

MATUTECH, INC.

PO BOX 310069
NEW BRAUNFELS, TX 78131
PHONE: 800-929-9078
FAX: 800-570-9544

Notice of Independent Review Decision

DATE OF REVIEW: January 31, 2012

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

L4-L5 and L5-S1 ALIF with 3-day LOS

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

Diplomat, American Board of Orthopaedic Surgery
Fellowship trained in spine surgery

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.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

:

- Office visits (08/11/10 - 11/15/11)
- Diagnostics (11/09/11)
- Peer reviews (11/23/11 – 12/15/11)
- Utilization reviews (12/17/11 – 12/17/11)

:

- Office visits (01/07/10 – 12/28/11)
- Diagnostics (11/09/11)

TDI:

- Utilization reviews (11/28/11 – 12/17/11)

ODG has been utilized for the denials.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a female who injured her lower back on xx/xx/xx, while moving 50-60 pound boxes of paperwork.

2010: On January 7, 2010, M.D., spine surgeon, performed a right L5-S1 hemilaminectomy, decompression right S1 nerve root and excision of large herniated nucleus pulposus (HNP) with foraminotomy at L5-S1.

Magnetic resonance imaging (MRI) of the lumbar spine revealed postoperative change at L5-S1 with evidence of right laminotomy and partial discectomy. There was significant enhancement along the right lateral aspect of the thecal sac and along the posterior disc margin and around the nerve root on right at L5-S1 level that was not significantly greater. There was also mild degenerative disc disease (DDD) at L4-L5 that was stable from previous study.

Per functional capacity evaluation (FCE) dated August 11, 2010, the patient was functioning at a less-than-sedentary physical demand level (PDL). Her job required her to function at a medium-heavy PDL.

On November 23, 2010, M.D., spine surgeon, performed percutaneous placement of a St. 30-cm 8-contact percutaneous lead to T12-L1 and advanced to T7-T8 just to the right of midline.

X-rays of the thoracic spine showed a spinal stimulator placement to the level of the inferior endplate of T7 utilizing the provided numbering system.

On December 15, 2010, Dr. performed a trial of dorsal column stimulator (DCS). This was the second trial for chronic pain syndrome with the patient achieving dramatic response to pain control with the implant trial.

On December 27, 2010, M.D., evaluated the patient status post implemented trial. The patient reported that she had been doing well and was looking forward to her battery placement. She had been utilizing Xanax and hydrocodone. Dr. removed the sutures.

2011: On January 26, 2011, Dr. performed an implantation of the DCS.

Dr. evaluated the patient for some radiating pain into the chest area with the stimulation. X-rays showed good positioning of the two leads present midline to the superior aspect of the T10 level.

From March 21, 2011, through July 14, 2011, M.D., evaluated the patient for status post spinal cord stimulator (SCS) implantation. The patient reported some confusion, trouble speaking, difficulty walking, dizziness, a severe headache and later on hemiplegia. Dr. sent the patient back to Dr. for consideration of removing the stimulator.

On August 18, 2011, Dr. performed removal of DCS due to increased pain. Postoperatively, Dr. and Dr. treated the patient with Norco, Xanax and oxycodone.

Office note dated September 30, 2011, indicates the stimulator was removed and MRI was ordered. The patient was utilizing six Norco daily which was mostly beneficial and also took Xanax. Oxycodone was ordered for flare-ups of severe pain.

MRI of the lumbar spine revealed status post right-sided laminectomy and appearance of granulation tissue at L5-S1 with enhancing soft tissue within the right anterior lateral and right lateral margins of spinal canal surrounding right S1 nerve root sleeve. There was also enhancement within posterior aspect of the disc space most compatible with post discectomy changes. There was broad-based posterior disc protrusion at L4-L5 with ligamentum flavum hypertrophy causing mild central canal narrowing and mild narrowing of the right neural foramen similar to previous study. There was a 2-mm annular bulge and mild degenerative facet joint changes at L3-L4.

Ph.D., performed a presurgical psychological evaluation and opined that the patient had significant factors for reduced spine surgery outcome. He added that the patient was clear to proceed with a discogram and should not undergo elective spine surgery.

Dr. obtained a lumbar discogram which revealed normal disc at L3-L4. There was a posterior leak and reproduction of pain at L4-L5 that was concordant as well as severe concordant pain at L5-S1. Examination revealed positive sitting root test for low back and leg pain and paraspinal tenderness. X-rays of discogram revealed leakage at L4-L5 and L5-S1. Computerized tomography (CT) showed normal disc at L3-L4 and posterior lateral fissuring out to the left at L4-L5 and central protrusion at L5-S1. Some slight narrowing of the spinal canal at L4-5 was also noted. Dr. diagnosed chronic low back pain and right leg pain status post right L5-S1 hemilaminectomy with failure of conservative treatment including SCS with reproduction of pain at L4-5 and L5-S1 without significant stenosis and recommended an anterior posterior fusion.

On November 23, 2011, M.D., performed a peer review and opined that the request for an L4-L5 and L5-S1 anterior lumbar interbody fusion (ALIF) was not necessary.

Per utilization review dated November 28, 2011, the request for L4-L5 and L5-S1 ALIF was denied based on the following rationale: *"The claimant was not cleared for spinal surgery per the recent psychological evaluation. The evaluation stated that there are significant risk factors for a poor outcome with spine surgery. There was a recommendation for additional follow-up with the psychologist prior to surgery. Therefore, based on the submitted clinical documentation, the request for an L4-L5 and L5-S1 ALIF with a three-day LOS was not medically necessary."*

On December 15, 2011, M.D., performed a peer review and opined that the appeal for L4-L5 and L5-S1 ALIF with three day LOS was not medically necessary.

Per the utilization review dated December 17, 2011, the appeal for L4-L5 and L5-S1 ALIF with three-day LOS was denied based on the following rationale: *"As per ODG, "X-rays demonstrating spinal instability and/or myelogram, CT-myelogram, or discography (see discography criteria) & MRI demonstrating disc pathology correlated with symptoms and exam findings". The patient does not meet the guidelines as radiographic evidence did not reveal spinal instability."*

Furthermore, there was no significant neurocompromise noted on imaging. Therefore, this request was not medically necessary."

On December 28, 2011, Dr. noted that the patient was still complaining low back pain and right leg pain. Examination showed absence of the deep tendon reflexes (DTRs) at the right Achilles. Sitting root test was productive of right leg pain. Dr. Guyer diagnosed chronic low back pain and right leg pain status post right L5-S1 hemilaminectomy, failure of conservative treatment with spinal instability and retrolisthesis at L5-S1, reproduction of pain by discography at L5-S1 as well as at L4-L5. Dr. planned to resubmit for an anterior-posterior fusion at the L4-L5 level.

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

This patient is a who injured her low back on xx/xx/xx, moving 50 to 60-lb. boxes of paperwork for . On January 7, 2010, she had a right L5-S1 hemilaminectomy and decompression of the right S1 nerve root with excision of herniated nucleus pulposus on her right side with foraminotomy at L5-S1. The patient's interval records after the operative notes are not forwarded but the patient was sent for another MRI of the lumbar spine with a clinical history given that the patient was having low back pain with bilateral extremity discomfort. The MRI showed postoperative changes at L5-S1 with evidence of the right laminotomy and partial discectomy with enhancement along the right lateral aspect of the thecal sac. The patient had degenerative disc disorder noted at L4-L5 which was apparently stable from the previous study.

On August 11, 2010, an FCE was performed showing that she was not able to perform at the medium-to-heavy PDL level which was her previous job but that she could work at less than a sedentary physical demand level.

On November 23, 2010, Dr. (M.D.) placed trial percutaneous St. spinal cord stimulator leads up to T7-T8 junction just to the right of the midline. Due to some difficulties, the lead was removed and the patient was presented for a second trial utilizing double lead on December 15, 2010. The patient reported that there was significant improvement in her pain control with this implant trial.

On December 27, 2010, Dr. reassessed the patient after the trial. She was looking forward to a permanent placement. She was still utilizing Xanax and hydrocodone.

The patient then had implantation of the dorsal column stimulator on January 26, 2011. She however was noted postoperatively to have some radiating pain into the chest area. However the x-rays showed good positioning of the leads.

There were several evaluations done with Dr. and his physician assistant. The patient on March 21st reported to Dr. that she was having frustration in terms of her pain control. The spinal cord stimulator was not providing adequate coverage. She was to continue with her home exercise program. On March 21, 2011, Dr. noted that she had had four major flare-ups over the last month with

her pain control even with the stimulator. She had been taking hydrocodone 6-8 a day as before.

On April 25, 2011, she reported to Dr. and his physician assistant that she was utilizing the spinal cord stimulator only three days a week. She also reported that she had some confusion, trouble speaking, difficulty walking, and dizziness as well as a severe headache. She considered these all to be related to her spinal cord stimulator use.

Dr. on April 25, 2011, proposed that there be further coordination regarding her stimulator use. Dr. also proposed that she be detoxed off her Norco and Xanax.

Dr. on July 14, 2011, noted that she reported that over time the stimulator had made her feel worse. She also noted that if she kept the stimulator on she gets hemiplegia essentially. She was referred back for spinal cord stimulator removal. The spinal cord stimulator was then removed on August 18, 2011. On August 29, 2011, Dr. noted that the source of her pain still remained unclear. Dr. on September 30, 2011, proposed that she be given oxycodone 10 mg p.o. b.i.d. for more severe pain. Dr. on October 3, 2011, noted that the patient had a degenerative disc noted at L4-L5 and L5-S1. He also went over the unusual scenario of her stimulator providing inadequate benefit and almost worsening of her dysfunction.

Dr. psychologist, evaluated her for candidacy for discography, psychologically. He noted that she had significant risk factors for reduced spine surgery outcome according to the pre-surgical psychological screening algorithm but that she was fit to proceed with the discography.

She did see Dr. on October 24, 2011, who proposed that she was a candidate for operative intervention. She was to undergo lumbar discography L3-L4 to L5-S1.

The discogram was performed in L3-L4, L4-L5 and L5-S1 at Pain Group. L4-L5 was abnormal with posterior leak and moderate concordant pain. L5-S1 had the most concordant pain.

Dr. noted on November 15, 2011, that she was now having difficulty with further pain control just with the oxycodone and that two of the Norco were more effective. He proposed increasing the dosage of the oxycodone to the 20.

Dr. on November 16, 2011, proposed that Ms. was a better candidate for a fusion surgery at L4-L5 and L5-S1 than disc replacement.

There were two preauthorization reviews completed both denying the proposed fusion surgery at L4-L5 and L5-S1.

On December 28, 2011, the patient was reassessed by Dr.. He proposed that the fusion was still the most appropriate treatment to include both the L5-S1 level but also L4-L5 as there were degenerative changes in the right L4-L5 facet.

This patient has had an unsuccessful discectomy and laminotomy. She then had apparent failure of conservative treatment postoperatively and then had two spinal cord stimulator trials. The one trial was allegedly very successful and this

lead to implantation of the spinal cord stimulator done by a qualified expert. She has had a very unusual response to this spinal cord stimulator with reported even "hemiplegia." The spinal cord stimulator was then removed. Her medication use has been excessive. She has no reported spinal instability that is objectively documented. The rationale for her having success with a fusion surgery does not appear any more likely than the previous other surgeries that have been unsuccessful. Moreover, this fusion surgery does not meet ODG criteria as there is no noted spine instability on the radiographic studies. Thus, the proposed surgery is not considered a medical necessity given the records and ODG criteria.

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

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES