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Notice of Independent Review Decision

January 25, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Two day inpatient stay for mini 360 fusion at L4-S1

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
This physician is Board Certified in Orthopedic Surgery with over 13 years of experience.

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)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

07/09/1998: History and Physical
07/22/1998: Diagnostic/Therapeutic Injection
08/24/1998: Diagnostic/Therapeutic Injection
09/09/1998: Diagnostic/Therapeutic Injection
12/02/1998: Diagnostic/Therapeutic injection
12/28/1998: Diagnostic/Therapeutic injection
01/15/1999: Follow Up Progress Note
03/05/1999: Procedure Note
03/31/1999: Operative Report
09/08/2000: History and Physical
08/21/2002: Lumbar Myelogram
08/21/2002: CT Scan of the Lumbar Spine with Intrathecal Contrast
09/23/2002: Procedure Note
04/24/2008: History and Physical
05/19/2008: Operative Report

08/19/2010: Operative Report
01/21/2013: Operative Report
02/04/2013: Office Visit
02/11/2013: Office Visit
02/15/2013: MRI of the Lumbar Spine Without Contrast
03/14/2013: Office Visit
04/23/2013: Office Visit
06/18/2013: Office Visit
08/13/2013: Office Visit
09/16/2013: Lumbar Spine 4-Views
09/19/2013: Office Visit
11/01/2013: Behavioral Medicine Evaluation
11/13/2013: UR
12/11/2013: Appeal/Reconsideration Acknowledgement Letter
12/18/2013: UR

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a female who was injured on xx/xx/xx. She fell on the floor after tripping over a phone cord and injured her lower back. Surgical history is positive for a right LRS in 1985. She reportedly did well until 1993 when she had another disc herniation and underwent a laminectomy. She was reportedly worse after that surgery and had no feeling in her leg and foot and had a foot drop which necessitated the use of an AFO as well as physical therapy. She regained function in her right foot after 6 to 8 months, but continued to have a slap foot when walking. She was well up until the work injury in xx/xxxx. Initial treatment for the work injury included medication, therapy and injections. She underwent placement of a spinal cord stimulating unit on July 26, 1999. In 200, she underwent revision of the stimulating generator pocket.

07/22/1998: Diagnostic/Therapeutic Injection. Procedure: 1. Caudal epidural injection with corticosteroid. 2. Caudal intraspinal myelography without dural puncture. 3. C-arm fluoroscopy. 4. Fluoroscopic interpretation, no radiologist present.

08/24/1998: Diagnostic/Therapeutic Injection. Procedure: 1. Caudal epidural injection with corticosteroid. 2. Caudal intraspinal myelography without dural puncture. 3. C-arm fluoroscopy. 4. Fluoroscopic interpretation, no radiologist present.

09/09/1998: Diagnostic/Therapeutic Injection. Procedure: 1. Caudal epidural injection with corticosteroid. 2. Caudal intraspinal myelography without dural puncture. 3. C-arm fluoroscopy. 4. Fluoroscopic interpretation, no radiologist present.

12/02/1998: Diagnostic/Therapeutic injection. Procedure: 1. L4-5 and L5-S1, right, intra-articular facet joint injection. 2. Right L4-5 and L5-S1 intra-articular

facet joint arthrograms. 3. C-arm fluoroscopy. 4. Fluoroscopic interpretation, no radiologist present.

12/28/1998: Diagnostic/Therapeutic injection. Procedure: 1. Right sacroiliac joint injection with corticosteroid. 2. Right sacroiliac joint arthrogram. 3. C-arm fluoroscopy. 4. Fluoroscopic interpretation, no radiologist present.

03/05/1999: Procedure Note. Procedure: 1. Facet injections at L4-5 and L5-S1 anesthetics only using 1% Xylocaine, total volume of 2 cc into the facet area. 2. Facet arthrography bilaterally L4-5 and L5-S1 with interpretation.

03/31/1999: Operative Report. Postoperative Diagnosis: 1. Morbid obesity. 2. Mechanical low back pain secondary to lumbar facet syndrome L3, L4, L5 and S1 bilaterally. Procedure: Radiofrequency facet rhizotomy L3, L4, L5 and S1 bilaterally with two _____ _____, one at the _____ of the superior facet of S1 and the sacral ala and then one in the isthmus between the 1st sacrum ___ foramen and the L5-S1 facet joint.

08/21/2002: Lumbar Myelogram. Impression: 1. Prominent ventral extradural indentation of the thecal sac at L4-5 raising the possibility of an L4-5 disc herniation. 2. The root sleeve on the right at S1 does not fill out compared to the left and there may be compromise of the right S1 root sleeve.

08/21/2002: CT Scan of the Lumbar Spine with Intrathecal Contrast. Impression: Central and left paracentral protrusion at L4-5 which I suspect is an HNP flattening and indenting the ventral aspect of the thecal sac. 2. Severe degenerative disc disease at L5-S1. The right S1 nerve root sleeve does not fill out as well as on the left. I suspect there may be a disc herniation extending below the level of the disc at this configuration of the soft tissue density but I see on images #72 and $75 really resembles the root sleeve however it is not enhancing.

09/23/2002: Procedure Note. Post Procedure Diagnosis: Lumbar radicular syndrome, L5 right nerve root. Procedures Performed: 1. Selective nerve root block at the neuroforamen of the right L5 nerve root. 2. Conscious sedation. 3. Fluoroscopic guidance of nerve root block.

05/19/2008: Operative Report. Postoperative Diagnosis: 1. Chronic pain syndrome. 2. Lumbar radiculitis. 3. Lumbar herniated nucleus pulposus. 3. Lumbar herniated nucleus pulposus. Operations performed: 1. Implantation of spinal cord stimulating generator. 2. Revision of spinal cord stimulating electrode. 3. Analysis and programming of spinal cord stimulating system.

08/19/2010: Operative Report. Postoperative Diagnoses: 1. Lumbar herniated nucleus pulposus. 2. Lumbar facet arthropathy. Operations performed: 1.

Radiofrequency thermocoagulation of right L5 dorsal medial branch. 2. Radiofrequency thermocoagulation of right S1 dorsal medial branch.

01/21/2013: Operative Report. Postoperative Diagnoses: 1. Lumbar herniated nucleus pulposus. 2. Lumbar radiculitis. Operations Performed: 1. Explantation of spinal cord stimulating electrode. 2. Explantation of spinal cord stimulating generator.

02/04/2013: Office Visit. Removal of some of the staples. Remaining to be removed in one week. **Physical Examination:** Straight leg raise is positive for pain over the right lateral thigh and calf. Numbness over the right lateral thigh and calf in an L5 distribution. **Plan:** Explant the spinal cord stimulator device in hopes of obtaining MRI scan to determine where we are in regard to treatment options.

02/15/2013: MRI of the Lumbar Spine Without Contrast. Conclusion: 1. Hemilaminectomy on the right side at L5-S1 level with evidence of soft tissue swelling which may represent recurrent disc vs scar formation. There is impingement on right tS1 nerve root. Contrast enhanced study is needed for further evaluation. 2. High signal intensity zone in the posterior aspect of the annulus which may represent annular tear or fissure with central disc protrusion and mild degree of spinal stenosis. 3. No evidence of spondylclysis or spondylolistheses. 4. Extensive subcutaneous edema posteriorly which may secondary to postoperative change, however infection could not be excluded.

03/14/2013: Office Visit. She has increasing low back pain with radiation into lower extremities. Her functional status has diminished. She was placed on Elavil with a positive response. **Physical Examination:** There is tenderness over the lumbar paraspinal segments, worse with hyperextension and lateral bending. Straight leg raise is positive for pain over lateral thighs. She does favor a forward flexed position. **Assessment:** 1. Lumbar herniated nucleus pulposus. 2. Lumbar radiculitis. **Plan:** To stop Elavil and add baclofen for pain management and functional status. Consider epidural steroid injections.

04/23/2013: Office Visit. Placed on baclofen without relief. She has shooting pain down the right lateral thigh and calf. **Physical Examination:** There is tenderness over the lumbar paraspinal segments, worse with hyperextension and lateral bending. Straight leg raise is positive for pain over right lateral thigh and calf. She has decreased sensation over the right lateral calf. The patient has a limping gait. **Plan:** She has a previous laminectomy at L5-S1. She has extruded and sequestered disc fragment at L5-S1 lateralizing to the right side causing some foraminal encroachment. There is high intensity zone at the annulus of L4-L5 due to her annular tear. I would like to proceed with caudal epidural steroid injection. The next step would be to consider surgical reevaluation. Discontinue baclofen.

06/18/2013: Office Visit. **Physical Examination:** The patient has a limping gait. There is decreased sensation over the right L5-S1 distribution of the right lower extremity. Straight leg raise is positive over the right lateral thigh and calf pain at 30 degrees**.** **Plan:** Placed her on Medrol Dosepak and Amrix for pain and

nocturnal difficulty with sleep. Increase hydrocodone to 10mg. She has sequestered disc fragment at L5-S1 lateralizing to the right side and annular tear at L4-L5. She wants to defer surgery if at all possible. Epidural steroid injections have been denied, so at this point in time there is little else to offer.

09/16/2013: Lumbar Spine 4-Views. Examination of the lumbar spine in AP, Lateral, lateral flexion and extension views were obtained. No previous films are available for comparison. There is considerable degenerative disc disease with anterior osteophyle formation at L5-S1 level. In the lateral flexion view, there is 3 to 4 mm anterolisthesis of L5 vertebral body with reference to S1. In the lateral extension view, there is 2 to 3 mm anterolistheses of L5 vertebral body with reference to S1. There is also slight degree of anterollsthesis of L3 vertebral body with reference to L4 in the lateral flexion view which gets reduced in the lateral extension view. Pedicles and spinous process appear intact. Prevertabral soft tissues appear normal. No other abnormalities.

09/19/2013: Office Visit. Claimant presents with back pain, neck pain, arm pain and leg pain located on both the right and left side. **Physical Examination:** Patient stands with erect posture and has normal gait pattern. Negative for pelvic obliquity. There is significant spinal tenderness in the paraspinal muscles. Bilateral straight leg raise is negative. There are no Waddell sign's present. There is normal sensation to light touch seen in both upper and lower extremities. There is normal motor strength to upper and lower extremities except for 4/5 strength testing with EHL and dorsiflexion, right foot. Reflexes in upper and lower extremities are normal at 2 out of 4. There is a negative Spurlings test and negative Lhermitte's sign. The patient demonstrates poor range of motion and spinal motion is with pain. **X-ray** performed in office today AP, Lateral Flexion and Extension views of the lumbar spine demonstrates 5 mobile Lumbar segments. Pedicles are well visualized. Normal appearance to the Sacroiliac joints. Normal appearing Vertebral bodies. There is instability seen. There is a normal appearance to the discs except for severe disc space narrowing at L5-S1 with instability. Also some disc space narrowing noted at L4-5. Assessment: Low back pain and lower extremity pain secondary to severe lumbar disc disease L4-L5, L5-S1 with instability neuroforaminal stenosis motor weakness and sensory loss involving L5 myotomes dermatomes. **Plan:** At this point, she has failed conservative treatment consisting of physical therapy, medication management, and injections. She had a spinal cord stimulator trail implant and then removal. She continues to have severe persistent pain where she can no longer function even with activities of daily living. She is only able to get about 2 hours of sleep in a state where she has significant pain. At this point, she has severe collapse of the disk at L5-S1 and changes at L4-5 disk, both of which are contributing to her severe pain, her radiculopathy, motor weakness, and sensory loss. At this point, I have recommended fusion at L4-5 and L5-S1.

11/01/2013: Behavioral Medicine Evaluation. **Recommendations:** Based on the presurgical psychological screening, the patient is clear for the surgery with a fair to good psychosocial prognosis for pain reduction and functional improvement.

11/13/2013: UR. Rationale for Denial: Based on the clinical data provided, right-sided L5 symptoms/signs are most likely related to degenerative changes at L5-S1, including spondylosis, disc recurrence vs. scar and a spondylolistheses. A central annular tear with protrusion effacing the ethical sac is noted without foraminal narrowing at L4-5. No instability was noted at the L4-5 level. Based on this clinical history and findings, the requested services are denied. Official Disability Treatment Guidelines are not met.

12/18/2013: UR. Rationale for Denial: The appeal request cannot be supported based on the documentation provided. The request was previously denied on November 8, 2013, due to lack of clinical documentation of instability. Additional documentation provided for review includes X-rays from September 16, 2013, noting evidence of instability as well as the progress notes from November 2013. The request remains denied, however, as the physical examination findings and objective documentation does not note significant instability of greater than 4.5 millimeters. The diagnostic imaging notes instability of up to 4 millimeters, three to four millimeters of L5 to S1 in the lateral flexion view. Without significant instability of greater than 4.5 millimeters, the request cannot be supported per the Official Disability Guidelines recommendations and physical examination findings provided.

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

The previous adverse determinations are partially overturned. The claimant is not indicated for lumbar fusion at both L4-5 and L5-S1.

The ODG requires documentation of instability prior to consideration of lumbar spinal fusion. Instability is appropriately documented at L5-S1. The claimant's right leg symptoms are most likely due to the right S1 nerve impingement identified on the 2/15/13 MRI. In the setting of degenerative disc disease and instability, fusion at L5-S1 would be appropriate.

Fusion at L4-5 is not required in this claimant. No instability is documented at this level. There is no evidence of neural compression associated with the annular tear at L4-5. I am not convinced that L4-5 is a pain generator.

The request for two day inpatient stay does meet ODG recommendations and would be appropriate for the fusion at L5-S1.

Therefore, the request for two day inpatient stay for mini 360 fusion at L4-S1 is partially overturned as only the two day inpatient stay for mini 360 fusion at L5-S1 found to be medically necessary.

PER ODG:

Patient Selection Criteria for Lumbar Spinal Fusion:
For chronic low back problems, fusion should not be considered within the first 6 months of symptoms, except for fracture, dislocation or progressive neurologic loss. Indications for spinal fusion may include: (1) Neural Arch Defect - Spondylolytic spondylolisthesis, congenital neural arch hypoplasia. (2) Segmental Instability (objectively demonstrable) - Excessive motion, as in degenerative spondylolisthesis, surgically induced segmental instability and mechanical intervertebral collapse of the motion segment and advanced degenerative changes after surgical discectomy, with relative angular motion greater than 20 degrees. (Andersson, 2000) (Luers, 2007)] (3) Primary Mechanical Back Pain (i.e., pain aggravated by physical activity)/Functional Spinal Unit Failure/Instability, including one or two level segmental failure with progressive degenerative changes, loss of height, disc loading capability. In cases of workers' compensation, patient outcomes related to fusion may have other confounding variables that may affect overall success of the procedure, which should be considered. There is a lack of support for fusion for mechanical low back pain for subjects with failure to participate effectively in active rehab pre-op, total disability over 6 months, active psych diagnosis, and narcotic dependence. Spinal instability criteria includes lumbar inter-segmental movement of more than 4.5 mm. (Andersson, 2000) (4) Revision Surgery for failed previous operation(s) if significant functional gains are anticipated. Revision surgery for purposes of pain relief must be approached with extreme caution due to the less than 50% success rate reported in medical literature. (5) Infection, Tumor, or Deformity of the lumbosacral spine that cause intractable pain, neurological deficit and/or functional disability. (6) After failure of two discectomies on the same disc, fusion may be an option at the time of the third discectomy, which should also meet the ODG criteria. (See ODG Indications for Surgery -- Discectomy.)
Pre-Operative Surgical Indications Recommended: Pre-operative clinical surgical indications for spinal fusion 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 (see discography criteria) & MRI demonstrating disc pathology correlated with symptoms and exam findings; & (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. (Colorado, 2001) (BlueCross BlueShield, 2002)
For average hospital LOS after criteria are met, see Hospital length of stay (LOS).

ODG hospital length of stay (LOS) guidelines:
Discectomy (*icd 80.51 - Excision of intervertebral disc*)
Actual data -- median 1 day; mean 2.1 days (± 0.0); discharges 109,057; charges (mean) $26,219
Best practice target (no complications) -- *Outpatient*
Laminectomy (*icd 03.09 - Laminectomy/laminotomy for decompression of spinal nerve root*)
Actual data -- median 2 days; mean 3.5 days (±0.1); discharges 100,600; charges (mean) $34,978
Best practice target (no complications) -- *1 day*
Note: About 6% of discharges paid by workers' compensation.
Lumbar Fusion, posterior (*icd 81.08 - Lumbar and lumbosacral fusion, posterior technique*)
Actual data -- median 3 days; mean 3.9 days (±0.1); discharges 161,761; charges (mean) $86,900
Best practice target (no complications) -- *3 days*
Note: About 15% of discharges paid by workers' compensation.
Lumbar Fusion, anterior (*icd 81.06 - Lumbar and lumbosacral fusion, anterior technique*)
Actual data -- median 3 days; mean 4.2 days (±0.2); discharges 33,521; charges (mean) $110,156
Best practice target (no complications) -- *3 days*
Lumbar Fusion, lateral (*icd 81.07 - Lumbar fusion, lateral transverse process technique*)
Actual data -- median 3 days; mean 3.8 days (±0.2); discharges 15,125; charges (mean) $89,088
Best practice target (no complications) -- *3 days*

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

- ☐ **ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE**
- ☐ **AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES**
- ☐ **DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES**
- ☐ **EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN**
- ☐ **INTERQUAL CRITERIA**
- ☒ **MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**
- ☐ **MERCY CENTER CONSENSUS CONFERENCE GUIDELINES**
- ☐ **MILLIMAN CARE GUIDELINES**
- ☒ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**
- ☐ **PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**
- ☐ **TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS**
- ☐ **TEXAS TACADA GUIDELINES**
- ☐ **TMF SCREENING CRITERIA MANUAL**
- ☐ **PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)**
- ☐ **OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**