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Notice of Independent Review Decision

DATE OF REVIEW: MAY 2, 2011 **Amended Date:** May 5, 2011

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Ant Lumbar Interbody Fusion w/ instrumentation @ L5-S1/posterior Instrumentation

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

This physician is a Board Certified Neurosurgeon 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)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

On April 20, 2010 the claimant attended an initial consultation appointment with MD. The physical examination states the claimant was displaying appropriate pain behavior. The left heel walk produced left low back pain. Significantly decreased lumbar flexion and extension both producing end-range left low back pain. Positive left and right SLR/slump increasing left low back pain with left maneuver increasing posterior thigh pain. Neurologically intact including calf raise x5. 2+ and symmetrical knee and ankle reflexes. Distal pulses intact. Medical decision making states Lumbar MRI, 5/17/09 documented L5-S1 central extrusion abutting the bilateral S1 nerve roots. Treatment for current event Prednisone taper completed yesterday with incomplete response. Ongoing Flexeril, Vicodin prn. For the prior event L5-S1 translaminar LESI with benefit. The impression states recurrent left sciatica-consistent with S1 radiculopathy. Positive ipsilateral and crossed SLR/slump suggests recurrent HNP. The plan states reinstate physical rehabilitation, given the positive but incomplete response to oral corticosteroid and positive response to prior procedure, proceed with lumbar epidural steroid injection-L5-S1 translaminar approach pending authorization, and continue Vicodin; Flexeril prn.60 produced posterior leg pain. Medical decision making states interval L-ESI, 4/30/2010 with 20% improvement. D.C. initiated x1 only thus far. Vicodin 3-4 times per day. Flexeril not approved. Impression states recurrent left sciatica consistent with S1 radiculopathy, possible recurrent HNP. Interval improvement. Plan physical rehabilitation per D.C., reinstate oral anti-inflammatory: Mobic, continue Vicodin, Flexeril consider repeat L-ESI.

On May 19, 2010 the claimant attended a follow up appointment with MD. The physical examination states right LR 60 degrees produced posterior thigh pain and left SLR

June 2, 2010 the claimant had an MRI of the Lumbar Spine without contrast at Clinic read by MD. The impression states posterior midline disc protrusion L5-S1, diminished in volume compared to the previous exam. This contacts the ventral thecal sac and descending S1 nerve roots without impingement in this neutral supine position; 2. Very minimal distal lumbar facet arthrosis without significant foraminal compromise or exiting nerve root impingement; 3. No adverse interval change compared to the prior study.

On June 9, 2010 the claimant attended a follow up office appointment with MD. The physical examination states very limited lumbar flexion and extension produced end-range lumbar pain. Right and left SLR less than 60% produced ipsilateral posterior thigh pain. Impression bilateral sciatica-S1 distribution with somewhat correlating MRI as above. Positive SLR objective neurological intact. The plan states Transforaminal epidural steroid injections, reinstate physical rehabilitation post procedure.

On June 28, 2010 there is a precert request for Lumbar Transforaminal Steroid Injection by MD.

On July 16, 2010 the claimant attended a follow up office appointment with MD. The note states the claimant has persistent left, right and occasionally bilateral lower extremity pain, right lateral leg pain maximum 4/10, improved s/p S1 TF-ESI; left lateral knee pain maximum 6/10. They both increase with sitting more so than walking. Claimant notes intermittent diffuse bilateral lower extremity ache "like I just walked 10 miles" occurring several times per week lasting hours at a time. Physical examination SLR produced symmetrical ipsilateral posterior thigh tightness. Impression: bilateral sciatica of uncertain etiology. Weak nerve root tension, not reproducing chief complaint; non-diagnostic response to S1 nerve block; equivocal MRI. Total duration of sciatic symptoms >one year; aggravation three months s/p twisting injury x/xx/xx. Plan consider surgical consult, Neurontin 300 increasing to 1800 mg q day in divided doses.

On August 13, 2010 the claimant attended a follow up appointment with MD. The report states the claimant reports a spontaneous "20%" improvement, however, persistent lumbar ache associated with right much more so than left proximal lateral leg pain aggravated with sitting equal to walking and improved to change in position. The physical examination states right more so than left SLR produced ipsilateral posterior thigh pain; right pain shooting distally to the ankle. Impression right > left sciatica of uncertain etiology. Weak nerve root tension and non –diagnostic response to S1 nerve block mitigate minor imaging L5-S1 protrusion. Plan states overall improvement remains encouraging. However, given persistent symptoms and the patient's frustration recommended surgical second opinion. Trial Lyrica 75mg bid.

On September 14, 2010 the claimant attended a follow up appointment with MD. The report states the claimant returns reporting interval symptoms progression/aggravation: right equal to left posterior leg pain with less frequent involvement of the posterior thigh and buttock; occasionally involving the plantar feet; symptoms aggravated with sitting somewhat more than walking and standing; sitting shifted to one side aggravates the contralateral extremity. The physical examination states right and left SLR 30% produced ipsilateral posterior thigh pain. Impression bilateral sciatica of uncertain etiology. S1 pattern without objective neurological deficit. Positive nerve root tension; L5S1 protrusion; however non diagnostic response to S1 nerve block. The plan states give progressive symptoms, clarify with electrodiagnostics, follow through with Tran, MD second opinion, reattempt Lyrica 75mg bid, increase after one week to 150mg bid.

On September 16, 2010 there is a precert request for EMG Nerve conduction study of bilat lower extremities.

On September 20, 2010 the claimant attended an initial consultation appointment with MD. The report states back pain is worse than leg pain. He has pain most of the time at level 5 and 6 and seemed to be worse with prolonged sitting and

prolonged standing. He seemed to be walking fair. The morning is the worst time for the patient. If he bends forward, he has a hard time getting up straight.. Sitting causes right sided leg discomfort or left leg discomfort and sometimes none at all. The back pain is more persistent and more reliable, exacerbated when he sits. The physical examination states SLR is equivocal, at worse, it is causing some tightness in the back of the thigh but no pain per se shooting down his leg. Strength examination is 5/5 in all the muscle groups. Reflex is symmetric.. The assessment states mostly mechanical back pain more than leg pain. To the best of my ability, he may be symptomatic from the L5-S1 disc herniation and disc degeneration. The plan states that the belief is that the back and leg pain come from the continued wear and tear at L5-S1 disc, the option for the patient right now is to continue with pain management. If he continues to have a lot of symptoms, then the fusion surgery between L5 and S1 with bilateral L5-S1 decompression is probably the best answer for the patient's problem. The claimant has failed conservative treatment, I will recommend fusion surgery at L5-S1, he will need bilateral L5-S1 decompression as well.

On October 1, 2010 the claimant was evaluated by LPC LSOTP the reason for the referral was to assess and identify any potential psychosocial barriers to successful implantation of fusion back surgery, no severe psychological risk factors are reported or observed the evaluator requested 2 hours of testing.

On October 26, 2010 there is a prescription for pre surgical psych eval.

On November 4, 2010 there is an initial psychological evaluation completed by M.A., LPA, LSSP, The conclusion of the report states "At this time, there are no significant concerns regarding surgical prognosis; however this cannot be confirmed without the psychological testing. Therefore I am requesting 4 hrs. of psychological testing to complete assessment.

On December 21, 2010 the claimant attended a follow up appointment with MD the report states the claimant reports "slightly" improved symptoms; constant low back pain with intermittent left posterolateral proximal leg more to the lateral thigh. Symptoms; aggravated with prolonged sitting. Physical examination is deferred. The impression states low back pain with recurrent left predominant sciatic symptoms of uncertain etiology. Significant neuropathies component seems likely. The plan states encouraged reconsideration of Cymbalta and or Lyrica explained Norco is not ideal long term therapeutic option.

On January 18, 2011 the claimant attended a follow up office appointment with MD. The report states the claimant reports interval flare approximately three weeks ago for no apparent reason, sharp low back pain aggravated with sitting more so than walking; sporadic left lateral knee as well as left lateral ankle pain-both occurring approximately three times per week lasting one to two hours at a time. Physical examination states notable for symptom magnification. The plan states continue Cymbalta increased to 50 mg qd as tolerated, increase compliance with Lyrica 150mg qd Norco warnings well understood.

On January 20, 2011 the claimant attended a psychological evaluation by MD, LPA, LSSP. The results of this evaluation suggest that claimant has a GOOD prognosis for surgical outcome. Claimant is a GOOD candidate for surgery.

On February 22, 2011 the claimant attended a follow up office visit with MD the report state the claimant reports some improvement but plateau; constant left lumbar sharp pain with intermittent pinpoint pain, left posterior lateral proximal leg and occasional tenderness lateral thigh; aggravated with sitting more so than walking. Physical examination states symptom magnification remains, very limited lumbar flexion and extension with end range lumbar pain, neurologically intact. Impression states low back pain with pseudosciatic symptoms of uncertain etiology. Significant neuropathic component seems likely the plan states increase Lyrica to 450 mg qe in divided doses, continue Cymbalta 50mg qd Norco.

On March 14, 2011 the claimant attended a follow up office visit with MD. The note states chief complaint is low back pain. At worst, claimant may have left calf discomfort. Pain is at 4-5 most of the time and worse with prolonged sitting. The physical examination states SLR is negative bilaterally, strength is 5/5 in all the muscle groups. The assessment states mostly mechanical back pain that is most likely related to the L5-S1 disc. . Please note that the patient did have a disc herniation on MRI in June 2009. That disc herniation got smaller in 2010, but in return the patient has more disc dehydration signal evidence. The plan state the number one choice is to continue pain management and the second option is to offer him surgery at L5 and S1 via anterior lumbar interbody fusion. I want to offer him a fusion surgery at L5 and S1. I do not believe that he needs decompression surgery because he has no leg pain, no SLR maneuver. So, the surgery will be an anterior lumbar interbody fusion between L5 and S1 with just a unilateral pedicle screw between L5 and S1 for back fixation.

On March 15, 2011 there is a precert request for Anterior Lumbar interbody fusion with instrumentation at L5 S1 with posterior instrumentation at left L5-S1.

On March 18, 2011 there is a Notification of Adverse Determination from Carrier to Clinic. The Notification was carbon copied to the claimant and MD. The Reviewer Comments state the medical record dated 3/14/11 showed persistent low back pain. Physical examination from 2/22/11 revealed very limited lumbar flexion and extension with end range lumbar pain. MRI showed no spondylolysis or spondylolisthesis. Posterior midline disc protrusion L5-S1, diminished in volume compared to the previous exam. This contacts the ventral thecal sac and descending S1 nerve roots without impingement in this neutral spine position. Treatment has included medication, ESI, and physical therapy. However, there is no documentation of imaging showing instability. Therefore, the necessity of the request could not be established at this time. The determination states based on the clinical information submitted for this review and using the evidence-based, peer-reviewed guidelines referenced above, this request for anterior lumbar interbody fusion with instrumentation at L5-S1 with posterior instrumentation and left L5-S1 is non-certified.

On March 28, 2011 the claimant attended a follow up appointment with MD. The chief complaint is 1. Mechanical low back pain (about 70%) of the problem). 2 bilateral leg pain, left worse than right that he feels in the buttock, back of the thigh, and the back of the calf, left worse than right in the 80-20 distribution. Again, back is worse than leg and left leg is predominantly worse than the right. The back pain is more constant. It is worse with activity like prolonged sitting, prolonged standing and walking. The leg pain usually gets worse with twisting his back wrong. The leg pain is less constant than the back pain. The physical examination states the patient walks with a limp mostly because of back pain but no leg pain. In the sitting position, SLR on the right side causing left sided back pain, some tightness, and discomfort down his right leg in the buttock, back of the thigh, and back of the calf. Left leg straight leg raise shows increasing discomfort in the buttock, thigh, and calf. This is not a tightness sensation, it is actually pain. Strength examination is 5/5 in all the muscle groups.. Reflex seems to be slightly down on the left ankle, 2 on the right. The assessment states more mechanical back pain than left leg pain in the S1 distribution. I believe that the mechanical back pain comes from the continued degeneration of the L5-S1 disc due to the initial large disc herniation, seen on MR in 2009, which continued to show us a very large disc herniation in 2010. Even though it is smaller but it continues to show wear and tear, more disc degeneration, more dehydration, more disc space narrowing, and continues to touch the medial aspect of the S1 nerve root bilaterally. Please note that the patient has left leg pain and continues to show positive straight leg raise and slight left-sided decreasing reflex on the left ankle.

On March 29, 2011 there is a request for reconsideration by MD

On April 7, 2011 there is a Notification of Reconsideration Determination from Carrier to MD. In the reviewer's comments it states as per medical records, the patient complains of persistent low back pain. On physical examination, there is positive Straight Leg Raise test in sitting position on the left with decrease reflex on the left ankle. The official results of the MRI scan of the lumbar spine; however, there is no documentation of imaging showing instability. As noted, there is very minimal distal lumbar facet arthrosis without significant foraminal compromise or exiting nerve root impingement. Furthermore, there was no flexion and extension views to confirm and qualify the lumbar instability. The clinical records indicated that the patient has been treated conservatively with oral medications, Epidural Steroid injection and physical therapy. However, the objective response to the pain medications given was not included for review. Likewise, the clinical information did not provide objective documentation of the patient's clinical and functional response from the mentioned Epidural Steroid Injection that includes sustained pain relief, increased performance in the activities of daily living and reduction in medication use. The maximum potential of the conservative treatment done was not fully exhausted to indicate a surgical procedure. With this, the medical necessity of the requested appeal has not been fully established. Determination: This request is not certified.

PATIENT CLINICAL HISTORY:

No significant medical history

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

The previous decisions are upheld. There was no documentation of lumbar instability via flexion and extension X-Rays. Furthermore, per the MRI of the Lumbar Spine on 6/2/10 states “there is very minimal distal lumbar facet arthrosis without significant foraminal compromise or exiting nerve root impingement.”

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; & (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).

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)