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Notice of Independent Review Decision

DATE: November 20, 2012

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

L4-L5 Arthroplasty with One Day LOS

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

The reviewer is certified by the American Board of Orthopaedic Surgeons with over 40 years of experience.

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

Upheld (Agree)

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:

03/04/03: MRI Lumbar Spine report (no impression, only one page submitted)
03/18/09: MRI Lumbar Spine report
08/24/09: Consultation
08/24/09: Radiology Report
11/16/09: Behavioral Medicine Evaluation Report/Pre-Surgical Psychological Screening
12/07/09: Operative Report
12/07/09: Intraoperative Neuro-Physiological Monitoring
01/13/10: Physical Therapy Initial Evaluation
02/22/10: Office Visit
03/02/10, 04/22/10, 08/30/10, 10/15/10, 03/24/11, 04/22/11: Followup Visits
05/13/11: MRI Lumbar Spine report
05/13/11, 06/17/11, 07/15/11: Followup Visits
06/13/11: Physical Therapy Initial Evaluation

08/08/11: Followup Visit
08/21/11: Behavioral Medicine Evaluation
07/30/12: Followup Visit
08/24/12: MRI Lumbar Spine with and without Contrast report
08/31/12: Followup Visit
09/10/12: Consultation
09/10/12: Surgery Scheduling Slip/Checklist
09/21/12: Bone Density report
10/04/12: Independent Medical Examination
10/05/12: Behavioral Medicine Evaluation
10/24/12: UR performed
11/01/12: UR performed

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a female who sustained a work-related injury to her low back when she felt a “sharp pain” in her back while unfolding a chair. She is status post lumbar rhizotomy, L4-L5 laminectomy discectomy, and foraminotomy, and L4-L5 discectomy.

The claimant was evaluated by MD for low back pain and right leg pain. PLAN/RECOMMENDATIONS: After discussing nonsurgical management with the patient, she has not shown signs of improvement with epidural steroids and physical therapy or anti-inflammatories, we discussed the fact that surgical management would be warranted at this time to relieve her leg pain and possibly some of her back pain. We would like to, based on the MRI findings, recommend a microdiscectomy on the right side at L4-L5 and believe that this would be the best option to relieve her radicular pain.

12/07/09: Operative Report. POSTOPERATIVE DIAGNOSIS: Lumbar disc herniation L4-L5, right side at second. PROCEDURE: Laminectomy and discectomy at second mobile segment right side with foraminotomy of the right-sided nerve root, and discectomy at that level for decompression of the spinal canal. Neuromonitoring both upper and lower extremities. Fluoroscopic interpretation. No radiologist present. Application of free fat graft.

05/13/11: MRI Lumbar Spine report. IMPRESSION: L2-L3 1-2 mm disc bulge most pronounced left posterolaterally where there is a circumferential annular tear. Disc desiccation. L3-L4 mild facet arthropathy. L4-L5 laminotomy changes just right of midline. 5 mm quite focal disc herniation versus scarring centrally and just right of midline, producing apparent thecal compression and moderate central stenosis (8 mm AP canal diameter). Please note that gadolinium contrast would be necessary to differentiate residual or recurrent disc herniation from enhancing scar. There is mild facet arthropathy. Significant disc narrowing and degenerative change with disc desiccation. L5-S1 mildly hypoplastic, sacralized appearance to the disc. 2-mm broad-based central disc bulge with disc desiccation and mild facet arthropathy.

07/30/12: The claimant was evaluated by MD for complaints of back pain and leg pain. She stated that her pain was the same as before her surgery in October of 2011. It was noted that she was having pain in her right lower back radiating down the leg in an L4 distribution. She was doing a home exercise program. She also noted burning in the dorsum of both feet, right greater than left. On Physical exam, her paravertebral muscles were nontender with no evidence of spasm or trigger point. Positive SLR on the right at 90 degrees. Pain with seated SLR that was located at back. SLR normal on the left side. Lumbar range of motion was painful and restricted to the following: flexion was painful at 50% of normal. SLR positive on the right side at 90 degrees. Pain with seated SLR that is located at back. Lower strength was symmetrical in all lower extremity muscle groups. Lower reflexes were symmetric and normal. Sensation was normal. Fortin Finger test was positive to the right and left. Yeoman's test was positive to the right and left. Coccyx manipulation was non-painful. Faber test was positive to the right and negative to the left. ASSESSMENT: Recurrent lumbar radicular syndrome status post L3-L4 discectomy on the right. Sacroiliac joint dysfunction bilateral. PLAN: Increase Lyrica to 75 mg t.i.d. Order EMG of the right leg. She may need new MRI and/or diagnostic sacroiliac joint injections, local anesthetic only.

08/24/12: MRI Lumbar Spine with and without Contrast report. IMPRESSION: L2-L3: Mild disc narrowing with a 3-mm left posterolateral disc bulge/protrusion. 1-2-mm central and right-sided disc bulge. Mild facet arthropathy. Multilevel disc desiccation. L4-L5: Quite severe disc narrowing and degenerative change with disc desiccation. Prior right laminotomy and discectomy. 7-8-mm right posterior paracentral residual or recurrent nonenhancing disc extrusion and small osteophyte with mild facet arthropathy. Severe theca compression. L5-S1: 1-2-mm broad-based central disc bulge with mild facet arthropathy. No abnormal enhancement at any level post-contrast.

08/31/12: The claimant was reevaluated by MD for complaints of back pain, which had been present for more than one year. It was noted that she had recurrence of the L4-L5 herniation on the right consistent with her symptoms. She continued on her Robaxin, Lyrica, and Celebrex as before. ASSESSMENT: Recurrent L4-L5 herniated nucleus pulposus. PLAN: I talked with her extensively about her options. She has Aleve. Does not want corticosteroid injections because of the untoward affects. She really is not wanting to get a fusion. Because this is the third herniation at the same level, usually a surgeon would do a fusion or a disc prosthesis at that level. I will refer her for the surgical opinion. I refilled her Flexeril, which she uses rarely.

09/10/12: The claimant was reevaluated by MD for complaints of low back pain with right leg pain/numbness for at least three months. She described her pain as being sharp, stinging, burning, and pressure. Average pain intensity was 7. Aggravating facts include physical exertion. Relieving factors include medications. On examination, she had a kyphotic deformity at the lumbar spine. Her gait was balanced. Paravertebral muscles are non-tender with no evidence of spasm or trigger point. Lumbar range of motion was normal in all directions.

Spinous processes were non-tender. SLR normal bilateral with no issues. Femoral stretch positive on the right and negative on the left. Strength was normal. Sensation was normal. Review of her MRI performed on 08/12/12 revealed L4-L5 8 mm paracentral herniation into the right foramen with evidence of previous right laminectomy and associated postoperative imaging changes. ASSESSMENT: She has a recurrent herniated disc at L4-L5. This is a second recurrence and she would be a candidate for a reconstructive procedure. She is adamantly against fusion, so we will proceed with obtaining approval for a n artificial disc at that level.

09/21/12: X-Ray Bone Density Axial, Dexa Study. IMPRESSION: According to the WHO criteria, the patient's bone mineral density is normal. A followup bone mineral density is recommended in two years to follow progress.

10/04/12: Independent Medical Examination by MD. OBSERVATIONS/OPINIONS/RECOMMENDATIONS: "The patient is motivated to continue working. The patient takes her medicine on what would appear to be a reasonable basis. She does not use medication during her work hours that would affect her ability to work. At this point, the patient needs more than a laminectomy and needs some type of stabilization of the spine. This stabilization in my mind would probably be best a spine fusion; however, a spine surgeon is more competent to make that final decision. At this point, it is based on reasonable probability and from the literature all conservative means have been tried. Minimal surgeries have been tried. It is this at this time the patient can do something to have a more stabilizing effect on the outcome."

10/05/12: Behavioral Medicine Evaluation. GENERAL CONCLUSIONS: Mild-moderate reactive emotional distress. These psychosocial concerns should have minimal impact on the outcome of the surgery. Continues to work, takes no narcotic medications. Worries about vocational issues. Continue her counseling, but no other need for mental health intervention. Based on this presurgical psychological screening, she is clear for the surgery with a fair-good prognosis for pain reduction and functional improvement. She is single and her sole income source comes from her employment. As such, she is very worried about a fusion and feels she cannot risk the possibility of adjacent segment degeneration if she has a fusion. She needs and wants a disc replacement surgery, which would lessen such a possibility. The client may have difficulty pacing activity increases. Clear rehabilitation guidelines should be given. The client should be included in the development of all treatment plans. She has some underlying anxiety and depressive affect, which may worsen. Watch carefully for a worsening of emotional state, in which case she should be referred back to me.

10/24/12: UR performed. CONCLUSION: The patient underwent two previous decompressions at L4-L5 and presents with a recurrent disc extrusion at L4-L5. However, ODG states that lumbar disc prostheses are not recommended in the lumbar spine. Other than spinal fusion, there are currently no direct comparison studies, and artificial disc outcomes in the lumbar spine are about the same as

lumbar fusion, but neither results have demonstrated superiority compared with recommended treatments, including nonoperative care. Though L-ADR for degenerative disc disease has been compared with lumbar fusion, not all patients who get a fusion are candidates for L-ADR, including patients with nerve root compression, spondylolisthesis, stenosis, facet mediated pain, and osteoporosis. In addition, given two prior failed decompressions, there is no consideration for a second opinion. Recommend non-certification. As the surgical request is non-certified, the associated request for one day LOS is also non-certified.

11/01/12: UR performed. CONCLUSION: The claimant has a history of recurrent disc herniations at the L4-L5 level. The claimant has previously undergone modification of the posterior elements and would not be a candidate for single level arthroplasty. The claimant does not meet FDA inclusion criteria. Given the previous surgical interventions, the integrity of the posterior elements is questionable and the ability to tolerate the disc prosthesis in clinical circumstance has not been adequately studied to support a recommendation for this procedure.

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

The previous adverse decisions are upheld. I agree with Dr. review. I would not recommend lumbar artificial disc replacement. The claimant has had multiple back surgeries. There is a question of her stability. The ODGs do not support artificial disc replacement. Therefore, the request for L4-L5 Arthroplasty with One Day LOS is non-certified.

ODG:

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| Disc prosthesis | <p>Not recommended. While artificial disc replacement (ADR) as a strategy for treating degenerative disc disease has gained substantial attention, it is not possible to draw any positive conclusions concerning its effect on improving patient outcomes. The studies quoted below have failed to demonstrate superiority of disc replacement over lumbar fusion, which is also not a recommended treatment in ODG for degenerative disc disease. The anatomic implications of total disc replacement are different from total hip or total knee replacements, and the perceived corollary between total disc replacement and total hip or knee replacement is not justified. Furthermore, longevity of this new procedure is unknown, especially with a relatively young average age in workers' comp patients, and the consequences of failure of an implant in close proximity to caudal equina and vital organs (e.g., aorta, vena cava and iliac arteries) are of concern. Plus, adjacent segment disease seems to be a natural aging process, and despite early intentions, ADR has not proven any benefit in altering that progression compared to fusion. See separate document with all studies focusing on Disc prosthesis. (Cinotti-Spine, 1996) (Klara-Spine, 2002) (Zeegers, 1999) (Blumenthal, 2003) (Zigler, 2003) (McAfee, 2003) (Anderson-Spine, 2004) (Gamradt-Spine, 2005) (Gibson-Cochrane, 2005) See also the Neck Chapter. Total disc replacements should be considered experimental procedures and should only be used in strict clinical trials. (deKleuver, 2003) At the current time radiculopathy is an exclusion criteria for the FDA studies on lumbar disc replacement. (McAfee-Spine, 2004) Even though medical device manufacturers expect this to be a very large market (Viscogliosi, 2005), the role of total disc replacement in the lumbar spine remains unclear and predictions that total disc replacement (TDR) will replace fusion are premature. One recent study indicates</p> |
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| | <p>that only a small percentage (5%) of the patients currently indicated for lumbar surgery has no contraindications to TDR. (Huang-Spine, 2004) Because of significantly varying outcomes, indications for disc replacement need to be defined precisely. In this study better functional outcome was obtained in younger patients under 40 years of age and patients with degenerative disc disease in association with disc herniation. Multilevel disc replacement had significantly higher complication rate and inferior outcome. (Siepe, 2006) On the other hand, this case series reporting on the long-term results of one-level lumbar arthroplasty reported that after a minimum 10-year follow-up, 90% of patients had returned to work, including 78% of patients with hard labor level employment returning to the same level of work. (David, 2007) According to this prospective, randomized, multicenter FDA IDE study, the ProDisc-L has been shown to be superior to circumferential fusion by multiple clinical criteria. (Zigler, 2007)</p> <p><i>Recent research:</i> A high quality meta-analysis/health technology assessment concluded that there is insufficient evidence to draw extensive efficacy/effectiveness conclusions comparing artificial disc replacement (ADR) with a broad range of recommended treatment options, including conservative nonoperative care, since, other than spinal fusion, there are currently no direct comparison studies. With respect to the comparison of lumbar artificial disc replacement (L-ADR) and fusion, overall clinical success was achieved in 56% of patients receiving L-ADR and 48% receiving lumbar fusion. Though the results suggest that 24-month outcomes for L-ADR are similar to lumbar fusion, it should be noted that for the lumbar spine, the efficacy of the comparator treatment, lumbar fusion, for degenerative disc disease remains uncertain, especially when it is compared with nonoperative care. Given what is known about lumbar fusion as a comparator and having evidence that only compares L-ADR with lumbar fusion limits the ability to fully answer the efficacy/effectiveness question. (Zigler, 2007) (Blumenthal, 2005) (Dettori, 2008) Although there is fair evidence that artificial disc replacement is similarly effective compared to fusion for single level degenerative disc disease, insufficient evidence exists to judge long-term benefits or harms. (Chou, 2009) The ECRI health technology assessment concluded that the safety data on lumbar ADR are inadequate to draw conclusions about long-term safety. (ECRIa, 2009) This RCT compared disc prosthesis with multidisciplinary rehabilitation for 12-15 days, and found differences in favor of surgery, but the difference between groups was smaller than the difference that the study was designed to detect. In concluding, given the association of surgery with potentially serious complications, and the considerable improvement in the rehabilitation group, they recommended considering a multidisciplinary rehabilitation first. (Hellum, 2011) A just-released Cochrane systematic review concludes that the lumbar artificial disc is still not ready for routine clinical use because the long-term risks and benefits of this treatment have not been documented adequately. (Jacobs, 2012) A <i>Back Letter</i> article entitled, "Future Still Uncertain for the Lumbar Artificial Disc," reports that patients, physicians, and healthcare systems were wise to resist the massive wave of publicity in favor of the artificial disc for the treatment of chronic back pain. (Wiesel, 2012)</p> <p><i>Safety & Complications:</i> There is moderate evidence that L-ADR is as safe as lumbar anterior or circumferential fusion. The studies primarily reflect outcomes measured up to 24 months and therefore questions remain regarding the long-term safety and efficacy of L-ADR compared with fusion. This is an important matter, particularly in workers' comp patients who may be younger. Since these are mechanical devices, future failure is a possibility and may influence complication rates and costs in the longer-term. (Dettori, 2008) Revision procedures have included posterior stabilization or anterior revision or conversion to arthrodesis. Risk of great vessel and retroperitoneal injury is greater than with primary procedures. (Patel, 2008) We do not know the long-term failure rate or impact of particular wear on these devices, and the theoretical position that symptomatic adjacent segment disease leads to more surgery after fusion compared to less aggressive treatment is poorly founded, plus these devices appear at best to yield</p> |
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| | <p>results equal to or only incrementally better than fusion for the same indications. (Resnick, 2007)</p> <p>Indications: Indications for L-ADR include, among other factors, primary back pain and/or leg pain in the absence of nerve root compression with single level disease. This group of patients is different than those undergoing cervical ADR and results from one group should not be inferred to the other. Cervical ADR is performed in patients with radiculopathy (cervical nerve root compression) causing arm pain and possibly motor weakness, or even myelopathy (compression of the spinal cord that could affect upper extremities, lower extremities, bowel, and bladder function). The problem of identifying those likely to respond to treatment is of concern for L-ADR in that the surgical procedure is designed to treat degenerative disc disease that is thought to be the origin of the patient's pain, but certainty around the diagnosis as the cause of low back symptoms varies. Though L-ADR for degenerative disc disease has been compared with lumbar fusion, not all patients who get a fusion are candidates for L-ADR, including patients with nerve root compression, spondylolisthesis, stenosis, facet mediated pain and osteoporosis. In fact, the proportion of patients who have an indication for L-ADR make up only about 5% of those who might undergo lumbar fusion. (Dettori, 2008)</p> <p>Current US treatment coverage recommendations: Variations exist in coverage policies for ADR for CMS and selected bell-weather payers. <i>Medicare:</i> The Centers for Medicare and Medicaid Services (CMS) will not cover lumbar ADR for patients older than 60 years of age and decisions regarding coverage of patients younger than 60 years of age are at the discretion of local CMS contractors. (Medicare, 2007) <i>Aetna</i> considers prosthetic intervertebral discs medically necessary for degenerative disc disease at one level. (Aetna, 2007) <i>Blue Cross/Blue Shield:</i> Coverage is not recommended. (Blue Cross/Blue Shield, 2007) <i>Cigna</i> covers the lumbar intervertebral disc prosthesis. (Cigna, 2007) <i>Harvard Pilgrim</i> does not cover artificial disc replacement for DDD as an alternative to spinal fusion. (Harvard Pilgrim, 2006) <i>Washington State Department of Labor and Industries:</i> Initially concluded that data insufficient to draw conclusions, L-ADR should be considered experimental only. (Washington LNI, 2004) Then in March of 2009, based on the 2008 Washington Technology Assessment (Dettori, 2008), Washington LNI released an official Coverage Determination stating that Lumbar ADR would be covered under these conditions: (1) Post-completion of a multi-disciplinary pain program; (2) Age 60 or less; (3) Consistent with FDA approved indications (i.e., failure of 6-months non-operative treatment, skeletally mature patient, single disc only, no infection, no sensitivity to implant materials, no osteoporosis or spondylosis). (Washington, 2009) <i>Health Net</i> considers both artificial lumbar and cervical disc replacements investigational and therefore not medically necessary. (Health Net, 2012)</p> <p>For average hospital LOS if criteria are met, see Hospital length of stay (LOS).</p> |
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| <p>Hospital length of stay (LOS)</p> | <p>ODG hospital length of stay (LOS) guidelines:</p> <p>Artificial disc (84.65 - <i>Insertion of total spinal disc prosthesis, lumbosacral</i>) Actual data -- median 3 days; mean 2.6 days (± 0.1); discharges 1,653; charges (mean) \$65,041 Best practice target (no complications) -- <i>Never recommended</i> <i>Note: About 30% of discharges paid by workers' compensation.</i></p> <p>Artificial disc revision (84.68 - <i>Revision/replacement artificial spinal disc prosthesis, lumbar</i>) Actual data -- median 3 days; mean 4.4 days (± 0.8); discharges 169; charges (mean) \$58,355 Best practice target (no complications) -- <i>Never recommended</i></p> |
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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)**