

Notice of Independent Review Decision

**November 20, 2013**

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:**

Medical Necessity: Laminotomy (Hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar

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

The physician performing this review is Board Certified, American Board of Orthopedic Surgery. The physician has been in practice since 1998 and is licensed in Texas, Oklahoma, Minnesota and South Dakota.

**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 medical necessity exists for each of the health care services in dispute.

*Upon independent review, the physician finds that the previous adverse determination should be upheld.*

**INFORMATION PROVIDED TO THE IRO FOR REVIEW:**

Records Received: 26 page fax 10/31/13 Department of Insurance IRO request, 72 pages of documents received via fax on 11/1/13 URA response to disputed services including administrative and medical. Provider response to disputed services including administrative and medical. Dates of documents range from 12/18/08 to 10/31/13.

**PATIENT CLINICAL HISTORY [SUMMARY]:**

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reportedly has complaints of bilateral back pain, hips, and right greater than left leg pain with numbness in the toes, according to the medical records. She had had previous laminectomy surgery in 2001, which relieved the back pain and right leg pain that the patient was having at that time. Over time, she developed worsening symptoms described above. The records would indicate that she has done physical therapy, epidural steroid injections, nerve blocks, TENS units, medications, and other conservative measures. Her symptoms appear to be worse with standing upright but relieved with sitting or leaning over a shopping cart.

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

The physician's notes make it apparent that the proposed procedure includes percutaneous endoscopic laser discectomy. Under *ODG* guidelines, these are specifically not recommended. Additionally, there is no evidence that the patient has a disk herniation but rather has spinal stenosis, and discectomy would not be considered medically necessary under *ODG* guidelines.

### **ODG -TWC**

*ODG Treatment*

*Integrated Treatment/Disability Duration Guidelines*

#### **Low Back - Lumbar & Thoracic (Acute & Chronic)**

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. ( <a href="#">Gibson-Cochrane, 2000</a> ) ( <a href="#">Malter, 1996</a> ) ( <a href="#">Stevens, 1997</a> ) ( <a href="#">Stevenson, 1995</a> ) ( <a href="#">BlueCross BlueShield, 2002</a> ) ( <a href="#">Buttermann, 2004</a> ) For unequivocal evidence of radiculopathy, see AMA Guides. ( <a href="#">Andersson, 2000</a> ) Standard discectomy and microdiscectomy are of similar efficacy in treatment of herniated disc. ( <a href="#">Bigos, 1999</a> ) 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. ( <a href="#">Osterman, 2006</a> ) 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. ( <a href="#">Weinstein, 2006</a> ) ( <a href="#">Weinstein2, 2006</a> ) 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. ( <a href="#">Malmivaara, 2007</a> ) Patients undergoing lumbar discectomy are generally satisfied with the surgery, but only half are satisfied with preoperative patient information. ( <a href="#">Ronnberg, 2007</a> ) If patients are pain free, there appears to be no contraindication to their returning to
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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 nonoperative 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

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overall high success rate, patient satisfaction, and return to physically demanding activities. ([Dewing, 2008](#)) Workers' comp back surgery patients are at greater risk for poor lumbar discectomy outcomes than noncompensation patients. ([DeBerard, 2008](#)) In workers' comp it is recommended to screen for presurgical biopsychosocial variables because they are important predictors of discectomy outcomes. ([DeBerard, 2011](#))

*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](#)) A comparison of surgical and nonoperative outcomes between degenerative spondylolisthesis and spinal stenosis patients from the SPORT trial found that fusion was most appropriate for spondylolisthesis, with or without listhesis, and decompressive laminectomy alone most appropriate for spinal stenosis. ([Pearson, 2010](#)) 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. ([Weinstein2, 2008](#)) In most patients with low back pain, symptoms resolve without surgical intervention. ([Madigan, 2009](#)) This study showed that surgery for disc herniation was not as successful as total hip replacement but was comparable to total knee replacement in success. Pain was reduced to within 60% of normal levels, function improved to 65% normal, and quality of life was improved by about 50%. The study compared the gains in quality of life achieved by total hip replacement, total knee replacement, surgery for spinal stenosis, disc excision for lumbar disc herniation, and arthrodesis for chronic low back pain. ([Hansson, 2008](#)) For radiculopathy with herniated lumbar disc, there is good evidence that standard open discectomy and microdiscectomy are moderately superior to nonsurgical therapy for improvement in pain and function through 2 to 3 months, but patients on average experience improvement either with or without surgery, and benefits associated with surgery decrease with long-term follow-up. ([Chou, 2009](#)) According to a new study, surgery provides better results than non-surgical treatment for most patients with back pain related to a herniated disk, but not for those receiving workers' compensation. ([Atlas, 2010](#)) Use of appropriateness criteria to guide treatment decisions for each clinical situation involving patients with low back pain and/or sciatica, with criteria based upon literature evidence, along with shared decision-making, was observed in one prospective study to improve outcomes in low back surgery. ([Danon-Hersch, 2010](#)) An updated SPORT trial analysis confirmed that outcomes of lumbar discectomy were better for patients who have symptoms of a herniated lumbar disc for six months or less prior to treatment. Increased symptom duration was related to worse outcomes following both operative and nonoperative treatment, but the relative increased benefit of surgery compared with nonoperative treatment was not dependent on the duration. ([Rihn,](#)

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	<p><a href="#">2011</a>) Comparative effectiveness evidence from SPORT shows good value for standard open discectomy after an imaging-confirmed diagnosis of intervertebral disc herniation [as recommended in ODG], compared with nonoperative care over 4 years. (<a href="#">Tosteson, 2011</a>)</p> <p><b>ODG Indications for Surgery™ -- Discectomy/laminectomy --</b>          Required symptoms/findings; imaging studies; &amp; conservative treatments below:</p> <p>I. <u>Symptoms/Findings</u> which confirm presence of radiculopathy. Objective findings on examination need to be present. Straight leg raising test, crossed straight leg raising and reflex exams should correlate with symptoms and imaging.          Findings require ONE of the following:</p> <ul style="list-style-type: none"> <li>A. L3 nerve root compression, requiring ONE of the following:             <ul style="list-style-type: none"> <li>1. Severe unilateral quadriceps weakness/mild atrophy</li> <li>2. Mild-to-moderate unilateral quadriceps weakness</li> <li>3. Unilateral hip/thigh/knee pain</li> </ul> </li> <li>B. L4 nerve root compression, requiring ONE of the following:             <ul style="list-style-type: none"> <li>1. Severe unilateral quadriceps/anterior tibialis weakness/mild atrophy</li> <li>2. Mild-to-moderate unilateral quadriceps/anterior tibialis weakness</li> <li>3. Unilateral hip/thigh/knee/medial pain</li> </ul> </li> <li>C. L5 nerve root compression, requiring ONE of the following:             <ul style="list-style-type: none"> <li>1. Severe unilateral foot/toe/dorsiflexor weakness/mild atrophy</li> <li>2. Mild-to-moderate foot/toe/dorsiflexor weakness</li> <li>3. Unilateral hip/lateral thigh/knee pain</li> </ul> </li> <li>D. S1 nerve root compression, requiring ONE of the following:             <ul style="list-style-type: none"> <li>1. Severe unilateral foot/toe/plantar flexor/hamstring weakness/atrophy</li> <li>2. Moderate unilateral foot/toe/plantar flexor/hamstring weakness</li> <li>3. Unilateral buttock/posterior thigh/calf pain</li> </ul> </li> </ul> <p>(<a href="#">EMGs</a> are optional to obtain unequivocal evidence of radiculopathy but not necessary if radiculopathy is already clinically obvious.)</p> <p>II. <u>Imaging Studies</u>, requiring ONE of the following, for concordance between radicular findings on radiologic evaluation and physical exam findings:</p> <ul style="list-style-type: none"> <li>A. Nerve root compression (L3, L4, L5, or S1)</li> <li>B. Lateral disc rupture</li> <li>C. Lateral recess stenosis</li> </ul> <p>Diagnostic imaging modalities, requiring ONE of the following:</p> <ul style="list-style-type: none"> <li>1. <a href="#">MR</a> imaging</li> <li>2. <a href="#">CT</a> scanning</li> <li>3. <a href="#">Myelography</a></li> <li>4. <a href="#">CT myelography</a> &amp; X-Ray</li> </ul> <p>III. <u>Conservative Treatments</u>, requiring ALL of the following:</p> <ul style="list-style-type: none"> <li>A. <a href="#">Activity modification</a> (not bed rest) after <a href="#">patient education</a> (&gt;= 2 months)</li> <li>B. Drug therapy, requiring at least ONE of the following:             <ul style="list-style-type: none"> <li>1. <a href="#">NSAID</a> drug therapy</li> <li>2. Other analgesic therapy</li> <li>3. <a href="#">Muscle relaxants</a></li> <li>4. <a href="#">Epidural Steroid Injection</a> (ESI)</li> </ul> </li> <li>C. Support provider referral, requiring at least ONE of the following (in order of priority):             <ul style="list-style-type: none"> <li>1. <a href="#">Physical therapy</a> (teach home exercise/stretching)</li> <li>2. <a href="#">Manual therapy</a> (chiropractor or massage therapist)                 <ul style="list-style-type: none"> <li>3. <a href="#">Psychological screening</a> that could affect surgical outcome</li> </ul> </li> <li>4. <a href="#">Back school</a> (<a href="#">Fisher, 2004</a>)</li> </ul> </li> </ul> <p>For average hospital LOS after criteria are met, see <a href="#">Hospital length of stay</a> (LOS).</p>
Laminectomy/ laminotomy	Recommended for lumbar spinal stenosis. For patients with lumbar spinal stenosis, surgery (standard posterior decompressive laminectomy alone, without discectomy) offered a significant advantage over nonsurgical treatment in terms of pain relief and

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	<p>functional improvement that was maintained at 2 years of follow-up, according to a new SPORT study. Discectomy should be reserved for those conditions of disc herniation causing radiculopathy. 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. (<a href="#">Weinstein, 2008</a>) (<a href="#">Katz, 2008</a>) This study showed that surgery for spinal stenosis and for disc herniation were not as successful as total hip replacement but were comparable to total knee replacement in their success. Pain was reduced to within 60% of normal levels, function improved to 65% normal, and quality of life was improved by about 50%. The study compared the gains in quality of life achieved by total hip replacement, total knee replacement, surgery for spinal stenosis, disc excision for lumbar disc herniation, and arthrodesis for chronic low back pain. (<a href="#">Hansson, 2008</a>) A comparison of surgical and nonoperative outcomes between degenerative spondylolisthesis and spinal stenosis patients from the SPORT trial found that fusion was most appropriate for spondylolisthesis, with or without listhesis, and decompressive laminectomy alone most appropriate for spinal stenosis. (<a href="#">Pearson, 2010</a>) In patients with spinal stenosis, those treated surgically with standard posterior decompressive laminectomy showed significantly greater improvement in pain, function, satisfaction, and self-rated progress over 4 years compared to patients treated nonoperatively, and the results in both groups were stable between 2 and 4 years. (<a href="#">Weinstein, 2010</a>) Comparative effectiveness evidence from SPORT shows good value for standard posterior laminectomy after an imaging-confirmed diagnosis of spinal stenosis [as recommended in ODG], compared with nonoperative care over 4 years. (<a href="#">Tosteson, 2011</a>) Decompressive surgery (laminectomy) is more effective for lumbar spinal stenosis than land based exercise, but given the risks of surgery, a self-management program with exercise prior to consideration of surgery is also supported. (<a href="#">Jarrett, 2012</a>) This study indicates that in patients with a primary diagnosis of lumbar spinal stenosis (LSS), the rate of fusions and the use of implants has increased, and the decompression rate has decreased. Trends in the surgical management of stenosis have become increasingly important to study because more invasive procedures, including the addition of fusion and the use of implants, have been associated with greater use of resources and increased complications. (<a href="#">Bae, 2013</a>) Laminectomy is a surgical procedure for treating spinal stenosis by relieving pressure on the spinal cord. The lamina of the vertebra is removed or trimmed to widen the spinal canal and create more space for the spinal nerves. See also <a href="#">Discectomy/laminectomy</a> for surgical indications, with the exception of confirming the presence of radiculopathy. For average hospital LOS after criteria are met, see <a href="#">Hospital length of stay</a> (LOS).</p>
Percutaneous endoscopic laser discectomy (PELD)	<p>Not recommended. Given the extremely low level of evidence available for percutaneous endoscopic laser discectomy (PELD), it is recommended that this procedure be regarded as experimental at this time. (<a href="#">Boult, 2000</a>) (<a href="#">Stevens, 1997</a>) (<a href="#">BlueCross BlueShield, 2005</a>) The UK has concluded that the current evidence on the safety and efficacy of percutaneous endoscopic laser lumbar discectomy is inadequate, and the procedure should only be used in a research setting. (<a href="#">NICE, 2009</a>) The literature review was recently updated, with no change in conclusion. (<a href="#">NICE, 2010</a>) This systematic review found no benefit from minimally invasive endoscopic techniques, and a tendency for more safety in open procedures in lumbar disc surgery. (<a href="#">Payer, 2011</a>) See also <a href="#">AccuraScope procedure</a> (North American Spine).</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)