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Notice of Independent Review Decision

October 2, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Bone growth stimulator- Lumbar E0748, Lumbar Back Brace Off The Shelf L0637, TENS unit one month rental E0730 (PNR Conductive Garment E0731) and VenaPro Compression Device – Lumbar E0767 x 2

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:

Partially Overturned (Agree in part/Disagree in part)

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

ODG criteria have been utilized for the denials.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male, who sustained a work-related injury to his lumbar area on xx/xx/xx. The patient felt a shock-like pain in the right lower extremity. He started with sharp low back pain with radiation into the right lower extremity posteriorly and laterally down to the foot.

2013: On March 2, 2013, a magnetic resonance imaging (MRI) of the lumbar spine revealed transitional vertebra, spondylolisthesis without spondylolysis at L4-L5 grade I, narrow central canal/relative spinal stenosis and degenerative changes of the intervertebral discs at L4-L5 and L5-S1. The degenerative changes at L4-L5 were the most significant related to large disc protrusion resulting in further severe spinal stenosis. The study was indicated for low back pain extending into left leg since three weeks after heavy lifting.

On April 22, 2013, the patient underwent lumbosacral myelography. Three view x-rays of the lumbar spine revealed grade I to II anterolisthesis of the L4 relative to L5. The L5-S1 level was transitional showing features of sacralization with a rudimentary disc. There was loss of disc space height mainly at L4-L5, but also minimally at L3-L4. The T12 level showed rudimentary ribs. The myelography findings revealed significant disc displacement due to disc protrusion/extrusion centrally and to the right of midline at L4-L5 and slightly diminished right nerve root sleeve filling at the L4-L5 and L5-S1 level. There was at least grade I anterolisthesis of the L4 relative to L5. Minimal displacement of the contrast column was also demonstrated at the L3-L4 level, which might be due to shallow annular bulging at L2-L3 and L3-L4. A post myelography CT scan of the lumbar spine showed at L3-L4, there was a broad-based 2 mm annular bulge which minimally contracted the thecal sac below the level of the exiting nerve roots. The canal and foramen otherwise appeared uncompromised. At L4-L5, bilateral pares defects were demonstrated. Because there was solitary 3-4 mm length linear bone or calcific fragments at the level of the right and left pars defect, the possibility of bony trauma related to the patient's recent work related accident at the level of the pars (combined with underlying developmental spondylolysis) might be a consideration. There was an 8 mm broad-based soft tissue disc extrusion with an additional 8-9 mm right lateral intra-foraminal component. There was no evidence for sequestration. The L4-L5 disc extrusion extended 3 mm above the interspace. The AP spinal canal diameter was narrowed to 9.9 mm compatible with borderline spinal canal stenosis. Effacement of the thecal sac was noted. The L5-S1 level showed a rudimentary disc with transitional features of sacralization, 1-2 mm of broad-based annular bulging and bilateral S1 nerve root sleeve contact is noted without displacement. The foramen and canal at L5-S1 otherwise appeared uncompromised.

On May 17, 2013, evaluated the patient for sharp low back pain radiating into the right lower extremity posteriorly and laterally down to the foot. He rated the pain at 9/10 with worsening of symptoms after prolonged sitting, standing, coughing, sneezing or Valsalva maneuver. The history was remarkable for hypertension. Examination revealed decreased range of motion (ROM) in forward flexion secondary to pain. Motor examination revealed 4/5 strength of the extensor hallucis longus and tibialis anterior muscles on the right. There was marked difficulty with heel walk and no difficulty with toe walk. Straight leg raise (SLR) was positive on the right at 30 degrees. Sensory examination revealed a hypesthetic region of the L4, L5 and S1 distribution on the right to pin prick and light touch. reviewed the CT myelogram and diagnosed spondylolytic/spondylolisthesis L4-L5 grade I, lumbar mechanical/discogenic pain syndrome at L4-L5, lumbar spinal stenosis, lumbar radiculopathy, herniated nucleus pulposus at L4-L5 and lumbago. recommended initiating supervised physical therapy (PT), possible epidural steroid therapy and surgical intervention. A lumbar spine series including flexion, extension and oblique views was recommended.

From June 3, 2013, through June 28, 2013, the patient underwent eight PT visits at Medical Center with modalities to include therapeutic exercises and neuromuscular re-education.

On July 8, 2013, noted the patient had completed supervised PT and was to be evaluated for epidural steroid therapy. The patient reported no significant improvement in the low back pain with radiation. There was associated numbness and tingling. He reported pain level of 8/10. He had marked difficulty with heel walk and very little difficulty with toe walk. Tandem walk was difficult secondary to pain. recommended evaluating the patient for epidural steroid therapy and return after the regimen was completed to discuss surgical intervention if symptoms did not abate.

On November 26, 2013, the patient reported that the epidural steroid therapy was denied by his insurance carrier. He still had no improvement in his symptoms. He rated his symptoms at 8/10. The patient had failed conservative medical therapy including PT and had pain duration greater than six months. recommended anterior lumbar interbody fusion at L4-L5 with posterior lumbar decompression, posterolateral fusion and pedicle screw instrumentation at L4-L5. The procedure was discussed with the patient and the patient wished to proceed. A lumbar spine series in standing position to include flexion, extension and bending views were recommended.

2014: On January 20, 2014, performed a pre-surgical behavioral evaluation on the patient to assess his current emotional condition and psychological suitability for surgery and risk of poor outcome. The patient was scheduled for anterior lumbar interbody fusion at L4-L5 with posterior lumbar decompression, posterolateral fusion and pedicle screw instrumentation at L4-L5. The patient denied any other health problems. The patient scored 1 on the Beck Depression Inventory (BDI) and Beck Anxiety Inventory (BAI). The testing indicated that the patient was not experiencing any significant mental health issues that would deem him a poor candidate for spinal fusion surgery. The patient was diagnosed Axis I: Chronic pain disorder associated with both psychological features and a general medical condition. Mr. cleared the patient for the proposed surgery. No psychological treatment was needed.

On February 10, 2014, x-ray of the lumbar spine revealed transitional appearance of the lumbar spine with apparent partial sacralization of L5, bilateral pars deficit at L4 with grade I spondylolisthesis L4 and L5 with severe disc space narrowing, batwing deformities at L5 with pseudoarthrosis and probable partial fusion leftward, severe disc space narrowing at L5-S1 and mild degenerative changes inferior aspect of both sacroiliac (SI) joints.

On March 11, 2014, noted the patient had 6-7/10 pain in the low back. recommended epidural steroid therapy and lumbar spine series x-ray.

On April 10, 2014, evaluated the patient for ongoing low back pain symptoms. The patient continued with pain, numbness and weakness in his right leg. He was

utilizing meloxicam. Examination revealed lumbar spine with tenderness in the axial and peri-axial lumbar spine, greatest at L4-L5. There was positive SLR on right at 50 degrees. He had +1/4 extensor hallucis longus on the right, altered sensation to sharp testing at L5 dermatome to right foot and leg. diagnosed lumbar radiculitis in right lower extremity at L5 distribution and felt the patient might benefit from epidural steroid injection (ESI). Surgical intervention was recommended if no relief from ESI.

On May 27, 2014, noted the patient continued with positive SLR on right at 40-45 degrees. There was no extension of the extensor hallucis longus, right great toe. There was altered sensation in L5 dermatome right foot and great toe. The back pain was minimal, but had right gluteal pain consistent with sciatic nerve irritation. diagnosed right L5 radiculopathy neuropathy secondary to work-related injury and no improvement with conservative treatment including therapy and anti-inflammatory medication. The patient was scheduled for ESI at right L5 distribution and recommended continuing PT.

On June 10, 2014, noted that the ESI injection was denied due to unable to review written MRI. The patient had increased pain in the right leg and was unable to find a comfortable position due to the annoying pain in posterior leg and buttocks. He denied any change in activity and admitted to leg pain with sneezing, coughing or tightening his abdominal muscles to stand up. Examination revealed his gait was upright. There was minimal tenderness in axial peri-axial lumbar spine and over right gluteal area with sciatic nerve distribution. SLR was positive at 40-45 degrees. There was weakness with extensor hallucis longus right great toe, altered sensation to L5 dermatomes, heel raise +1/4 on right and +4/4 on left. recommended ESI at right L5-S1 and to see the attached MRI report.

Per a certificate of medical necessity from Universal DME dated July 9, 2014, prescribed bone growth stimulator, LSO brace, TENS unit, conductive garments, hot/cold therapy system and DVT equipment for home use.

On July 15, 2014, the patient reported no significant improvement in his symptoms. He continued to have 7/10 pain. He had marked difficulty with heel walking and less difficulty with two walking. Tandem walk was within normal limits. SLR was positive at 30-40 degrees on right. recommended anterior lumbar interbody fusion at L4-L5 posterior lumbar, decompression, posterolateral fusion with pedicle screw instrumentation at L4-L5. Preoperative medical clearance and postoperative bracing was recommended.

On July 22, 2014, performed arthrodesis posterolateral technique at L4-L5, posterior lumbar laminectomy of L4 and L5, bilateral foraminotomies at L4 and L5, posterior non-segmental pedicle screw fixation at L4 and L5, bone marrow aspiration of the left posterior iliac crest and L4 vertebral body, autograft for spine surgery, neuro-monitoring of SSEPs, motor evoked potentials, nerve root and pedicle screws, application of intervertebral cage at L4-L5, and use of intraoperative fluoroscopy.

Per a utilization review dated July 28, 2014, the request for NU lumbar back brace off the shelf, TENS unit one month rental, VenaPro compression device – lumbar and NU bone growth stimulator – lumbar was denied with 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 lifting. Medications were not stated. Surgical history was not stated. Diagnostic studies included an MRI of the lumbar spine dated April 22, 2013, that documented the patient had a grade 1-2 anterolisthesis of the L4 on the L5. A CT scan of the lumbar spine dated April 23, 2013, documented there was a disc protrusion of the L5-S1. The therapies included an epidural steroid injection and physical therapy. The patient is a male who reported an injury on xx/xx/xx. The patient was evaluated on July 15, 2014. Physical findings included decreased motor strength in the right extensor hallucis longus with decreased deep tendon reflexes of the right ankle, positive right-sided straight leg raising test at 30-40 degrees and decreased sensation in the L4-S1 distributions in the right lower extremity. A recommendation was made for surgical intervention. Postsurgical requests included a back brace, bone stimulator, a TENS unit and a VenaPro compression device. Official Disability Guidelines do not support the use of a bone growth stimulator in the absence of evidence of non-fusion or multilevel fusion. Clinical documentation submitted for review does indicate that the patient will undergo an L4-L5 fusion. There is no evidence that the patient is a smoker or has any other co-morbidities that would inhibit the healing process and require the use of a bone growth stimulator. Additionally, Official Disability Guidelines do not support the use of a postsurgical brace after fusion surgery unless there is evidence of instability or multilevel fusion. Official Disability Guidelines do support the use of a TENS unit for a one month rental in the postsurgical management of pain. Official Disability Guidelines do not specifically address a compression device in the low back chapter. However, Official Disability Guidelines do recommend a compression device in the knee and leg chapter for patients who will have a period of immobilization and cannot participate in active therapy. The clinical documentation submitted for review does not support that the patient will have a period of immobilization, and is at significant risk for development of deep vein thrombosis following the surgical procedure. Although the use of a TENS unit is recommended in the postsurgical management of pain, the other requested medical equipment is not supported by guideline recommendations. Therefore, the request as a whole is not supported. I discussed the case who had no additional clinical information to provide. As such, the requested stat NU bone growth stimulator lumbar E0748, and NU lumbar back brace off the shelf L0737, TENS unit one month rental 110730 and VenaPro compression device lumbar E0767 x 2 is non-certified.”*

Per a letter of medical necessity dated July 30, 2014, noted the patient had undergone 360 fusion of L4-L5 on both front and back. The surgery was medically necessary to stabilize the area of fusion. Due to nature of the procedure, there was associated significant muscular weakness. Also the post-operative condition put him at a significant risk predisposing him to a potential injury and/or exacerbation. Therefore, by placing the patient in a L0637 chair-

back brace post surgically would provide a greater sense of muscular comfort and stability which would lead to faster or greater mobilization, reduced hospital stay, faster recovery, reduced adhesion, faster transition to post-surgical PT and greater recovery rate. Each patient needed to be evaluated on an individual basis and therefore the use of brace was medically necessary.

On July 31, 2014, noted the patient had an unremarkable postoperative course and had near complete resolution of the preoperative symptomatology. The patient described peri-incisional muscle spasms that come and go with numbness in the right lower extremity along the non-dermatomal distribution. There was 0/10 pain. He had worsening of symptoms after prolonged sitting and standing, however denied worsening after coughing, sneezing or Valsalva maneuver. Examination revealed decreased lumbar ROM in forward flexion secondary to muscle spasm. The strength was 5/5 throughout. The patient had no difficulty with heel or toe walk. Tandem walk was within normal limits. SLR was negative. Sensory examination revealed no hypesthetic region to pin prick and light touch. Skin staples were replaced with Steri-Strips on his anterior abdominal incision and posterior lumbar incision. Neither incision demonstrated any evidence of drainage. diagnosed status-post anterior lumbar interbody fusion at L4-L5 with posterior lumbar decompression, posterolateral fusion and pedicle screw instrumentation at L4-L5 for a previous history of spondylolisthesis at L4-L5 grade I with spondylosis and lumbar spinal stenosis. recommended initiating a postoperative walking program at home for five weeks. The patient was recommended to return after completion of the regimen. He was also recommended a lumbar spine series including flexion and extension views in three months' time.

Per reconsideration review dated August 29, 2014, the appeal for NU lumbar back brace off the shelf, TENS unit one month rental, VenaPro compression device – lumbar and NU bone growth stimulator – lumbar was denied with the following rationale: *“The patient is a male who sustained an injury on xx/xx/xx, from lifting (as per report dated May 17, 2013). He is currently diagnosed with spondylolisthesis at L4-5 grade I with spondylosis; lumbar mechanical/discogenic syndrome at L4-5; lumbar spinal stenosis at L4-5; lumbar radiculopathy; herniated nucleus pulposus at L4-5; and lumbago. An appeal request is made for an NU Bone Growth Stimulator, NU lumbar back brace (off-the-shelf), TENS unit one month rental and VenaPro compression device. The previous determination was not seen in the records submitted. The rationale for non-certification is unknown. The lumbar MRI study dated March 2, 2013 revealed transitional vertebra, grade I spondylolisthesis without spondylosis at L4-5, narrow central canal/relative spinal stenosis and intervertebral disc degenerative changes at L4-L5 and L5-S1 (most significant at L4-L5 related to large disc protrusion resulting in further severe spinal stenosis). The lumbar myelography study dated April 22, 2013 showed significant disc displacement due to disc protrusion/extrusion centrally and to the right at L4-L5; significantly diminished right nerve root sleeve filling at L4-L5 and L5-S1; at least grade "I" anterolisthesis of L4 relative to L5; and minimal displacement of the contrast column at L3-L4 which might be due to shallow annular bulging at L2-L3 and L3-L4. The post-myelogram CT scan study revealed*

a broad-based 2 mm annular bulge at L3-L4 which minimally contacts the thecal sac; bilateral pars defect at L4-L5; disc extrusion at L4-L5 with borderline spinal canal stenosis and effacement of the thecal sac; and a rudimentary disc with transitional features of sacralization at L5-S1 with broad-based annular bulging and bilateral S1 nerve root sleeve contact without displacement. The lumbar x-ray study dated February 10, 2014 revealed transitional appearance of the lumbar spine; bilateral pars defects at L4 with grade I spondylolisthesis of L4 on L5 and severe disc space narrowing at this level; batwing deformities at L5 with pseudoarthrosis and probable partial fusion leftward; and severe disc space narrowing at L5-S1. The progress report dated June 10, 2014, states that following his injury, the patient went through extensive physical therapy and management and underwent an MRI and diagnostic studies showing right lower extremity radiculopathy. It was mentioned that the patient had evidence of right L5 and S1 radiculopathy on examination. He was recommended for epidural steroid injection but was denied. He returned on this visit with increased pain in the right leg. He is unable to find a comfortable position due to the annoying pain in his posterior leg and buttocks. Examination of the spine showed tenderness, positive SLR on the right, weakness with "extensor hallucis longus right great toe", and altered sensation on the L5 dermatome. Heel raise was 1+/4 on the right and 4+/4 on the left. The medical report dated July 15, 2014, states that the patient has no significant improvement from his previous symptomatology, which he describes as severe and sharp low back pain with radiation to the right lower extremity with associated numbness and tingling. He rated his pain at 7/10. Physical examination revealed BMI of 27.3. The patient's lumbar spine has decreased forward flexion secondary to pain. Motor strength was decreased on the right extensor hallucis longus and anterior tibialis muscles. The right ankle reflex was also decreased at 1+. Gait was antalgic. The patient had marked difficulty with heel walking and less difficulty with toe walking. The SLR was positive on the right. The right L4 and S1 dermatomes were hypoesthetic. The provider recommended ALIF at L4-L5 with posterior lumbar decompression and posterolateral fusion with pedicle screw instrumentation at L4-L5. Treatments rendered to date include physical therapy (completed eight visits, as per report dated June 27, 2013), medications, off work, activity restrictions, Home Exercise Program, rest, stretching, and ESIs. Diagnostic examinations performed include CT/myelogram studies. It is noted that the requested Durable Medical Equipment will be utilized post-operatively. There is none in the records to indicate that the recommended lumbar surgery has been authorized and scheduled. In addition, even if the surgery has been certified, the post-operative use of a bone growth stimulator is not supported given that the patient has no significant risk factors for a failed spinal fusion. Evidence-based literature to show that the patient is at risk for venous thrombosis/thromboembolic events after lumbar decompression and fusion is not found at this time as well, to necessitate the use of a VenaPro compression device. In addition, the presence of immobility post-surgery cannot be demonstrated at this point. Based on these grounds, the medical necessity of the requested NU bone growth stimulator, NU lumbar back brace (off-the-shelf), TENS unit one month rental, and VenaPro compression device is not established in agreement with the previous determination."

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

This patient had a work incident on xx/xx/xx. In the process of lifting he felt shock-like pain to the right lower extremity. He underwent MRI on March 2, 2013, of the lumbar spine showing a spondylolisthesis without noting spondylolysis at L4-L5 with disc protrusion at L4-L5 resulting in narrowing of the spinal canal. On April 22, 2013, the patient did have a lumbar myelogram CT scan, which was interpreted to show a grade I anterolisthesis of L4 relative to L5 with also pars defects at L4. There was also an 8-mm broad-based soft disc extrusion towards the right foramen. The thecal sac was effaced. The L5-S1 had rudimentary disc.

The patient was then assessed on May 17, 2013 on referral. The patient was noted to have a positive straight leg raise (SLR) on the right at 30 degrees. The patient was reportedly hypoesthetic of the L4, L5 and S1 distribution on the right to pinprick and light touch. recommended PT and possible epidural steroid injections and if this was inadequate then surgical intervention.

The patient underwent formal physical therapy for eight sessions.

On reassessment noted that the patient had had no improvement with his back pain as of July 8, 2013. He also had associated numbness and tingling into the right lower extremity. The patient was to be assessed for steroid injection and returned if this was inadequate to control his symptoms.

The patient returned on November 26, 2013, reporting that he was not improving. proposed an anterior lumbar interbody fusion at L4-L5 as well as posterior decompression and posterolateral fusion with pedicle instrumentation at that same level. The patient underwent a psychological assessment who found no psychological treatment was necessary and the patient was cleared for the proposed surgery.

X-rays to include flexion/extension of the lumbar spine were completed on February 10, 2014, and interpreted to show that on the lateral flexion x-rays there was a minimal increase of the subluxation at L4-L5.

On April 10, 2014 evaluated the patient for pain management. He proposed that the patient have an ESI and if no relief, then the patient would warrant surgical intervention.

reassessed the patient on May 27, 2014, and noted that the patient was scheduled for a right L5 ESI. However, the ESI was denied as of June 10, 2014. The patient then had DME ordered as of July 9, 2014, from Universal DME. doing prescription of bone growth stimulator, TENS unit conductive garment, hot/cold therapy system as well as an LSO brace and also the DVT equipment for home use.

On July 22, 2014, the patient underwent an arthrodesis of the L4-L5 level after decompression of that level as well as the posterior lumbar laminectomy of L4 and L5. Pedicle instrumentation was utilized at those two levels utilizing autograft as well as aspiration of the iliac crest. Interbody cage was also used.

There were two preauthorization reviews in the records one as well as one. These reviews did not authorize the use of the DME that had been proposed as it was considered inconsistent with the ODG except for possible use of the TENS for one month on a rental postop.

No further records were available regarding the DME although there were follow-up records noting that the patient postoperatively had improvement of his leg pain. The patient's current status is not reported as of September.

SYNOPSIS: A patient who has L4-L5 spondylolisthesis isthmic type with noted disc protrusion/ herniation at L4-L5 was treated surgically on July 22, 2014. The patient is now two months post surgery. The patient did not have a multilevel fusion or other risk factors for development of pseudoarthrosis. He is a nonsmoker. Thus, the necessity for the bone growth stimulator is not consistent with the ODG.

The patient is already two months post surgery. The necessity for the lumbar back brace off-the-shelf is also not supported as a medical necessity at this time. The patient has the interbody fusion device as well as pedicle instrumentation. There was no indication that the patient has other intrinsic instability.

The use of a TENS unit one month rental would be consistent with the ODG. However, the patient is already at two month's post surgery. Thus the use of the TENS unit at this time would not be consistent with the ODG but the rental for the first month post surgery would be allowable. There would be no necessity for a conductive garment.

There was no indication that the patient was being kept at bedrest beyond that of the hospitalization. Thus, the necessity for the VenaPro compressive device is not substantiated by these records. The patient is not noted to have a predisposition to deep vein thrombosis.

Thus, the only portion of this request for DME that would be medically consistent and necessary as related to the ODG would be the potential for a one month rental of the TENS unit without conductive garment. However, whether or not this device was used was not able to be substantiated by these records. It would not be medically necessary to institute the TENS unit at this time. Thus, if the unit was provided initially at the time of surgery then the use of one month rental without conductive garment would be allowable.

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

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES