impinging upon the nerve roots within the neural foramina and lateral recesses. (3) Diverticulosis without diverticulitis. diagnosed postlaminectomy syndrome lumbar region, lumbar radiculopathy, back pain, failed back syndrome, scoliosis and kyphosis and felt that the patient would require revision posterior spinal surgery based on instability of L2-L3 level caused by adjacent segment degeneration. Continuation of the non-operative care versus the risks associated with surgery was discussed at length. The patient was not interested in reconstructive spine surgery presently. She would like to proceed with a SCS placement.

On December 31, 2013, a request for authorization for outpatient surgery to include laminectomy and SCS was placed.

Per utilization review dated January 6, 2014, the request for laminectomy, spinal cord stimulator was denied based on the following rationale: *"The requested SCS placement cannot be recommended as medically necessary. Although, the claimant appears to meet criteria for failed back syndrome and has failed conservative treatment and also passed a SCS trial, the records reviewed do not indicate that the claimant has received psychological clearance for the operation. Official Disability Guidelines (ODG) require that the patient's have psychological clearance indicating that they have realistic expectations and clearance from a mental health standpoint for the procedure. Accordingly, the requested procedure cannot be recommended based on the information reviewed. Unfortunately, was unavailable for discussion."*

On January 6, 2013, evaluated the patient for ongoing low back pain. The patient stated that she was having more frequent muscle spasms. She was primarily at the clinic for her medication refill visit. It looked like had tentatively scheduled her for her surgery on the 21st of that month for her stimulator implant procedure. Her medicines continued to offer her modest relief of her symptoms. refilled Norco, Oxybutynin, venlafaxine, calcium, trazodone, glimepiride, vitamin D, Herceptin and exemestane. was looking forward to be being in the operating room to assist with the patient's implant.

Per the reconsideration review dated January 24, 2014, the request for reconsideration of spinal cord stimulator was denied based on the following rationale: *“The request for a spinal cord stimulator is not certified. The documentation submitted for review elaborates the patient complaining of ongoing low back pain.” The ODG recommends a SCS implantation provided meets the specific criteria to include the patient not being a candidate for a possible surgery. The clinical notes indicate that the patient having instability at the L2-L3 level resulting in a recommendation for surgical intervention. Given the patient having significant findings leading to the possibility of surgery, this request does not meet guideline recommendations. Peer-to-peer contact was attempted and unsuccessful.”*

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

The review was performed utilizing the ODG. The requested SCS placement is approved. The initial review denied the service because “records reviewed do not indicate that the claimant received psychological testing”. The current records reviewed reveal the patient had psychological testing that stated the patient was a candidate psychologically for the SCS.

The second review denied the service based on additional surgical recommendations. However, the patient has elected not to proceed with the extensive fusion surgery, thus is not a candidate for surgery.

In conclusion, the patient has post-laminectomy syndrome and meets the ODG criteria for SCS placement. 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.

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

X ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES