Proposed
Oklahoma Treatment Guidelines

January 10, 2012
### Diagnostic Imaging and Testing Procedures

A. One diagnostic imaging procedure may provide the same or distinctive information as does another procedure. Therefore, prudent choice of a single diagnostic procedure, a complement of procedures, or a sequence of procedures will optimize diagnostic accuracy, and maximize cost effectiveness (by avoiding redundancy), and minimize potential adverse effects to patients.

B. All imaging procedures have a degree of specificity and sensitivity for various diagnoses. No isolated imaging test can assure a correct diagnosis. Clinical information obtained by history taking and physical examination should form the basis for selecting an imaging procedure and interpreting its results.

C. Magnetic resonance imaging (MRI), myelography, or computed axial tomography (CT) scanning following myelography may provide useful information for many spinal disorders. When a diagnostic procedure, in conjunction with clinical information, provides sufficient information to establish an accurate diagnosis, the second diagnostic procedure will become a redundant procedure. At the same time, a subsequent diagnostic procedure can be a complementary diagnostic procedure if the first or preceding procedures, in conjunction with clinical information, cannot provide an accurate diagnosis. Usually, preference of a procedure over others depends upon availability, a patient’s tolerance, and/or the treating practitioner’s familiarity with the procedure.

### Cervical Imaging

Basic views are the anteroposterior (AP), lateral, right, and left obliques, swimmer’s, and odontoid. CT scans may be necessary to visualize C7 and odontoid in some patients. Lateral flexion and extension views are done to evaluate instability but may have a limited role in the acute setting. MRI or CT is indicated when spinal cord injury is suspected. The mechanism of injury and specific indications for the imaging should be listed on the request form to aid the radiologist and x-ray technician. Alert, non-intoxicated patients, who have isolated cervical complaints without palpable midline cervical tenderness, neurologic findings, or other acute or distracting injuries elsewhere in the body, may not require imaging. The following suggested indications are:

- History of significant trauma, especially high impact motor vehicle accident, rollover, ejection, bicycle, or recreational vehicle collision or fall from height greater than one meter;
- Age over 65 years;
- Suspicion of fracture, dislocation, instability, or neurologic deficit - Quebec Classification Grade III and IV;
- Unexplained or persistent cervical pain for at least 6 weeks or pain that is worse with rest;
- Localized pain, fever, constitutional symptoms, suspected tumor, history of cancer, or suspected systemic illness such as a rheumatic/rheumatoid disorder or endocrinopathy.

### CT Myelogram

CT Myelogram provides more detailed information about relationships between neural elements and surrounding anatomy and is appropriate in patients with multiple prior operations or tumorous conditions.

### Discography

(Not Recommended in ODG)

Cervical provocation discography is an image guided procedure in which a contrast agent is injected into the nucleus pulposus of the intervertebral disc. It is intended to both identify a painful cervical intervertebral disc and depict internal derangements (1-4). Over 50 years ago, Smith and Nichols (25, 26) emphasized pain reproduction as the principal feature of cervical discography. Cloward (6,7) described 2 types of pain during cervical disc stimulation: pain arising from internal disc disruption (IDD) (i.e., discogenic pain) and neurogenic pain that stems from a herniated disc fragment causing nerve root or dural irritation. Cloward (8) stimulated cervical discs mechanically and electrically to verify that the evoked pain originated in the discs themselves, rather than from irritation of adjacent structures. Schellhas et al (20) found that pressurizing normal discs failed to provoke pain in both symptomatic and asymptomatic patients, whereas
abnormal discs tended to produce concordant pain. Validity of cervical discography is shown by disc stimulation symptom mapping (11, 12) in pain patients and asymptomatic volunteers. Ohnmeiss et al (13) found a significant relationship between imaging and symptom provocation, with 86% of normal-looking discs either producing no pain (60%) or atypical pain (26%). Conversely, 78% of disrupted discs were clinically painful on injection. Viikari-Juntura et al (27) demonstrated that discography provides additional information regarding structural changes not available by any other non invasive and non radiation method of examination. In general, nuclear signal changes observed on MRI in cadavers tended to underestimate the degree of pathology appreciated with discography or gross examination. Parfenchuck and Janssen (19) found that while certain MRI patterns correlated well with positive and negative cervical discography responses, many other patterns revealed equivocal responses. They concluded that MRI is a useful adjunct to cervical discography, but that some MRI patterns should not be considered pathologic, and discography is necessary to identify a painful disc(s). Discography, whether alone or in combination with other diagnostic tests, should be described clearly. At a minimum, pain provocation, disc morphology, and a controlled disc evaluation should be reported. The study should report that the discography was performed in accordance with modern principles utilizing fluoroscopy, pain provocation, and a control disc.

Cervical Discography is indicated by the Oklahoma Treatment Guidelines:
- Neck pain of at least 3 months duration
- Failure of recommended conservative treatment including physical therapy
- Intended as a screen for surgery
- Briefed on potential risks and benefits from discography and surgery
- Use of control disc
- Use of Derby guidelines for description of discogram outcomes.
- Use of anxiolytic levels of sedation are permitted
- Discograms shall be performed by the following: board certified pain physician; board certified orthopedic surgeon with spine fellowship; board certified neurosurgeon, or anesthesiologist.

### Myelography

Myelography is the injection of radiopaque material into the spinal subarachnoid space, with x-rays then taken to define anatomy. It may be used as a diagnostic procedure to obtain accurate information of characteristics, location, and spatial relationships among soft tissue and bony structures. Myelography is an invasive procedure with complications including nausea, vomiting, headache, convolution, arachnoiditis, CSF leakage, allergic reactions, bleeding, and infection. Therefore, myelography should only be considered when CT and MRI are unavailable, for morbidly obese patients or those who have undergone multiple operations, and when other tests prove non-diagnostic. The use of small needles and a less toxic, water-soluble, nonionic contrast is recommended.

### Zygapophyseal (Facet) Blocks

Facet blocks are generally accepted but should not be considered diagnostic blocks for the purposes of determining the need for a rhizotomy (radiofrequency medial branch neurotomy), nor should they be done with medial branch blocks.

- These blocks should not be considered a definitive diagnostic tool. They may be used diagnostically to direct functional rehabilitation programs. A positive diagnostic block should result in a positive diagnostic functional benefit and a 50 percent reduction in pain appropriate for the anesthetic used as measured by accepted pain scales (such as a VAS). They then may be repeated per the therapeutic guidelines when they are accompanied by a functional rehabilitation program. (Refer to Therapeutic Spinal Injections.)
  - Time to Produce Effect: Less than 30 minutes for local anesthesia; corticosteroids up to 72 hours for most patients.
  - Frequency and Maximum Duration: Once per suspected level, limited to two levels.
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<td><strong>Therapeutic Procedures - Non-Operative/Active</strong></td>
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<td>A. Before initiation of any therapeutic procedure, the authorized treating provider, employer, and insurer must consider these important issues in the care of the injured worker.</td>
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<td>B. First, patients undergoing therapeutic procedure(s) should be released or returned to modified or restricted duty during their rehabilitation at the earliest appropriate time. Refer to “Return-to-Work” in this section for detailed information.</td>
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<td>C. Second, cessation and/or review of treatment modalities should be undertaken when no further significant subjective or objective improvement in the patient’s condition is noted. If patients are not responding within the recommended duration periods, alternative treatment interventions, further diagnostic studies or consultations should be pursued.</td>
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<td>D. Third, providers should provide and document education to the patient. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms</td>
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<td>E. Lastly, formal psychological or psychosocial evaluation should be performed on patients not making expected progress within 6 to 12 weeks following injury and whose subjective symptoms do not correlate with objective signs and tests.</td>
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<td>F. Home therapy is an important component of therapy and may include active and passive therapeutic procedures as well as other modalities to assist in alleviating pain, swelling, and abnormal muscle tone.</td>
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#### Cervical Epidural Steroid Injection

Epidural injections are recommended as treatment options for acute and chronic pain. They are considered a viable treatment for radicular, neurogenic and discogenic pain. In addition, epidural injections are shown to be beneficial in the acute and chronic setting in those with disc herniation with and without radiculitis, discogenic pain without disc herniation, spinal stenosis, and post surgery syndrome. Epidurals are recommended if they facilitate an improvement in functionality via activity, exercise or a decrease in pain. Use of fluoroscopy with contrast is a requirement for all spinal injections. Contrast-enhanced fluoroscopy improves the accuracy of medication delivery (1,2,3) Nonfluoroscopically-guided caudal epidural injections have a rate of inaccurate placement ranging from 25-53%. Nonfluoroscopically-guided cervical interlaminar epidural injections have a rate of inaccurate placement ranging from 17-30%. Accurate needle placement and success rates are affected by technician experience. (4,5,6,7,8) A “Series of Three” epidural steroid injections are no longer recommended. A “multiple injection regimen” should be distinguished from a “series of three” epidural series. In a multiple injection protocol, a patient is a candidate for additional injections when their pain recurs or becomes severe again and is provided on either patient demand or when the patient’s pain exceeded a preset level. The purpose is to control pain over a longer period of time in order to maximize the chance that a patient will respond to medical/interventional therapy (8). The “Series of Three” approach was based on non-fluoroscopically guided injections prior to the advent of fluoroscopic guidance, performed at predetermine intervals regardless of the patient’s symptoms.

Chronic Pain: Use of fluoroscopy has improved outcome and duration of steroid effect. Reiw et al. (10) reported a significant decrease in back pain associated with herniated disc or spinal stenosis in those who underwent a multiple injection regimen, with only 47% proceeding to surgery. Manchikanti et al (6) reported outcomes of a randomized, double-blind, controlled caudal injections for Post Lumbar Surgery measured numeric pain scores, Oswestry Disability Index, employment status and opioid intake at 3, 6, and 12 month intervals. This indicated a greater than 50% reduction in pain scores from baseline. Participants received on average, 4 injections per year.
### Discriminatory Pain: Numerous studies support chemical nociception leading to low back pain without overt evidence of disc herniation. Manchikanti et al (12) measured NRS, ODI, employment status and opiate use at 3, 6 and 12 months after treatment in patients treated with standard caudal ESI, on average, 3-4 times per year. When participants were separated into successful responses (>50%) and failed groups, significant differences in relief rates were seen. In summary, if the response is fair to poor with the first 2 procedures, patients will continue to exhibit a poor response with future treatments and no additional caudal ESIs are indicated. Those who respond to interventional treatment should continue to receive injections in order to improve function and activity levels.

### Criteria for use of ESIs:

**Note:** The purpose of ESI is to reduce pain and inflammation, thereby facilitating progress is more active treatment programs, reduction medication use and avoiding surgery, but this treatment alone offers no significant long-term functional benefit.

1. Radiculopathy must be documented. Objective findings on examination need to be present. For unequivocal evidence of radiculopathy, see AMA Guides, 5th Edition, page 382-383. (Andersson 2000) Radiculopathy must be corroborated by imagining studies and/or electrodiagnostic testing.
2. Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants).
3. Injections should be performed using fluoroscopy (live x-ray) and injection of contrast for guidance.
4. **Diagnostic Phase:** At the time of initial use of an ESI (formally referred to as the “diagnostic phase”) as initial injections indicate whether success will be obtained with this treatment intervention), a maximum of one to two injections should be performed. A repeat block is not recommended if there is inadequate response to the first block (<30% is a standard placebo response). A second block is also not indicated if the first block is accurately placed unless: (a) there is a question of the pain generator; (b) there was possibility of inaccurate placement; or (c) there is evidence of multilevel pathology. In these cases a different level or approach might be proposed. There should be an interval of at least one to two weeks between injections.
5. No more than two nerve root levels should be injected using transforaminal blocks.
6. No more than one interlaminar level should be injected at one session.
7. **Therapeutic phase:** If after the initial block/blocks are given (see “Diagnostic Phase” above) and found to produce pain relief of at least 50-70% pain relief for at least 6-8 weeks, additional blocks may be supported. This is generally referred to as the “therapeutic phase.” Indications for repeat blocks include acute exacerbation of pain, or new onset of radicular symptoms. The general consensus recommendation is for no more than 4 blocks per region per year. (CMS, 2004) (Boswell 2007)
8. Repeat injections should be based on the continued objective documented pain relief, decreased need for pain medications, and functional response.
9. Current research does not support a routine use of “series-of-three” injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections for the initial phase and rarely more than 4 for the therapeutic treatment.
10. It is currently not recommended to perform epidural blocks on the same day of treatment as facet blocks or sacroiliac blocks or lumbar sympathetic blocks or trigger points as this may lead to improper diagnosis.
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| **Radio Frequency (RF) Medial Branch Neurotomy/ Facet Rhizotomy (Not Recommended in ODG)** | - A procedure designed to denervate the facet joint by ablating the corresponding sensory medial branches. Continuous percutaneous radio-frequency is the method generally used.  
- There is good evidence to support this procedure in the cervical spine but benefits beyond one year are not yet established. Radio-frequency medial branch neurotomy is the procedure of choice over alcohol, phenol, or cryoablation. Precise positioning of the probe under fluoroscopic guidance is required since the maximum effective diameter of the device is a 5 x 8 millimeter oval. Permanent images should be recorded to verify placement of the device.  
- Indications. Those patients with proven, significant, facetogenic pain. This procedure is not recommended for patients with multiple pain generators or involvement of more than three medial branch nerves.  
- Individuals should have met the following indications: pain of well-documented facet origin, unresponsive to active and/or passive therapy, manual therapy, and in which a psychosocial screening has been performed (e.g., pain diagram, thorough psychosocial history, screening questionnaire). It is generally recommended that this procedure not be performed until three months of active therapy and manual therapy have been completed. All patients should continue appropriate exercise with functionally directed rehabilitation. Active treatment, which patients will have had prior to the procedure, will frequently require a repeat of the sessions previously ordered (Refer to Active Therapy).  
- All patients should have a successful response to a diagnostic medial nerve branch block and a separate comparative block. ISIS suggests controlled blocks using either placebo or anesthetics with varying lengths of activity (i.e., bupivacaine longer than lidocaine). To be a positive diagnostic block the patient should report a reduction of pain of 50 percent or greater from baseline for the length of time appropriate for the local anesthetic used. In almost all cases this will mean a reduction of pain to 1 or 2 on the VAS 10-point scale correlated with functional improvement. The patient should also identify activities of daily living (which may include measurements of range-of-motion) that are impeded by their pain and can be observed to document functional improvement in the clinical setting. Ideally, these activities should be assessed throughout the observation period for function. The observer should not be the physician who performed the procedure. It is suggested that this be recorded on a form similar to ISIS recommendations.  
- A separate comparative block may be performed on a different date to confirm the level of involvement. A comparative block uses anesthetics with varying lengths of activity.  
- Complications. Appropriate medical disclosures should be provided to the patient as deemed necessary by the treating physician.  
- Post-Procedure Therapy. Active therapy. Implementation of a gentle reconditioning program within the first postprocedure week is recommended, barring complications. Instruction and participation in a long-term home-based program of ROM, cervical, scapular, and thoracic strengthening, postural or neuromuscular re-education, endurance, and stability exercises should be accomplished over a period of four to ten visits post-procedure.  
- Requirements for repeat RF neurotomy (or additional level RF |
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| Procedure/topic | neurotomies). In some cases pain may recur [ISIS]. Successful rhizotomy usually provides from six to eighteen months of relief.  
• Before a repeat RF neurotomy is done, a confirmatory medial branch injection should be performed if the patient’s  
• pain pattern presents differently than in the initial evaluation. In occasional patients, additional levels of RF neurotomy may be necessary. The same indications and limitations apply. |
| Zygapophyseal (Facet) Injection (Not Recommended in ODG) | • A generally accepted intra-articular or pericapsular injection of local anesthetic and corticosteroid. There is conflicting evidence to support long-term therapeutic effect using facet injections. There is no justification for a combined facet and medial branch block.  
• Indications. Patients with pain 1) suspected to be facet in origin based on exam findings and 2) affecting activity; OR, patients who have refused a rhizotomy; OR, patients who have facet findings with a thoracic component. In these patients, facet injections may be occasionally useful in facilitating a functionally-directed rehabilitation program and to aid in identifying pain generators. Patients with recurrent pain should be evaluated with more definitive diagnostic injections, such as medial nerve branch injections, to determine the need for a rhizotomy. Because facet injections are not likely to produce long-term benefit by themselves and are not the most accurate diagnostic tool, they should not be performed at more than two levels.  
• Facet injections may be repeated if they result in increased documented functional benefit for at least 4 to 6 weeks and at least a 50 percent initial improvement in pain scales as measured by accepted pain scales (such as VAS).  
(a). Time to Produce Effect: Up to 30 minutes for local anesthetic; corticosteroid up to 72 hours.  
(b). Frequency: 1 injection per level with a diagnostic response. If the first injection does not provide a diagnostic response of temporary and sustained pain relief substantiated by accepted pain scales, (i.e., 50 percent pain reduction substantiated by tools such as VAS), and improvement in function, similar injections should not be repeated. At least four to six weeks of functional benefit should be obtained with each therapeutic injection.  
(c). Optimum Duration: two to three injections for each applicable joint per year. Not to exceed two joint levels.  
(d). Maximum Duration: four per level per year. Prior authorization must be obtained for injections beyond two levels. |
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| Cervical Collars (Not recommended in ODG) | • Soft Collars are well-tolerated by most patients but may not significantly restrict motion in any plane and are associated with delayed recovery. There is no evidence that their use promotes recovery from cervical sprain. In acute strain/sprain type injuries, use of cervical collars may prolong disability, limit early mobilization, promote psychological dependence, and limit self-activity. There is some evidence that patients encouraged to continue usual activity have less neck stiffness and headache than patients placed in cervical collars following motor vehicle crashes.  
• Rigid Collars, such as a Philadelphia Orthosis, are useful post-operative or in emergency situations. These collars restrict flexion and extension motion, and to a lesser degree, lateral bending and rotation. Duration of wear post surgery is dependent upon the surgeon and degree of cervical healing but is generally not used beyond eight weeks, per week or greater may be associated with rebound pain upon cessation. |
| Halo Devices                             | Halo Devices used in the treatment of cervical fracture, dislocation, and instability at the discretion of the treating surgeon. Refer to Halo Devices in the Operative Treatment section. |
| Poster Appliances                        | Poster Appliances such as the Miami brace, restrict flexion and extension motion to about the same degree as a Philadelphia collar, and to a greater degree, lateral bending and rotation. Not recommended in sprain or strain injuries. |
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<td><strong>Therapy - Active</strong></td>
<td>The following active therapies are widely used and accepted methods of care for a variety of work-related injuries. They are based on the philosophy that therapeutic exercise and/or activity are beneficial for restoring flexibility, strength, endurance, function, range-of-motion, and can alleviate discomfort. Active therapy requires an internal effort by the individual to complete a specific exercise or task. This form of therapy requires supervision from a therapist or medical provider such as verbal, visual, and/or tactile instruction(s). At times, the provider may help stabilize the patient or guide the movement pattern but the energy required to complete the task is predominately executed by the patient.</td>
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<td>Aquatic Therapy (Not Mentioned in ODG)</td>
<td>A well-accepted treatment which consists of the therapeutic use of aquatic immersion for therapeutic exercise to promote strengthening, core stabilization, endurance, range-of-motion, flexibility, body mechanics, and pain management. Aquatic therapy includes the implementation of active therapeutic procedures in a swimming or therapeutic pool. The water provides a buoyancy force that lessens the amount of force gravity applies to the body. The decreased gravity effect allows the patient to have a mechanical advantage and more likely have a successful trial of therapeutic exercise. The therapy may be indicated for individuals who: i. Cannot tolerate active land-based or full-weight bearing therapeutic procedures; ii. Require increased support in the presence of proprioceptive deficit; iii. Are at risk of compression fracture due to decreased bone density; iv. Have symptoms that are exacerbated in a dry environment; v. Would have a higher probability of meeting active therapeutic goals than in a dry environment; vi. The pool should be large enough to allow full extremity range-of-motion and fully erect posture. Aquatic vests, belts, and other devices may be used to provide stability, balance, buoyancy, and resistance. (a). Time to Produce Effect: four to five treatments (b). Frequency: three to five times per week (c). Optimum Duration: four to six weeks (d). Maximum Duration: eight weeks (e). A self-directed program is recommended after the supervised aquatics program has been established, or, alternatively a transition to a self-directed dry environment exercise program. (f). Functional Activities: are well-established interventions which involve the use of therapeutic activities to enhance mobility, body mechanics, employability, coordination, balance, and sensory motor integration. (i). Time to Produce Effect: four to five treatments (ii). Frequency: three to five times per week (iii). Optimum Duration: four to six weeks (iv). Maximum Duration: six weeks</td>
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<td>Transcutaneous Electrical Nerve Stimulation (TENS) (Not Recommended in ODG)</td>
<td>Transcutaneous Electrical Nerve a generally accepted treatment which should include at least one instructional session for proper application and use. Indications include muscle spasm, atrophy, and decreased circulation and pain control. Minimal TENS unit parameters should include pulse rate, pulse width and amplitude modulation. Consistent, measurable, functional improvement must be documented prior to the purchase of a home unit. • Time to Produce Effect: Immediate • Frequency: Variable</td>
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| Ultrasound (Including Phonophoresis) (Not Recommended in ODG) | Ultrasound (Including Phonophoresis) is an accepted treatment which uses sonic generators to deliver acoustic energy for therapeutic thermal and/or non-thermal soft tissue effects. Indications include scar tissue, adhesions, collagen fiber and muscle spasm, and the need to extend muscle tissue or accelerate the soft tissue healing. Ultrasound with electrical stimulation is concurrent delivery of electrical energy that involves dispersive electrode placement. Indications include muscle spasm, scar tissue, pain modulation, and muscle facilitation.

Phonophoresis is the transfer of medication through the use of sonic generators to the target tissue to control inflammation and pain. These topical medications include, but are not limited to, steroidal anti-inflammatory and anesthetics.

- Time to Produce Effect: 6 to 15 treatments
- Frequency: three times per week
- Optimum Duration: four to eight weeks
- Maximum Duration: eight weeks |
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| **Therapeutic Procedures - Operative** | A. All operative interventions should be based on a positive correlation with clinical findings, the natural history of the disease, the clinical course, and diagnostic tests. A comprehensive assimilation of these factors should have led to a specific diagnosis with positive identification of the pathologic condition(s). It is imperative for the clinician to rule out non-physiologic modifiers of pain presentation, or non-operative conditions mimicking radiculopathy or instability (peripheral compressive neuropathy, chronic soft tissue injuries, and psychological conditions), prior to consideration of elective surgical intervention. Early intervention may be required in acute incapacitating pain or in the presence of progressive neurological deficits. Patients who are not candidates for or refuse surgical treatment should be treated with non-operative therapy as indicated.  
B. Operative treatment is indicated when the natural history of surgically treated lesions is better than the natural history for non-operatively treated lesions. All patients being considered for surgical intervention should first undergo a comprehensive neuromusculoskeletal examination to identify mechanical pain generators that may respond to non-surgical techniques, or may be refractory to surgical intervention.  
C. In situations requiring the possible need for re-surgery, a second opinion may be necessary. Psychological evaluation is strongly encouraged when surgery is being performed for isolated axial pain to determine if the patient will likely benefit from the treatment.  
D. Interdisciplinary interventions should be strongly considered post-operatively in patients not making functional progress within expected time frames (Refer to Interdisciplinary Programs).  
E. Return to work activity restrictions should be specific according to the recommendations in Return to Work. Most cervical non-fusion surgical patients can return to a limited level of duty between three to six weeks. |
| Acute fractures and dislocations | Decisions regarding the need for surgery in acute traumatic injury will depend on the specific injury type and possibility of long-term neurologic damage. Acute disc herniations may occur in the presence of traumatic injury. |
| Disc Prosthesis (Not Recommended in ODG) | **(Excerpted from Blue Cross-Blue Shield Guidelines)**  
When conservative treatment of spinal degenerative disc disease fails, a common surgical approach is spinal fusion. However, the outcomes of spinal fusion have been controversial. Spinal fusion also alters the biomechanics of the spine, potentially leading to premature disc degeneration at adjacent levels, a particular concern for younger patients. During the past 30 years, a variety of artificial intervertebral discs have been investigated as an alternative approach to fusion. This approach, also referred to as total disc replacement or spinal arthroplasty, is intended to maintain motion at the operative level once the damaged disc has been removed and to maintain the normal biomechanics of the adjacent vertebrae. Potential candidates for artificial disc replacement have chronic symptoms attributed to degenerative disc disease, and lack of improvement with non-operative treatment. Contraindications for the procedure include multilevel disease, spinal stenosis, spondylolisthesis and previous major spinal surgery.  
The major potential advantage of a prosthetic intervertebral disc over current therapies for degenerated discs (such as spinal fusion or discectomy) is that the prosthetic intervertebral disc is intended to restore or preserve the natural biomechanics of the intervertebral segment and to reduce further degeneration of adjacent levels. |
| **CERVICAL DISC REPLACEMENT** (Excerpted from Blue Cross-Blue Shield Guidelines) | The cervical spine (neck) is composed of vertebral bodies (the boney building blocks of the spine) and intervertebral discs, which act as combination universal joints and shock absorbers between the vertebrae. |
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<td>With time, the discs can become worn out and cause pain and/or other symptoms, these symptoms usually include any combination of arm, shoulder, or neck pain. Patients may also feel numbness or tingling sensations in their fingers, hands, or arms. Certain muscles may feel weak. Most patients with these types of symptoms do not need surgery. They typically can improve with conservative (non-surgical) treatment, which may include anti-inflammatory medications, physical therapy, or cold/heat therapy. Over 90% of patients will experience pain relief with these modalities within four to six weeks.</td>
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In July 2007 the Food and Drug Administration approved the Prestige Cervical Disc for the treatment of single-level cervical disc disease (C3-C7). The FDA approval was based on the findings of a study by Mummaneni et al that reported the results of a prospective randomized multi-center study in which the results of cervical disc arthroplasty were compared with anterior cervical discectomy and interbody fusion (ACDF) in patients treated for symptomatic single-level cervical degenerative disc disease (DDD). A total of 541 patients with single-level cervical DDD and radiculopathy were enrolled at 32 sites and randomly assigned to one of two treatment groups; 276 patients in the investigational group underwent anterior cervical discectomy, decompression and arthroplasty with the Prestige ST Cervical Disc System; and 265 patients in the control group underwent decompressive ACDF. A total of 80% of the arthroplasty-treated patients (223 of 276) and 75% of the control patients (198 of 265) completed clinical and radiological followup examinations at routine intervals for two years after surgery. Analysis of all of the currently available postoperative 12- and 24-month data indicated a two-point greater improvement in the neck disability index score in the investigational group than in the control group. The arthroplasty group also had a statistically significantly higher rate of neurological success (p=0.0277) and supplemental fixation (p=0.0031). The mean improvement in the 36-item Short Form Survey Physical Component Summary scores was greater in the investigational group at 12 and 24 months, as was relief of neck pain. The patients in the investigational group returned to work 16 days sooner than those in the control group, and the rate of adjacent-segment reoperation was significantly lower in the investigational group as well (p=0.0492). The cervical disc implant maintained segmental sagittal angular motion averaging more than seven degrees. In the investigational group, there were no cases of implant failure or migration. The authors concluded that the Prestige Cervical Disc maintained physiologic segmental motion at 24 months after implantation and was associated with improved neurological success, improved clinical outcomes, and a reduced rate of secondary surgeries compared with ACDF.

In another prospective, randomized, controlled, double-blinded study, Sekhon and colleagues compared postoperative imaging characteristics of the four currently available cervical arthroplasty devices (Bryan, Prodisc-C, Prestige LP, and PCM) at the level of implantation and at adjacent levels. Preoperative and postoperative MRI scans of 20 patients who had undergone cervical arthroplasty were evaluated for imaging quality. Five cases of each of the four devices were analyzed by six “blinded” spinal surgeons that scored twice sagittal and axial T2-weighted images using the Jarvik 4-point scale. Statistical analysis was performed comparing quality before surgery and after disc implantation at the operated and adjacent levels, and between implant types. Moderate intra-observer and inter-observer reliability was noted. Preoperative images of patients in all implant groups had high-quality images at operative and adjacent levels.
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<td>The Bryan and Prestige LP devices allowed satisfactory visualization of the canal, exit foramina, cord, and adjacent levels of arthroplasty. Visualization was significantly impaired in all PCM and ProDisc-C cases at the operated level in both the spinal canal and neural foramina. At the adjacent levels, image quality was statistically poorer in the PCM and ProDisc-C than those of the Prestige LP or Bryan. The authors concluded that postoperative visualization of neural structures and adjacent levels after cervical arthroplasty is variable among currently available devices. Devices containing non-titanium metals (cobalt-chrome-molybdenum alloys in the PCM and ProDisc-C) prevent postoperative assessment with magnetic resonance imaging at the surgical and adjacent levels. On the other hand, titanium devices, with or without polyethylene (Bryan disc or Prestige LP), allow for satisfactory monitoring of the adjacent and operated levels. This information is crucial for any surgeon who wishes to assess adequacy of neural decompression, and when monitoring of adjacent levels is desired.</td>
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Hannibel et al examined whether there is clinical difference between the one-level ProDisc patients versus the two-level ProDisc patients at a minimum of two-year followup. Patients were part of the FDA clinical trial for the ProDisc II versus circumferential fusion study at a single institution. These investigators identified 27 patients who received ProDisc at one level and 32 who received it at two levels with at least a two-year followup, for a total of 59 patients. Unpaired tests were performed on the mean results of VAS, ODI, SF-36 Healthy Survey Physical Component Summary, and satisfaction using 10-cm line VAS to determine a clinical difference, if any, between the two populations. While patients receiving ProDisc at two levels scored marginally lower in all evaluation indexes, score differences in each category were also found to hold no statistical significance. The authors concluded that this study was unable to identify a statistically significant difference in outcome between one and two-level ProDisc arthroplasty patients in a cohort from a single center. They stated that the quality of clinical effectiveness between one and two-level ProDisc has yet to be determined. |

### 2010 Update Cervical Disc Replacement

Murrey et al reported two-year results from the pivotal FDA randomized noninferiority trial to determine the safety and efficacy of ProDisc-C in comparison with ACDF. In this trial, 103 patients received the ProDisc-C implant and 106 were treated with fusion; participations were blinded to intervention until following surgery. Followup between six weeks and two years was reported to be 85% in the summary of safety and effectiveness data presented to the FDA. Reasons for the loss to followup were not described but appear to have included two patients in the ProDisc-C group who had the implant removed and five patients in the fusion group who had undergone additional surgical procedures to modify the original implant. Non-inferiority was achieved for the FDA-defined combined endpoint of neurologic examination, neck disability index, adverse events, and device success, with 72% of ProDisc-C and 68% of fusion patients achieving success in all four component endpoints. Clinical outcomes at 24 months’ followup were reported to be similar in the ProDisc-C and fusion groups for the following components: neurological success (91% vs. 88% respectively), neck disability index (21.4 vs 20.5 points), reduction in pain scores (e.g., 46mm vs 43mm reduction in neck pain on a visual analogue scale), and patient satisfaction (83mm vs. 80mm).
## Procedure Summary – Cervical Spine Injury Treatment Guidelines

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<td><strong>Heller et al</strong> reported two-year followup results from the FDA Investigational Device Exemption (IDE) trial for the Bryan disc. The trial employed inclusion/exclusion criteria for composite outcome identical to the ProDisc-C trial. A total of 582 patients were randomized to the Bryan disc (n=290) or ACDF (n=292). Thirty-seven patients declined surgery in the ACDF group. Twelve patients crossed over from the AIDA to ACDF, one crossed over from ACDF to AIDA, and two patients were excluded fro ACDF due to protocol violations, leaving 242 patients who underwent AIDA and 223 who underwent ACDF. In the AIDA and ACDF arms, mean age (44.4 and 44.7 years), sex (45.5% and 51.1% men) and Neck Disability Index (NDI) scores (51.4 and 50.2) were similar. All but one patient who underwent AIDA and three patients in the ACDF arm had documented neurological abnormalities. After two years followup, data were available for 230 (95%) patients from the AIDA group and 194 (87%) who underwent ACDF. The overall success outcome was achieved more than after AIDA (82.6% vs. 72.7%), with a mean 4.1 point greater improvement in the NDI scores. As measured by the composite endpoint, AIDA was superior to ACDF. At 24 months, neck pain scores were lower following AIDA, while other secondary outcomes were similar. Adverse event rates were similar in the two arms – 1.7% in AIDA and 3.2% in ACDF arms, requiring revision.</td>
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<td><strong>Chang et al</strong> reported two-year followup from a randomized controlled trial of the Bryan disc versus ACDF with autograft in 65 patients with two-level disc disease. One patient from the arthroplasty group and two patients from the ACDF group were lost to followup. Neck pain and arm pain measured by visual analog scores (VAS) tended to be better in the Bryan group (1.8 and 1.9, respectively) than the ACDF group at 12-month followup (2.5 and 2.4, respectively). The NDI and SF-36 physical component scores were also significantly better in the Bryan group at both 12- and 24-month followup. These results support the short-term safety of the Bryan disc in two-level disc disease; longer-term results are needed to evaluate the safety and efficacy of this device in comparison with ACDF for two-level disc disease.</td>
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<td>In 2010, four-year followup was reported from one site (47 patients; 21 Bryan and 26 ACDF) that participated in the Bryan IDE trial described above. The preoperative NDI scores were 51.1 for the Bryan and 51.5 for the ACDF groups. Followup in the patients who underwent arthroplasty was 100% at two years and 86% at four years. Followup in the ACDF group was 96% at two years and 77% at four years. At two years, postoperative NDI scores were 12.4 for the Bryan group and 19 for the ACDF group. At four years, NDI scores were 10 in the Bryan group and 15.9 in the ACDF group (reported as 16.7 in the abstract). The NDI success (&gt;15 points improvement) at 48 months was 93.3% for Bryan arthroplasty and 82.4% for the ACDF group. Similar results were obtained for neck pain and arm pain. SF-36 scores were not different between the groups. Six patients required reoperation from the Index procedures; six procedures were performed in the control group (three for adjacent level disease, one for remote level disease, and two for pseudoarthrosis) compared with one in the arthroplasty group (adjacent level disease).</td>
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| **Goffin et al** reported four- and six-year followup from phase I and phase II trials of the Bryan disc in 2010. The total potential patient population for long-term followup was 98 patients (89 with one level and nine with two-level); 59 of the patients were at least six years postoperative. Although four patients from the phase I study declined to participate in the extended
follow up. Although four patients from the phase I study declined to participate in the extended followup study, their results were included in the safety data. Mean neck pain at four and six years postoperatively was 2.2 and 2.0, respectively. Mean arm pain at four and six years was 2.4 and 2.3, respectively. Six patients experienced events that were believed to be related to the device, including minor device migration, device removal, hoarseness and vocal cord paralysis, while three of the six cases involved pain or neurological symptoms. The prosthesis was removed from one patient at six years after the index surgery because of progressive spinal cord compression due to recurrent posterior osteophyte formation. About 90% of patients were classified as having excellent or good outcomes at four and six years. The success rate estimated by Kaplan-Meier analysis was 94% at seven years following surgery.

There is limited published information about the impact of cervical arthroplasty devices on clinical outcomes over the long term (five or more years). While the early results are encouraging, given the natural history of the disease, two-year followup (limited evidence on four-year followup) is inadequate to evaluate long-term results, in particular any effect of the device on adjacent-level disc degeneration, device durability, adverse events and revisability. As noted by others, “at least five years of followup will be needed to assess the long-term functionality of the prosthesis and protective influence on adjacent levels.” Longer term results are expected, given the FDA requirements for a seven-year post approval clinical study of the safety and function of the device, and a five-year enhanced surveillance study of the disc to more fully characterize adverse events in a broader patient population.

The Prestige ST Cervical Disc® (Medtronic) received U.S. Food and Drug Administration (FDA) premarket application (PMA) approval as a Class III device on July 16, 2007. The FDA approval states the Prestige ST Cervical Device is indicated in skeletally mature patients for reconstruction of the disc from C3 to C7 following single-level discectomy. The device is implanted via an open anterior approach. Intractable radiculopathy and/or myelopathy should be present, with at least one of the following items producing symptomatic nerve root and/or spinal cord compression as documented by patient history (e.g., pain (neck and/or arm pain), functional deficit, and/or neurological deficit) and radiographic studies (e.g., computed tomography, magnetic resonance imaging, x-rays): herniated disc and/or osteophyte formation. The FDA has required the Prestige disc manufacturer to conduct a seven-year post-approval clinical study of the safety and function of the device, and a five-year enhanced surveillance study of the disc to more fully characterize adverse events in a broader patient population.

Another disc arthroplasty product, the ProDisc-C® (Synthes Spine) received FDA PMA approval in December 2007. As with the Prestige ST Cervical Disc, the FDA approval of ProDisc-C is conditional on seven-year followup of the 209 subjects included in the noninferiority trial, seven-year followup on 99 continued access subjects, and a five-year enhanced surveillance study to more fully characterize adverse events when the device is used under general conditions of use. The post-approval study reports are to be delivered to the FDA annually.

The Bryan® Cervical Disc (Medtronic Sofamor Danek) consists of two titanium-alloy shells encasing a polyurethane nucleus, and has been available outside of the United States since 2002.
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<td>was approved by the FDA in May 2009 and is designed to replicate normal, physiologic motion of the cervical spine in patients suffering from degenerative disc disease (DDD) in the neck. Degenerative disc disease is defined as any combination of the following: disc herniation with radiculopathy, spondylotic radiculopathy, disc herniation with myelopathy, or spondylotic myelopathy resulting in impaired function and at least one clinical neurological sign associated with the cervical level to be treated, and necessitating surgery as demonstrated using computed tomography (CT), myelography and CT, and/or magnetic resonance imaging. Patients receiving the Bryan cervical disc should have failed at least six weeks of nonoperative treatment prior to implantation of the Bryan cervical disc.</td>
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### Cervical Disc Replacement Recommendations:

- Single level to be reconstructed following cervical discectomy within C3-C7 region.
- Intractable radiculopathy and/or myelopathy due to herniated disc or osteophyte formation
- Lack of improvement with 6 weeks of conservative care
- Symptomatic nerve root and/or spinal cord decompression are documented by all of the following
  - Neck and/or arm pain
  - Functional and/or neurologic deficit
  - Radiographic imaging (e.g., computed tomography (CT), magnetic resonance imaging (MRI), x-rays, etc).

Currently only three artificial discs are approved by the FDA:
- Prestige ST Cervical Disc (Medtronic)
- ProDisc-C (Synthes Spine)
- Bryan Cervical Disc (Medtronic Sofamor Danek)

### Cervical Laminectomy with or without Foraminotomy or Fusion

- Description. Surgical removal of the posterior portion of a vertebrae in order to gain access to the spinal cord
- or nerve roots with or without stabilization fusion. /instrumentation.
- Complications. May include perineural fibrosis, kyphosis in fractures without fusion or with failed fusion, nerve injury, post surgical instability (with foraminotomies), CSF leak, infection, in-hospital mortality, non-union of fusion, donor site pain (autograft only).
- Surgical Indications. Neural compression.
- Operative Treatment. Laminotomy, partial discectomy, and nerve root decompression.
- Post-Operative Therapy. Cervical bracing may be appropriate (usually 6 to 12 weeks with fusion). Home programs with instruction in ADLs, sitting, posture, and a daily walking program should be an early part of the rehabilitation process. Referral to a formal rehabilitation program with emphasis on cervical, scapular, and thoracic strengthening and restoration
- of ROM is appropriate for most patients once the cervical spine is deemed stable and without complication. The goals of the therapy program should include instruction in a long-term home-based exercise program. (Refer to Active Therapy).

### Cervical Laminoplasty

- Description. Technique that increases anterior or posterior dimensions of the spinal canal while leaving posterior elements partially intact. It
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<td>may be performed with or without the use of a microscope.</td>
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<td>• Complications. Loss of cervical motion, especially extension.</td>
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<td>• Surgical Indications. Multi-level disease: cervical spinal stenosis or spondylitic myelopathy. Not indicated in cervical kyphosis.</td>
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<td></td>
<td>• Operative Treatment. Posterior approach, with or without instrumentation.</td>
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<td></td>
<td>• Post-Operative Therapy. May include 4 to 12 weeks of cervical bracing. Home programs with instruction in ADLs, sitting, posture, and daily walking program should be an early part of the rehabilitation process. Referral to a formal rehabilitation program with emphasis on cervical, scapular, and thoracic strengthening and restoration of ROM is appropriate once the cervical spine is stable and without complication. Active treatment which patients should have had prior to surgery will frequently require a repeat of the sessions previously ordered. The goals of the therapy program should include instruction in a long-term, home-based exercise program. (Refer to Active Therapy).</td>
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<tr>
<td>Disc herniation and other cervical conditions</td>
<td>Operative treatment is indicated only when the natural history of an operatively treatable problem is better than the natural history of the problem without operative treatment. All patients being considered for surgical intervention should undergo a comprehensive neuromuscular examination to identify pain generators that may respond to nonsurgical techniques or may be refractory to surgical intervention. Timely decision making for operative intervention is critical to avoid deconditioning, and increased disability of the cervical spine.</td>
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### Plate Fixation

**Pertinent ICD-9 Diagnostic Codes:** 722.4, 723.1, and 723.4

Nearly 50 years ago, cervical plates were invented for surgery to treat traumatic instability of the spine (Böhler 1967). In 1986, an improved plate design was introduced that led to more widespread use (Morscher 1986). In the subsequent 25 years, enhancements in cervical plate designs have evolved and the devices are routinely used with ACDF.

A number of studies demonstrate that ACDF with anterior plating provides clinical benefit for many common conditions of the cervical spine. Conversely, some studies show no clinical benefit over ACDF without plates; however, some authors have highlighted other advantages, key to a workers’ compensation population such as earlier return to work. Highlights from several systematic reviews and articles follow.

- In a meta analysis, Fraser (2007) reported that plates significantly increased the fusion rate regardless of number of levels (i.e., includes single level procedures).
- Fehlings (2009) reported that with multiple level anterior decompressions, there is compelling evidence that ACDF with plating is superior to anterior cervical discectomy (ACD). The addition of plating improves arm pain compared with ACDF alone and reduces the risk of pseudarthrosis. However, Fehlings noted that no convincing evidence suggests that the addition of instrumentation results in long-term improvements in outcome.
- In an evidence-based review, the North American Spine Society (2010) concluded that both ACDF with or without a plate are suggested as comparable treatment strategies, producing similar clinical outcomes and fusion rates, in the treatment of single level cervical radiculopathy from degenerative disorders. The addition of a cervical plate is suggested to improve sagittal alignment following ACDF. While plate stabilization may be indicated in...
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<tr>
<td>Procedure/topic</td>
<td>some patients undergoing multilevel ACDF, there is insufficient evidence that this practice results in significant improvement in clinical outcomes for degenerative cervical radiculopathy.</td>
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<td>Procedure/topic</td>
<td>• Rao (2007) reported that in single level procedures with autograft, a plate does not improve clinical results or fusion, but reduces graft collapse, and a plate may be beneficial when allograft used. In addition, a plate reduces the pseudarthrosis rates following a single level corpectomy. Anterior plating improves the rate of fusion, reduces the length and type of postoperative immobilization, reduces the prevalence of graft-related complications, and leads to less postoperative kyphosis, particularly in patients undergoing two or more levels of anterior cervical discectomy and fusion.</td>
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<td>Procedure/topic</td>
<td>• Matz (2009) noted that with respect to 1-level disease, plating may reduce the risk of pseudarthrosis and graft problems but does not necessarily improve clinical outcome alone</td>
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<td>Procedure/topic</td>
<td>• Resnick (2007) reported results from a systematic literature review and concluded that clinical results were similar for single-level disease for anterior cervical decompression without fusion to fusion with a plate. However, Resnick also commented that “the absence of proof is not proof of absence.” He noted that the few randomized studies may be too small to detect a difference between groups, and “hundreds if not thousands of patients” may be needed for this type of study. Despite the literature for single level plate fusion, Resnick noted that use is common and other socioeconomic factors are an important consideration. Plated patients receive immediate rigid fixation and can return to activities/work sooner, which also provides a cost advantage. Patients who are not plated must be immobilized. Resnick also noted that for traumatic instability and multilevel procedures, there are advantages in using a plate.</td>
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<td>Procedure/topic</td>
<td>ODG recognized potential benefits and downsides with anterior cervical discectomy and fusion including a plate as follows: “Potential benefits - (1) provide rigid fixation; (2) resist graft setting with less development of kyphosis; (3) provide higher fusion rates; (4) allow for less cumbersome instrumentation; (5) reduce the rate of graft extrusion; &amp; (6) reduce the need for prolonged external immobilization of the neck. Potential downsides: (1) increased surgical time and cost; (2) increased potential of morbidity and mortality during revision as the plate must be removed; &amp; (3) numerous implant related complications including esophageal erosion, injury to adjacent structures due to hardware, and adjacent level ossification.” These benefits are consistent with the literature; however, the downsides are not. The statement that includes “numerous implant related complications” needs to be substantiated and supported by other literature. For example, Fountas (2007) reported results from a clinical study comparing patients with ACDF with and without a plate. For the most common complications (i.e., dysphagia, hematoma, recurrent laryngeal nerve palsy), there were no differences in the rates for patients with or without a plate.</td>
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<tr>
<td>Procedure/topic</td>
<td>Specific Indications for Plate Fixation include:</td>
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<tr>
<td>Procedure/topic</td>
<td>(a). for Patients with Myelopathy immediate surgical evaluation and treatment is indicated;</td>
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<tr>
<td>Procedure/topic</td>
<td>(b). for Patients with Cervical Radiculopathy.</td>
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<td>Procedure/topic</td>
<td>Summary of medical evidence</td>
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<td>(i). early intervention may be required for acute incapacitating pain or in the presence of progressive neurological deficits;</td>
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<td>(ii). persistent or recurrent arm pain with functional limitations, unresponsive to conservative treatment after six weeks; or</td>
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<td>(iii). progressive functional neurological deficit; or</td>
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<td>(iv). static neurological deficit associated with significant radicular pain; and</td>
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<td>(v). confirmatory imaging studies consistent with clinical findings.</td>
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<td>(c). For Patients with Persistent Non-radicular Cervical Pain in the absence of a radiculopathy, it is recommended that a decisive commitment to surgical or nonsurgical interventions be made within four to five months following injury. The effectiveness of three-level cervical fusion for non-radicular pain has not been established. In patients with non-radicular cervical pain for whom fusion is being considered, required pre-operative indications include all of the following.</td>
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<td>(i). In general, if the program of non-operative treatment fails, operative treatment is indicated when:</td>
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<td>[a]. improvement of the symptoms has plateaued, and the residual symptoms of pain and functional disability are unacceptable at the end of 6 to 12 weeks of active treatment, or at the end of longer duration of non-operative programs for debilitated patients with complex problems; and/or</td>
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<td>[b]. frequent recurrences of symptoms cause serious functional limitations even if a non-operative active treatment program provides satisfactory relief of symptoms, and restoration of function on each recurrence;</td>
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<td>[c]. mere passage of time with poorly guided treatment is not considered an active treatment program;</td>
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<td>(ii). all pain generators are adequately defined and treated; and</td>
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<td>(iii). all physical medicine and manual therapy interventions are completed; and</td>
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<td>(iv). x-ray, MRI, or CT/discography demonstrating disc pathology or spinal instability; and</td>
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<td>(v). spine pathology limited to two levels; and</td>
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<td>(vi). psychosocial evaluation for confounding issues addressed;</td>
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<td>(vii). for any potential surgery, it is recommended that the injured worker refrain from smoking for at least six weeks prior to surgery and during the period of healing. Because smokers have a higher risk of non-union and higher postoperative costs, it is recommended that insurers cover a smoking cessation program peri-operatively</td>
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**Surgical Indications:**

When surgery is recommended for a patient, the clinical evidence is conflicting regarding which procedure offers superior benefit (i.e., anterior cervical decompression alone, anterior cervical decompression with fusion with an interbody autograft or allograft, plate fixation or interbody prosthetic cage). However, as each method has potential benefits that may address a patient’s condition, the decision as to which approach best serves the patient should be left to the surgeon and the patient based on anatomy, the patient's pathology, and surgeon's experience and preference.

As Cunningham (2010) noted, “the lack of conclusive data indicating one procedure as being superior to the others reiterates the fact that many good options exist—each with its own set of rewards and failures”. Highlights
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<td>of various recent systematic reviews noted the following regarding different surgical approaches.</td>
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<td>• NASS (2010) reported that an interbody graft for fusion is suggested to improve sagittal alignment following ACD, and the addition of a cervical plate is suggested to improve sagittal alignment following ACDF. While plate stabilization may be indicated in some patients undergoing multilevel ACDF, there is insufficient evidence that this practice results in significant improvement in clinical outcomes for degenerative cervical radiculopathy.</td>
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<td>• Jacobs (2011) reported that in an assessment of fusion rates in various interbody techniques compared to discectomy alone, iliac crest autograft was the gold standard for prevention of nonunions. However, none of the evidence indicated that any technique resulted in a clinically relevant better pain relief to treat chronic cervical DDD or disc herniation.</td>
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<td>• In the treatment of cervical myelopathy, Mummaneni (2009) concluded that multiple approaches existed with similar near-term improvements; however, laminectomy (decompression alone) appeared to have a late deterioration rate that may need to be considered.</td>
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### Halo Immobilization

| Description | Intervention that restricts flexion-extension motion. Halo vest will provide significant but not complete rotational control and is the most effective device for treating unstable injuries to the cervical spine. |
| Complications | May include pin infection, pin loosening, and palsy of the sixth cranial nerve. |
| Surgical Indications | Cervical fractures requiring the need for nearly complete restriction of rotational control, and to prevent graft dislodgment, spine mal-alignment, or pseudarthrosis. Decision for use of halo is at the discretion of the surgeon based upon the patients’ specific injury. Not indicated for unstable skull fractures or if skin overlying pin sites is traumatized. |
| Operative Treatment | Placement of the pins and apparatus. |
| Post-Operative Therapy | Traction may be required for re-alignment and or fracture reduction (amount to be determined by surgeon), active and/or passive therapy, pin care. |

### Intraoperative monitoring

Intraoperative monitoring is a common intraoperative electrodiagnostic technique that may include somatosensory evoked potentials (SSEP), motor evoked potentials (MEP), or pedicle screw monitoring. The monitoring procedure may be used at the discretion of the surgeon. The use of intraoperative monitoring can be anticipated to become more common as percutaneous spinal procedures gain greater acceptance.
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| **Follow-Up Diagnostic Imaging and Testing Procedures** | A. One diagnostic imaging procedure may provide the same or distinctive information as does another procedure. Therefore, prudent choice of a single diagnostic procedure, a complement of procedures, or a sequence of procedures will optimize diagnostic accuracy, and maximize cost effectiveness (by avoiding redundancy), and minimize potential adverse effects to patients.  
B. All imaging procedures have a degree of specificity and sensitivity for various diagnoses. No isolated imaging test can assure a correct diagnosis. Clinical information obtained by history taking and physical examination should form the basis for selecting an imaging procedure and interpreting its results. |
| Bone Scan (Radioisotope Bone Scanning) (Not Recommended In ODG) | Bone Scan (Radioisotope Bone Scanning) is generally accepted, well-established, and widely used. Bone scanning is more sensitive but less specific than MRI. 99mTc Technetium diphosphonate uptake reflects osteoblastic activity and may be useful in diagnosing metastatic/primary bone tumors, stress fractures, osteomyelitis, and inflammatory lesions, but cannot distinguish between these entities. |
| Computed Axial Tomography (CT) (Not Recommended In ODG) | Computed Axial Tomography (CT) provides excellent visualization of bone and is used to further evaluate bony masses and suspected fractures not clearly identified on radiographic evaluation. It may sometimes be done as a complement to MRI scanning to better delineate bony osteophyte formation in the neural foramen. Instrument-scatter reduction software provides better resolution when metallic artifact is of concern. |
| CT Myelogram (Not Recommended In ODG) | CT Myelogram provides more detailed information about relationships between neural elements and surrounding anatomy and is appropriate in patients with multiple prior operations or tumorous conditions. |
| Imaging studies | Imaging studies are generally accepted, well-established and widely used diagnostic procedures. In the absence of myelopathy, or progressive neurological changes, or history of cancer, imaging usually is not appropriate until conservative therapy has been tried and failed. Six to eight weeks of treatment are usually an adequate period of time before an imaging procedure is in order, but the clinician should use judgment in this regard. When indicated, imaging studies can be utilized for further evaluation of the low back, based upon the mechanism of injury, symptoms, and patient history. Prudent choice of a single diagnostic procedure, a complementary combination of procedures, or a proper sequential order of complementary procedures will help ensure maximum diagnostic accuracy and minimize adverse effect to the patient. When the findings of the diagnostic imaging and testing procedures are not consistent with the clinical examination, the clinical findings should have preference. There is good evidence that in the asymptomatic population, disc bulges, annular tears, or high intensity zone areas, and disc height loss are prevalent 40–60 percent of the time depending on the condition, study, and age of the patient. Therefore, the existence of these anatomic findings should not be considered relevant without physiologic and clinical correlation in an individual patient. |
| Magnetic resonance imaging (MRI), myelography, or Computed Axial Tomography (CT) scanning | Magnetic resonance imaging (MRI), myelography, or Computed Axial Tomography (CT) scanning following myelography may provide useful information for many spinal disorders. When a diagnostic procedure, in conjunction with clinical information, can provide sufficient information to establish an accurate diagnosis, the second diagnostic procedure will become a redundant procedure. At the same time, a subsequent diagnostic procedure can be a complementary diagnostic procedure if the first or preceding procedures, in conjunction with clinical information, cannot provide an accurate diagnosis. Usually, preference of a procedure over others depends upon availability, a patient’s tolerance, and/or the treating practitioner’s familiarity with the procedure. |
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<tr>
<td><strong>Medial Branch Blocks</strong></td>
<td>Medial Branch Blocks is generally accepted diagnostic injections, used to determine whether a patient is a candidate for radiofrequency medial branch neurotomy (also known as facet rhizotomy). ISIS suggests controlled blocks, using either placebo or anesthetics with varying lengths of activity (i.e., bupivacaine longer than lidocaine). To be a positive diagnostic block, the patient should report a reduction of pain of 50 percent or greater relief from baseline for the length of time appropriate for the local anesthetic used. In almost all cases, this will mean a reduction of pain to one or two on the Visual Analog Scale (VAS) 10-point scale correlated with functional improvement. The patient should also identify activities of daily living (which may include measurements of range of motion) that are impeded by their pain and can be observed to document functional improvement in the clinical setting. Ideally, these activities should be assessed throughout the observation period for function. The observer should not be the physician who performed the procedure. It is suggested that this be recorded on a form similar to ISIS recommendations or American Society of Interventional Pain Physicians (ASIPP).&lt;br&gt;• A separate comparative block on a different date may be performed to confirm the level of involvement. A comparative block uses anesthetics of varying lengths of activity. Medial Branch blocks are probably not helpful to determine the likelihood of success for spinal fusion.&lt;br&gt;• Frequency and Maximum Duration: May be repeated once for comparative blocks. Limited to four levels.</td>
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<tr>
<td><strong>Myelography</strong> <em>(No Detail in ODG)</em></td>
<td>Myelography is the injection of radiopaque material into the spinal subarachnoid space, with x-rays then taken to define anatomy. It may be used as a diagnostic procedure to obtain accurate information of characteristics, location, and spatial relationships among soft tissue and bony structures. Myelography is an invasive procedure with complications including nausea, vomiting, headache, convulsion, arachnoiditis, cerebral-spinal fluid (CSF) leakage, allergic reactions, bleeding, and infection. Therefore, myelography should only be considered when CT and MRI are unavailable, for morbidly obese patients or those who have undergone multiple operations, and when other tests prove non-diagnostic. The use of small needles and a less toxic, watersoluble, nonionic contrast is recommended.</td>
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<tr>
<td><strong>Other Radioisotope Scanning</strong> <em>(Not mentioned in ODG)</em></td>
<td>Indium and gallium scans are generally accepted, well-established, and widely used procedures usually to help diagnose lesions seen on other diagnostic imaging studies. 67Gallium citrate scans are used to localize tumor, infection, and abscesses. 111Indium-labeled leukocyte scanning is utilized for localizing infection or inflammation.</td>
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<tr>
<td><strong>Specialized MRI Scans</strong> <em>(Not mentioned in ODG)</em></td>
<td>MRI with three-dimensional reconstruction. On rare occasions, MRI with three-dimensional reconstruction views may be used as a pre-surgical diagnostic procedure to obtain accurate information of characteristics, location, and spatial relationships among soft tissue and bony structures. Dynamic-kinetic MRI of the spine. Dynamic-kinetic MRI of the spine uses an MRI unit configured with a tofront open design which enables upright, weight-bearing patient positioning in a variety of postures not obtainable with the recumbent images derived from conventional, closed unit MRI systems. Imaging can be obtained in flexion, extension, and rotation of the spine, as well as in erect positioning. There is a theoretical advantage to imaging sequences obtained under more physiologic conditions than in the supine position. There is currently ongoing research to establish whether the theoretical advantages of positional and kinetic MRI result in improved sensitivity and specificity in detecting spine pathology. Currently it remains investigational and is not recommended until the correlation with clinical syndromes and outcomes is firmly established.</td>
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| Transforaminal injections/Spinal Selective Nerve Block (SSNB) | Transforaminal injections/Spinal Selective Nerve Block (SSNB) is generally accepted and useful in identifying spinal pathology. When performed for diagnosis, small amounts of local anesthetic up to a total volume of 1.0 cc should be used to determine the level of nerve root irritation. A positive diagnostic block should result in a positive diagnostic functional benefit and a 50 percent reduction in nerve-root generated pain appropriate for the anesthetic used as measured by accepted pain scales (such as a VAS).  
  - Time to produce effect: Less than 30 minutes for local anesthesia; corticosteroids up to 72 hours for most patients.
  - Frequency and Maximum Duration: Once per suspected level. Limited to two levels. |
| Zygapophyseal (Facet) Blocks | Facet blocks are generally accepted but should not be considered diagnostic blocks for the purposes of determining the need for a rhizotomy (radiofrequency medial branch neurotomy), nor should they be done with medial branch blocks.  
  - These blocks should not be considered a definitive diagnostic tool. They may be used diagnostically to direct functional rehabilitation programs. A positive diagnostic block should result in a positive diagnostic functional benefit and a 50 percent reduction in pain appropriate for the anesthetic used as measured by accepted pain scales (such as a VAS). They then may  
    - Be repeated per the therapeutic guidelines when they are accompanied by a functional rehabilitation program. (Refer to Therapeutic Spinal Injections).  
      (a). Time to produce effect: Less than 30 minutes for local anesthesia; corticosteroids up to 72 hours for most patients;  
      (b). Frequency and maximum Duration: Once per suspected level, limited to two levels. |
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<td><strong>Therapeutic Procedures - Non-Operative &amp; Operative</strong></td>
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<td>A. Before initiation of any therapeutic procedure, the authorized treating provider, employer, and insurer must consider these important issues in the care of the injured worker.</td>
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<td>B. First, patients undergoing therapeutic procedure(s) should be released or returned to modified or restricted duty during their rehabilitation at the earliest appropriate time. Refer to “Return-to-Work” in this section for detailed information.</td>
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<td>C. Second, cessation and/or review of treatment modalities should be undertaken when no further significant subjective or objective improvement in the patient’s condition is noted. If patients are not responding within the recommended duration periods, alternative treatment interventions, further diagnostic studies or consultations should be pursued.</td>
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<td>D. Third, providers should provide and document education to the patient. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms.</td>
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<td>E. Lastly, formal psychological or psychosocial evaluation should be performed on patients not making expected progress within 6 to 12 weeks following injury and whose subjective symptoms do not correlate with objective signs and tests</td>
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**BMP**

Bone Morphogenetic Proteins (BMP) are members of a family of cytokines capable of inducing bone formation. Numerous studies of BMP with respect to Lumbar Fusions (Anterior and Posterior) have been undertaken to establish efficacy and safety. Dimer, Burkus et al (2009) demonstrated equivalent on enhanced rates of fusion with BMP when compared to Autograft bone. Mannion et al (2011.) Reviewed several studies reporting demonstrated improvements in Lumbar Spine Surgery when BMP was compared to either Allograft or Autograft and with or without transpedicular screw fixation. Also reporting a diminished Pseudoarthrosis Rate. Hu (2011) reported fusion rates in single level posterolateral instrumented lumbar fusions with iliac crest are generally 75% to 95% as assessed by a variety of methods. However, in smaller comparison BMP equaled or exceeded Autograft bone.

The use of BMP does eliminate the need to Harvest Iliac bone, often cited as a potentially significant source of Post Operative Pain, Vaccaro and Anderson et al. (2005) reported at 1.5 month; at least 20% of patients having iliac bone harvested for non-spinal surgeries were still suffering severe pain. For patients undergoing a lumbar fusion at 1.5 months 24% complained of donor site pain and at 6 months they found up to 30% of patients had some complaint related to the bone harvest. Kim, et al. The Spine Journal, November 2009. "Postoperative data regarding pain were collected as six week, six and twelve month follow-up and consisted of visual analog scale, VAS scores for local pain at the iliac crest bone graft harvest site and at the primary surgical site. VAS was assessed on a continuous scale from 0, no pain, to 100, the worst pain imaginable. Because of the difficulty patients often experience discrimination harvest site pain from other potential sources of back and buttock pain, a full-time dedicated research assistant was hired to supervise administrations of the pain scores in the final questionnaire. Pain scores did not vary significantly among individual surgeons or on the basis of one graft harvesting technique, that is, via the primary posterior lumbar midline incision or a second posterior longitudinal iliac crest incision. The twelve month questionnaire revealed relatively high rates of persistent symptoms resulting from iliac crest bone graft harvest. Persistent pain at the harvest site was reported by 16.5% that was greater than pain form the primary surgical site. Because of persisting graft site pain, 15.1% reported difficulty walking, 5.2% difficulty with their job 12.98% difficulty with recreational activities, 14/.1% difficulty with household chores, 7.6% difficulty with sexual activity, and 5.9% irritation.
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<td>BMP does carry some risk; BMP should not be used in an Anterior Cervical Fusion. Reported complications have included an acute inflammatory reaction with soft tissue swelling, potential airway obstruction and death. Additionally, posterior application in a cage with a direct pathway to the spinal canal has been associated with ectopic bone formation and neurologic Impingement.</td>
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<td>Currently two BMP’s have been approved. rhBMP-2(infuse) has been approved as an allograft replacement in anterior interbody fusions and for treatment of open tibial fractures. rhBMP-7(op-1) has been approved under the Humanitarian Device Exemption (HDE) process as an autograft substitute of long bone nonunion and for Revision Posterolateral Fusion, for whom autologous bone and bone marrow harvest are not feasible or are not expected to promote fusion. All other applications are considered off label and not FDA approved.</td>
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| **Recommendation:**  
- rhBMP-2(infuse): Anterior Lumbar Interbody Fusion  
- rhBMP-7(op-1): Revision Posterolateral Fusion when Autograft bone is unavailable or a substantial hardship to the patient. | |
| **Bracing** | Historically braces as well as strict bed rest were used to immobilize the lumbar spine following fusion. Gradually the orthopedic community appreciated the benefits of an active patient with respect to reducing complications (pulmonary issues, pressure ulcers and deep venous thrombosis). Additionally, patients did not become as “deconditioned” when adhering to a postoperative exercise program. We agree that there may be a tradition in spine surgery of using a brace post-fusion and this tradition may be based on logic that antedated internal fixation. Some have suggested a comparison of lumbar fusion bone healing to that of a long bone and intimated that immobilization is undesirable. The physiology of bone healing for a fusion is different than that of a long bone fracture treated in a closed fashion just as a long bone fracture treated surgically with plate fixation differs from closed treatment (Orthopedic Knowledge Update 5 1996).  
Lantz and Schultz (1986) studied gross body motions, with patients wearing a lumbar corset, chairback brace and TLSO. Four trunk movements (flexion, extension, lateral bending and rotation) were examined in five healthy adult men while they were standing or sitting. Mean motion restrictions were largest when wearing the TLSO and least in the lumbosacral corset. Connolly and Grob (1998) reviewed the controversy of bracing patients after fusion for degenerative lumbar spinal conditions.  
Rationale for wearing a brace included  
- Reducing segmental instability and gross body motion  
- Protecting screw fixation in osteoporotic bone  
- Reducing pain and analgesic consumption  
Axelsson et al evaluated the effect of a lumbar orthosis (corset) on intervertebral mobility. Results suggested an orthosis provides neither immobility nor increased fusion rates.  
Most agree there are certain situations that may well benefit from a brace. Unstable fractures of the cervical, thoracic, or lumbar spine; unstable |
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<td>conditions in which only anterior or posterior fixation is obtained; osteoporosis or other instances in which less than ideal fixation is noted and multilevel fusions.</td>
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<td>It is believed a standard chairback or molded brace appears to be as advantageous as a custom post-op lumbosacral orthosis, and provides significantly more protection than a lumbar corset.</td>
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<td>To determine the efficacy of postoperative bracing, a comparison between patients undergoing similar lumbar fusion procedures, randomized to brace therapy or no such therapy, would provide high quality evidence to support or refute the hypothesis that bracing improves fusion rates and/or functional outcome following lumbar fusion procedures in treatment of lumbar degenerative disc disease.</td>
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<td>Until further definitive data exists our recommendation is that the decision to brace or not brace a patient is to be at the discretion of the attending surgeon.</td>
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<td>Disc Prosthesis</td>
<td>When conservative treatment of spinal degenerative disc disease fails, a common surgical approach is spinal fusion. However, the outcomes of spinal fusion have been controversial. Spinal fusion also alters the biomechanics of the spine, potentially leading to premature disc degeneration at adjacent levels, a particular concern for younger patients. During the past 30 years, a variety of artificial intervertebral discs have been investigated as an alternative approach to fusion. This approach, also referred to as total disc replacement or spinal arthroplasty, is intended to maintain motion at the operative level once the damaged disc has been removed, and to maintain the normal biomechanics of the adjacent vertebrae. Potential candidates for artificial disc replacement have chronic symptoms attributed to degenerative disc disease, and lack of improvement with non-operative treatment. Contraindications for the procedure include multilevel disease, spinal stenosis, spondylolisthesis and previous major spinal surgery.</td>
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<td>The major potential advantage of a prosthetic intervertebral disc over current therapies for degenerated discs (such as spinal fusion or discectomy) is that the prosthetic intervertebral disc is intended to restore or preserve the natural biomechanics of the intervertebral segment and to reduce further degeneration of adjacent levels.</td>
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<td>(Excerpted from Blue Cross-Blue Shield Guidelines)</td>
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<td>LUMBAR DISC REPLACEMENT</td>
<td>Van Ooij et al (2003) reported a series of 27 patients that presented the authors with unsatisfactory results or complications after Charite disc replacement. Most patients were operated on at the L4-L5 and/or the L5-S1 vertebral levels. The patients were evaluated with plain radiography, some with flexion-extension x-rays, and most of them with CT scan. The group consisted of 15 women and 12 men. Their mean age was 40 years (range, 30-67) at the time of operation. The patients presented to the investigators a mean of 53 months (range 11-127) months following disc replacement surgery. In two patients, an early removal of a prosthesis was required and in two patients a late removal. In 11 patients, a second spinal reconstructive salvage procedure was performed. Mean follow-up for 26 patients with mid- and long-term evaluation was 91 months (range 15-157 months). Early complications were the following: in one patient, an...</td>
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<td>anterior luxation of the prosthesis after one week necessitated removal and cage insertion, which failed to unite. In another patient with prosthesis at L4-L5 and L5-S1, the prosthesis at L5-S1 dislocated anteriorly after three months and was removed after 12 months. Abdominal wall hematoma occurred in four cases. Retrograde ejaculation with loss of libido was seen in one case and erection weakness in another case. A temporary benefit was experienced by 12 patients, while 14 patients reported no benefit at all. Main causes of persistent complaints were degeneration at another level in 14, subsidence of the prosthesis in 16, and facet joint arthrosis in 11. A combination of pathologies was often present. Slow anterior migration was present in two cases, with compression on the iliac vessels in one case. Polyethylene were was obvious in one patient 12 years after operation. In eight cases, posterior fusion with pedicle screws was required. In two cases, the prosthesis was removed and the segment was circumferentially fused. These procedures resulted in suboptimal long-term results. In this relatively small group of patients operated on with Charite disc prosthesis, most problems arose from degeneration of other lumbar discs, facet joint arthrosis at the same or other levels, and subsidence of the prosthesis.</td>
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In a multicenter, prospective, randomized investigational device exemption study of the Charite intervertebral disc, Geisler et al (2004) compared the Charite artificial disc with lumbar fusion using the BAK cages in patients with lumbar degenerative disc disease (n=304). The authors found that the neurological status was equivalent between the two groups at 6, 12 and 24 months, postoperatively. They concluded that the Charite intervertebral disc is safe and effective for the treatment of single-level degenerative disc disease, resulting in no higher incidence of neurological complications compared with BAK-assigned fusion, and leading to equivalent or better outcomes (as indicated by visual analog scale and Oswestry Disability Index scores) compared with fusion with those obtained in the control group and those reported in the lumbar fusion literature. However, the authors concluded that, while the finding of this study is promising, longer follow-up is needed to determine the durability of the Charite artificial disc and its long-term safety and effectiveness. |

The Charite artificial disc was approved by the FDA based on a clinical trial that compared the device to anterior lumbar interbody fusion (ALIF) with BAK cages filled with iliac crest autograft in subjects with symptomatic single level degenerative disc disease from L4 to S1 who had failed at least six months of conservative management. The purpose of the study was to demonstrate the non-inferiority of the Charite Artificial Disc to an interbody fusion system. A total of 304 patients were enrolled in the study using a 2:1 (Charite to BAK) randomized scheme. One-hundred eighty four subjects receiving Charite Artificial Disc and 81 subjects receiving interbody fusion (controls) completed 24 months follow-up. Safety of the Charite Artificial Disc was assessed by monitoring the intraoperative and postoperative complications, including infection, thrombosis, disc migration, and disc subsidence, as well as reoperation and other adverse events. Efficacy of the Charite Artificial Disc was assessed primarily by a success criteria comprised of: level of disability (Oswestry Low Back Disability Index (ODI), neurological assessment (functional status) and information from adverse event data. To be considered an overall success, a subject must have had: 1) an improvement of at least 25 percent in the ODI score at 24 months compared to baseline; 2) no device failures requiring revision, reoperation, or removal; 3) absence of major complications, defined as major blood vessel injury,
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<td>neurological damage, or nerve root injury; and 4) maintenance or improvement in neurological status at 24 months, with no permanent neurological deficits compared to baseline. Based on these criteria, the overall success rate was 64 percent for subjects receiving the Charite Artificial Disc and 57 percent receiving interbody fusion. The FDA requested that the data be analyzed and reported using an improvement in the Oswestry Disability Index of greater than 15 points at 24 months compared to the score at baseline. Based on these alternate criteria, the overall success rate for subjects receiving the Charite Artificial Disc was 58 percent, and success rate for control subjects was 54 percent. The study sponsor considered the study a success if the overall success rates of two treatment groups were non-inferior, i.e., the difference in overall success rates (i.e., non-inferiority margin) in no greater than 15 percent. However, the FDA requested that the data also be analyzed and reported using a non-inferiority margin of 10 percent. Blumenthal et al (2005)</td>
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<td>Because of the long-term safety and effectiveness of the Charite Artificial Disc is unknown, the FDA has required the manufacturer to conduct a post-approval study using a maximum of 366 subjects (201 randomized investigational subjects; 67 training investigational subjects; and 98 control subjects). The manufacturer will be required to evaluate subjects on overall success and secondary endpoints, and submit annual reports for a total of five years post-implantation.</td>
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<td>No additional randomized controlled trials had been published since the FDA approval of the ProDisc-L in August 2006. One case series was identified that followed up to 55 patients for an average of 8.7 years after disc replacement with the ProDisc-L. Although 60% of patients report an excellent result, it is not possible, based on case series data, to compare results to other treatments. Additional publications report on case series including patients who receive artificial discs at two levels in the lumbar spine. BCBSA TEC noted on its review that, “Case series data provide little evidence of efficacy, particularly in the case of back pain due to degenerative disc disease, where outcomes can be influenced by patient selection, placebo effects or natural history.” TEC concluded that the evidence supporting the effective of the ProDisc-L and Charite artificial disc was limited, and that there was no immediately discernible advantage to use of the artificial disc.</td>
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<td>Procedure/topic</td>
<td>Guyer and colleagues (2009) reported a five-year follow-up of a subset of the patient cohort who had participated in the IDE trial of the Charite artificial disc. Of the initial 14 sites, six declined participation in the five-year continuation study, and an additional eight patients were excluded from analysis, leaving 233 patients from the original randomized study. There were 133 cases included in the five-year assessment (57% from the eight sites). Based on a denominator of 375 patients originally enrolled in the IDE trial, this report represents 30% of the study population. Given the limitations of the original randomized controlled trial (described above) and the 50% to 70% loss to follow-up, the results from the five-year follow-up cannot be interpreted.</td>
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<td>Preliminary results on the FlexiCore metal on metal intervertebral disc were presented from two of the sites involved in the investigational device trial in 2008. Results were reported for 76 patients enrolled at the two sites (out of the entire study cohort of 401 patients) who had been randomized with a ratio of 2:1 to either FlexiCore or fusion control; nine subjects did not receive the index surgery, 44 patients were treated with</td>
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<td>the artificial disc, and 23 patients were treated with fusion. Compared with fusion, placement of the artificial disc was associated with less blood loss (97 mL vs. 179 mL), reduced operating time (82 min vs. 179 min), and reduced length of hospital stay (two vs. three days). Oswestry disability index analogue scale (VAS) pain scores were not significantly different between the groups. At 24 months the Oswestry scores had decreased from 62 to six in the FlexiCore group and from 58 to 12 in the fusion group. VAS scores decreased from 86 to 16 in the FlexiCore group and from 82 to 20 in the fusion group. Eight patients in each group had complications requiring interventional surgery. Complications are emerging with longer-term follow-up. One study from Asia reported that clinical outcomes of both the Charite and the ProDisc were fairly good, but the facet joint of the index level and the disc at the adjacent level showed an aggravation of the degenerative process in a significant number of patients regardless of the device used. Another study reported that progression of facet degeneration (29% of levels replaced with the ProDisc II) was associated with female gender, malposition of the prosthesis on the frontal plane, and two-level total disc replacement. Analysis of postoperative pain patterns in 58 patients of 175 (33%) implanted with the ProDisc II showed facet joint pain in 22 (13%) and sacroiliac joint pain in 21 (12%). Another report describes late complications in 75 patients who had received an earlier generation SB Charite prosthesis. As all of the patients had been originally treated by other surgeons, the percentage of implant failure cannot be determined in this report. The mean interval between insertion and retrieval of the prosthesis was 8 years and 11 months (range of 3-16 years). The most frequent complications included (subsidence (n=39), disc prosthesis too small (n=24), adjacent disc degeneration (n=36), degenerative scoliosis (n=11), facet joint degeneration (n=25), and metal wire breakage (n=10). The report indicated that good placement and good sizing of the disc prosthesis appeared problematic for many of the patients, many patients showed adjacent disc degeneration and that polyethylene wear with inflammatory fibrous tissue containing wear debris was observed. The report concluded that wear mechanisms of articulation discs may be similar to artificial hips and knees, and that due to nearby vascular structures and scar tissue from the original surgery, retrieval of artificial disc prosthesis can be difficult and dangerous. Therefore, long-term health outcomes following disc implantation in young active patients may become a clinically significant issue. After consideration of the clinical input in 2008, it was concluded that due to limitations of the only two available randomized controlled trials (described here), combined with the marginal benefit compared to fusion, evidence is insufficient to determine whether artificial lumbar discs are beneficial in the short term. In addition, serious questions remain about potential long-term complications from these implants. 2010 Update Lumbar Disc Replacement A search of the MEDLINE database through September 2010 identified a randomized controlled trial of 1- and 2- level total disc replacement from Sweden. Patients (n=152) with symptomatic degenerative disc disease in one or two motion segments between L3 and S1, with lower back pain as a predominant symptom, were randomized to one of three total disc...</td>
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replacement devices available in Sweden (Charite, Prodisc, or Maverick, n=80) or to instrumented fusion (posterolateral or posterior lumbar interbody fusion, n=72). The randomization was stratified for number of levels, with 56% of total disc replacement patients having one-level surgery compared to 46% of fusion patients. Only patients who did not have a preference to the type of treatment were enrolled in the trial, and they were informed of the result of randomization upon arrival at the hospital for surgery. No patient left the study when informed of the randomization, and there was 100% follow-up at the one- and two-year assessments. The primary outcome, which does not appear to be a validated measure, was a global assessment of back pain consisting of “total relief”, “much better”, “better”, “unchanged”, or wore. At both one and two year follow-up, 30% of patients in the disc replacement group reported being pain free. In the fusion group, 10% reported being pain free at one year and 15% were pain free at two years. The total disc replacement group showed lower mean visual analog scores for pain at one and two years (25.4 vs. 29.2), and had better outcome scores on a quality of life scale (EQ5D) and the Oswestry Disability Index at one year (19.5 vs. 24.9) but not the two-year follow-up (20.0 vs. 23.0). The rate of complications was similar in the two groups, with eight reoperations (10%) in the disc replacement group and seven (9.7%) in the fusion group. The most common cause of reoperation in the disc replacement group was to fuse the index level that was believed to cause persistent or recurrent pain (5%). The most common cause of reoperation in the fusion group was operation at an adjacent level (7%). Twenty-two disc replacement patients underwent postoperative facet block due to remaining pain. Twenty fusion patients had their instrumentation removed due to persistent or recurrent pain. As of the two-year follow-up, no differences were observed between one-level and two-level treatment.

Two systemic reviews, published in 2010, concluded that high quality randomized controlled trials with a relevant control group and long-term follow-up are needed to evaluate the effectiveness and safety of artificial lumbar disc replacement. The design of a U.S. multicenter clinical trial to evaluate the safety and effectiveness of the Aesculap Activ-L artificial disc has also been reported. The study is a single-blinded, randomized non-inferiority trial comparing Activ-L with a control artificial lumbar disc (Charite or ProDisc-L) for a single-level degenerative disc disease of the lumbar spine. Following surgeon training with an initial 90 patients, it is expected that 324 patients will be randomized in a 2:1 ratio. The patients will be followed for five years post-treatment.

**Lumbar Disc Replacement Recommendations:**

Single level degenerative disc disease with discogenic low back pain with lack of improvement with 6 months of conservative care

None of the following:
- Multilevel disease.
- Spinal stenosis or spondylolisthesis.
- Scoliosis.
- Previous major spine surgery.
- Neurologic symptoms (patients who require procedures in addition to fusion such as laminectomy and/or decompression are not candidates for artificial disc replacement.)
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<td>Discectomy/ Laminectomy</td>
<td>Lumbar Spinal Stenosis (Resnick 2005)</td>
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<td>Currently only two artificial discs are approved by the FDA.</td>
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<td>Charite (DePuy) for levels L4-5 or L5-S1</td>
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<td>ProDisc-L (Synthes Spine) for L3-4, L4-5 or L5-S1</td>
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<td>Lumbar Spinal Stenosis</td>
<td>Lumbar spinal stenosis refers to a narrowing of the spinal canal. This encroachment on the neurological structures typically produces low back pain and neurogenic claudication, although periodically specific nerve root entrapment may occur producing typical radiculopathy. Surgical management of patients with lumbar stenosis without spondylolisthesis traditionally involves a posterior decompressive laminectomy or laminotomy, and partial medial facetectomies and foraminotomies with or without discectomy. Spinal stenosis is the most common reason for surgery in adults over 65 years.</td>
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<td>Weinstein et al (2006) recently studied 289 patients enrolled in a randomized cohort and 365 patients in an observational cohort. At 2 years 67% of patients who were randomly assigned to surgery had undergone surgery, whereas 43% of those randomly assigned to receive non-surgical care had also undergone surgery. Patients with a history of 12 weeks of symptoms and spinal stenosis confirmed by imaging were considered surgical candidates. Patients were followed for two years and evaluated with the SF-36 and Oswestry Disability Index. In the combined as-treated analysis patients who underwent surgery showed significantly more improvement in all primary outcomes than did patients who were treated nonsurgically at two years as well as four years. (Weinstein 2010)</td>
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<td>Albeit a small study, Mummaneni (2007) randomized 50 patients with stenosis to decompression and 44 patients to non-surgical treatment. Patients with decompression had favorable affect on leg and back pain and overall disability.</td>
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<td>Turner et al (1992) attempted a meta-analysis of 74 articles dealing with lumbar decompression for spinal stenosis. They identified such disarray in information that they abandoned the meta-analysis and simply reviewed the information and offered the following information. On average 64% of patients treated surgically for lumbar spinal stenosis were reported to have good to excellent results they concluded. Despite the widespread treatment, uncertainties remain concerning diagnostic criteria, indications for surgery, optimal surgical procedures and patient characteristics associated with favorable outcome.</td>
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|                  | Caputy and Lussenhop (1992) analyzed 100 laminectomy treated patients, finding the main risk factor for five year clinical and radiographic failure was preoperative spondylolisthesis. The authors stressed the importance of identifying spondylolisthesis and scoliosis as significant risk factors for failure. Multilevel laminectomies and wide decompression have also been shown to have a positive correlation with an increased incidence of progressive spondylolisthesis. Whereas spondylolisthesis and scoliosis are easily identified on preoperative studies, several techniques have been advocated as a means of identifying more subtle forms of preoperative spinal hypermobility or deformity. The most popular of these are based on dynamic lateral flexion-extension x-rays. Jolles et al (2001) reported that...
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<td>only in 9% of 155 decompression-treated patients without preoperative evidence of instability did delayed slippage eventually develop. Hopp and Tsou (1998) as well as others (Brunon et al and Foreth) have reported that aggressive wide decompression and facetectomy performed at the time of decompression result in iatrogenic destabilization in certain patients and may account for delayed deformity in those with stenosis and no preoperative evidence of instability. Fox et al (1996) performed a retrospective analysis of 124 patients they treated for symptomatic lumbar stenosis. They observed that 91% of those who had undergone laminectomy and fusion reported good outcomes compared to 75% of those treated with laminectomy alone. The majority of those patients selected for fusion were reported to have preoperative instability or spondylolisthesis. Only two patients with instability underwent fusion. This paper provides class III evidence supporting the use of lumbar fusion in patients with lumbar stenosis, particularly those with evidence of preoperative instability. Katz et al (1997) reported on 272 patients who had undergone treatment for lumbar stenosis. This was a multicenter retrospective trial. Seventy-one percent of patients treated with laminectomy alone and 29% with instrumented/non-instrumented fusion. At six months the fusion treated patients fared better with regard to back pain and walking tolerance. This benefit deteriorated by the time of the 24 month follow-up. However, for the subset of patients with preoperative spondylolisthesis or scoliosis, the benefit of fusion was statistically significant and more stable over time.</td>
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### Spinal Stenosis Criteria

Required symptoms/findings: imaging studies: and conservative treatments below:

I. Symptoms/Findings which confirm presence of Radiculopathy or neurogenic claudication.

A. L-3 nerve root compression, requiring ONE of the following:
   1. Severe unilateral quadriceps weakness/mild atrophy
   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

E. Symptoms of Neurogenic Claudication (EMG’s are optional to rule out peripheral neuropathy. Diabetic
# Procedure Summary – Lower Back Treatment Guidelines

## Procedure/topic

**Summary of medical evidence**

neuropathy, or other similar conditions.)

II. **Imaging Studies**, requiring ONE of the following, for concordance between radicular findings or neurogenic claudication findings on radiologic evaluation and physical exam findings.

A. Nerve Root Compression
B. Lateral Recess, foraminal or central stenosis
C. Diagnostic Imaging Modalities requiring ONE of the Following:
   1. MR Imaging
   2. CT myelography and XRay

III. **Conservative Treatments**, requiring ALL of the following:

A. Activity modification (not bed rest) after patient education (>=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

## Recommendations: Treatment for Spinal Stenosis

**Spinal Stenosis with no evidence of instability and/or no anticipation of facet destabilization:**
- Lumbar Decompressive laminectomy without a fusion.

**Spinal Stenosis with instability or anticipation of facet destabilization (iatrogenic instability):**
- Lumbar decompressive laminectomy with fusion and instrumentation.

## Lumbar Discectomy Criteria

Surgical discectomy for carefully selected patients with radiculopathy due to lumbar disc prolapse provides faster relief of leg pain than conservative (nonsurgical) management. Albert et al (1996) studied 41 patients with the SF-36 before and 2 years following lumbar laminectomy and discectomy. The study statistically confirms that surgery for radiculopathy does improve quality of life and function of patients with the disorder.

Cost-effectiveness of lumbar discectomy reported by Malter et al (1996) concluded that in carefully selected patients with herniated discs, surgical discectomy resulted in a substantial positive effect on quality of life at a moderate cost compared to medically treated patients.

Tosteson (2008) confirms higher treatment costs when comparing nonsurgical to operative intervention suggesting it is wise and proper to wait before initiating surgery, but should the patient continue to experience
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<td>Pain and miss work, then the higher cost option such as surgery may be worthwhile.</td>
<td>Surgical management by lumbar laminectomy and disectomy is viewed as highly successful in the relief of patients’ symptoms, but the success rate is highly predicated by the surgeon’s ability to properly screen the patients so that only the appropriate surgical candidates are selected. Garfin (1988), Goald (1980), Hakelius (1992), Spengler (1982).</td>
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<td>Early improvement with lumbar disectomy was extensively studied in the Cochrane Review (Gibson 1999). Twenty-six randomized controlled trials of surgery for degenerative lumbar disc prolapse and 14 trials of surgery for degenerative lumbar spondylosis were identified. In conclusion it was stated that there is now strong evidence on the relative effectiveness of surgical disectomy versus chemonucleolysis versus placebo. Further stating there is considerable evidence of the clinical effectiveness of disectomy for carefully selected patients with sciatica caused by lumbar disc prolapse that fails to resolve with conservative management.</td>
<td>Weinstein et al (SPORT) (2006) also reported on a multicenter randomized clinical trial for surgical and nonsurgical management of lumbar disc herniations. Five hundred and one patients were enrolled and evaluated for up to 2 years. Unfortunately, the major limitation of SPORT is the degree of non-adherence with the randomized treatment assignment. Nonetheless in the as-treated analysis, between the group differences in improvement were consistently in favor of surgery for all outcomes. Relief of leg pain was the most striking and consistent improvement with surgery. These results continued in the analysis of four-year follow-up (Weinstein 2008).</td>
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<td>It has been noted that some patients fare less well than others following lumbar disectomy. The continuance and/or development of low back pain with disability has been identified.</td>
<td>Several studies have confirmed improvement in patient outcomes with disectomy for lumbar disc herniation. Yorimitsu et al (2001) reported on long term outcomes of standard disectomy. The retrospective study reviewed 131 patients followed for ten years, concluding favorable results particularly with preserved disc space heights. Residual low back pain was identified in 73% and 13% reported severe low back pain.</td>
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<td>Loupasis et al (1999) reported on a 7 to 20 year outcome with respect to lumbar discectomy. Early encouraging results were identified and over time results were noted to be less positive. Twenty-eight percent still complained of significant back or leg pain. Although 65% were very satisfied. Sociodemographic factors predisposing to unsatisfactory outcomes, involving female gender, low vocational education and jobs requiring significant physical strenuousness. The disc deterioration is not surprising as a degenerative herniated disc would be expected to progress, similar to the effect of a meniscal tear in the knee over time. Reported early results of surgical discectomy have shown success of over 90%. Hanley (1995) and Spengler (1982) reported long term results to be been less positive with success rates of 40 to 79 percent. There appears to be a significant deterioration with time after surgery.</td>
<td>There are a subset of patients that fare poorly following lumbar</td>
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- **Procedure/Topic:** Lower Back Treatment Guidelines

- **Summary:** Discectomy for prolapse. Several studies have indicated a considerable number of patients that develop severe low back pain and are unable to return to work and another group that develop low back pain over time, (Yorimitsu and colleagues). Loupasis et al (1999) reported 28% with chronic low back pain following discectomy and Dvorak (1988) and Associates found 23% complained of constant heavy low back pain.

Several papers have reviewed patients comparing discectomy to discectomy and fusion. Takeshina (2000) prospectively studied 95 patients (45 discectomy alone and 51 discectomy and fusion) followed for 7 years, 73% of the discectomy-only group scored excellent or good results, compared with 82% of the discectomy fusion group. There was a lower disc recurrence rate among the fusion group.

Young (1962) retrospectively reviewed a large Mayo Clinic series of patients, 450 patients underwent discectomy and posterolateral fusion and 555 underwent discectomy alone. Patients were followed for 8 years. The fusion group had a superior long-term relief of sciatica (73%) and lumbar (68%) compared with discectomy alone group (48% sciatica and 52% lumbago). Reporting a 95% satisfaction in the fusion group and 84% in the discectomy group. Selection criteria for fusion included spondylolisthesis, spondylosis, localized degenerative arthritis, partial sacralization, scoliosis, fractures, facet joint degeneration, six lumbar vertebrae congenital anomalies, and recurrent disc herniation.

One proposed rationale for the addition of a fusion to a primary discectomy is the prevention of chronic low back pain and late instability.

Kotilainen et al (1998) reported 22 percent of patients developed clinical and radiographic signs of lumbar instability following microdiscectomy. Thirty-nine patients developed instability and only 38% of those patients were able to work. The author hypothesized that if instability could be identified preoperatively or if the surgeon could identify patients at risk for postoperative instability, these patients might be better treated with a stabilization at the time of discectomy.

Other authors have reported better results without lumbar fusion. Donceel and DuBors (1998) and Cauchoir et al (1978), and suggest few chronic low back pain nor instability issues after discectomy.

A second rationale for fusion with discectomy in the treatment of patients suffering radiculopathy and significant axial pain or patient performing heavy manual labor. Advocates suggest that even though there is no true radiographic evidence of lumbar instability, there is often significant lumbar pain or “fatigue”. This may prevent return to manual labor in a large portion of patients despite operative discectomy.

Inoue et al (1984) reports anterior lumbar discectomy and fusion treating 350 patients with disc herniation followed in excess of 8.5 years. Indicating 75 percent good outcome rate. They concluded that primary fusion provides sustained improvement in these select patients compared with historical results of series of similar patients treated with discectomy alone.

Eie (1978) examined 259 patients with a herniated disc who underwent one of two treatments discectomy alone (119) or discectomy and noninstrumented fusion. The author observed equivalent rates of good
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<td>outcome between the two treatment groups during the first few months after surgery. It was also identified that the satisfaction rates reported by the discectomy alone group deteriorated over time compared with the satisfaction rate reported by the discectomy fusion group. At 6 years post surgery 76% of the discectomy group reported satisfaction compared with 85% of the discectomy fusion patients. Additionally, the discectomy alone group reported a significantly higher incidence of pain recurrence (27% vs. 15%) manual laborers with significant preoperative axial back pain were especially likely to suffer recurrences of pain when treated with discectomy alone. Class III evidence for fusion at the time of discectomy in laborers and those with significant preoperative low back pain. Matsunaga et al (1993) performed retrospective study of 80 manual laborers or athletes who underwent either open or percutaneous discectomy (51) or open discectomy combined with fusion (29). Primary outcome measure was return to work or participation in athletics. At 1-year 54% of the discectomy group and 89% of the discectomy/fusion group were able to return and maintain preoperative work or athletic activity. They found that although discectomy-treated patients returned to work earlier (12 weeks) than the discectomy/fusion-treated group (25 weeks), 22% of the discectomy alone group could not maintain their previous activity level because of so called lumbar fatigue. Class III evidence for addition of fusion with discectomy in heavy laborers and athletes.</td>
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## OTG 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. Straight leg raising test, crossed straight leg raising and reflex exam show 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
   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 option 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:

   - Nerve root compression (L3, L4, L5 or S1)
   - Lateral disc rupture
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<td>Lateral recess stenosis</td>
<td>Diagnostic imaging modalities, requiring ONE of the following: 1. MR imaging 2. CT scanning 3. Myelography 4. CT myelography &amp; X-ray</td>
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<td>III. Conservative Treatments, requiring ALL of the following:</td>
<td>Activity modification (not bed rest) after patient education (&gt;= 2 months) 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)</td>
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**RECOMMENDATIONS:**

1. Lumbar spinal fusion is not recommended as routine treatment following primary disc excision in patients with a herniated lumbar disc causing radiculopathy.

2. Lumbar spinal fusion is recommended as a potential surgical adjunct in patients with a herniated disc in whom there is evidence of preoperative lumbar spinal deformity or instability.

3. Lumbar spinal fusion is recommended as a potential surgical adjunct in patients with significant chronic axial low back pain associated with radiculopathy due to a herniated lumbar disc.

4. Reoperative discectomy is recommended as treatment option in patients with a recurrent lumbar disc herniation.

5. Reoperative discectomy combined with fusion is recommended as a treatment option in patients with a recurrent disc herniation associated with lumbar instability, deformity or chronic axial low back pain.

Infrequently disc herniations may occur at L12 or L23, provided clinical signs/symptoms and imaging studies correlate and the same treatment pathways are followed, the potential for surgery will be considered the same methodology as other caudal levels (L34, L45, L5S1).

**Discography**

The recommendations for lumbar provocation discography include appropriate indications with patients with low back pain to prove the diagnostic hypothesis of the discogenic pain specifically after exclusion of other sources of lumbar pain and identification of the disc that should be targeted for treatment, or to establish either that no disc or too many discs are symptomatic, in which case surgery may not be indicated. Concerns regarding pain provocation in asymptomatic patients and normal discs have been raised, and were most recently addressed by Wolfer et al (1) in a meta-analysis of false-positive rates. Contrary to recently published studies, they concluded that discography is associated with a low false-
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<td>positive rate. Derby et al (2005) published multiple studies. Derby et al (1999) published a retrospective study evaluating the effect pressure controlled discography had on surgical and non-surgical outcomes. They found that patients with chemically-sensitive discs obtained better long-term outcomes with interbody/combined fusion than with intertransverse fusion. This suggests that categorization of positive discographic diagnoses can facilitate therapeutic decision-making. Schwarzer et al. (1995) performed discography in 92 patients with chronic low back pain utilizing International Association for the Study of Pain (IASP) criteria in an effort to identify historical or physical exam features associated with discogenic pain. In addition to concordant pain reproduction at a disc containing a grade 3 or 4 radial fissure, a negative control disc had to be present for a disc to be deemed a pain generator. Overall, 36 patients, or 39%, satisfied the criteria for a positive discogram. The 95% confidence limits for this proportion were 29% to 49%. The authors concluded that a diagnosis of painful IDD can only be made with discography. The study by Manchikanti et al (5) evaluated the relative contributions of potential pain generators in 120 patients with chronic non-radicular low back pain. All patients initially underwent controlled comparative diagnostic facet joint nerve blocks with lidocaine and bupivacaine. In patients with negative medial branch blocks, sacroiliac joint injections were performed in those patients with tenderness overlying the joint and positive provocative maneuvers. In subjects in whom the facet and SI joints were ruled out as causative factors, provocation discography was performed in accordance with IASP criteria. Overall, the prevalence of discogenic pain was estimated to be 26% (95% CI, 18%, and 34%).</td>
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Despite these benefits, the value and even safety of discography have been debated over the years. Criticisms of discography include a high false-positive rate, increased risk of complications, and the potential for iatrogenic disk injury and degeneration. Holt was the first to question the value of discography after he published an article detailing his results with a study population of asymptomatic inmates. In that widely cited study, pain was elicited in all patients after disk injection, and dye leakage was seen in 93% of cases. This study seemed to suggest that discography is associated with an alarmingly high false-positive rate. However, this conclusion has since been disputed because of inherent flaws in study design, and similar studies have been performed by using modern techniques that have shown a low false-positive rate with discography. In addition, discography is used to reproduce pain in symptomatic patients, making it difficult to interpret the results of studies of subjects without pain. |

Discography is associated with certain risks such as infection, including diskitis and epidural abscess, vascular injury, and spinal cord injury. All of these complications have been reported after discography, although the vast majority of serious adverse events were reported during the early days of discography and have not occurred as frequently with newer techniques. |

Carragee et al.(2000,2006, and 2009)) have reported on the results of discography in asymptomatic subjects. A controlled, randomized study of the pain response after discography in symptomatic and asymptomatic patients was conducted, drawing patients from a cohort of 240 patients who had undergone discography(2000). Twenty asymptomatic volunteers with normal psychometric screening from this group underwent discography, and the results were compared with a group of 27 symptomatic patients, also after previous discectomy. Twenty of the 27
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| patients in the control group had abnormal psychological testing. Forty percent of the asymptomatic patients had a positive response to the injection, compared with 63% in the symptomatic group. Among symptomatic patients, there was a higher rate of positive responses in patients with abnormal psychometric scores. Although this study demonstrated that injection of asymptomatic discs can be painful, it is important to note that the purpose of discography is to provoke existing clinical pain. Be definition this is impossible, to do in asymptomatic patients. Therefore, the validity of discography is, to some extent, dependent on the patient’s ability to distinguish between the kind of pain that might be elicited in asymptomatic discs and the patient’s existing pre-injection pain.

Some authors have raised concern over the potential for injury to the disc during the long-term. A study published by Carragee et al. (2009) detailed the results of a matched cohort of patients who underwent discography 10 years previously, specifically looking at the incidence of disc pathology and comparing that with matched controls. Of 75 subjects who had undergone 3 level discography in 1997, 50 patients and 52 control subjects met eligibility requirements for follow-up study and had repeat MRI scans. Discs subjected to injection had a higher incidence of degeneration (35% versus 14% in controls) and new disc herniation (55 new herniations versus 22 in controls). Disc height loss and signal changes were also greater after injection. All differences were statistically significant. This study raised obvious concerns about the safety of discography and its possible effect on the long-term health of the disc. However, most of the patients with demonstrable MRI disc changes were not symptomatic, and the authors would not have known about the disc abnormalities if the MRI had not been performed. The future implications of these disc changes remain undetermined. It should be noted that patients were described as “asymptomatic or minimally symptomatic” or “without serious low back pain.” The authors did not report whether patients who originally had minimal symptoms were more likely to be among those who later had degenerative changes regardless of discography.

Other studies published on this issue have had different findings. Flanagan and Chung (1986) found no more radiographic changes at 10-20 years among discs that had previously undergone discography than in those that had not had discography. In a study involving patients who underwent a second discogram for diagnostic purposes, the authors found no evidence of disc injury from the first procedure. Finally, in a canine study, histologic analysis failed to identify any changes in disc tissue after disc injection.

Discography, whether alone or in combination with other diagnostic tests, should be described clearly. At a minimum, pain provocation, disc morphology, and a controlled disc evaluation should be reported. The study should report that the discography was performed in accordance with modern principles utilizing fluoroscopy, pain provocation, and a control disc.

**Discography indicated by the Oklahoma Treatment Guidelines:**
- Back pain of at least 3 months duration
- Failure of recommended conservative including physical therapy
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| - Intended as a screen for surgery  
- Briefed on potential risks and benefits from discography and surgery  
- Use of control disk  
- Use of manometry and Derby guidelines for description of discogram outcomes.  
- Use of anxiolytic levels of sedation are permitted  
- Discograms shall be performed by the following: Board certified pain physician; board certified orthopedic surgeon with spine fellowship; board certified neurosurgeon | 

**Epidural Steroid Injection (ESI)**

Epidural injections are recommended as treatment options for acute and chronic pain. They are considered a viable treatment for radicular, neurogenic and discogenic pain. In addition, epidural injections are shown to be beneficial in the acute and chronic setting in those with disc herniation with and without radiculitis, discogenic pain without disc herniation, spinal stenosis, and post surgery syndrome. Epidurals are recommended if they facilitate an improvement in functionality via activity, exercise or a decrease in pain. Use of fluoroscopy with contrast is a requirement for all spinal injections. Contrast-enhanced fluoroscopy improves the accuracy of medication delivery. Nonfluoroscopically-guided caudal epidural injections have a rate of inaccurate placement ranging from 25-53%. Nonfluoroscopically-guided lumbar interlaminar epidural injections have a rate of inaccurate placement ranging from 17-30%. Accurate needle placement and success rates are affected by technician experience. (ESI ref#4,5,6,7,8) A “Series of Three” epidural steroid injections are no longer recommended. A “multiple injection regimen” should be distinguished from a “series of three” epidural series. In a multiple injection protocol, a patient is a candidate for additional injections when their pain recurs or becomes severe again and is provided on either patient demand or when the patient’s pain exceeded a preset level. The purpose is to control pain over a longer period of time in order to maximize the chance that a patient will respond to medical/interventional therapy. (8) The “Series of Three” approach was based on non-fluoroscopically guided injections prior to the advent of fluoroscopic guidance, performed at predetermine intervals regardless of the patient’s symptoms.

**Chronic Pain**: Use of fluoroscopy has improved outcome and duration of steroid effect. Reiw et al (2000) reported a significant decrease in back pain associated with lumbar herniated disc or spinal stenosis in those who underwent a multiple injection regimen, with only 47% proceeding to surgery. Manchikanti et al (2010) reported outcomes of a randomized, double-blind, controlled caudal injections for Post Lumbar Surgery measured numeric pain scores, Oswestry Disability Index, employment status and opiate use at 3, 6, and 12 month intervals. This indicated a greater than 50% reduction in pain scores from baseline. Participants received on average, 4 injections per year.

**Discogenic Pain**: Numerous studies support chemical nociception leading to low back pain without overt evidence of disc herniation. Manchikanti et al (2011) measured NRS, ODI, employment status and opiate use at 3, 6 and 12 months after treatment in patients treated with standard caudal ESI,
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<td>on average, 3-4 times per year. When participants were separated into successful responses (&gt;50%) and failed groups, significant differences in relief rates were seen. In summary, if the response is fair to poor with the first 2 procedures, patients will continue to exhibit a poor response with future treatments and no additional caudal ESI are indicated. Those who respond to interventional treatment should continue to receive injections in order to improve function and activity levels.</td>
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### ESI’s indicated by the Oklahoma Treatment Guidelines:

*Note: The purpose of ESI is to reduce pain and inflammation, thereby facilitating progress is more active treatment programs, reduction medication use and avoiding surgery, but this treatment alone offers no significant long-term functional benefit.*

1. Radiculopathy must be documented. Objective findings on examination need to be present. For unequivocal evidence of radiculopathy, see AMA Guides, 5th Edition, page 382-383. (Andersson 2000) Radiculopathy must be corroborated by imagining studies and/or electrodiagnostic testing.
2. Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants).
3. Injections should be performed using fluoroscopy (live x-ray) and injection of contrast for guidance.
4. **Diagnostic Phase:** At the time of initial use of an ESI (formally referred to as the “diagnostic phase) as initial injections indicate whether success will be obtained with this treatment intervention), a maximum of one to two injections should be performed. A repeat block is not recommended if there is inadequate response to the first block (<30% is a standard placebo response). A second block is also not indicated if the first block is accurately placed unless: (a) there is a question of the pain generator; (b) there was possibility of inaccurate placement; or (c) there is evidence of multilevel pathology. In these cases a different level or approach might be proposed. There should be an interval of at least one to two weeks between injections.
5. No more than two nerve root levels should be injected using transforaminal blocks.
6. No more than one interlaminar level should be injected at one session.
7. **Therapeutic phase:** If after the initial block/block(s) are given (see “Diagnostic Phase” above) and found to produce pain relief of at least 50-70% pain relief for at least 6-8 weeks, additional blocks may be supported. This is generally referred to as the “therapeutic phase.” Indications for repeat blocks include acute exacerbation of pain, or new onset of radicular symptoms. The general consensus recommendation is for no more than 4 blocks per region per year. (CMS, 2004) (Boswell 2007)
8. Repeat injections should be based on the continued objective documented pain relief, decreased need for pain medications, and functional response.
9. Current research does not support a routine use of a “series-of-three” injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections for the initial phase and rarely more than 4 for the therapeutic treatment.
10. It is currently not recommended to perform epidural blocks on the same day of treatment as facet blocks or sacroiliac blocks or lumbar sympathetic blocks or trigger points as this may lead to improper diagnosis or unnecessary treatment.
11. Cervical and lumbar epidural steroid injection should not be performed on the same day. (Doing both injections on the same day could result in an excessive dose of steroids, which can be dangerous, and not...
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<td>Hardware Removal</td>
<td>There are both absolute and relative indications for the removal of pedicle screw fixation of the lumbar spine. Spinal instrumentation developed as a means to stabilize the spine and allow for a fusion to consolidate. Fusion rate has substantially improved with the advent of instrumentation. (Zdeblick 1993, Fischgrund 1997 and Fritzell 2001) Instrumentation will become loose if the fusion does not heal; most generally this is identified at the bone-screw interface although failure of the screw, rod/plate with fracture or loosening of the fixation sites is also identified. With pseudoarthrosis of the fusion and excessive motion at the bone-screw interface, screw pullout and/or erosion of the pedicle wall may be identified. Even with a solid arthrodesis, over time screw loosening or fracture has been identified. Loosening may occur as a result of the differing modulus of elasticity of bone and implant material, and fracture secondary to metal fatigue failure. Infection may be an indication to remove hardware particularly if loosening or instability is identified. However, should the screw purchase remain stable the hardware may be an advantage in an acute infectious process. Instrumentation in the face of a chronic infection likely offers no advantage and may diminish the chances of resolving the infectious process. Many consider hardware removal following an acute infection despite apparent resolution of the condition and a solid arthrodesis, suggesting higher potential for recurrent infection with the retained hardware. Spinal instrumentation by nature of the posterior spinal anatomy may protrude and have a high profile. This is known to produce an inflammatory reaction in the surrounding muscles and soft tissues. Resulting swelling and tenderness leading to pain, diminished range of motion and activity has been documented. Patients may potentially recover from this inflammation with rest, time, non-steroidals and exercise. Some patients do not recover and should be considered candidates for hardware removal. Hardware removal has been investigated Kim et al (2009) retrospectively reviewed patients with a thoracolumbar fusion. Following removal of instrumentation patients were followed an average of 18 months. 93% of patients reported excellent or good results when evaluated with modified MacNab criteria. Alexander et al (2003) studied 45 patients all presenting with recurrent low back pain and leg pain. Preoperative radiographic evaluation suggested all fusions were solid. Hardware was removed by a single surgeon. Intraoperative finding categorized the patients into two groups, loose or solid instrumentation. Patients with loose instrumentation reported 82% favorable results. Patients whose instrumentation was deemed solid reported 77% favorable results. This study indicates that the removal of instrumentation in the absence of a pseudoarthrosis is beneficial in the relief of low back pain and leg symptoms. Success rates were noted in patients with loose instrumentation.</td>
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<tr>
<td>Hardware Blocks</td>
<td>May be helpful in determining if the patient’s complaints are specifically secondary to irritation of surrounding soft tissue and muscles or other etiologies. Generally performed with a minimally or nonsedated patient under fluoroscopic guidance, Marcaine or another long acting anesthetic being utilized.</td>
</tr>
</tbody>
</table>

**Hardware Removal indicated by the Oklahoma Treatment Guidelines:**

Removal indicated for:
- **A)** Hardware failure
  - 1. bone screw interface
  - 2. fractured screw
  - 3. loss of fixation
- **B)** Malpositioning
- **C)** Chronic infection
- **D)** Following acute infection
- **E)** Following failed fusion
- **F)** Following successful fusion with irritations of soft tissues producing limitation of activities and/or need for narcotic medications

| Intraoperative Spinal Monitoring | Resnick (2005) – Recent advances in the field of spinal monitoring have provided a wide array of techniques to assess the functional integrity of the nervous system. These methods have been used as an adjunct to clinical evaluation and for neurologic surveillance during surgical procedures which place the spinal cord or nerve roots at risk of injury. Use of intraoperative neurophysiologic monitoring (IONM) has become commonplace during spine surgery. The purpose of modern IONM is to provide feedback to surgeons and anesthesiologists regarding changes in neural function before the development of irreversible neural injury, thereby permitting intervention to prevent or minimize postoperative neurologic deficit. Historically, the Stagnara wake-up test was the first widely used method for spinal monitoring. (Bieber 1988). Although this test provides assessment of gross integrity of motor function during and at the conclusion of a spine procedure, it cannot be administered in a continuous fashion during surgery and is unable to provide information regarding spinal cord sensory tract function or individual nerve root function. Perhaps the greatest shortcoming of the wake-up test is its performance at a single point in time during surgery. Balzer et al 1998 reported on a group of 44 patients studied with SSEPAS as well as EMG and evoked EMG monitoring. Although the negative predictive value of normal SSEPs was high (97%), the incidence of safe screw placement was also high (97%). Manninen (1998) reported in a series of 309 patients treated surgically specificity of spinal monitoring was 95% in determining new deficits. Norcross-Nechay et al (1999) monitored 70 patients they treated with lumbar decompression, instrumentation and fusion with continuous SSEP monitoring and noted significant changes in 12 cases. In all 12 instances immediate intraoperative “adjustments” were made and high dose steroids were given to these patients whose responses did not return to normal. Three patients had persistent deficits postoperatively. |
Clements et al (1996) prospectively studied the efficacy of evoked and spontaneous EMG in a series of 25 patients who were treated with instrumented lumbar fusion procedures. One hundred twelve screws were placed. Authors found that a pedicle breach was predicted with 100% accuracy when the stimulating threshold was less than 11ma. Pedicle breech was confirmed by visualization or palpation of the medial pedicle wall at the time of surgery.

Darden and colleagues (1996, 1998) published two papers that provide useful information. They prospectively evaluated 132 consecutive patients treated with an instrumented lumbar fusion, and analyzed data using arbitrary threshold cutoffs of 20 and 40v. Patients were divided into 3 groups. Group I no positive EMG response noted. Group II positive response with no corrective action undertaken. Group III corrective action taken after a positive response. Using 40v as a cutoff, Group I 10% of patients had postoperative deficits. Group II 15% had postoperative deficits and Group III no patients exhibited deficits. In the 1998 papers the authors demonstrated that using a 20v threshold was more specific and sensitive for pedicle wall violation.

Application is equally if not more essential in cervical procedures. Epstein et al. (1993) compared the morbidity and mortality of 100 consecutive SSEP monitored cervical procedures with a historical cohort population of 218 patients who underwent unmonitored cervical procedures for myelopathy and radiculopathy. SSEPs were determined to be valuable in improving patient outcome after cervical surgery in the monitored group. In the unmonitored group 3.7% became quadriplegic and 0.5% died whereas no instances of quadriplegia or death were noted in the monitored group. May et al (1996) reported a series of 191 patients undergoing cervical surgery for diverse diagnoses. Upper limb SSEP responses were recorded reliably in 182 patients with a sensitivity of 99% and specificity of 27% in 10 patients who developed neurologic signs postoperatively. Potential risk factors for electrophysiologic and neurologic deterioration were determined as 1) preoperative myelopathy, 2) long segmental extent of surgery, 3) upper cervical surgery, 4) use of instrumentation and 5) application of corrective forces to the neck. It was argued that the false-positives in this series may have included a number of patients in whom neurologic deterioration was successfully prevented as a consequence of the surgeon’s response to the SSEP amplitude loss.

Kombos et al (2003) prospectively evaluated SSEP monitoring in 100 patients (Group I – cervical myelopathy; Group 2 – radiculopathy or mild hyperreflexia; Group 3 – acute neurologic deficit) treated with anterior cervical decompression and fusion. SSEPs were performed during five stages of the procedure: M1, after induction of anesthesia; M2, during positioning; M3, during distraction of the intervertebral space; M4, throughout decompression; and M5, during graft placement. No SSEP changes were identified in any patients during induction (M1). Deterioration of SSEPs was seen across all groups (35% of all patients; 41% in Group 1, 23% in Group 2, 47% in Group 3) during positioning (M2) and 5 minutes afterward. Deterioration of SSEPs were reported with distraction of the intervertebral space (M3) in Group 1 (17%) and Group 3 (40%). No SSEP changes were noted with decompression of the spinal cord (M4) in any group. Acute deterioration of SSEPs was recorded in one Group 2 patient during graft placement (M5). In this study, intraoperative SSEP monitoring during anterior cervical spine surgery permitted...
### Procedure Summary – Lower Back Treatment Guidelines

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<tr>
<td>Modification of surgical strategy to reduce the SSEP deterioration. The most common changes occurred during patient positioning and were more frequent in patients with myelopathy. Medical evidence exists to support the validity of neurophysiologic monitoring as a diagnostic tool for assessment of neurologic function during cervical spine surgery. Devlin et al (2006) use of intraoperative spinal monitoring is recommended in those circumstances during instrumented lumbar spinal fusion procedures. Spinal monitoring provides immediate “real time” intraoperative information regarding the potential of a neurologic injury.</td>
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### Spinal monitoring IS recommended for patients with the following diagnosis/procedures:
- Cervical or thoracic myelopathy
- Anterior cervical disectomy and fusion
- Posterior cervical fusion
- Multilevel posterior cervical decompression (stenosis)
- Trauma fracture, subluxation, dislocation, potentially unstable pathology with or without neurologic deficit cervical, thoracic or lumbar
- Lumbar fusions with instrumentation (anterior or posterior)
- Severe multilevel stenosis(lumbar)

### Spinal monitoring IS NOT recommended for patients with the following diagnosis/procedures:
- Posterior cervical laminectomy for disc herniation or foraminal stenosis
- Lumbar disectomy (1 or 2 levels)
- Hardware removal cervical, thoracic or lumbar

### Sacroiliac Joint Injection
Sacroiliac Joint Injection is a generally accepted injection of local anesthetic in an intra-articular fashion into the sacroiliac joint under radiographic guidance. May include the use of corticosteroids. Long-term therapeutic effect has not yet been established.
- Indications - primarily diagnostic to rule out sacroiliac joint dysfunction vs. other pain generators. Intra-articular injection can be of value in diagnosing the pain generator. There should be documented relief from previously painful maneuvers (e.g., Patrick’s test) on post-injection physical exam. These injections may be repeated if they result in increased documented functional benefit for at least 6 weeks and at least a 50 percent initial improvement in pain scales as measured by accepted pain scales (such as VAS). Sacroiliac joint blocks should facilitate a functionally directed rehabilitation program.
  (i). Time to produce effect: Approximately 30 minutes for local anesthetic; 48 to 72 hours for corticosteroid.
  (ii). Frequency and optimum duration: two to three injections per year. If the first injection does not provide a diagnostic response of temporary and sustained pain relief substantiated by accepted pain scales, (i.e.,50 percent pain reduction substantiated by tools such as VAS), and improvement in function, similar injections should not be repeated. At least six weeks of functional benefit should be obtained with each therapeutic injection.
  (iii). Maximum duration: four injections per year.

### Zygaphophyseal (Facet) Injection
Zygaphophyseal (Facet) Injection is a generally accepted intra-articular or pericapsular injection of local anesthetic and corticosteroid.
- Medial branch nerve blocks are diagnostic only. There is conflicting
Procedure Summary – Lower Back Treatment Guidelines

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<tr>
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<td>evidence to support a long-term therapeutic effect using facet injections. There is no justification for a combined facet and medial branch block.</td>
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<td>• Indications - patients with pain 1) suspected to be facet in origin based on exam findings and 2) affecting activity; OR, patients who have refused a rhizotomy; OR, patients who have facet findings with a thoracic component. In these patients, facet injections may be occasionally useful in facilitating a functionally-directed rehabilitation program and to aid in identifying pain generators. Patients with recurrent pain should be evaluated with more definitive diagnostic injections, such as medial nerve branch injections, to determine the need for a rhizotomy. Because facet injections are not likely to produce long-term benefit by themselves and are not the most accurate diagnostic tool, they should not be performed at more than two levels.</td>
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<tr>
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<td>(i). Facet injections may be repeated if they result in increased documented functional benefit for at least four to six weeks and at least an 50 percent initial improvement in pain scales as measured by accepted pain scales (such as VAS).</td>
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<tr>
<td></td>
<td>[a]. Time to produce effect: Up to 30 minutes for local anesthetic; corticosteroid up to 72 hours.</td>
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<td></td>
<td>[b]. Frequency: one injection per level with a diagnostic response. If the first injection does not provide a diagnostic response of temporary and sustained pain relief substantiated by accepted pain scales, (i.e., 50 percent pain reduction substantiated by tools such as VAS), and improvement in function, similar injections should not be repeated. At least four to six weeks of functional benefit should be obtained with each therapeutic injection.</td>
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<tr>
<td></td>
<td>[c]. Optimum duration: two to three injections for each applicable joint per year. Not to exceed two joint levels.</td>
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<td>[d]. Maximum Duration: four per level per year. Prior authorization must be obtained for injections beyond two levels.</td>
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Occupational Rehabilitation

Aquatic Therapy

Aquatic Therapy is a well-accepted treatment which consists of the therapeutic use of aquatic immersion for therapeutic exercise to promote strengthening, core stabilization, endurance, range of motion, flexibility, body mechanics, and pain management. Aquatic therapy includes the implementation of active therapeutic procedures in a swimming or therapeutic pool.

The water provides a buoyancy force that lessens the amount of force gravity applies to the body. The decreased gravity effect allows the patient to have a mechanical advantage and more likely have a successful trial of therapeutic exercise. The therapy may be indicated for individuals who:

i. cannot tolerate active land-based or full-weight bearing therapeutic procedures;

ii. require increased support in the presence of proprioceptive deficit;

iii. are at risk of compression fracture due to decreased bone density;

iv. have symptoms that are exacerbated in a dry environment;

v. would have a higher probability of meeting active therapeutic goals than in a dry environment.

(a). The pool should be large enough to allow full extremity range of motion and fully erect posture. Aquatic vests, belts and other devices can be used to provide stability, balance, buoyancy, and resistance.

(i). time to produce effect: four to five treatments;

(ii). frequency: three to five times per week;
# Procedure Summary – Lower Back Treatment Guidelines

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<tr>
<td>(iii). optimum duration: four to six weeks; (iv). maximum duration: eight weeks; (b). A self-directed program is recommended after the supervised aquatics program has been established, or, alternatively a transition to a self-directed dry environment exercise program. (c). Functional Activities: are well-established interventions which involve the use of therapeutic activity to enhance mobility, body mechanics, employability, coordination, balance, and sensory motor integration. (i). time to produce effect: four to five treatments; (ii). frequency: three to five times per week; (iii). optimum duration: four to six weeks; (iv). maximum duration: six weeks.</td>
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<tr>
<td>Spinal Stabilization</td>
<td>Spinal Stabilization a generally well-accepted treatment. The goal of this therapeutic program is to strengthen the spine in its neural and anatomic position. The stabilization is dynamic which allows whole body movements while maintaining a stabilized spine. It is the ability to move and function normally through postures and activities without creating undue vertebral stress. (i). time to produce effect: four to eight treatments; (ii). frequency: three to five times per week; (iii). optimum duration: four to eight weeks; (iv). maximum duration: eight weeks.</td>
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<tr>
<td>Transcutaneous Electrical Nerve Stimulation (TENS).</td>
<td>Transcutaneous Electrical Nerve Stimulation (TENS) is a generally accepted treatment. TENS should include at least one instructional session for proper application and use. Indications include muscle spasm, atrophy, and decreased circulation and pain control. Minimal TENS unit parameters should include pulse rate, pulse width and amplitude modulation. Consistent, measurable functional improvement must be documented prior to the purchase of a home unit. (i). time to produce effect: Immediate; (ii). frequency: Variable; (iii). optimum duration: three sessions; (iv). maximum duration: three sessions. If beneficial, provide with home unit or purchase if effective.</td>
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## Procedure Summary – Patient Selection Criteria for Lumbar Spinal Fusion

### (Overview)

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<tr>
<td><strong>Spinal Fusion:</strong> Patient Selection Criteria</td>
<td><strong>Oklahoma Treatment Spinal Fusion Guidelines:</strong> The following guidelines are more in line with indemnity carriers (United Healthcare, BCBS of Oklahoma and Aetna), as well as other state sponsored treatment guidelines for injured workers Colorado, Delaware, Louisiana and New York.</td>
</tr>
<tr>
<td></td>
<td>For chronic low back problems, fusion should not be considered within the first 4 to 5 months of symptoms, except for fracture, dislocation/subluxation or progressive neurologic loss. Indications for spinal fusion may include</td>
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<tr>
<td></td>
<td>1) Neural arch defect – spondylotic spondylolisthesis, spondylolisthesis with pars interarticularis defect, and congenital neural arch hypoplasia</td>
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<td></td>
<td>2) Segmental instability objectively demonstrable on radiographs. a. Excessive motion on flexion-extension radiographs as in spondylolisthesis (\backslash\text{b. Identification of antero or retrolisthesis of 3.5mm on lateral x-ray} )</td>
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<td></td>
<td>(\text{c. Mechanical intervertebral collapse of the motion segment or advanced degenerative changes after surgical discectomy to include retrolisthesis following disc herniation.} )</td>
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<td>Additionally, fusion is indicated when it is anticipated that adequate decompression requires creation of a pars defect or removal of either 75% of one facet joint or 50+% of both facet joints.</td>
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<td></td>
<td>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 disc height, disc loading capacity. Prior to surgical considerations patients should participate actively in a physical therapy rehab program for 6 to 8 weeks. May require psychological evaluation if symptoms of significant depression or abnormal pain behaviors exist and any narcotic dependence should be managed</td>
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<td></td>
<td>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 caution due to lessor outcomes with revision surgery</td>
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<td></td>
<td>5) Infection, tumor or deformity of the lumbosacral spine that cause intractable pain, neurological deficit and/or functional disability</td>
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<td>6) After failure of discectomy affecting the same disc either ipsilateral or contralateral if indicated</td>
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</table>

**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) Psychological screen with confounding issues addressed and if necessary; (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.
### Procedure Summary – Patient Selection Criteria for Lumbar Spinal Fusion (Overview)

<table>
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| Spinal Fusion Indications | **Indications for spinal fusion may include**  

#### I. Neural Arch Defects

Neural arch defect includes (A) spondylolisthesis: in the workers’ compensation area most commonly presents as isthmic or spondylotic. The isthmic variety is further subdivided into lytic-fatigue fractures of the pars interarticularis, elongated but intact pars and acute pars fracture. Spondylolysis refers to a disruption of the pars, however the vertebral body shows no slippage. Spondylosis: refers to a pattern of degenerative changes, disc and facet joints that allows subluxation. Neural arch defects allow movement anteriorly of the vertebral body with the pars defect relative to the vertebral body below. Presentation most often occurs at L5-S1 with the isthmic type and L4-5 with the spondylotic variety.

Symptoms may include mechanical, radicular pain or both. Patients may develop foraminal, lateral recess or central stenosis. Potential disc failure and/or herniation may occur and further compound the neurologic impingement.

Several studies have advocated improved clinical results with surgery for degenerative spondylolisthesis. A most recent report Wernstein (2007 SPORT) compared surgical and nonsurgical treatment of lumbar degenerative spondylolisthesis. Three hundred and four patients were enrolled and randomized into surgical and nonsurgical arms. The as-treated analysis for both cohorts combined showed a significant advantage for surgery at 3 months, increasing at 1 year and diminished only slightly at 2 years.

Available literature suggests a strong correlation with surgical decompressive laminectomy coupled with a fusion and instrumentation for improvement of symptoms when compared to a decompressive laminectomy without fusion.

Herkowitz and Kurz (1991) prospectively studied 50 patients with spinal stenosis associated with degenerative spondylolisthesis. All patients underwent a decompressive laminectomy; one group also received a posterolateral fusion. Patients were followed for a mean of 3 years. In the patients receiving the concomitant arthrodesis, results were significantly better with respect to relief of low back and lower limb pain. Class I, the addition of a fusion improves back pain and lower limb pain in patients with spondylolisthesis.

Feffer et al (1985) reported on 19 patients with degenerative spondylolisthesis, 8 patients underwent decompression with fusion, and 11 patients received decompression alone. Of the 8 with fusion greater than half had good or excellent results and none graded out as poor. Of the 11 with decompression alone less than half reported good or excellent results and 3 were poor. In addition, 4 patients developed gross instability following decompression alone. Mochida et al (1990) divided 102 patients with degenerative spondylolisthesis into 3 groups (group I nonrigid instrumentation 33 patients, group II rigid instrumentation 34 patients and group III no instrumentation 35 patients.) The results favored rigid instrumentation with the best outcomes and lowest pseudoarthrosis rate, while the noninstrumented group noted diminished good and excellent results and the highest rate of pseudoarthrosis. Lombardi et al (1985) studied 47 patients comparing decompressive laminectomy to decompressive laminectomy with fusion. The results suggested the addition of a fusion was beneficial. These articles suggest the addition
### Procedure Summary – Patient Selection Criteria for Lumbar Spinal Fusion

#### (Overview)

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<td>of a fusion to a decompression will enhance long term results, and represent class III evidence for stabilizing a spondylolisthesis by means of a lumbar fusion. Katz et al reported results of a retrospective multicenter observational trial involving 272 patients, 71 percent treated with laminectomy alone and 29 percent treated with an instrumented or noninstrumented fusion in addition to the laminectomy. Fusion treated patients reported better outcomes with respect to back pain scores (p&lt;.005). Patients treated with fusion/decompression continued to enjoy improved outcomes at the 24 month re-evaluation. Class II Fusion with Instrumentation improves outcomes in spinal stenosis with spondylolisthesis. Fischgrund et al (1997) discovered 76 patients studied prospectively reporting good or excellent results in 78 percent without instrumentation and 85 percent with instrumentation. Class II Fusion with instrumentation improves outcomes in spinal stenosis with spondylolisthesis. Bridwell et al (1993) performed a prospective study of 44 patients with neurogenic claudication symptoms and stenosis due to spondylolisthesis. Patients randomized into one of three groups. Decompression alone (group I), decompression and non-instrumented fusion (group II) and decompression and instrumented fusion (group III). All patients with preoperative instability were placed automatically into group III. Outcomes were assessed using a satisfaction scale approximately 3 years following surgery. Improved radiographic and functional outcomes among patients in group III compared with the other two treatment groups was identified. Scheufler et al (2007) reported results of percutaneous transforaminal lumbar interbody fusions as an alternative to posterolateral fusions in treating degenerative lumbar instability. Forty-three patients received a single level fusion and 10 patients a two level procedure. At 16 months postop, 87 percent of patients reported good and excellent results. Patients were required to have suffered from low back pain for at least 2 years and were required to have radiographic and clinical evidence of spondylosis at L4-L5, L5-S1 or both levels. Lumbar fusion is recommended as a treatment for carefully selected patients with disabling low back pain due to one or two level spondylolisthesis that have failed six to eight weeks of physical therapy and are three to four months from the date of injury. Three additional Class III reviews suggest strong correlation with instrumented fusion and decompression, Gertzien et al (1996) reported a 2 year followup on circumferential fusions. In the subgroup with degenerative spondylisis, more favorable results were identified and return to work was greater. Pain was significantly reduced from 7.1 – 2.1 (back) and 5.8 – 1.5 (leg). Nork et al (1999) reported on 30 patients with degenerative spondylolisthesis with SF-36 outcomes data; 93 percent were satisfied at followup at 37 months. Patients improved significantly in ability to perform heavy and light activities, social activities, sit and sleep. Pain, depression and medication usage also improved (P&lt; 0.00001). Kimura et al (2001) retrospectively studied 57 patients with an L4-5 degenerative spondylolisthesis undergoing decompression and fusion with and without instrumentation. In the instrumentation group the satisfactory rate was higher and nonunion rate lower. Isthmic Spondylolisthesis: In addition there are several articles that specifically address treatment of isthmic...</td>
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| Isthmic Spondylolisthesis: |
| In addition there are several articles that specifically address treatment of isthmic... |
Moeller and Hedlund (2000) performed a randomized study of surgery versus conservative management in adult isthmic spondylolisthesis. One hundred eleven patients randomly allocated to an exercise program (34) or posterolateral fusion with or without instrumentation. Inclusion criteria was any grade of isthmic spondylolisthesis, at least one year of low back pain or sciatica and severely restricted functional ability in patients 18 to 55 years of age. The two year follow-up rate was 93%. The functional outcome, as assessed by the disability rating index and pain reduction was better in the surgically treated group than the exercise group at both 1 and 2 year assessments.

Recent spine publication Wood et al (2011) studied surgical versus structured rehabilitation in chronic low back pain with and without isthmic spondylolisthesis. This study consisted of a literature review and analysis. Standardized mean differences for pain and function in favor of a fusion were modest at 2 years among those without isthmic spondylolisthesis, but large in favor of fusion among those with isthmic spondylolisthesis compared with rehabilitation.

The previous referenced articles do not suggest criteria for fusion including segmental instability, only that significant stenosis and/or neurologic compression with appropriate symptoms were identified.

**IIA. Segmental Instability**

Primarily the work of White, Panjabi, et al (1981) although several publications exist. An excellent review was published in the American Academy of Orthopedic Surgeons Instructional Course lecture series volume 30, 1981. This was created to assist with the challenging issue of determining when an injured spine is unstable and in need of treatment. Clinical instability is defined as the loss of the ability of the spine under physiologic load to maintain relationship between vertebrae in such a way that there is neither damage nor subsequent irritation to the spinal cord or nerve roots and in addition there is no development of incapacitating deformity of pain from structural changes.

Identification of an unstable motion segment

<table>
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<tr>
<th>Cervical</th>
<th>Angulatory: &gt;11° angulation greater than interspace above or below the sagittal plane</th>
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<td>Translational: Exceeds 3.5 mm listhesis sagittal plane</td>
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<tr>
<th>Lumbar</th>
<th>Angulatory: &gt;11° angulation greater than interspace above or below sagittal plane</th>
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<tr>
<td></td>
<td>Translational not specified in article, others have used the following to ascribe instability</td>
</tr>
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<td>Listhesis ≥ 3.5 to 4 mm</td>
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Studies from Frymoyer JW (1991), Mirkovic S, Garfin SR (1991), and Denning et al. (1980). All suggest that anterior listhesis of 3 to 4 mm suggests spinal instability.

**Types of Spinal Instability:**

Type 1 is defined as axial rotational instability. Farfan and Kirkaldy-Willis reported a fixed rotary deformity in some patients who present with low-back pain on twisting about the spine. Plain radiographs revealed narrowing of the disc space, facet...
### Procedure Summary – Patient Selection Criteria for Lumbar Spinal Fusion (Overview)

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<td>degeneration, malalignment of the spinous processes, and a rotational deformity of the pedicles.</td>
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<tr>
<td>Type 2, or transitional instability, (41) manifests as episodes of recurrent back pain associated with forward translation at the affected level. On plain radiographs, the disc space is narrowed, but the alignment of the spinous processes and pedicles is normal. Lateral flexion-extension radiographs show angulatory collapse of the disc space and forward subluxation at the affected level. This type of instability typically affects women and is most common at L4-5.</td>
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<tr>
<td>Type 3, or retrograde spondylolisthetic instability, is most common at L5-S1 and affects as many as one-third of the patients with low-back pain. Plain lateral radiographs demonstrate posterior translation, collapse of the disc space, and facet subluxation. Radiographic imaging of the neural canal often shows lateral stenosis of the spinal cord.</td>
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<td>Type 4, or postoperative instability, occurs after aggressive decompressive surgery of the lateral spinal canal. Removal of an entire facet, pars interarticularis, or half of each facet at the same level may produce instability. Lateral radiographs demonstrate anterior or posterior spondylolisthesis of the affected level compared with preoperative films.</td>
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<tr>
<td>Sagittal Plane Subluxation Evaluation (Lateral X-ray)</td>
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<tr>
<td>Static or Flex/Ext Static or Flex/Ext Static or Flex/Ext Static or Flex/Ext</td>
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<tr>
<td>Static Static Static Static</td>
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<tr>
<td>Cervical spine 3.5 mm 3.5 mm &gt;11° difference compared to level above and below</td>
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<tr>
<td>Lumbar spine 3.5 mm 3.5 mm &gt;11° difference compared to level above and below</td>
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<td>Instability patterns may develop via trauma, either acute or accumulative, degenerative changes (or tumor although not typically considered a work injury). Instability patterns treated surgically require stabilization procedures. Fusions to stabilize the spine more frequently heal with internal fixation. Fusion with instrumentation is well documented in the following articles.</td>
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<td>Spinal Instrumentation has been extensively studied Lorenz et al (1991). Prospectively randomizing 68 patients with greater than 6 months of disabling back pain. Group I (29 PLF w/o instrumentation), Group II (39 PLF with instrumentation) mean F/U 26 months, fusion based on flexion/extension x-rays, 59% solid Group I and 100% solid instrumented Group II. Return to work 31% Group I and 72% Group II instrumented.</td>
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<td>Fischgrund et al (1997). A Prospective randomized of 76 patients, all patients received a posterolateral intertransverse process arthrodesis. Two groups: when fusion with and without segmental transpedicular instrumentation. Overall fusion occurred in 82% of instrumented fusions and 45% noninstrumented fusions.</td>
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<td>Zdeblick (1993) Prospective randomized study consists of 3 groups, Group I posterior lumbar fusion without instrumentation, Group 2 posterolateral fusion with semirigid fixation and Group 3 posterolateral fusion with rigid fixation, both fusion rate and clinical outcome improved with rigid fixation.</td>
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</tbody>
</table>
IIB. Surgically induced segmental instability

It is generally recognized the surgical excision of >50% of both facet joints or removal of two-thirds, White (1981), 75% (ISASS July 2011) or complete removal, Grogawala (2004) of a single facet will create an unstable motion segment with potential for progressive subluxation either an anterolisthesis or retrolisthesis. The reported rate of postoperative slippage has ranged from as low as 9% in patients with no evidence of preoperative lumbar spinal instability. Jolles (2001) to as high a 73% in those with preoperative evidence of spondylolisthesis. Fox (1996) Multilevel laminectomies and wide decompressions have also been shown to have a positive correlation with an increased incidence of progressive spondylolisthesis. Hopp (1998), Shenlein (1979). In an analysis of 100 laminectomy – treated patients, Caputy and Luessenhop (1992) found that the main risk factor for five year clinical and radiographic failure was preoperative spondylolisthesis. 25 In topic reviews and meta-analysis of the literature, several authors have stressed the importance of identifying spondylolisthesis and scoliosis as risk factors for progressive instability and poor outcomes.

Whereas spondylolisthesis and scoliosis are easily identified on radiography as potential risks for post decompression instability, several techniques have been advocated as a means by which to identify most subtle forms of preoperative spinal hypermobility or deformity. The most popular of these methods are criteria based on dynamic lateral flexion-extension images. Grob (1995), Herkowitz (1991), Yone (1999), Yone (1996). Both studies show no benefit with addition of a fusion if no preoperative instability is identified.

Several studies have shown that in patients undergoing decompressive laminectomy for spinal stenosis should they have no risk factors for spondylolisthesis or instability the addition of a fusion does not improve overall results. Corneford et al retrospectively reviewed 124 patients of whom 96 were available for followup. Grob et al randomized 45 patients with stenosis but no evidence of preoperative spondylolisthesis or instability. Grob (1995), Cornefjord (2000).

Nasca (1987) reported a retrospective review of 80 patients and two years later described 114 patients treated for lumbar stenosis. In addition to decompression, fusion was performed in 51 patients and decompression alone was performed in 58. He reported overall good outcome in 70%. There was a trend toward better results with fusion in patients with instability patterns (e.g.: spondylolisthesis, scoliosis, severely degenerated facet joints, collapsed disc spaces and preoperative movement noted on dynamic spinal radiographs.) Fox (1996) performed a retrospective analysis of 124 patients they had treated for symptomatic lumbar stenosis. They observed that 91% of those who had undergone laminectomy and fusion reported good outcomes compared to 75% of those treated with laminectomy alone. The majority of patients selected for fusion were reported to have preoperative instability or spondylolisthesis.

Recommendation for: Facet Destabilization (Iatrogenic instability)

The literature supports arthrodesis with instrumentation in patients undergoing a lumbar decompressive laminectomy when either 75% of a single facet joint is sacrificed or when it is necessary to remove 50% or greater of two-facet joints at the same level. Additionally severe facet arthrosis or disc space collapse has been shown...
II C. Surgically induced segmental instability and mechanical intervertebral collapse of the motion segment and advanced degenerative changes after discectomy.

Several authors have reported unsatisfactory results ranging from 5% to 20% following lumbar discectomy. The intervertebral disc acts as a primary stabilizer, injury can lead to segmental spinal instability, which may present as low back pain or radiculopathy. Recurrent disc herniation may also be identified on gadolinium enhanced MRI, symptoms may occur early or more often over a number of years.

Kotilainen (1998) found that 22% of their patients developed clinical and radiographic signs of lumbar spinal instability following microdiscectomy. Kotilainen then follow up 5 years later in 39 of the patients in whom clinical and radiographic instability after primary disc excision developed, concluding that patients who experience instability after lumbar discectomy did not do well.

Caochoix et al (1978) reported followup of patients treated with discectomy alone nothing 5.9% developed signs and symptoms of mechanical instability that subsequently developed and required fusion. Padoa and colleagues studied 150 patients, 30 patients developed radiographic signs of instability.

Yorimitsu (2001) reported that 76% of patients following discectomy and followed for 10 years suffered from residual low back pain. Thirteen percent reported severe low back pain, many of whom were unable to return to work. Thirteen percent reported severe low back pain, many of whom were unable to return to work. Similarly, Loupasis (1999) reported that 28% who they treated with discectomy continued to complain of significant back or leg pain 7 to 10 years after surgery.

Dvorak (1988) found 23% complained of “heavy constant” back pain that often limited ability to work four to seventeen years following discectomy.

 IID. Recurrent lumbar disc herniation

Recurrent lumbar disc herniation has been reported between 9% and 15% of patients after lumbar disc excision. Since the overall rate of unsatisfactory results is between 5% and 20% it is therefore a major cause of failure. Although several conditions have been termed “recurrent disk herniation,” it is defined as disc herniation at the same level, regardless of ipsilateral or contralateral herniation, with a pain free interval greater than six months. Diagnosis is best identified with gadolinium enhanced magnetic resonance imaging.

Many of these re-herniations are accompanied by additional radiculopathy and low back pain. In these patients treatment typically involves a partial discectomy and lysis of adhesions without the addition of a fusion. The intervertebral disc acts as the primary stabilizer of the functional spinal units and decreases the biomechanical forces transmitted to the adjacent vertebral endplates. Injury to the intervertebral disc can potentially lead to segmental spinal instability, which may result in chronic low back pain or recurrent disc herniation.

Suk et al (1976) reported on 28 patients with a recurrent disc herniation, levels included L4-5 (19 patients) and L5-S1 (9 patients). Gadolinium MRI confirmed the diagnosis. Revision surgery means of open discectomy. Authors reported
Procedure Summary – Patient Selection Criteria for Lumbar Spinal Fusion
(Overview)

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|                  | satisfactory results, with no significant differences in age, gender, smoking, level and degree of herniation. Cinotti et al. 1998 reviewed 26 patients with recurrent disc herniation. Fifty consecutive patients who had a disc excision during the study period but did not have recurrent radicular pain were analyzed as a control group. T2-weighted MRI performed before primary discectomy showed that patients in the recurrent group had significantly more disc degeneration than compared to the control group. All patients treated with revision discectomy, reporting satisfactory results in 85%.

Other authors have advocated a spinal fusion with revision discectomy. Quimjian and Mattrka (1988) and Vishteh and Dickman (2001). Additionally, patients may present with mechanical low back pain with or without radicular features.

Additional evidence:
Choi (2005), Fu (2005), Papadopoulos (2006) have published studies evaluating the treatment of recurrent disc herniation and post-discectomy with fusion. In single cohort, retrospective studies, Choi, Chen, and Papadopoulos reported significant improvement in outcomes. Fu conducted a retrospective comparative study of patients with current disc herniation. Patients received treatment with either a discectomy or a discectomy with fusion. The decision to apply fusion was made during the procedure. If a facetectomy was required to prevent neurologic injury and excessive nerve root manipulation and to ensure adequate exploration and excision of the disc fragment, lumbar fusion was performed to reduce the risk of iatrogenic instability. Excellent/good clinical outcomes were reported for 78% of patients who had discectomy alone and in 83% of patients with fusion.

No large randomized prospective studies of recurrent disc herniation have been identified.

Bernard (1993) reviewed 45 patients that required repeat surgery following lumbar discectomy. Thirty-eight patients were fused at the time of the revision discectomy. Factors predicting a good outcome included
- Greater than 6 month pain relief after surgery
- Leg pain worse than back pain
- Nerve root decompression from disc or bone
- Diagnostic studies that correlate with clinical examination
- Neurologic deficit
- Solid fusion achieved
- With regard to work status at the time of followup 14 patients were working outside of the home. Ten patients returned to their same employment and four began new employment after surgery. All of these 14 patients had good result from revision surgery. Among the three patients who stopped working and started school after surgery, two had a good result, and one a failed result. Nine patients older than age 65 who were working before their first back operation but considered themselves totally disabled from gainful employment after revision surgery. In this group, there were nine good and six failed results.

III. Primary Mechanical Back Pain

Primary Mechanical Back Pain (discogenic, internal disc disruption) (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
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<td>height, disc loading capacity. 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 lack of support for fusion for mechanical low back pain for patients with failure to participate in active rehab preoperatively, active psychologic diagnosis, and narcotic dependence.</td>
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<td>Received the 2001 Volvo Award Winner in Clinical Studies. Fritzell et al (2001) prospectively randomized 294 patients into a control group treated with physical therapy and three surgical groups managed with three fusion techniques. The patients had suffered from low back pain for a mean 8.0 years and had been on such leave due to back pain for approximately 3.0 years. The Visual Analogue Scale (VAS) was used to measure pain. The Oswestry Low Back Pain Questionnaire, the Million Score, and the General Function Score (CFS) were used to measure pain. The Zung Depression Score was used to measure depressive symptoms. At the two year followup, 98% of patients were examined. Back pain, disability, and depression were much improved in the surgical group compared to the nonsurgical group. Likewise, in the surgical group, 63% rated themselves as “much better or better” compared with 29% in the nonsurgical group, and the net back to work rate also significantly in favor of the surgical treatment group (class I endurance).</td>
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<td>Blumenthal et al (1988) reported on internal disc disruption (mechanical LBP). Diagnosis confirmed by discography with concordant reproduction and the affected level or levels. Thirty-four patients with single level involvement underwent anterior lumbar discectomy and fusion. A successful result was determined when the patient returned to work or normal activities and required either no medication or a non-steroidal anti-inflammatory agent only. By the above criteria 25 patients (73%) had a successful outcome. Average time to return to work was 6.1 months.</td>
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<td>Loquidice et al (1988) reported 85 patients undergoing anterior lumbar interbody fusion for treatment of painful disc disruption (78%) (mechanical LBP) or symptomatic pseudoarthrosis (22%). Fifty six of the patients were involved with workers’ compensation, additionally 9 patients had additional litigation pending. Therefore, 76% of patients were involved with a compensation/litigation issue. Pseudoarthrosis rate from 16% at L5-S1, 21% at L4-5 and 31% at L3-4. (Noninstrumented fusions) There was a significant increase in pseudoarthrosis rate in smokers greater than 1 pack per day. Sixty-eight percent of patients were “able to work” after surgery.</td>
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<td>Another randomized controlled trial was conducted by Fairbank Et al (2005) that compared lumbar fusion with an intensive nonoperative therapy program. 349 patients were randomized between 1996 and 2002. 176 randomized to surgery and 173 to nonoperative care. This publication was the culmination of the Medical Research Council in the United Kingdom Spine Stabilization trial. Follow-up interval was 24 months. The ODI improved greater in the surgical group, suggesting a more favorable outcome. It appeared that more than 30% of patients allocated to rehabilitation actually had surgery by the 24 month follow-up.</td>
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<td>Ohtori et al (2011) summarized a randomized clinical trial comparing surgical versus nonsurgical care for selected patients with discogenic low back pain without radiculopathy. All patient diagnoses confirmed by discogenic evaluation. A total of 41 patients were randomized with 21 treated surgically and 20 managed with walking and daily exercises. They identified a strong treatment effect in favor of surgical intervention at both 1 and 2 year follow-up. Outcome measures including ODI &amp; VAS scores were significantly more improved in the surgical group.</td>
</tr>
</tbody>
</table>
IV. Infection, tumor, or deformity
Infection, tumor, or deformity of the thoracic or lumbosacral spine that cause intractable pain, neurological defect and/or function disability.

Recommendations:
• Prompt treatment
• Surgical management should best address neurologic status and stability regardless of levels involved

V. Trauma Thoracic or lumbar
Traumatic fractures producing known instability features – to include but not necessarily limited to:
1. Unstable burst fractures.
2. Compression fractures exceeding 50%.
3. Fracture dislocations.
5. Ligamentous disruption with instability or potential instability.
6. Patients with neurologic compromise with any combination above.

Recommendations:
• Prompt treatment.
• Surgical management should best address neurologic status and stability regardless of levels involved.

VI. Lumbar fusion for Scheuermann’s kyphosis
Recommended as an option for adult patients with severe deformities (e.g. more than 70° for thoracic kyphosis), neurological symptoms exist, and pain cannot be adequately resolved non-operatively (e.g. physical therapy, back exercises). Good outcomes have been found in a relatively large series of patients undergoing either combined anterior-posterior or posterior only fusion for Scheuermann’s kyphosis. (Lonner 2007)

Recommendations:
• Surgical management should best address kyphotic deformity regardless of levels to be fused.

OTG Indications for Surgery: Lumbar Fusion

Neural Arch Defects include spondylolisthesis, congenital unilateral neural arch hypoplasia, spondyloysis, and spondylolisthesis. Required symptoms/findings: imaging studies: and conservative treatments below:

1. Symptoms/Findings which confirm presence of Radiculopathy or neurogenic claudication. Symptoms, Physical Exam should correlate with imaging studies. Findings require ONE of the Following:
   A. L-3 nerve root compression, requiring ONE of the following:
      1. Severe unilateral quadriceps weakness/mild atrophy
      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:
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<td><strong>D.</strong> S1 nerve root compression, requiring ONE of the following:</td>
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<td>1. Severe unilateral foot/toe/plantar flexor hamstring weakness/atrophy</td>
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<td><strong>E.</strong> Neurogenic Claudication</td>
<td>(EMG’s are optional to obtain unequivocal evidence of radiculopathy but not necessary if radiculopathy is already clinically obvious.)</td>
</tr>
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</table>

| **II.** Imaging Studies, requiring ONE of the following, for concordance between radicular findings: |  
| A. Nerve Root Compression |  
| B. Disc protrusion |  
| C. Lateral recess, Foramenal or central stenosis |  

| **III.** X-Rays must show evidence of: |  
| A. Static Listhesis of 3.5mm on lateral films anterior or Posterior |  
| B. Dynamic instability, motion 3-5mm or greater of flexion-extension lateral X-rays. |  
| 1. Diagnostic imaging modalities, requiring ONE of the following: |  
| a. MR imaging |  
| b. CT imaging |  
| c. Myelography |  
| d. CT myelography & XRay |  

| **IV.** Conservative Treatments, requiring ALL of the following: |  
| A. Activity modification (not bed rest) after patient education (>=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 |  

Recommend: Decompressive laminectomy and fusion with instrumentation. It is generally accepted that a single level fusion is appropriate for a grade I or II spondylolisthesis and two level fusions used to treat higher grades of spondylolisthesis. Infrequently spondylolisthesis may occur at L1-2 or L2-3, provided clinical signs/symptoms and imaging studies correlate and the same treatment pathways are followed, the potential need for surgery will be considered with the same methodology as other caudal levels (L3-4, L4-5, L5-S1).

### Segmental Instability, Surgically Induced Segmental Instability and Mechanical Intervertral Collapse of the motion segment and Advanced degenerative changes after discectomy.

Required symptoms/findings: imaging studies: and conservative treatments below:

1. Symptoms/Findings which confirm presence of Radiculopathy or neurogenic
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<td>B. L4 nerve root compression, requiring ONE of the following:</td>
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<td>E. Neurogenic Claudication</td>
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<td>Symptoms require Chronic Low Back Pain unresponsive to conservative treatment (&gt; 4-5 months)</td>
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<td>II. Imaging Studies, requiring ONE of the following, for concordance between radicular findings:</td>
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<td>B. Disc protrusion</td>
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<td>C. Stenosis Lateral recess, Foramenal or central stenosis</td>
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<td>III. X-Rays must show evidence of:</td>
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<td>A. Angulatory: &gt;11 angulation greater than interspace above or below: sagittal plane</td>
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<tr>
<td>B. Translational listhesis ≥ 3.5mm flexion – extension anterior or posterior: sagittal plane</td>
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<td>C. For surgically induced segmental instability and mechanical intervertebral collapse of the motion segment and advanced degenerative changes after discectomy</td>
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<td>X-rays: Require two of the following:</td>
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<td>C1. Dynamic angulatory or translational instability or static listhesis of 3.5 mm anterior or posterior</td>
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<td>C2. Advanced modic spondylotic changes of the vertebral bodies</td>
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<td>C3. Advanced facet arthrosis</td>
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<td>C4. Disc space narrowing</td>
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<td>Diagnostic imaging modalities, requiring ONE of the following:</td>
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<td>IV. Conservative Treatments, requiring ALL of the following:</td>
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Recommend: Decompressive laminectomy and fusion with instrumentation. Fusions limited to two levels.

Infrequently pathology may occur at L1-2 or L2-3, provided clinical signs/symptoms and imaging studies correlate and the same treatment pathways are followed, the potential need for surgery will be considered with the same methodology as other caudal levels (L3-4, L4-5, L5-S1).

**Recurrent Lumbar Disc Herniation**

Required symptoms/findings: imaging studies: and conservative treatments below:

**I. Symptoms/Findings** which confirm presence of Radiculopathy or neurogenic claudication or mechanical low back pain. Symptoms and Physical Exam should correlate with imaging studies. Findings require ONE of the Following:

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<td>B. L4 nerve root compression, requiring ONE of the following:</td>
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**II. Imaging Studies**, requiring ONE of the following, for concordance between radicular findings:

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<thead>
<tr>
<th>Procedure/topic</th>
<th>Summary of medical evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Nerve Root Compression (L3,L4,L5, or S1)</td>
<td></td>
</tr>
<tr>
<td>B. Disc protrusion</td>
<td></td>
</tr>
<tr>
<td>C. Lateral recess, Foramenal or central stenosis</td>
<td></td>
</tr>
<tr>
<td>D. Diagnostic imaging modalities, requiring ONE of the following:</td>
<td></td>
</tr>
<tr>
<td>1. MR imaging</td>
<td></td>
</tr>
<tr>
<td>2. CT imaging</td>
<td></td>
</tr>
</tbody>
</table>
**Procedure Summary – Patient Selection Criteria for Lumbar Spinal Fusion**

(Overview)

<table>
<thead>
<tr>
<th>Procedure/topic</th>
<th>Summary of medical evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Myelography</td>
<td></td>
</tr>
<tr>
<td>4. CT myelography &amp; XRay</td>
<td>If patient’s complaints included significant low back pain and imaging studies confirm advanced spondylosis, consider fusion.</td>
</tr>
</tbody>
</table>

### III. Conservative Treatments, requiring ALL of the following:

- **A. Activity modification (not bed rest) after patient education (>2-4 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

Several broad categories are identified.

1. Patients with radiculopathy only (or minor low back pain), a recurrent disc herniation on gadolinium enhanced MRI and no instability changes on radiographs. Best treated with simple revision discectomy.
2. Patients with radiculopathy only (or minor low back pain) gadolinium enhanced MRI showing epidural fibrosis and no instability on radiographs. Best treated non-operatively.
3. Patients with radiculopathy and severe low back pain: A recurrent disc herniation on gadolinium enhanced MRI. Best treated with revision discectomy and fusion.

**Fusion Limited to Two Levels.**

**Mechanical Low Back Pain** (Internal Disc disruption, discogenic pain)

Required symptoms/findings: imaging studies: and conservative treatments below:

1. Symptoms chronic low back pain with or without radicular or referred pain.

2. Imaging studies, requires two of the following:
   - MRI spondylosis annular disruption
   - Myelogram/CT scan
   - XRays: lumbar spondylosis, disc space narrowing, endplate spondylosis, or facet arthrosis.
   - Discogram concordant pain response.

3. Conservative Treatments, requiring ALL of the following:
   - Activity modification (not bed rest) after patient education (>2-4 months)
   - 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)
   - 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)
### Procedure Summary – Patient Selection Criteria for Lumbar Spinal Fusion

(Overview)

#### Summary of medical evidence

3. Psychological screening that could affect surgical outcome

**Recommended:**
- One or two level Fusion with instrumentation
- Single level lumbar disc replacement

**NOT Recommended:**
- Fusions exceeding two levels.
- Lumbar disc replacement exceeding one level
- Laminectomy/discectomy without fusion

#### IV. Infection, tumor, or deformity

**Recommendations**
- Prompt treatment
- Surgical management should best address neurologic status and stability regardless of levels involved

#### V. TraumaThoracic or lumbar

**Recommendations**
- Prompt treatment
- Surgical management should best address neurologic status and stability regardless of levels involved

#### VI. Lumbar fusion for Scheuermann’s kyphosis:

**Recommendations**
- Surgical management should best address kyphotic deformity regardless of levels to be fused

### Fusion in Worker Compensation Patients

Published studies of workers’ compensation patients treated with lumbar fusion report variable results. Carreon (2010), Franklin (1994), Juratli (2006) and DeBerard (2001) concluded that the results for fusion were not favorable in a workers’ compensation population. Bell (1994) critiqued Franklin’s study in terms of its use of a historical comparison group from 25 years prior to the study group and surveys regarding patient satisfaction were conducted 4 to 5 years after the surgery. Hinkley (1997) noted that the follow-up interviews were completed for only 65% of the study patients, and that many of the phone interviews were conducted by the patients’ attorneys, a fact that threatened the validity of Franklin’s study. Juratli (2006) provided results from a more contemporary study of workers’ compensation patients; however, the authors noted that the study was limited by its retrospective, observation design and lack of control group.

In another study of workers’ compensation patients (Hinkley 1997) compared prospectively 91 patients receiving workers compensation for low back pain, 81 were treated surgically with a 360 degree spinal fusion with instrumentation. Sixteen similar patients did not receive surgery because of administrative reasons outside the author’s control. Patients were followed for up to two years. Ninety-one percent of patients who underwent surgery reported a positive response compared to the nonsurgery group. These patients reported reduced pain intensity, increased activity level, decreased disability and improved confidence in performing routine activities. Mayer (1998) compared outcomes of workers’ compensation patients to matched controls who did not have a fusion. All patients followed a function restoration
## Procedure Summary – Patient Selection Criteria for Lumbar Spinal Fusion

### (Overview)

<table>
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<tr>
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<tbody>
<tr>
<td>program (exercise, psychotherapeutic intervention, and monitoring). Fusion patients had better outcomes of work retention, re-op, and health use compared to the control patients.</td>
<td></td>
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</table>

Carreon et al. *Spine* (2010) compared clinical outcomes and lumbar fusion in patients receiving workers’ compensation with a case matched control group who were not workers’ compensation. Of 783 patients who underwent a posterolateral fusion with complete preoperative and two year post operative outcome measures, 60 patients who were receiving workers’ compensation were identified. Outcome measures included the Oswestry Disability Index, short form 36 and back and leg pain numerical rating scales. At two years after surgery, patients not receiving workers’ compensation had greater improvements in back and leg pain compared to those receiving workers’ compensation; however this did not reach statistical significance.

ODG Recommendation is Inconsistent with Other National and/or State Treatment Guidelines:

ODG “under study” recommendation for chronic low back pain in general and for patients on workers’ compensation conflicts with other medical societies, organizations and states, that publish guidelines for the same patient population. The recommendations in the July 2011 policy statement on lumbar fusion by the International Society for the Advancement of Spine Surgery (ISASS) are contrasted to ODG in the table below. Also, as mentioned earlier, several states that have state-developed guidelines: Washington, Colorado, Delaware, New York, and Louisiana, all recommend lumbar fusion and do not carve out workers’ compensation patients.

In a recent JBJS publication, there is a further analysis of the Spine Patient Outcomes Research Trial (SPORT) authorized by Weinstein et al (2011). A comparison was made between patients who had symptoms resulting from lumbar disc herniation for six months or less (927 patients) and those who had symptoms for more than six months (265 patients). At all follow-up intervals, the primary outcome measures were significantly worse in patients who had had symptoms for more than six months prior to treatment, regardless of whether the treatment was operative or nonoperative. Adverse long term effects of delayed treatment were assessed by SF-36 and the Oswestry Disability Index and persisted at the four year follow-up. The above study infers that treatment should be prompt and within a six month time frame and documents long term adverse implications for delayed treatment. Delaying surgical management secondary to guidelines that suggest a disc herniation or similar condition requires an absolute six months of nonoperative treatment seems arbitrary and not necessarily in the patient’s best interest.

Several studies found a high association with length of time off work and a diminished likelihood of returning to gainful employment. Statistics indicate that if a patient is off work for one year, then less than 10% will return and if off for two years, only a disappointing 1% will return. Infante-Rivard (1996) TDI (2007).

ODG’s discussion of endoscopic fusion significantly understates the technical advances made with minimally invasive surgery (MIS) for lumbar fusion. In addition, one of the ODG cited articles (Knight 2003) does not discuss fusion; the article describes endoscopic decompression. Inclusion of the Endius reference is puzzling, as there are many FDA-cleared devices and accessories for minimally invasive lumbar spine surgery, as well as a number of other devices that provide a lateral approach that are comparable to the cited NuVasive XLIF.

Patients treated by surgeons with MIS expertise have the potential to benefit from
## Procedure Summary – Patient Selection Criteria for Lumbar Spinal Fusion
### (Overview)

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<tr>
<td></td>
<td>these techniques compared to open surgery. A summary of the history of these MIS techniques follows Oppenheimer (2009). Open lumbar fusion surgical procedures require extensive muscle dissection and retraction, and may involve less blood loss, fewer complications, shorter hospital stay and earlier rehabilitation. MIS techniques for the lumbar spine were first reported in the mid-1970s for percutaneous discectomy and microdiscectomy. By the mid to late 1990s, MIS applications for lumbar fusion were initiated. These techniques have advanced significantly over the past 25 years. Based on endoscopic techniques in other surgical specialties, beginning in the 1990s laparoscopic, endoscopic, mini-open retroperitoneal and open/endooscopic-assisted methods were introduced for anterior lumbar fusion surgery. In the mid-1990s tubular retractors (e.g., MED evolved to METRx, Medtronic Sofamor Danek, Memphis, TN), which were developed for microdiscectomy, were also adapted for posterior lumbar fusion. Unlike traditional retractor blades, the tube is thin-walled and it can circumferentially create a working channel for decompression, pedicle screws and interbody fusion. Results from MIS techniques for lumbar spinal fusion compared to conventional open techniques have been shown to reduce blood loss, post-operative narcotic use, pain and hospital stay (Park 2007, Saraph 2004), offering the potential for faster return to work. Kim (2006) demonstrated that a minimally invasive approach to posterior lumbar interbody fusion compared to a conventional open approach resulted in reduction of muscle injury and systemic inflammatory reactions, as measured by serum enzymes. Comparable clinical and radiographic results for conventional open and minimally invasive techniques for lumbar fusion have been reported Park (2007); Saraph (2004), reported a longer surgical time and noted attention to the risk of technical complications, Isaacs (2005) reported no complications and Saraph (2004) reported comparable complication rates between groups. ODG’s recommendations with regard to lumbar fusion Broadby attempts to narrow indications for spinal fusion and specifically restrict an injured worker from qualifying for a fusion, simply due to their workers compensation status. These recommendations are inconsistent with other national and/or state treatment guidelines.</td>
</tr>
</tbody>
</table>

<p>| ODG Compared to International Society of Advanced Spine Surgery: Lumbar Fusion |
|------------------|------------------|------------------|
| <strong>Condition</strong>    | <strong>ODG: July 12, 2011</strong> | <strong>ISASS: July 2011</strong> |
| Emergency situation with risk permanent neurologic/ function deficit | Indicated for intractable pain, neurologic deficit and/or functional disability | Indicated |
| Tumor | Indicated | Indicated |
| Infection | Indicated | Indicated |
| Unstable fractures or other diseases leading to lumbar segment instability | While not listed in “Patient Selection Criteria”, included in initial paragraph as “fracture, dislocation, spondylolisthesis or frank neurogenic compromise” | Indicated (trauma) |
| Deformity | Indicated | Indicated* |
| Isthmic spondylolisthesis | Indicated | Indicated (spondylolysis)** |
| Degenerative spondylolisthesis | Indicated | Indicated* (any spondylolisthesis) |</p>
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<tr>
<td><strong>Condition</strong></td>
<td><strong>ODG: July 12, 2011</strong></td>
</tr>
<tr>
<td>Disc herniation: radiculopathy</td>
<td>Not indicated</td>
</tr>
<tr>
<td>Recurrent disc herniation</td>
<td>Indicated third diskectomy</td>
</tr>
<tr>
<td>Spinal stenosis</td>
<td>Not indicated</td>
</tr>
<tr>
<td>Spinal stenosis with concomitant instability or deformity</td>
<td>Stenosis with instability presumed included with degenerative spondylolisthesis. Deformity indicated as for infection and tumor</td>
</tr>
<tr>
<td>Spinal stenosis with intra-op instability</td>
<td>Indicated (surgically induced segmental instability)</td>
</tr>
<tr>
<td>Degenerative disc disease</td>
<td>Indicated (1- or 2-level segmental failure with progressive degenerative changes, loss of height, disk loading capability)**&lt;br&gt;Add asymmetric collapse and subluxation?</td>
</tr>
<tr>
<td>Revisions</td>
<td>Indicated (same level when causing clinical symptoms or patient risk)</td>
</tr>
<tr>
<td>Flat back syndrome</td>
<td>Indicated</td>
</tr>
<tr>
<td>Pseudarthrosis</td>
<td>Indicated</td>
</tr>
<tr>
<td>Adjacent segment disease</td>
<td>Indicated</td>
</tr>
<tr>
<td>Facet syndrome</td>
<td>Not indicated</td>
</tr>
<tr>
<td>Rare/unusual cases</td>
<td>Indicated (consult with at least 2 other surgeons/patient agree to have results published)</td>
</tr>
</tbody>
</table>
## Procedure Summary – Patient Selection Criteria for Lumbar Spinal Fusion

### (Overview)

<table>
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<tbody>
<tr>
<td><strong>Implantable spinal cord stimulators</strong></td>
<td>Implantable spinal cord stimulators reserved for those low back pain patients with pain of greater than six months duration who have not responded to the standard non-operative or operative interventions previously discussed within this document. Refer to OWCC’s Chronic Pain Disorder Medical Treatment Guidelines.</td>
</tr>
<tr>
<td><strong>Intraoperative Monitoring</strong></td>
<td>Intraoperative Monitoring is a common intraoperative electrodiagnostic technique that may include somatosensory evoked potentials (SSEP), motor evoked potentials (MEP), or pedicle screw monitoring. The monitoring procedure may be used at the discretion of the physician. The use of intraoperative monitoring can be anticipated to become more common as percutaneous spinal procedures gain greater acceptance.</td>
</tr>
</tbody>
</table>
| **Kyphoplasty** | Description. A surgical procedure for the treatment of symptomatic thoracic or lumbar vertebral compression fractures, most commonly due to osteoporosis or other metabolic bone disease, and occasionally with post-traumatic compression fractures and minor burst fractures that do not significantly compromise the posterior cortex of the vertebral body. Pain relief can be expected in approximately 90 percent of patients. Vertebral height correction is inconsistent, with approximately 35 percent to 40 percent of procedures failing to restore height or kyphotic angle.  
- Complications: Cement leakage occurs in approximately nine percent of kyphoplasties and may cause complications.  
- New vertebral compression fracture may occur following kyphoplasty, but their occurrence does not appear to exceed that of osteoporotic patients who did not receive treatment.  
- Operative Treatment: Kyphoplasty involves the percutaneous insertion of a trocar and inflatable balloon or expanding polymer into the vertebral body, which re-expands the body, elevating the endplates and reducing the compression deformity.  
- Polymethylmethacrylate (PMMA) bone cement is injected under low pressure into the cavity created by the balloon inflation. In contrast to vertebroplasty, which introduces PMMA cement under high pressure, the space created by balloon inflation allows a higher viscosity PMMA to be injected under lower pressure, which may reduce the risks associated with extravertebral extravasation of the material. There may be an advantage to performing the procedure within one month of the fracture, since the elevation of the endplates may be more readily achieved than when the procedure is delayed.  
- Surgical Indications. Kyphoplasty is an accepted treatment for the following indications:  
  i. compression fracture;  
  ii. vertebral height loss between 20 percent and 85 percent;  
  iii. vertebral height restoration. Kyphoplasty is more likely to increase vertebral height if performed within 30 days of fracture occurrence.  
- Contraindications  
  i. the presence of neurologic compromise related to fracture;  
  ii. high-velocity fractures with a significant burst component;  
  iii. significant posterior vertebral body wall fracture;  
  iv. severe vertebral collapse (vertebra plana);  
  v. infection, and  
  vi. coagulopathy. |
| **Sacroiliac joint fusion** | Description. Use of bone grafts, sometimes combined with metal devices, to produce a rigid connection between two or more adjacent vertebrae providing symptomatic instability as a part of major pelvic ring disruption.  
b. Complications. Instrumentation failure, bone graft donor site pain, in-hospital mortality, deep infection, superficial infection, and graft extrusion.  
c. Surgical Indications. Sacroiliac (SI) joint fusion may be indicated for stabilization of a traumatic severe disruption of the pelvic ring. This procedure has limited use in minor trauma and would be considered only on an individual case-by-case basis. In patients with typical mechanical low back pain, this procedure is considered to be investigational. Until the efficacy of this procedure for mechanical low back pain is determined by an independent valid prospective outcome study, this procedure is not recommended for mechanical low back pain. |
Proposed

Oklahoma Treatment Bibliography

January 10, 2012


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   PMID:7217885  JBJS Level III  ODG:3b

   PMID:117112842  JBJS Level V  ODG:5b

   PMID:7608225  JBJS Level II  ODG:2a

   PMID:4651046  JBJS Level III  ODG:3c

   PMID:8747269  JBJS Level V  ODG:11a

   PMID:21729801  JBJS Level III  ODG:3c

   PMID:19112337  JBJS Level II  ODG:5a

   PMID:19047724  JBJS Level V  ODG:5a

   PMID:2071615  JBJS Level II  ODG:3b

   PMID:9051894  JBJS Level III  ODG:3b

   PMID:12790220  JBJS Level II  ODG:2c

   PMID:2962798  JBJS Level II  ODG:3b

   PMID:21729802  JBJS Level V  ODG:5c


**ODG:3b**

**ODG:2c**

**ODG:2a**

**ODG:3b**

**ODG:2c**

**ODG:5b**

**ODG:3b**

**ODG:2b**

**ODG:2a**

**ODG:2a**

**ODG:5c**

**ODG:3b**

**(Comp Study) ODG:3b**

**(Retro) ODG:3c**

No PMID  
JBJS Level V  
ODG: 6a

No PMID  
JBJS Level V  
ODG: 6a

No PMID  
JBJS Level V  
ODG: 6a

PMID: 20838371  
JBJS Level II  
ODG: 2c

PMID: 17768224  
JBJS Level III  
ODG: 3b

PMID: 197222824  
JBJS Level V  
ODG: 5a

PMID: 10190857  
JBJS Level III  
(Retro)  
ODG: 3b

PMID: 16741457  
JBJS Level III  
ODG: 3c

PMID: 17334287  
JBJS Level II  
ODG: 3b

PMID: 6766236  
JBJS Level III  
ODG: 3c

No PMID: No Ref  
JBJS Level V  
ODG: 5

PMID: 3387325  
JBJS Level III  
ODG: 3b

PMID: 16028729  
JBJS Level II


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ESI


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PMID: 14976837   JBJS Level:V   ODG:5c


PMID: 8747238   JBJS Level:III   ODG:3a


PMID:8742210   JBJS Level:II   ODG:3b


PMID:2398088   JBJS Level:II   ODG:3b


PMID: No Ref   JBJS Level:V   ODG:8a


PMID: No Ref   JBJS Level:V   ODG:8a


PMID: No Ref   JBJS Level:V   ODG:8a


PMID:14588285   JBJS Level:II   ODG:2c


PMID:10888949   JBJS Level:II   ODG:3b


PMID:17139225   JBJS Level:II   ODG:3a


PMID:16508542   JBJS Level:II   ODG:3b


PMID:15131439   JBJS Level:II   ODG:3b


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*JBJS Level: V*  
*ODG:8a*

*PMID:8742205*  
*JBJS Level:III*  
*ODG:3c*

*JBJS Level: V*  
*ODG:5a*

*JBJS Level:II*  
*ODG:3c*

*JBJS Level:II*  
*ODG:11c*

*JBJS Level: V*  
*ODG:11a*

*JBJS Level: V*  
*ODG:11a*

*JBJS Level:II*  
*ODG:3b*

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*ODG:1a*


JBJS Level II  ODG:2b


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   JBJS Level I  ODG:1a

   JBJS Level I  ODG:4c

**THERAPY – ACTIVE**


   JBJS Level III  ODG:1a

   JBJS Level: II ODG:2a

   JBJS Level:II  ODG:2a


   JBJS Level: II  ODG:2a

   JBJS Level: II  ODG:1a

   JBJS Level: II  ODG:2b

    JBJS Level: II  ODG:2a

    JBJS Level: V  ODG:5c

    JBJS Level:II  ODG:2b

    JBJS Level: III  ODG:3b

    JBJS Level: V  ODG:5c

    JBJS Level: V  ODG:5c

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*ODG: 3a*

*JBJS Level:1*  
*ODG: 2b*
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