



Medical Review Institute of America, Inc.
America's External Review Network

DATE OF REVIEW: March 16, 2009

IRO Case #:

Description of the services in dispute:

Medical necessity for lumbar laminectomy, discectomy, foraminotomy, and partial facetectomy at L5-S1.

A description of the qualifications for each physician or other health care provider who reviewed the decision

The physician who provided this review is board certified by the American Osteopathic Board of Surgery in Neurological Surgery. This reviewer is a member of the American Osteopathic Association, the American College of Osteopathic Surgeons, the Texas Osteopathic Medical Association and the Texas Medical Association. This reviewer has been in active practice since 1995.

Review Outcome

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

Upheld

Upon review of the clinical information, the operative intervention is not medically indicated due to the conflicting data contained in the record.

Information provided to the IRO for review

Initial Request:

Medical Necessity Review, 12/24/08, 6 pgs

Preauth request, Dr. 12/29/08, 2 pgs

Appeal:

Medical Necessity Review, 1/7/09, 7 pgs

Texas Administration Code, 12/22/08, 6 pgs

Records from insurance Company:

LLP, 7/11/04, 4 pgs

Initial Medical Report, 8/4/06, 10 pgs

diagnostic Center, MRI Report, 12/19/06, 1/22/09, 4 pgs
Anesthesia and pain management, 7/12/07, 8/15/07, 8/29/07, 6 pgs
Anesthesia and pain management report, 8/22/07, 1 pg
PA, Dr. report, 9/18/08, 11/14/08, 7 pgs
Diagnostic Imaging Procedure Report, 10/15/08, 10/18/08, 2 pgs
PA, Dr. Rx 10/23/08, 1/8/09, 2 pgs
Clinical Update, 11/10/08, 6 pgs
Report, 12/26/08, 1/7/09, 1/19/09, 13 pages
PA, Dr. Prior auth request, 12/30/08, 2 pgs
MRI report, 2/21/09, 1 pg
Request for MDR/IRO, Dr. 1/14/09, 1 pg
Authorization form, 1/21/09, 1 pg
Texas Dept of Insurance, IRO form, 2/25/09, 1 pg

Patient clinical history [summary]

The patient is a male who is reported to have sustained an injury to his low back on xx/xx/xx. On this date he was struck by pallet jack. Clinical records suggest the patient has had extensive conservative treatment with no significant improvement in his condition. Records indicate the patient was diagnosed with lumbar disc extrusion at L5-S1, and subsequently underwent a series of lumbar epidural steroid injections. The first was on 07/12/07, second on 08/15/07, and the third on 08/29/07.

The patient was referred for an MRI of the lumbar spine on 12/19/06, which indicated a mild generalized disc bulge extending 2 mm in AP extent with mild facet hypertrophy at L5-S1. There is no spinal stenosis or foraminal narrowing noted.

On 09/18/08, the patient was seen by Dr. At this time, the patient reported a deep stabbing pain with radiation into the left lower extremity along the lateral thigh and calf intermittently into the left lateral ankle with associated numbness and tingling in the similar distribution. The patient is reported to be status post physical therapy, epidural therapy, and trigger point injections with no significant improvement. The patient denies any bowel or bladder dysfunction. The patient describes a previous history of low back pain secondary to a work related injury in 2001. On physical examination, range of motion was decreased in forward flexion. The patient had 4/5 strength in the gastrocnemius muscle on the left, otherwise 5/5 throughout. Deep tendon reflexes were 1+ in the left ankle, otherwise 2+ throughout. Gait was antalgic. The patient had difficulty with toe walking and less difficulty with heel walking. Straight leg raise is positive on the left at 50 degrees. Sensory examination revealed a hypoesthetic region in the L5 distribution on the left to pinprick and light touch. An MRI of the lumbar spine was reviewed. The patient subsequently was opined to be a surgical candidate and was recommended to undergo anterior lumbar interbody

fusion at L5–S1 with posterior lumbar decompression and posterolateral fusion with pedicle screw instrumentation at L5–S1.

The patient was then recommended to undergo lumbar discography with post discography CT scan. The patient was approved for this procedure on 10/15/08. The records indicate that this was performed at L3–4, L4–5, and L5–S1. At L5–S1, the disc accepted 1 cc of contrast. Disc morphology was normal on lateral projection. There was some discomfort with the infusion, but the patient was very clear this was non–concordant pain. At L4–5, the disc accepted 1.5 milliliters of contrast. Disc morphology appeared normal in lateral projection. The disc was pain free. At L3–4, the disc accepted 1 milliliters of total volume. The disc morphology was normal in appearance and lateral projection. The disc was also pain free. Post procedurally, a CT scan indicates contrast present in the right half of the disc, and the left half is not visualized. Contrast is evident within the annular fibers on the right. There is no osseous central canal or osseous foraminal stenosis. There is mild facet joint hypertrophy at this level. At L4–5 there is a normal nucleogram at this level. There is mild facet joint hypertrophy. There is a mild broad based disc bulge, which likely results in central volume loss. However, there is no osseous central canal or osseous foraminal stenosis. At L5–S1 there is a degenerative disc at this level. Posterior annular tears are evident with contrast coursing along the annular fibers posteriorly. The anterior disc margin is normal. There is no epidural extravasation of contrast. Mild facet joint hypertrophy is evident. There is a mild broad based disc bulge. On 11/10/08, the patient was referred for preoperative psychiatric evaluation. The patient was found to be an acceptable candidate for operative intervention noting he has mild to moderate symptoms of mental or emotional disturbance stemming from his work injury.

On 11/14/08, the patient was seen in follow–up by Dr. Dr. reported the patient has made no improvement. His physical examination remained unchanged. The patient is reported to have nonconcordant pain at L5–S1. Dr. subsequently recommended the patient would benefit from lumbar laminectomy, discectomy, foraminotomy, and partial facetectomy at L5–S1. The record includes a letter of appeal.

On 01/29/09, the patient was referred for an MRI of the lumbar spine. This study reported mild facet ligamentum flavum hypertrophy at L3–4 and L4–5 without evidence of focal disc protrusion and central canal or neural foraminal stenosis. At L5–S1 there is a broad based annular disc bulge that is 2–3 mm in AP extent. There is no focal mass effect on the nerve roots and no critical central or neural foraminal stenosis. On 02/21/09, Dr. reviewed the patient’s MRI. The patient is reported to have bilateral spondylolysis at L5 with a 3 mm posterior disc protrusion that moderately narrows both the lateral recesses at L5–S1. There is a reported full thickness radial tear seen on the posterior fibers of the intervertebral disc.

The record contains a utilization review determination dated 12/24/08. The record was evaluated

by Dr. Dr. noted that the patient previously had an independent medical examination and was deemed to be at maximal medical improvement on 02/24/05, which was performed by Dr. The patient was again seen for maximal medical improvement on 10/26/06. He was later reevaluated by Dr. on 04/05/07. Dr. did not recommend lumbar discography and noted no abnormal neurologic findings on his examination. He reported the patient had abnormal sensation in the L4 area. He apparently reported positive Waddell's sign, but does note that the patient is a surgical candidate. Dr. noted clear differences between Dr. 's physical examination and that of Dr. He subsequently non-certified the request for surgery and subsequently recommended an independent medical evaluation.

This case was subsequently appealed and reviewed by Dr. on 01/07/09. Dr. subsequently non-certified the request and noted the patient's imaging studies revealed pathology at L5-S1 with findings of a 3 mm left sided foraminal stenosis and herniated nucleus pulposus at L5-S1. He noted discography did not reveal concordant pain. Dr. opined that the request is not medically necessary noting discrepancies between independent medical examinations and that of Dr.

Analysis and explanation of the decision include clinical basis, findings and conclusions used to support the decision.

Items in dispute: Medical necessity for lumbar laminectomy, discectomy, foraminotomy, and partial facetectomy at L5-S1.

Upon review of the clinical information, the operative intervention is not indicated due to the conflicting data contained in the record.

The initial clinical records indicate that the patient underwent a lumbar epidural steroid injection with no sustained relief. The record contains imaging studies dated 12/21/06, which notes a generalized disc bulge at L5-S1 with mild facet hypertrophy; however, there is no spinal stenosis or foraminal narrowing noted. The patient's physical examination is consistent with left L5 radiculopathy. The patient later underwent lumbar discography on 10/15/08. This study clearly indicated there was normal disc morphology post injection at L5-S1, and there was some discomfort to the infusion; however, it is very clear this was nonconcordant pain. One would expect if the patient had a significant disc herniation that, with pressurization of the disc, there would be increased pain in the L5 distribution. It is further noted that there is no significant protrusion during the pressurization of the disc. A repeat MRI was performed on 01/22/09, and this again showed a small annular disc bulge with no focal mass in the nerve roots. This was subsequently reviewed by Dr. and is now reported to show a 3 mm posterior disc protrusion at L5-S1 extending into the epidural fat, moderately narrowing both the lateral recesses. This reported over-read is inconsistent with the 2 previous radiology reports.

In summary, the record contains some significantly conflicting information. The previous IME reports were not included for review, and are pertinent to the discussion. The patient has undergone lumbar discography, which did not result in concordant pain reproduction. This report suggested normal disc morphology at L5-S1. Given the conflicting data that is presented in the record, I agree with the previous reviewers that operative intervention is not warranted at this time. Given the equivocal data contained in the record, the patient should be referred for electrodiagnostic studies to confirm or deny the presence of a clinical radiculopathy. If this study is found to be positive and coincides with the patient's physical examination, then operative intervention would be warranted.

A description and the source of the screening criteria or other clinical basis used to make the decision:

1. The Official Disability Guidelines, 13th edition, The Work Loss Data Institute.

Discectomy/Laminectomy:

Recommended for indications below. Surgical discectomy for carefully selected patients with radiculopathy due to lumbar disc prolapse provides faster relief from the acute attack than conservative management, although any positive or negative effects on the lifetime natural history of the underlying disc disease are still unclear. Unequivocal objective findings are required based on neurological examination and testing. (Gibson-Cochrane, 2000) (Malter, 1996) (Stevens, 1997) (Stevenson, 1995) (BlueCross BlueShield, 2002) (Buttermann, 2004) Standard discectomy and microdiscectomy are of similar efficacy in treatment of herniated disc. (Bigos, 1999) While there is evidence in favor of discectomy for prolonged symptoms of lumbar disc herniation, in patients with a shorter period of symptoms but no absolute indication for surgery, there are only modest short-term benefits, although discectomy seemed to be associated with a more rapid initial recovery, and discectomy was superior to conservative treatment when the herniation was at L4-L5. (Osterman, 2006) The SPORT studies concluded that both lumbar discectomy and nonoperative treatment resulted in substantial improvement after 2 years, but those who chose discectomy reported somewhat greater improvements than patients who elected nonoperative care. (Weinstein, 2006) (Weinstein2, 2006) A recent RCT compared decompressive surgery with nonoperative measures in the treatment of patients with lumbar spinal stenosis, and concluded that, although patients improved over the 2-year follow-up regardless of initial treatment, those undergoing decompressive surgery reported greater improvement regarding leg pain, back pain, and overall disability, but the relative benefit of initial surgical treatment diminished over time while still remaining somewhat favorable at 2 years. (Malmivaara, 2007) Patients undergoing lumbar discectomy are generally satisfied with the surgery, but only half are satisfied with preoperative patient information. (Ronnberg, 2007) If patients are pain free, there appears to be no contraindication to their returning to any type of work after lumbar discectomy. A regimen of stretching and strengthening the abdominal and back muscles is a crucial aspect of the recovery

process. (Burnett, 2006) According to a major recent trial, early surgery (microdiscectomy) in patients with 6–12 weeks of severe sciatica caused by herniated disks is associated with better short-term outcomes, but at 1 year, disability outcomes of early surgery vs conservative treatment with eventual surgery if needed are similar. The median time to recovery was 4.0 weeks for early surgery and 12.1 weeks for prolonged conservative treatment. The authors concluded, "Patients whose pain is controlled in a manner that is acceptable to them may decide to postpone surgery in the hope that it will not be needed, without reducing their chances for complete recovery at 12 months. Although both strategies have similar outcomes after 1 year, early surgery remains a valid treatment option for well-informed patients." (Peul-NEJM, 2007) (Deyo-NEJM, 2007) A recent randomized controlled trial comparing decompression with decompression and instrumented fusion in patients with foraminal stenosis and single-level degenerative disease found that patients universally improved with surgery, and this improvement was maintained at 5 years. However, no obvious additional benefit was noted by combining decompression with an instrumented fusion. (Hallett, 2007) A recent British study found that lumbar discectomy improved patients' self-reported overall physical health more than other elective surgeries. (Guilfoyle, 2007) Microscopic sequestrectomy may be an alternative to standard microdiscectomy. In this RCT, both groups showed dramatic improvement. (Barth, 2008) There is consistent evidence that for patients with a herniated disk, discectomy is associated with better short-term outcomes than continued conservative management, although outcomes begin to look similar after 3 to 6 months. This is a decision to be made with the patients, discussing the likelihood that they are going to improve either way but will improve faster with surgery. Similar evidence supports the use of surgery for spinal stenosis, although the outcomes look better with surgery out to about 2 years. (Chou, 2008) Standard open discectomy is moderately cost-effective compared with nonsurgical treatment, a new Spine Patient Outcomes Research Trial (SPORT) study shows. The costs per quality-adjusted life-year gained with surgery compared with nonoperative treatment, including work-related productivity costs, ranges from \$34,355 to \$69,403, depending on the cost of surgery. It is wise and proper to wait before initiating surgery, but if the patient continues to experience pain and is missing work, then the higher-cost option such as surgery may be worthwhile. (Tosteson, 2008) Note: Surgical decompression of a lumbar nerve root or roots may include the following procedures: discectomy or microdiscectomy (partial removal of the disc) and laminectomy, hemilaminectomy, laminotomy, or foraminotomy (providing access by partial or total removal of various parts of vertebral bone). Discectomy is the surgical removal of herniated disc material that presses on a nerve root or the spinal cord. A laminectomy is often involved to permit access to the intervertebral disc in a traditional discectomy.

Patient Selection: Microdiscectomy for symptomatic lumbar disc herniations in patients with a preponderance of leg pain who have failed nonoperative treatment demonstrated a high success rate based on validated outcome measures (80% decrease in VAS leg pain score of greater than 2 points), patient satisfaction (85%), and return to work (84%). Patients should be encouraged to

return to their preinjury activities as soon as possible with no restrictions at 6 weeks. Overall, patients with sequestered lumbar disc herniations fared better than those with extruded herniations, although both groups consistently had better outcomes than patients with contained herniations. Patients with herniations at the L5–S1 level had significantly better outcomes than did those at the L4–L5 level. Lumbar disc herniation level and type should be considered in preoperative outcomes counseling. Smokers had a significantly lower return to work rate. In the carefully screened patient, lumbar microdiscectomy for symptomatic disc herniation results in an overall high success rate, patient satisfaction, and return to physically demanding activities. (Dewing, 2008)

Spinal Stenosis: For patients with lumbar spinal stenosis, standard posterior decompressive laminectomy alone (without discectomy) offers a significant advantage over nonsurgical treatment. Discectomy should be reserved for those conditions of disc herniation causing radiculopathy. (See Indications below.) Laminectomy may be used for spinal stenosis secondary to degenerative processes exhibiting ligamentary hypertrophy, facet hypertrophy, and disc protrusion, in addition to anatomical derangements of the spinal column such as tumor, trauma, etc. (Weinstein, 2008) (Katz, 2008) See also Laminectomy.

Recent Research: Four-year results for the Dartmouth Spine Patient Outcomes Research Trial (SPORT, n= 1244) indicated that patients who underwent standard open discectomy for a lumbar disc herniation achieved significantly greater improvement than nonoperatively treated patients (using recommended treatments – active physical therapy, home exercise instruction, and NSAIDs) in all primary and secondary outcomes except work status (78.4% for the surgery group compared with 84.4%). Although patients receiving surgery did better generally, all patients in the study improved. Consequently, for patients who don't want an operation no matter how bad their pain is, this study suggests that they will improve and they will not have complications (e.g., paralysis) from nonoperative treatment, but those patients whose leg pain is severe and is limiting their function, who meet the ODG criteria for discectomy, can do better with surgery than without surgery, and the risks are extremely low. (Weinstein, 2008) In most patients with low back pain, symptoms resolve without surgical intervention. (Madigan, 2009)

ODG Indications for Surgery -- Discectomy/laminectomy --

Required symptoms/findings; imaging studies; & conservative treatments below:

I. Symptoms/Findings which confirm presence of radiculopathy. Objective findings on examination need to be present. For unequivocal evidence of radiculopathy, see AMA Guides, 5th Edition, page 382–383. (Andersson, 2000) Straight leg raising test, crossed straight leg raising and reflex exams should correlate with symptoms and imaging.

Findings require one of the following:

A. L3 nerve root compression, requiring one of the following:

1. Severe unilateral quadriceps weakness/mild atrophy

2875 S. Decker Lake Drive Salt Lake City, UT 84119 / PO Box 25547 Salt Lake City, UT 84125-0547

(801) 261-3003 (800) 654-2422 FAX (801) 261-3189

www.mrioa.com A URAC & NCQA Accredited Company

2. Mild-to-moderate unilateral quadriceps weakness
3. Unilateral hip/thigh/knee pain

B. L4 nerve root compression, requiring one of the following:

1. Severe unilateral quadriceps/anterior tibialis weakness/mild atrophy
2. Mild-to-moderate unilateral quadriceps/anterior tibialis weakness
3. Unilateral hip/thigh/knee/medial pain

C. L5 nerve root compression, requiring one of the following:

1. Severe unilateral foot/toe/dorsiflexor weakness/mild atrophy
2. Mild-to-moderate foot/toe/dorsiflexor weakness
3. Unilateral hip/lateral thigh/knee pain

D. S1 nerve root compression, requiring one of the following:

1. Severe unilateral foot/toe/plantar flexor/hamstring weakness/atrophy
2. Moderate unilateral foot/toe/plantar flexor/hamstring weakness
3. Unilateral buttock/posterior thigh/calf pain

(EMGs are optional to obtain unequivocal evidence of radiculopathy but not necessary if radiculopathy is already clinically obvious.)

II. Imaging Studies, requiring one of the following, for concordance between radicular findings on radiologic evaluation and physical exam findings:

A. Nerve root compression (L3, L4, L5, or S1)

B. Lateral disc rupture

C. Lateral recess stenosis

Diagnostic imaging modalities, requiring one of the following:

1. MR imaging
2. CT scanning
3. Myelography
4. CT myelography & X-Ray

III. Conservative Treatments, requiring all of the following:

A. Activity modification (not bed rest) after patient education (\geq 2 months)

B. Drug therapy, requiring at least one of the following:

1. NSAID drug therapy
2. Other analgesic therapy
3. Muscle relaxants
4. Epidural Steroid Injection (ESI)

C. Support provider referral, requiring at least one of the following (in order of priority):

1. Physical therapy (teach home exercise/stretching)
2. Manual therapy (chiropractor or massage therapist)
3. Psychological screening that could affect surgical outcome
4. Back school (Fisher, 2004)