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Notice of Independent Review Decision

June 23, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Bone growth stimulator E0748, lumbar back brace, TENS unit E0730 one month trial use, conductive garment purchase E0731

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 Spine Surgeon

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:
ODG criteria have been utilized for the denials.

PATIENT CLINICAL HISTORY [SUMMARY]:
The patient is a male who on xx/xx/xx, injured his back. The patient twisted his back. He felt a pop in lower back.

On November 8, 2011, the patient underwent magnetic resonance imaging (MRI) of the lumbar spine that showed L4-L5 5 mm left herniated disc with compression of left L5 nerve root. There was a 2 mm disc bulge at L3-L4.

On November 9, 2011, the patient attended a physical therapy (PT) session at Medical Centers. It was the patient's tenth session out of 14. Modalities were neuromuscular reeducation and therapeutic exercises.

On October 18, 2012, computerized tomography (CT) scan lumbar myelogram showed a 3 mm broad posterior disc protrusion at L3-L4 which moderately effaced the thecal sac causing mild spinal canal and moderate lateral recess stenosis. There was a large 6 mm left paracentral disc protrusion at LL4-L5 which impinged upon the thecal sac and the left L5 nerve root. The disc protrusion resulted in non-opacification of the left L5 nerve root sheath and severe narrowing of the left lateral recess. There was mild degenerative spondylosis from L1-L2 through L4-L5.

On December 11, 2012, CT scan of the brain showed mild mucosal thickening bilateral ethmoid air cells.

On December 19, 2012, CT scan of the head showed mild chronic bilateral maxillary and bilateral ethmoid air cell sinusitis.

On March 7, 2013, evaluated the claimant for low back pain radiating into the left lower extremity along the internal thigh and calf and intermittently into the dorsum of the left ankle with associated numbness in a similar distribution in addition to foot drop. The patient had completed a selective nerve root injection. He currently described his pain level as a 6/10. recommended anterior lumbar interbody fusion at l4-L5 with posterior lumbar decompression, posterolateral fusion and pedicle screw instrumentation at L4-L5. The patient had failed conservative medical therapy including PT with concordant responses to selective epidural steroid injections (ESIs).

On March 18, 2013, completed a pre-surgical behavioral health evaluation. The patient did not exhibit psychological or behavioral risk factors. The patient was looking forward to proposed surgical procedure and to return to a more functional and productive lifestyle.

On October 2, 2013, noted no improvement in the previous symptomatology. diagnosed recurrent lumbar radiculopathy, recurrent herniated nucleus pulposus (HNP), lumbar mechanical/discogenic pain syndrome at L4-L5, foot droop on the left and lumbago, status post remote surgical decompression at L4-L5 on the left. He recommended surgery.

On October 11, 2013, x-rays of the lumbar spine showed mild degenerative spondylosis from L1-L2 through L4-L5. There was mild degenerative facet joint hypertrophy from L1-L2 through L5-S1.

On December 27, 2013, x-rays of the chest was unremarkable.

Laboratory reports dated December 27, 2013, showed higher glucose levels (251).

On January 22, 2014, evaluated the patient. The patient had one back surgery and now had continued back [pain radiating down to his left leg. He also had a left footdrop. His pain was increased with coughing and sneezing. He had not

responded to conservative therapy and due to his neurologic deficit and recurrent herniated disc at L4-L5 with a foot drop on the left he was scheduled for an anterior lumbar interbody fusion at L4-L5 with posterior lumbar decompression and posterior lateral fusion and pedicle screw instrumentation at L4-L5. The patient should be started on an insulin sliding scale and oral medications at the time of admission. Also should be started on an ACE inhibitor for blood pressure control and that could be arranged at the time of admission.

On April 16, 2014, gave a prescription for bone growth stimulator, LSO brace, transcutaneous electrical nerve stimulation (TENS) unit, hot/cold therapy system and conductive garment.

Per utilization review dated May 15, 2014, the request for lumbar back brace Off the Shelf Lo637, TENS unit E0730 one month trial use, conductive garment purchase E0731 and bone growth stimulator E0748 was denied based on the following rationale: *"The clinical information submitted for review fails to meet the evidence based guidelines for the requested service. The mechanism of injury was pulling and twisting. The patient's current medications were not included for review. The patient's surgical history includes an L4-L5 discectomy, on January 5, 2012. Other therapies include an unknown duration of physical therapy, epidural steroid injection and medications. The patient is a male who reported an injury on xx/xx/xx. As there were no medical records provided for review after March 2013, it is unclear what the patient's current complaints are, or what his clinical presentation is. The Official Disability Guidelines recommend bone growth stimulators, either invasive or noninvasive, as an adjunct to spinal fusion surgery if a patient exhibits certain risk factors. Risk factors include one or more previous failed spinal fusions, a grade III or worse spondylolisthesis, fusion that is to be performed at more than one level, a current smoking habit, diabetes, renal disease, alcoholism, or significant osteoporosis. No recent clinical notes were submitted for review, and therefore, it is unclear why the patient is in need of a bone growth stimulator. There is only evidence of a prior discectomy performed in January 2012, with no follow-up notes detailing the patient's healing course. In regard to a lumbar back brace, guidelines recommend lumbar supports for compression fractures or specific treatment of spondylolisthesis, instability, or for nonspecific lower back pain. Lumbar supports are not recommended for prevention. Again, as there were no recent clinical notes submitted for review, the patient's symptoms and clinical presentation is not available, to aid in making an informed decision regarding the need for this device. In regard to the one month trial of a TENS unit with conductive garment purchase, guidelines recommend TENS for chronic intractable pain lasting at least three months, when there is evidence of other failed modalities. If a garment is required, there should be documented evidence that the area for treatment is so large that a conventional system would not accommodate the treatment; that the patient has medical conditions preventing the use of a traditional system; or that the TENS unit is to be used under a cast. As no recent medical records were submitted for review, the medical necessity of this request cannot be determined. I discussed the case at 0940 CST on May 12, 2014. It was reported to me that the patient is scheduled for a lumbar fusion at L4-L5, but has no other criteria for the use of a bone growth*

stimulator or comorbidities lending themselves to poor postoperative outcomes, such as a prior failed fusion. In addition, there was no medical basis for the post-operative brace, other than an opinion that it helps patients both mentally and physically. As the TENS unit was reportedly to be used under the brace, it too, is not indicated. The peer to peer discussion did not provide any further clinical evidence to support the need for these items. Therefore, a non-certification determination was left with the physician along with information regarding the appeal process. As such, the request for bone growth stimulator, E0748, lumbar back brace off the shelf L0637, TENS unit E0730 one month trial use and conductive garment purchase, E0731 is non-certified."

Per the reconsideration review dated May 21, 2014, the appeal for lumbar back brace Off the Shelf Lo637, TENS unit E0730 one month trial use, conductive garment purchase E0731 and bone growth stimulator E0748 was denied based on the following rationale: *"The patient is a male who sustained an injury on xx/xx/xx (as per report dated March 18, 2013); from twisting (as per report dated March 23, 2013). His diagnoses include recurrent lumbar radiculopathy, recurrent herniated nucleus pulposus at L4-L5, lumbar mechanical/discogenic pain syndrome at L4-L5, left foot drop and lumbago, status post remote surgical decompression at L4-L5 on the left. An appeal request is made for a bone growth stimulator, lumbar brace, TENS (one month trial) and conductive garment purchase. The previous request for bone growth stimulator was noncertified based on the grounds that although the patient is scheduled for a lumbar fusion at L4-L5, he has no other criteria for the use of a bone growth stimulator or comorbidities lending themselves to poor postoperative outcomes, such as a prior failed fusion. The previous request for a lumbar brace was non-certified as there was no medical basis for its use. The previous request for the TENS unit was non-certified as it was reported to be used under the brace. The prior peer reviewer stated that the peer to peer discussion did not provide any further clinical evidence to support the need for the requested items. Updated documentation submitted for review includes the treatment notes/diagnostic study reports from October 2012 to April 2014. These did not address the above-mentioned reasons for non-certification. The patient is status post L4-L5 discectomy on January 5, 2012. The lumbar CT myelogram study dated October 18, 2012 revealed a 3-mm broad based protrusion at L3-4, which moderately effaces the thecal sac causing mild spinal canal and moderate lateral recess stenosis; a large 6 mm left paracentral disc protrusion at L4-L5 which impinges the thecal sac and the left L5 nerve root (there was non-opacification of the left L5 nerve root sheath and severe narrowing of the left lateral recess); and mild degenerative spondylosis from L1-L2 through L4-L5. In the October 2, 2013, follow-up, the patient was noted to have no improvements with regards to his symptoms. He complained of low back pain with radiation to the left lower extremity with associated numbness and foot drop. He rated his low back pain at 6/10. Physical examination revealed markedly decreased lumbar flexion secondary to pain. The left tibialis anterior and extensor hallucis longus have motor strength of 0/5. Motor strength was 5/5 otherwise. Deep tendon reflexes were 2+. The patient had an antalgic gait with evidence of foot drop on the left. The SLR test was positive bilaterally. There was a hypoesthetic region on the left L5 distribution. The previous lumbar incision was*

healed. The treatment recommendations include ALIF at L4-L5 with posterior decompression, posterolateral fusion and pedicle screw instrumentation at L4-L5. The lumbar x-ray study dated October 11, 2013 showed mild degenerative spondylosis from L1-L2 through L4-L5; and mild degenerative facet joint hypertrophy from L1-L2 through L5-S1. The records indicate that the requested Durable Medical Equipment will be utilized post-operatively. The Fax Cover Sheet dated May 14, 2014, indicates that the patient is scheduled for 360 fusion surgery at L4-L5 on May 13, 2014. Treatments rendered to date include a lumbar surgery, physical therapy, epidural steroid injections, medications and work/activity restrictions. Diagnostic examinations performed include x-ray, MRI, and CT/myelogram studies. As to the request for a bone growth stimulator, the referenced guidelines state that electrical bone growth stimulation may be considered medically necessary as an adjunct to spinal fusion surgery if the patient has any of the following risk factors for failed fusion previous failed spinal fusion; grade III or worse spondylolisthesis; fusion to be performed at more than one level; smoking history; diabetes, renal disease, or alcoholism; or significant osteoporosis demonstrated on radiographs. These were not noted in the patient to substantiate the request. As such, medical necessity is not established. As to the request for a lumbar brace, the ODG low back chapter states that there is no scientific information on the benefit of bracing for improving fusion rates or clinical outcomes following instrumented lumbar fusion for degenerative disease. As high-quality medical studies to support the use of the requested equipment is not found, medical necessity is also not established. As to the request for TENS, the ODG pain chapter states that TENS is recommended as a treatment option for acute post-operative pain in the first 30 days post-surgery. It was mentioned that the proposed necessity of the unit should be documented upon request. A post-operative evaluation of the patient was not presented. It was not demonstrated that traditional methods for treating post-operative pain (such as medications and cold applications) have failed to necessitate the request. In the absence of significant indications, the medical necessity of TENS is not established. Consequently, the medical necessity of a conductive garment purchase is also not established. Overall, the request is not substantiated in agreement with the previous determination."

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

The patient is a gentleman who had a back injury on xx/xx/xx. He felt a pop in his lower back. The patient had a MRI of the lumbar spine on November 8, 2011, showing an L4-L5 disc herniation 5-mm in size with compression of the left L5 nerve root. There was also a 2-mm disc bulge at L3-L4. The patient had initially been seen. The patient then subsequently apparently was seen as referenced in evaluation of March 7, 2013. In early 2012, the patient apparently had surgery of the L4-L5 level. The operative note for this surgery was not provided.

On October 18, 2012, the CT scan after myelogram done was read to show a large 6-mm left paracentral disc protrusions at L4-L5 with impact on the thecal sac as well as left L5 nerve root. There was also disc protrusion of 3-mm size at L3-

L4 and plain x-rays had shown spondylosis from L1-L2 through L4-L5. There was a report of a CT scan of the brain also interpreted on December 11, 2012, showing mucosal thickening of bilateral ethmoid air cells. The patient on December 11, 2012,had a CT scan of the brain without contrast was read to show a normal CT scan of the brain except for ethmoid air cells mucosal thickening.

The patient was seen on March 7, 2013. The records indicate that the patient had been seen previously on December 7, 2012. The patient was having pain radiation into the left lower extremity.

The patient was noted to have 0/5 strength in the tibialis anterior as well as extensor hallucis on the left, but otherwise was 5/5. proposed an anterior lumbar interbody fusion at L4-L5 with posterior lumbar decompression and posterior lateral fusion with pedicle instrument at L4-L5. There was no discussion of what was going to be done if anything at L3-L4.

The patient underwent a presurgical behavioral health evaluation who stated that the patient did not have psychological or behavioral risks factors that would predict a poor surgical outcome. He was placed into the fair prognosis category.

In October 2013 again proposed the patient was a surgical candidate. He also noted that the patient would require preoperative clearance and then he should undergo lumbar spine films including flexion/extension views.

X-rays taken on October 11, 2013 and interpreted showed no instability on flexion/extension of the lumbar spine, but there was degenerative spondylosis from L1-L2 through L4-L5 as mentioned as well as mild degenerative facet hypertrophy from L1-L2 through L5-S1.

There were preoperative lab assessments forwarded including an EKG. The patient did have a hemoglobin A1C of 8.9. noted the patient had had hypertension and diabetes in the past and was not currently taking his medications for quite a while. (The rationale for this noncompliance is not discussed.)

The records of May 7, 2014, are requesting a bone growth stimulator to be billed at $5923 and a lumbar back brace to be billed at $1603 and a TENS unit to be billed at $135 for a month trial and a conductive garment to be billed $461. The requests were reviewed through the preauthorization process and denied on the index and appeal.

There were no further records for review.

The medical necessity for these DME items which were listed are not supported in that the patient does not have any lumbar spine instability documented on the flexion/extension views for the lumbar spine In addition, the patient is being considered for the surgery to deal with the back pain issue, which is the indication

for the TENS unit. Moreover, it would be unusual to utilize a conductive garment for a one month trial. Thus the necessity for that garment even if the TENS were considered medically necessary is not established. The last DME item is the bone growth stimulator. However, there is no clear documentation that these surgeries have actually been approved. Moreover there is no discussion of why the patient would warrant the spine fusion operation versus just the decompression surgery. Regardless, the bone growth stimulator does not appear to meet ODG criteria or medical necessity as the patient is not a smoker nor does he have a multilevel fusion being proposed.

Thus the previous adverse decisions provided through the preauthorization process appeared to be appropriate and the adverse decisions are upheld based on the review of the records that are provided at this time.

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

☒ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**