

Maturus Software Technologies Corporation
DBA Matutech, Inc

881 Rock Street
New Braunfels, TX 78130
Phone: 800-929-9078
Fax: 800-570-9544

Notice of Independent Review Decision

April 18, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

E0748 Bone growth stimulator – Lumbar- purchase

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

Diplomate 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:

X Upheld (Agree)

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

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a female who on xx/xx/xx, felt cramping pain in her lumbar area. There was no history of trauma.

On May 11, 2012, magnetic resonance imaging (MRI) of the lumbar spine was performed for indication of back pain and radicular symptoms. The findings were as follows: (1) At L1-L2, L2-L3, L3-L4 and L4-L5, there was minimal changes of spondylosis consisting of endplate irregularity and mild osteophytosis. (2) At L5-S1, there were bilateral pars-articular defects at L5 with interval worsening in anterolisthesis (now grade I) of L5 on S1 with posterior disc uncovering resulting in a broad-based disc bulge with extension into the left neural foramen and contrast with exiting left L5 nerve root; Interval increase in number of T2 signal

hyperintense foci within both kidneys possibly representing benign renal cortical cysts.

On June 1, 2012, evaluated the patient for lumbar pain. The pain had started on xx/xx/xx, without any history of trauma. The pain lasted for about two weeks and she remained under the care. She was treated with medications and intramuscular (IM) steroids with resolution of lumbar pain after two weeks. She developed radicular symptoms. She had then developed left leg radicular gluteal numbness with stabbing, burning pain along the gluteal fold and groin. The baseline changes from 3-5/10 in a constant pattern without progression. She reported that the injection provided her about 60 % of improvement in the lumbar pain. With the overall radicular symptoms, she had also developed a limp of the left leg. Her history was remarkable for right rotator cuff repair. She was utilizing Lyrica, ibuprofen, Soma and Lortab. On examination, right hip internal rotation was painful. Deep tendon reflexes (DTRs) of the lower extremities were 0/4 in posterior tibialis bilaterally and 1/4 in right Achilles. X-rays of the pelvis showed right and left coxa versus deformity. The lumbar spine x-rays showed facet arthropathy of the bilateral L5-S1 facets and a grade I spondylolisthesis of L5-S1. diagnosed lumbago, lumbar radiculopathy and lumbar spondylolisthesis and recommended conservative treatment and if it provided no relief, then she was to be considered surgical intervention. stressed the need for proper body mechanics including no heavy lifting, keeping heavier objects close to the body as they were lifted and no bending at the waist. She was recommended to apply ice and heat to the affected area. The patient was encouraged to go walking, bicycling and swimming for generalized conditioning. She was recommended not to gain weight and continue taking the present analgesics, anti-inflammatory medications, muscles relaxants and anti-epileptic medication. also recommended lumbar computerized tomography (CT) to better evaluate her symptoms and also x-rays of the lumbar spine with lateral flexion and extension views in the next visit.

On July 11, 2012, the patient stated that medications use and rest had helped her symptoms. She continued to struggle with lumbar pain, but as not as aggressive as before. The left leg radicular pain had also improved on an intermittent basis that did not escalate as much as it used to be in the past. X-rays of the lumbar spine on flexion and extension views demonstrated a decreased disc height at L5-S1 with grade I spondylolisthesis that changed from 10 mm to 15 mm between flexion and extension. There was also a pars interarticularis fracture defect at the L5 and some generalized osteopenia as well. diagnosed grade I L5-S1 spondylolisthesis (unstable), L5 pars interarticularis fracture, lumbago and lumbar radiculopathy. recommended lumbar CT and encouraged her to stay active, avoid heavy lifting and maintained proper body mechanics.

On August 10, 2012, the patient complained of lumbar pain and left leg radicular pain. There was numbness and tingling along the buttocks, posterior thigh and occasionally into the groin. She rated the pain 6-8/10 on the pain scale. There was a denial from the previously requested lumbar facet block. submitted reconsideration for the lumbar CT for a full assessment of this fracture. He also recommended proceeding with a left-sided L5-S1 transforaminal epidural injection

with selective nerve root block to be both diagnostic and therapeutic for the patient's symptoms.

On September 6, 2012, performed a left L5-S1 transforaminal epidural injection with epidurogram and left S1 selective nerve root injection.

On September 21, 2012, the patient reported that constant radicular symptoms had become intermittent and had about 75% milder than before since the procedure. She still had reproducible pain into the right buttock. The lumbar pain had become intermittent and did not go above 8/10 in frequency. Overall, the patient was quite happy with the results of the injections. recommended the patient to remain active and avoid heavy lifting and maintain proper body mechanics.

Per a note dated September 28, 2012, was in agreement that the patient had reached maximum medical improvement (MMI) and therefore no impairment rating was indicated at this point. disagreed that the patient was accepted to reach MMI on December 18, 2012.

On October 12, 2012, the patient noted that he had not improved despite taking Soma, Lortab, ibuprofen and Lyrica. The use of exercise, modification of activities and therapy has not helped him. She has failed conservative treatment and now wished to proceed with spinal surgery. The patient wished to proceed with the posterior lumbar decompression and fusion at L5-S1 using bone graft, bone allograft, cage and posterior instrumentation.

On November 9, 2012, noted that the patient struggled with constant lumbar pain at 5/10 intensity with a stabbing pressure. The lower extremity radicular symptoms had become bilateral with a burning pain and numbness along the buttocks, both gluteal folds and the posterior aspect of both thighs. The symptoms were intermittent, but reproducible multiple times throughout the day. The previously suggestive surgical correction was approved, but the insurance company was disputing the level of the diagnosis for the patient. suggested the patient to file for a hearing to include the specific proven diagnoses. In the meantime, recommended the patient to stay active, avoid heavy lifting, maintain proper body mechanics and stretch regularly.

On December 14, 2012, the patient's lumbar pain was radiating superiorly with a cramping pattern and the left leg radicular symptoms had become more aggressive covering the greater surface area radiating down to the posterior lower legs and occasionally to the ankle. The patient's insurance company had rescheduled her hearing until January 4, 2014.

2013: On January 17, 2013, noted the patient had a second medical opinion from the insurance company named who agreed that she had spondylolisthesis with radiculopathy and needed treatment as well as lumbar sprain. The patient was scheduled to have a court hearing on March 15, 2013, for extensive treatment of her lumbar symptoms.

On February 22, 2013, the patient complained of lumbar pain on a daily basis at 4-8/10 on the pain scale. She reported that the medications only gave temporary relief of her pain. recommended continuing with her current management.

On March 22, 2013, noted that the patient was doing much better. The patient noted that the medications made her symptoms more comfortable and was able to function within her environment. She rated the lumbar pain from 2-6/10 and the radicular symptoms from 0-5/10.

Per a note dated April 17, 2013, disagreed with the certifying doctor's MMI of June 1, 2012, with 0% impairment. The patient had ongoing pain from the injury and still had not reached MMI.

On May 3, 2013, the patient was recommended to continue with current management.

On May 10, 2013, the patient reported that she had received the results from the hearing regarding the approval of her pathology for medical treatment. The judge ruled in her favor. recommended proceeding with the necessary medical treatment to include repeat lumbar MRI and lumbar CT in order to set forward a better surgical planning for anatomical structure.

On June 13, 2013, MRI of the lumbar spine showed. (1) At L1-L2 and L2-L3, there were degenerative endplate changes and anterior osteophytes present. (2) At L3-L4, there was mild left paracentral bulging of the disc. (3) At L5-S1, there was 3 mm of subluxation of L5 on S1. There was mild bilateral neural foraminal narrowing. There was grade I spondylolisthesis of L5 on S1.

On June 13, 2013, CT lumbar spine showed mild levoscoliosis and grade I spondylolisthesis of L5 on S1. There was no significant disc protrusion demonstrated. The L5-S1 interspace was mildly narrowed. There were degenerative facet changes bilaterally at L5.

On June 21, 2013, evaluated the patient for low back pain. The patient had failed conservative treatment and now wished to proceed with spinal surgery. On examination of the spine, there was pain with ROM of the lumbar spine. The left Achilles reflex had 1/2 reflex and the right 2/2. SLR was positive on the left. had recommended a posterior lumbar decompression and fusion as well as open reduction internal fixation (ORIF) of the L5-S1 spondylolisthesis using bone graft, bone allograft, cage and posterior instrumentation.

On August 23, 2013, had recommended to continue with the surgery as prescribed earlier. provided with a front wheel walker and a 3 in 1 commode to help safe transfers and ambulation.

On September 11, 2013, performed an ORIF of L5-S1 spondylolisthesis, L5 laminectomy, S1 laminectomy, posterior lateral lumbar fusion of L5-S1, non-

segmental posterior instrumentation of L5-S1 and intervertebral cage placement of L5-S1 on the patient.

Per a note dated September 11, 2013, opined that in order to increase the changes that she develops a solid spinal fusion it was medical necessary that she gets a bone stimulator to help achieve a solid fusion.

On September 25, 2013, the patient reported having had great relief in her lumbar pain and radicular symptoms. She was only experiencing a minimal tingling sensation along the left lateral thigh and an occasional pressure along the right posterior calf. She was very happy with the results of the surgery and stated that she was able to return to higher levels of functionality. She had decreased the amount of medication that she was taking on a regular basis. All the staples had been removed. She ambulated quite well throughout the room without any dyskinetic movements. There was still a diminished Achilles reflex present. X-rays of the lumbar spine demonstrated the hardware to be in a great location, as well as the intervertebral cage. There was some generalized osteopenia, but the remainders of the bony structures were unremarkable and intact. encouraged the patient to stay active, avoid heavy lifting, maintain proper body mechanics and continue with stretching regularly. She was recommended to return in a month.

On November 1, 2013, the patient reported to be doing great and had stopped her pain medication two weeks after her spinal fusion surgery. She denied any back pain or leg pain, but noted that her back did get a till tired. X-rays of the lumbar spine revealed the hardware to be in a good position. recommended the patient to take Lyrica at night to help with her sleep and continue exercising.

On December 5, 2013, the patient reported that she was back from her vacation and during this period noted that she had increase of a left-sided heel and lateral thigh pain that was intermittent with a baseline changes from 0-4/10, although not very aggressive in her suppressive therapy. She had been completely asymptomatic and had begun taking her medications on a nightly basis to help with her symptoms. On examination, the patient stood up from a sitting position with any difficulty. The lumbar spine had guarded motions, but reproduced left-sided gluteal pain with left tilt. The lower extremities were neurovascularly intact with a negative SLR and a negative Patrick's bilaterally. X-rays of the lumbar spine demonstrated the hardware to be in great location as well as intervertebral cage. There was already early osteoblastic activity formation through the sacral endplate. There were generalized osteopenia but the remainders of the bony structures were unremarkable and intact. encouraged the patient to stay active, avoid heavy lifting and maintain upper body mechanics. Soma and Lortab were prescribed.

2014: On January 3, 2014, it was noted that the patient continue to struggled on at night with some burning sensation and cramping pain. recommended to take medications at night and to continue on current care management.

On February 7, 2014, noted the patient continued to experience a reproducible left side lateral thigh pain multiple time throughout the day. reviewed the x-rays dated February 7, 2014, that demonstrated hardware to be in good location and intact as well as the intervertebral cage. There was already early osteoblastic activity occurring within the cage as well as on the lateral gutters. There was generalized osteopenia throughout. recommended proceeding with a lumbar MRI to evaluate the spinal canal and surrounding of tissues for possible nerve irritation or compression.

On February 12, 2014, MRI of the lumbar spine showed: (1) Slight anterior slippage of L5 on S1. There was some pedicle edema on the left at L4. There was mild anterior osteophytic ridging, most thorough L1-L2. (2) At L4, there was enhancing edema of the pedicle on the left. No linear fracture was seen. There was no expansion of the pedicle or cortical destruction seen. (3) At L5-S1, there was laminectomy on the left with wide patency to the canal. There was slight anterior slippage and disc bulging but no significant foraminal stenosis. There was enhancing scar at the surgical site but not in the lateral recesses. The interbody graft was in good position. SI showed typical appearance of pedicle screws. Further characterization with CT was to be considered if clinically indicated.

On February 24, 2014, the patient complained of burning sensation of the lateral thigh. She stated that it had started in December and had still continued. Physical activity increases her problem. She stated that she has not had any new trauma to her back and Lyrica helped. Occasionally, she would take Lortab and she remains to be active as possible. diagnosed L5-S1 spondylolisthesis, radiculopathy, lumbago and possible L4 pedicle fracture. discussed upper body mechanics and use of ice/heat over her left leg. She was recommended to remain active and walk for exercise. offered a left L4-L5 transforaminal epidural injection with selective nerve root block. The patient agreed. also recommended CT scan of the lumbar spine to see if she had left L4 pedicle fracture. It was noted that she had not yet received a bone stimulator.

On February 25, 2014, a preauthorization for bone growth stimulator was requested.

Per a utilization review dated February 27, 2014, the request for bone growth stimulator for lumbar spine was denied with the following rationale: *“Based upon the medical documentation presently available for review, the above noted reference would not support this specific request to be one of medical necessity. The records available for review do not provide any documentation to indicate that the patient is at an increased risk for fusion failure. Generally, for a one level lumbar spinal fusion, the requested piece of durable medical equipment is not considered a medical necessity. Based upon the records presently available for review, medical necessity for this specific request is not established.”*

On March 5, 2014, the patient complained of lumbar pain that occurred intermittently several times throughout the day depending of her activity

movement or position. She reported that the medications helped and she tried to be as active as possible. The patient was denied bone stimulator that was previously requested. On examination, the patient stood up from a seated position slowly but without pain. The lumbar spine had guarded movements that exacerbated on extension and flexion with tenderness of the paraspinal muscles. The lower extremities had some hyperesthesia along the left lateral thigh with a negative SLR test bilaterally. There was diminished left Achilles reflex. diagnosed L5-S1 spondylolisthesis, lumbar radiculopathy and L4 pedicle fracture. opined that the use of the bone stimulator would help with a L5-S1 fusion and also help indentifying the pedicle fracture. Should the fracture not healed, the patient might actually have the need for a future fusion of the L4-L5 to help relieve the pain. He further opined that the bone stimulator would help improve the symptoms and prevent the need for any other type of surgical correction. The patient was encouraged to stay active, avoid deep bending at the waist and avoid any type of direct heavy lifting.

On March 6, 2014, performed left L4-L5 transforaminal ESI with epidurogram and left L5 selective nerve root injection on the patient.

On March 12, 2014, CT of the lumbar spine showed: (1) Status post fusion on L5-S1. Bilateral pedicle screws and intervertebral disc cage was identified. There was a prior left-sided micro laminectomy seen. There was extensive soft tissue density seen in the surgical bed could represent epidural fibrosis/granulation tissue and encasement of the traversing left S1 nerve root and possible of the exiting L5 nerve root could be considered. Contrast-enhanced MRI of the lumbar spine might be benefit to help asses for epidural fibrosis. (2) The remainder of the spine showed moderate degenerative changes without high-grade canal stenosis or high grade neural foraminal narrowing. The kidneys were mildly irregular in appearance bilaterally with several small stones and mildly complex potential cystic lesions of the right kidney. There was L4 left pedicle and inferior facet fracture.

On March 12, 2014, preauthorization for bone growth stimulator was requested.

Per reconsideration review dated March 19, 2014, the request for bone growth simulator for lumbar spine was denied with the following rationale: *“Based on Official Disability Guideline criteria, the request for a bone growth stimulator purchase would not be indicated. The patient's clinical records fail to demonstrate appropriate indication for use of a bone growth stimulator at this stage in the postoperative setting. There appears to be no significant underlying risk factor in this otherwise healthy individual. The role of bone growth stimulator purchase for the sole purpose of a pedicle fracture would not be indicated particularly given absent clinical imaging demonstrating the process available for review. Peer to peer discussion was unsuccessful.”*

On April 2, 2014, an appeal was made for independent review organization (IRO).

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

I have reviewed the forwarded records including the following given in summarization.

May 11, 2012, there was an MRI of the lumbar spine compared to an April 25, 2006, MRI of the lumbar spine. He had noted the patient had re-demonstration of bilateral L5-S1 spondylolysis with interval worsening and anterolisthesis. There was bilateral pars intra-articular defect.

On June 1, 2012, indicated that this patient had cramping lumbar pain without any history of trauma. She was changing sheets on a bed while bending forward and felt cramping pain in her back.

The patient's neurological exam was 5/5. Reflexes were symmetrical except decreased on the right Achilles. Sensation was normal.

On July 11, 2012, reported there was a grade I spondylolisthesis that changed from 10 mm to 15 mm between flexion and extension, with a pars articularis fracture at L5 and generalized osteopenia.

On September 6, 2012, a left transforaminal ESI was performed at L5 and S1.

On October 21, 2012, reported that the patient was basically asymptomatic until April 13, 2012. She did not improve with the spinal injection. He proposed the patient proceed with operative intervention at L5-S1.

On November 9, 2012, pre-cert review apparently agreed with medical necessity for the surgical intervention. Subsequent office visits indicate there was administrative hearing to be scheduled.

On January 17, 2013, noted a court hearing on March 15 is scheduled.

On March 22, 2013, the patient was reported to have a positive straight leg raise bilaterally. Pain level varied from 2 to 6 on a 10 scale.

On May 3, 2013, the patient reported the hearing had been completed. She was scheduled to have an evaluation; however, the final decision had not been determined.

The patient on May 10, 2013, apparently had administrative approval for her lumbar pathology as related. A repeat MRI on June 13, 2013, done on a 1.5 field MRI as read showed only mild degenerative changes and a grade I spondylolisthesis of L5 and S1 but there was no bulging of the disc and only mild bilateral neural foraminal narrowing and no central canal stenosis at L5-S1.

The June 13, 2013, CT scan showed grade I spondylolisthesis at L5-S1 with mild degenerative disc disease at L5-S1. Mild scoliosis and spondylosis was noted.

On August 23, 2013, reported that the patient had spondylitic spondylolisthesis of grade II at L5-S1 with dynamic changes anywhere from 10 to 15 mm between flexion and extension.

On September 11, 2013, performed what he called an open reduction internal fixation at L5-S1 spondylolisthesis with an L5 and S1 laminectomy and posterior lumbar fusion at L5-S1 and intervertebral cage placement at L5-S1.

By December 5, 2013, reported that there was already early osteoblastic activity through the sacral endplate. Hardware was in great location.

On January 3, 2014, reported the patient to stand up from a sitting position without difficulty. She was neurovascularly intact but negative straight leg raise. There was also noted on x-ray stimulation of bone allograft along the lateral gutters and considerable improvement on the blastic activity within the cage.

On February 7, 2014, proposed a follow-up lumbar MRI with and without contrast to evaluate soft tissues. He also stated x-rays showed osteoblastic activity occurring within the cage as well as the lateral gutters.

On February 12, 2014, MRI was completed and interpreted to show the laminectomy with hardware intact at L5-S1 but enhancing epidural fibrosis (scar). There was also edema into the pedicle at L4 on the left but no pedicle fracture.

On February 24, 2014, proposed an L4-L5 transforaminal ESI as well as a bone growth stimulator.

The pre-cert request for the bone growth stimulator was denied through preauthorization review.

On March 6, 2014, the transforaminal ESI at L4 and L5 was completed.

Summary: The patient is a female who had an administratively determined spondylolisthesis aggravated by routine activity of life. The patient has undergone spinal fusion at L5-S1. No CT scans has been performed to access the aspect of healing of the L5-S1 fusion however, the records suggest that there is x-ray evidence of early osteoblastic healing through the cage as well as further formation in the gutters. The patient does not have any identified medical illnesses or smoking history to warrant proceeding with the proposed bone growth stimulator. Further definition of the healing of the fusion would be a prelude to any medical necessity for the bone growth stimulator. Therefore, the request as submitted is not considered a medical necessity.

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

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES