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Notice of Independent Review Decision

DATE OF REVIEW: February 15, 2010

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

L5-S1 anterior and posterior discectomy/fusion with removal of the total disc replacement/3 day LOS 22855, 22845, 22851, 22558, 63047, 22840, 22612, 20936, 20974, 69990

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

Certified, American Board of Orthopaedic Surgery

REVIEW OUTCOME

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

X Upheld (Agree)

Medical documentation **does not support** the medical necessity of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Texas Department of Insurance

- Utilization reviews (01/11/10 – 01/25/10)

Dr.

- Office notes (04/28/05 – 11/17/09)
- Procedures (08/02/05 – 08/01/08)
- Diagnostic tests (03/11/05 – 06/19/09)

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- Office notes (03/31/06 – 11/17/09)
- Procedures (03/31/06 – 08/01/08)
- Diagnostic tests (08/15/06 – 11/01/06)

Law Offices

- Carrier Submission (02/02/10)

ODG has been utilized for the denials.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient presented as a female alleging an injury to her lumbar spine and bilateral shoulders on xx/xx/xx, while she was pushing a huge 'shelf holding'

weighing approximately 1000 pounds, when the part she was pushing on gave loose and she felt a jolt in her upper and lower back. Her initial symptoms included low back pain with radiating symptoms from the left buttock to the left hallux.

2005: In March, x-rays of the lumbar spine revealed encroachment at the level of L5-S1 possibly affecting the L5 nerve roots and mild rotation and lateral flexion at the level of L1 and L2 vertebrae caused by moderate paravertebral muscle spasms in that region.

In April, magnetic resonance imaging (MRI) of the lumbar spine revealed loss of hydration of the disc at L5-S1, mixed hydration of the disc at L3-L4, posterior subligamentous bulge at L3-L4 and focal posterior subligamentous disc bulge effacing a focal area of anterior epidural space. There was no evidence of nerve root contact or compression. MRI of the thoracic spine was unremarkable.

D.C., evaluated the patient for pain in the lower and mid back, left gluteus maximus and radiating left leg pain down to the left big toe. History was positive for injury to the lumbar spine in 1996 which had resolved. Examination of the lumbar spine revealed pain and tenderness especially around the spinal segments from L2 to S1, stiffness due to pain, hypertonic muscles over the erector spinae muscles bilaterally and lower latissimus dorsi muscles bilaterally and lumbar paraspinal muscles. Orthopedic examination revealed positive Adams' and support Adams', Kemp's, straight leg raise (SLR), Yeoman's, Nachlas and Bechterew's tests. Dr. diagnosed possible lumbar herniated nucleus pulposus (HNP), lumbar sprain/strain and thoracic sprain/strain rule out radiculopathy. He recommended physical therapy (PT) consisting of spray and stretch, electrical muscle stimulation (EMS), phonophoresis, massage, joint mobilization and post isometric resistance. In May, Dr. noted decreased range of motion (ROM) of the shoulders and assessed shoulder impingement.

On 5/4/05, neurodiagnostic testing of the lower extremities was unremarkable for radiculopathy or any other abnormality, despite her complaint of left lower extremity radicular symptoms.

On 5/27/05, MRIs of both shoulders were obtained. MRI of the right shoulder revealed abnormal signal intensity in the rotator cuff tendon suggesting tendonitis, mild joint effusion and fluid collection in the acromioclavicular (AC) joint. MRI of the left shoulder revealed abnormal intermediate signal intensity in the distal rotator cuff tendon suggestive of tendonitis and subacromial bursitis.

M.D., an orthopedic surgeon, saw the patient for back and bilateral shoulder pain. Examination of the lumbar spine revealed tenderness in the lumbosacral paraspinal musculature, limited ROM with pain and pain with bilateral SLR. Examination of the right shoulder revealed tenderness and positive impingement test. He diagnosed lumbar HNP, impingement syndrome and left shoulder pain and performed a series of right shoulder injections without much improvement. Dr. recommended subacromial decompression which was denied.

In a medical evaluation, M.D., reviewed MRI of the lumbar spine and interpreted it as follows: Increased signal at the posterior annulus at L5-S1 possibly indicating an acute annular tear and disc bulge/protrusion producing right

foraminal narrowing. He recommended a series of three lumbar epidural steroid injections (ESI), corticosteroid injections to both the shoulders and passive chiropractic modalities.

On November 29, 2005, M.D., a designated doctor, opined that the patient was not maximum medical improvement (MMI) and recommended right shoulder arthroscopy.

2006: On January 10, 2006, the patient underwent right shoulder surgery, including arthroscopic examination of the glenohumeral joint with debridement of partial rotator cuff tear, subacromial decompression, and distal clavicle resection.

M.D., diagnosed lumbar and cervical radiculopathy, lumbar and cervical herniated disc, facet joint neuritis, lumbar and cervical disc syndrome, bilateral sacroiliac (SI) joint arthritis and neuritis, musculocutaneous syndrome and cervical and lumbar spondylosis. He treated the patient with facet joint nerve blocks x2 at right from L3-S1.

On 8/15/06, repeat MRI studies were obtained. Magnetic resonance imaging (MRI) of the lumbar spine revealed: (1) Some moderate low signal change in the discs at L3-L4 and L5-S1. (2) A 1-mm posterior bulge at L3-L4 with effacement of the thecal sac along the anterior 5% of its margin. (3) Mild encroachment on the neural foramina inferiorly at L4-L5. (4) A 2-mm posterior bulge at L5-S1 with effacement of the thecal sac along the anterior 5% of its margin. MRI of the right shoulder revealed mild hypertrophic change along the AC joint with abutment of the adjacent supraspinatus muscle consistent with mild impingement. MRI of the left shoulder revealed prominent thinning of cartilage along the glenohumeral joint, mild hypertrophic change along the AC joint with mild impingement upon the distal supraspinatus muscle.

The patient underwent a right shoulder subacromial injection.

On October 18, 2006, the patient underwent left shoulder surgery, including debridement of grade I SLAP and partial rotator cuff tear and subacromial decompression. She also underwent physical therapy (PT) to the back without any improvement.

Dr. obtained a lumbar discogram for discogenic back pain which was positive for concordant pain at the L5-S1 level.

2007: On January 18, 2007, Dr. performed L5-S1 anterior discectomy and Charite total disc replacement. A surgical pathology report revealed sections of fibrocartilage showing foci of apparent degeneration. Postoperatively, he started PT.

The patient reported tenderness and loss of lordosis of the lumbar spine. Examination of the left shoulder revealed tenderness over the acromion and painful arch. Dr. performed a series of steroid injection to the subacromial space.

On June 26, 2007, D.C., performed an impairment rating evaluation. He assessed maximum medical improvement (MMI) as of June 26, 2007, and assigned 11% whole person (WPI) rating.

2008: The patient complained of persistent residual pain into the back, right hip, and buttock area. She was treated with a right SI injection on May 12, 2008, with temporary improvement.

In February, Dr. performed steroid injection to the bilateral shoulders and prescribed Medrol Dosepak.

In May, Dr. performed an RME and opined that the patient had undergone bilateral shoulder procedures and an artificial disc displacement without improvement, the treatment rendered till date was not reasonable, the use of benzodiazepine was recommended only for a short period of time, and further treatment consisting of repeat imaging of both shoulders, removal of disc replacement and arthrodesis at least at L5-S1, and CT myelogram at L4-L5 and L3-L4, adjunctive use of antidepressant for chronic non-neuropathic pain was reasonable. Neurontin, Topamax or Lyrica were not reasonable.

In August, Dr. performed a left SI joint injection for persistent pain in the hips bilaterally.

On 9/26/08, the third MRI of the left shoulder revealed partial-thickness tear and tendinosis of the distal supraspinatus, mild tendinosis of the distal infraspinatus, osteophyte from moderate AC osteoarthritis indenting the supraspinatus myotendinous junction and os acromiale. Dr. reviewed the MRI and interpreted it to be showing evidence of distal clavicle resection, MRI of the left shoulder was interpreted to be showing no evidence of residual impingement MRI of the right shoulder revealed a full-thickness rotator cuff tear.

On December 3, 2008, Dr. performed right shoulder surgery, including diagnostic arthroscopy and open rotator cuff repair using mini deltoid split approach.

2009: In March, Dr. noted that the second SI joint injection was of no help. The patient complained of pain in the back radiating into the right buttock and occasionally into the foot. X-rays of the back revealed possible malalignment of the facets. Dr. recommended a computerized tomography (CT) myelogram of the lumbar spine to check on the current status of her total disc replacement surgery.

In August, Dr. opined that the surgical procedure performed on December 3, 2008, was reasonable, the patient was not at MMI, future treatment consisting of one or possibly two additional corticosteroid injections would be appropriate for the left shoulder, future treatment consisting of additional imaging with possibility of right shoulder reverse arthroplasty was reasonable, and additional consultation for the lumbar spine, artificial disc removal and arthrodesis of at least L5-S1, and a two-level discogram at L3-L4 and L4-L5 was reasonable. Soma was not reasonable.

In September, the patient complained of severe pain in the lumbar spine with constant numbness in the left lower extremity down into the left big toe associated with a pulling sensation down the posterior aspect of the left leg, exactly as the patient had presented initially. Dr. renewed the medications and submitted a request for CT myelogram of the lumbar spine, which was denied.

In November, Dr. noted tenderness in the lumbar region, diminished lumbar flexion as well as lateral bending and diminished sensation in the left foot. He opined the surgery had failed and discussed a salvage procedure, which would involve removal of the total disc replacement and placement of an interbody fusion.

2010: On January 11, 2010, M.D., denied the request for L4-L5 anterior and posterior discectomy/fusion with removal of total disc replacement with three-day length of stay with the following rationale: *“The clinical information provided for review did not meet the practice guidelines for the use of the requested procedure as referenced above. The patient is post total disc replacement last January 18, 2007, and is complaining of low back pain radiating to the right buttock with lumbar tenderness, decreased lumbar ROM, decreased motor strength on the right, decreased sensation on the anterior portion of shins and lateral aspect of the foot, blunted reflexes bilaterally, and positive SLR. No recent or postoperative imaging studies were submitted for review to make a determination of the condition of the disc prosthesis as well as the other lumbar segment. No records were provided of prior conservative treatment done such as PT, injection, back exercises, and optimized oral medications. Moreover, no psychosocial screening was done addressing confounding issues. Additional relevant information from a peer-to-peer contact is needed to substantiate the medical necessity of this request. Hence the request is not indicated.”*

On January 25, 2010, D.O., denied the appeal for an anterior and posterior discectomy/fusion at L5-S1 with removal of total disc replacement with three-day length of stay based on the following rationale: *“Patient underwent a total disc replacement on January 18, 2007, and still complains of low back pain. The submitted clinical records contain limited data regarding conservative measures. The records do not contain any recent radiographic reports and imaging studies to assess the status of the ADR or identify potential pathology causing the patient continued pain. Removal of an ADR is a very complicated procedure with a high potential for iatrogenic injury. The additional relevant information from a peer-to-peer contact is needed to substantiate the medical necessity of this request. Based on the clinical information submitted for this review and using the evidence-based, peer-reviewed guidelines referenced above, this request for L5-S1 anterior and posterior discectomy, fusion with removal of the total disc replacement and three day length of stay is not medically necessary.”*

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

The claimant's symptoms in the low back and left lower extremity have remained essentially unchanged from her initial presentation in 2005 (as stated by Dr. on 11/17/09, “her back is hurting as bad as ever”), despite having undergone multiple invasive interventions including injections and L5-S1 artificial disc replacement surgery. Although the disc replacement surgery may be considered a failure, it is not because the prosthesis itself has failed or is suffering from some other recognized and documented complication. Rather, the failure is most medically probably due to poor patient selection and lack of indication. Therefore it stands to reason that, on the same grounds that the artificial disc surgery failed, removal of the implant and interbody fusion of the segment is likely to fail as well.

The recommendation for removal of the implant and conversion to fusion does not appear to be based on objective factors, such as implant breakage or wear, malpositioning, subsidence, infection, etc. The decision to perform the additional surgery appears to be based on the subjective report of pain alone. The basis for denial of the requested surgery, as stated by the preauthorization reviewers, appears to be medically reasonable and consistent with evidence-based recommendations such as ODG.

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

X ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES