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Notice of Independent Review Decision

June 1, 2018
Amended 6/14/2018
Amended 6/15/2018

IRO CASE #: XXX

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Permanent spinal cord stimulator - percutaneous implantation of neurostimulator electrode
Insertion of spinal neurostimulator pulse generator
Electric analysis of implanted pulse generator

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTXX HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
American Board of Physical Medicine & Rehabilitation
American Board of Pain Medicine

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

☒ Overturned (Disagree)

Medical documentation **supports** the medical necessity of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:
The patient is a XX who injured XX back during a work-related injury in XXXX. The exact mechanism of injury was not available.

From XX, through XX, the patient received care at XX for back pain, leg paresthesias, left hip and leg pain. XX was status post lumbar decompression and fusion in XX. The diagnoses were L3-L4 adjacent segment disease above prior, L3-L4 HNP and radiculopathy, spinal stenosis of lumbar region, spondylosis without myelopathy and low back pain. The treatment included medications, exercise, trigger point injections and hardware blocks, epidural steroid injections (ESI) and surgeries.

On XX, a magnetic resonance imaging (MRI) of the lumbar spine was completed at XXXX. The study revealed an annular disc bulge at L3-L4 flattening the thecal sac with mild narrowing of the left neural foramen. The L4-L5 level revealed a bilateral laminectomy as well as posterior interbody fusion with internal fixation. At L5-S1, a 3.0 mm subligamentous disc protrusion was seen without nerve root impingement or foraminal encroachment.

On XX, MRI of the lumbar spine showed mild anterior degenerative spondylosis at L1-L2 and L2-L3; mild disc desiccation at L3-L4 with mild anterior degenerative spondylosis, mild posterior bulging of the annulus and mild degenerative facet disease; postoperative changes at L4-L5; disc desiccation at L5-S1 with slight posterior bulging of the annulus and mild degenerative facet disease.

On XX, MRI of the lumbar spine showed minimal disc bulge at T11-T12 without compromise of the spinal canal or neural foramina. There was mild disc bulge asymmetric to the left at T12-L1 without compromise of the spinal canal or neural foramina. There was a disc bulge at L3-L4 leading to moderate stenosis of the spinal canal, and mild left-sided neural foraminal stenosis. Postoperative changes of bilateral laminectomy and anterior and posterior fusion at L4-L5 was seen. Small central and left foraminal disc protrusions at L5-S1 without significant compromise of the spinal canal or neural foramina or definite nerve root impingement were seen.

On XX, XX M.D., performed decompressive lumbar laminectomy at L3-L4; bilateral L2-L3, L3-L4 medial facetectomies with bilateral L3 and L4 nerve foraminotomies and subarticular decompression – neurolysis; removal of painful L4-L5 M8 pedicle instrumentation bilaterally, segmental instrumentation; exploration of L4-L5 fusion masses bilaterally; epidural XX and intraoperative neuromonitoring.

On XX, XX performed decompressive lumbar laminectomies at L2-L3 and L3-L4; bilateral L2-L3 and L3-L4 medial facetectomies with bilateral L3 and L4 nerve root foraminotomies and subarticular decompression; L3-L4 posterior lumbar interbody fusion with BMP; left L3-L4 12 x 26 mm posterior cage insertion; L3-L4 bilateral segmental pedicle instrumentation 40 x 7 mm Leucadia screws, 4 cm rods bilaterally; L3-L4 bilateral posterolateral intertransverse fusion with autograft – BMP; harvesting of autograft; exploration of L4-L5 fusion masses; intraoperative spinal cord neural monitoring and epidural XX 3 cc.

On XX, XX performed decompressive lumbar laminectomies, L1-L2 and L2-L3; bilateral L1-L2 and L2-L3 medial facetectomies with bilateral L1, L2, L3 nerve root foraminotomies and subarticular decompression; left L2-L3 transforaminal lumbar interbody fusion with BMP; left L2-L3 transforaminal interbody cage 11 x 27 mm Zavation; L3-L4 removal of segmental pedicle instrumentation bilaterally; exploration of L3-L4 fusion masses bilaterally; L3-L4 segmental 40 x 7.5 mm and 45 x 7.5 mm Zavation screws with 45 mm segmental rods bilaterally, pedicle instrumentation; L3-L4 bilateral posterolateral intertransverse fusion with autograft – Mastergraft; harvesting of autograft; and intraoperative spinal cord neural monitoring.

On XX, the patient underwent a magnetic resonance imaging (MRI) of the lumbar spine at XX. The study was indicated for low back pain, numbness and tingling radiating to both lower extremities. The study was interpreted by XX, M.D. The study revealed possible marrow edema hardware artifact at the L2 and L3 vertebral bodies without loss of vertebral body height. This possibly represented postsurgical changes rather than marrow changes from infection. There were very small amount of either dorsal subdural or epidural fluid at the L2-L3 level. The appearance favored postsurgical changes rather than a complex subdural/epidural collection such as a bleed or infection. Fluid signal within the prior hardware tract of pedicular screws at L4 vertebral body was thought to be related to postsurgical changes rather than infection. There was no evidence of significant thecal sac compression, neuroforaminal stenosis, or clumping of the nerve roots.

On XX, the patient was seen by XX, M.D., for left-sided back pain with left greater than the right groin pain. The patient was one year status post revision decompression and fusion and was on XX. The exam revealed lumbosacral tenderness; decreased L3 sensation, left greater than right; positive straight leg raise (SLR) test bilaterally, left greater than right. The x-rays showed L2-L3 laminectomy, instrumentation and interbody fusion. Fusion was noted below at the L3-L4 and L4-L5 levels. MRI of the lumbar spine was recommended.

On XX, XX M.D., from XX saw the patient for chronic low back pain since the work-related injury of XX. Since that time, the patient had four back surgeries and a variety of injections. Over the last several years, XX experienced severe pain which was not responding to the conservative treatment. Currently, XX was on XX as needed, XX three times a day, XX three times a day XX once daily. XX had referred the patient for consideration of spinal cord stimulator as XX was not

a surgical candidate. The medical history was notable for anxiety, depression and hypertension. The surgical history was notable for lumbar laminectomy in XX, XX, XX, XX. The lumbar spine exam revealed painful extension and forward flexion past 20 degrees. The diagnoses were chronic pain syndrome, low back pain, long-term drug use and lumbar postlaminectomy syndrome. XX recommended spinal cord stimulator trial.

On XX, the patient was evaluated by XX Ph.D., for assessing the psychological factors affecting chronic pain management and assessing the candidacy for a surgical implant or spinal surgery. The test indicated that the patient was at some risk for stress related medical problems and repressed emotions contributing to some pain complaints. However, XX was no evidence of any mood or behavior disorder. The diagnoses were somatic symptom disorder with prominent pain, persistent, moderate to severe; and depressive disorder due to chronic pain with depressive and somatization features. XX opined the patient would benefit from brief pain management XX. The patient was considered as an acceptable candidate for the procedure from a psychological perspective.

On XX, XX evaluated the patient in a follow-up visit. The patient reported the pain scale of 9. XX had no change in XX pain. XX was sleeping most of the night waking two to three times during night. XX was taking XX as needed, XX three times daily, XX, XX three times daily. XX continued to have severe aching and burning in XX back and legs in a nondermatomal pattern. XX continued to have sensitivity to light touch of the skin and restless leg syndrome at night. XX performed placement of SCS.

On XX, XX noted the patient was five days status post spinal cord stimulator trial, and XX was experiencing about 40% overall relief with the high-density programming. XX was currently on anti-seizure medication-XX, XX, XX and XX. The neurological exam was unremarkable. The sensation of the trunk and lower extremities was intact. The reflexes were normal. The Tinel's and Phalen's tests were negative. XX provided reprogramming of the spinal cord stimulator.

On XX, XX noted the patient was moved from a high dose stimulator pattern to paresthesia pattern over the last couple of days. The current medications were continued. The patient was now 60% better. The back and legs symptoms were improved. XX removed the spinal cord stimulator leads and recommended follow-up in a couple of weeks.

On XX, XX noted the patient continued to take the pain medications to include XX as needed, XX three times daily, XX and XX times daily. XX had overall 80% pain relief of the back and leg pain with the SCS trial. XX was extremely pleased with the result and was anxious to move forward with the permanent implant. XX pain was back to its original level now, and XX felt that the last two weeks had solidified XX feeling that the stimulator was very effective for XX. XX recommended a permanent spinal cord stimulator.

On XX, XX completed a preauthorization request form and requested approval for permanent spinal cord stimulator.

Per Utilization Review dated XX, the request for percutaneous implantation of neurostimulator electrode, insertion of spinal neurostimulator pulse generator and electric analysis of implanted pulse generator was denied. Rationale: "*Based on the clinical information submitted for this review and using the evidence-based, peer-reviewed guidelines, this request is not-certified. Per evidence-based guidelines, spinal cord stimulator (SCS) is recommended only for selected patients with specific conditions and in cases when less invasive procedures have failed or are contraindicated. Permanent placement requires evidence of 50 percent pain relief and medication reduction or functional improvement after the temporary trial. According to Office Visit dated XX, the patient had 80 percent relief overall of back and leg pain two weeks after the trial of spinal cord stimulation. XX was extremely pleased with the results and was anxious to move forward with the permanent implant. XX psychological evaluation reported that the patient had no significant levels of depression or anxiety and suggested mild somatization. XX was at some risk for stress-related medical problems and repressed emotions contributing to some pain complaints. There was no evidence of any mood or behavior disorder. However, the evidence of pain relief and medication reduction or functional improvement in the medical reports to consider a permanent placement cannot be fully establiXXd as the patient was on an additional medication included XX three times a day; XX and XX three times daily. Thus, the entirety of the request is not supported at this time.*"

On XX, XX, PA-C, from XX responded to the denial. The letter documented that the request for a permanent spinal cord stimulator was denied on the basis that medication reduction and functional improvement was not noted at XX follow-up appointment at the completion of the stimulator trial. XX indicated that the patient suffered from chronic, burning pain in XX legs secondary to lumbar postlaminectomy syndrome that stemmed from work-related accident years ago. XX had failed conservative treatment and underwent a spinal cord stimulator trial on XX with 80% relief of XX back and leg pain, as documented at XX follow-up appointment on XX. We contacted the patient to question XX about XX medication usage and functional improvement during the trial, and XX stated XX was able to decrease XX medication use by 60% in regards to XX muscle relaxant and neuropathic pain medication. XX was also able to increase XX activity by 70%. XX also experienced improved mental clarity with the reduced medication use, had improved sleep and improved activity level without pain interference, XX felt the patient met the requirements for a permanent stimulator implant.

Per Reconsideration dated XX, the request for electric analysis of implanted pulse generator, insertion of spinal neurostimulator generator and permanent spinal cord stimulator percutaneous implantation of neurostimulator electrode was denied. Rationale: "*Based on the clinical information submitted for this review and using the evidence-based, peer- reviewed guidelines referenced above, this request is not medically necessary. In light of this presenting issues and in the absence of pertinent extenuating circumstances that would require deviation from the guidelines, the request for Permanent Spinal Cord Stimulator - Percutaneous Implantation of Neurostimulator Electrode; Insertion of Spinal Neurostimulator Pulse Generator; Electric Analysis of Implanted Pulse Generator is not medically necessary as a clear and measurable comparison could not be establishd in the records to objectively validate the patient's response from the spinal cord stimulator temporary trial to fully warrant a permanent placement.*"

On XX, XX noted the patient was on XX as needed, XX three times daily, XX and XX three times daily. The patient was now 90% worse than before XX last visit. XX had disturbed sleep. The neurological exam was unremarkable. The sensation of the trunk and lower extremities was intact. The reflexes were normal. The Tinel's and Phalen's tests were negative. The diagnosis was low back pain.

On XX, Carrier Submission from XX was documented.

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

The patient has had a Spinal Cord Stimulator trial. XX has reported >50% improvement in XX pain post trial. It is documented in the note dated XX, that the "Patient reports functional improvement in XX activities of daily living". The note dated XX states: "We contacted the patient to question XX about XX medication usage and functional improvement during the trial, and XX stated XX was able to decrease XX medication use by 60% in regards to XX muscle relaxant and neuropathic pain medication. XX was also able to increase XX activity by 70%. XX also experienced improved mental clarity with the reduced medication use, had improved sleep and improved activity level without pain interference, XX felt the patient met the requirements for a permanent stimulator implant".

Per evidence-based, ODG, guidelines, spinal cord stimulators (SCS) is recommended only for selected patients with specific conditions and in cases when less invasive procedures have failed or are contraindicated. The patient is diagnosed with post-laminectomy syndrome or FBSS. It is documented that the patient has had a variety of injections, therapy, CMT, and medications. XX is currently taking XX, XX, XX, and XX. According to the ODG, XX is not a candidate for chronic scheduled opiate analgesic medication, additional injections, or therapy at this time.

The previous denials focused on XX continued medication use during SCS trial. Per the ODG, permanent placement requires evidence of 50% pain relief and medication reduction **or** functional improvement after the temporary trial. Please see above. Thus, the patient has met the criteria. The request is certified provided that the patient is well aware

of the risks and potential complications associated with implantation of a permanent spinal cord stimulator. Medical documentation supports the medical necessity of the health care services in dispute.

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

X ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES