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DATE OF REVIEW: June 30, 2009

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE
Posterior lumbar fusion at L4-L5 with 3 day inpatient stay, purchase of external bone growth stimulator, purchase of lumbar brace

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

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male who was struck by a backhoe escavator and pushed into a manhole on xx-xx-xx. He fell on his right hip and buttock and also sustained injuries to his head, neck, and lower back.

Following the injury, the patient went to the hospital where he had x-rays and computerized tomography (CT) of the head. He then saw Dr. who took x-rays and treated the patient with four weeks of physical therapy (PT) which helped in the beginning.

Magnetic resonance imaging (MRI) of the lumbar spine showed: (1) Moderate spondylitic disc bulging at T11-T12 encroaching on the central spinal canal possibly impinging the distal thoracic spinal cord. (2) Stenosis of the spinal canal and thecal sac at L1-L2 secondary to spondylitic disc bulging with impingement of the intrathecal nerve roots. (3) Mild spondylitic disc bulging at L3-L4. (5) Spondylitic disc disease and asymmetric bulging or protrusion into the neural foramen at L4-L5 impinging exiting right L4 nerve root.

In a psychological evaluation, the patient was noted to have some cognitive impairment for approximately three weeks after the injury, however, it appeared to have abated and now he complained only of occasional migraine headaches. He was working full duty. He was utilizing Neurontin and Advil. The evaluator recommended work conditioning program (WCP) as the patient had greatly decreased functional abilities.

The patient complained of persistent right-sided low back pain and right buttock pain radiating down into the right leg and into the right foot associated with numbness, tingling, and weakness, predominantly in the right lower leg. Electrodiagnostic study was consistent with right L5 radiculopathy.

On February 23, 2009, , M.D., a neurosurgeon, noted: *Following the MRI, the patient was treated with two lumbar epidural steroid injections (ESIs). The first injection helped for six weeks but the second did not help. The patient attended WCP which helped. CT scan of the lumbar spine showed spondylosis at L1-L2, mild disc bulge at L2-L3, and a bulge at L4-L5 extending into the right neuroforamen.* The patient complained of low back pain and right leg pain and numbness. On examination, there was tenderness over L4-L5 and L5-S1, restricted and painful lumbar range of motion (ROM), positive straight leg raise (SLR) on the right, and hypesthesia over the right leg. Dr. assessed low back and right leg pain, lumbar facet syndrome, spondylosis at L1-L2, diffuse disc bulge at L2-L3, right L4-L5 foraminal spur with some L4 nerve root impingement, right L4 versus L5 radiculopathy, and chronic pain syndrome. He recommended bilateral L4-L5 and L5-S1 facet blocks and ordered flexion-extension x-rays to

evaluate retrolisthesis. He prescribed Relafen, Robaxin, tramadol, Tofranil PM and continued sedentary job work. The patient reported intolerable hip pain preventing him from performing his normal activities of daily living. The lumbar facet injections were denied by the carrier.

Flexion-extension views of the lumbar spine revealed multilevel retrolisthesis with disc narrowing at L4-L5 and T12-L1 and probably slight depression of the superior endplate of L1. On April 8, 2009, a lumbar myelogram with post-myelogram CT demonstrated a 2-mm central disc protrusion at L4-L5 indenting the dural sac close to the origins of the L5 root sleeves and leaving a 6-mm residual midsagittal dural diameter; a right foraminal disc protrusion, predominantly hard disc at L4-L5 impinging on the exiting right L4 root sleeve; epidural lipomatosis rendering the myelogram insensitive at L5-S1; retrolisthesis at T12-L1, L1-L2, and L3-L4 associated with disc narrowing and anterior spondylosis at T12-L1 and L1-L2; and mild right facet joint arthrosis at L3-L4 and L4-L5.

The patient reported his pain had become intractable and intolerable. The lower back pain radiated down his right side into the right hip and down the anterior portion of his right thigh to his knee with occasional exacerbations of pain in which his right leg pain radiated down his foot. He rated his pain at 8-9/10 that decreased to 3-4/10 with medications. Dr. recommended L4-L5 posterior lumbar interbody fusion (PLIF). He also reported presurgical psychological evaluation performed by Dr. found that there was no contraindication to this patient undergoing spinal surgery. Per Dr., the patient met all the ODG criteria for lumbar spine fusion and those were: He had been symptomatic for almost two years, segmental dysfunction at L4-L5, all pain generators had been identified, all physical medicine and manual therapy interventions had been completed and had not helped, EMG showed right L5 radiculopathy, CT myelogram showed pathology at L4-L5, he had psychological clearance for surgery, and he had agreed to smoking cessation.

On May 21, 2009, the request for lumbar fusion at L4-L5 was denied with the following rationale: "*The patient does not meet indicators for arthrodesis. Spine was not unstable and does not therefore meet the indicators as outlined in Official Disability Guidelines (ODG). Spine does not need to be destabilized to accomplish decompression. He also has multilevel disease.*"

On May 26, 2009, Dr. stated the patient needed surgery as he had stenosis present at L4-L5 from a combination of protruding discs, facet, and ligamentous hypertrophy with only 6 mm of mid sagittal dural diameter. He would need extensive decompression. Both L5 nerve roots were widened on his myelogram and therefore needed decompression both left and right side as well as L4-L5 discectomy. He would need an aggressive right L4-L5 facetectomy as he had a foraminal disc herniation. He would also need a partial left L4-L5 facetectomy as he had lateral recess stenosis with facet ligamentous hypertrophy. This amount of decompression would likely render the patient's spine unstable, he, therefore, would require a fusion as he had a high probability of developing instability at L4-L5 level by decompression alone. On June 3, 2009, Dr. noted the patient continued to have significant pain in the low back and right leg, which he rated at 6/10. Dr. refilled tramadol, Robaxin, Relafen, and Tofranil and awaited the results of an appeal for surgery.

On June 3, 2009, an appeal for lumbar fusion at L4-L5 with three-day inpatient stay, purchase of external bone growth stimulator, and purchase of lumbar brace was denied with the following rationale: *"The clinician has not demonstrated the clinical necessity for fusion. Records do not reflect the presence of instability or significant angular motion. Records do not reflect the psychological evaluation. The claimant is a smoker. Records do not reflect the clinical necessity for a bone growth stimulator since the requested procedures has been denied. Under the current guidelines back brace is not supported."*

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

L4-5 lumbar fusion with three day length of stay is not medically indicated and appropriate.

The 05/26/09 office visit notation by Dr. states that he would have to go far lateral in this decompression and may destabilize the spinal segment necessitating spinal fusion. However, there is no evidence of intrinsic instability, tumor, infection or progressive neurologic deficit.

It should be noted that the claimant complained of right-sided lower back, right buttock pain over the right leg and right foot with associated numbness and tingling. Care to date has included two epidural steroid injections providing transient relief, anti-inflammatories, sedentary duty. However, what is not clear within the records reviewed is a corresponding neural compressive lesion manifested on an objective examination. Therefore, without a corresponding examination, surgery of any sort, whether it be decompressive versus decompressive and fusion surgery and inpatient stay is not indicated and appropriate.

A bone growth stimulator is not medically indicated and appropriate, based on the fact the surgery cannot be recommended. In addition this request was for only a single-level and there is no documentation of any risk factors such as smoking to warrant a bone growth stimulator.

A lumbar brace is not indicated and appropriate, as the index procedure is not indicated and appropriate. This determination is based upon the records reviewed and is consistent with ODG guidelines.

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

Care Guidelines® Inpatient and Surgical Care 13th Edition

Official Disability Guidelines Treatment in Worker's Comp 2008 Updates: Low Back

Spinal Fusion, Bone Growth Stimulator and Back Brace Postop Fusion

Pre-Operative Surgical Indications Recommended: should include all of the following:

1) All pain generators are identified and treated; &
2) All physical medicine and manual therapy interventions are completed; &

3) X-rays demonstrating spinal instability and/or myelogram, CT-myelogram, or discography & MRI demonstrating disc pathology; &
4) Spine pathology limited to two levels; &
5) Psychosocial screen with confounding issues addressed.
6) For any potential fusion surgery, it is recommended that the injured worker refrain from smoking for at least six weeks prior to surgery and during the period of fusion healing.

Bone Growth Stimulator: Under study.

- There is no consistent medical evidence to support or refute use of these devices for improving patient outcomes; there may be a beneficial effect on fusion rates in patients at "high risk", but this has not been convincingly demonstrated.

Criteria for use for invasive or non-invasive electrical bone growth stimulators:

- Either invasive or noninvasive methods of electrical bone growth stimulation may be considered medically necessary as an adjunct to spinal fusion surgery for patients with any of the following risk factors for failed fusion:
    1) One or more previous failed spinal fusion(s);
    2) Grade III or worse spondylolisthesis;
    3) Fusion to be performed at more than one level;
    4) Current smoking habit (Note: Other tobacco use such as chewing tobacco is not considered a risk factor);
    5) Diabetes, Renal disease, Alcoholism; or
    6) Significant osteoporosis, which has been demonstrated on radiographs.

Back Brace Postop Fusion:

- Under study -- a standard brace would be preferred over a custom post-op brace
- There is no scientific information on the benefit of bracing for improving fusion rates or clinical outcomes following instrumented lumbar fusion for degenerative disease.