Clinical Policy Bulletin:
Spinal Surgery: Laminectomy and Fusion

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Policy

I. Aetna considers cervical laminectomy (and/or an anterior cervical diskectomy and fusion) medically necessary for individuals with herniated discs or other causes of spinal cord or nerve root compression (osteophytic spurring, ligamentous hypertrophy) when all of the following criteria are met:
   A. All other reasonable sources of pain have been ruled out; and
   B. Presence of neck or cervico-brachial pain with findings of weakness, myelopathy, or sensory deficit; and
   C. Imaging studies (e.g., CT or MRI) indicate nerve root or spinal cord compression at the level corresponding with the clinical findings; and
   D. Member has failed at least 6 weeks of conservative therapy (unless there is evidence of cervical cord compression, which requires urgent intervention); and
   E. Member has physical and neurological abnormalities confirming the historical findings of nerve root or spinal cord compression (e.g., reflex change, sensory loss, weakness) at or below the level of the lesion and may have gait or sphincter disturbance (evidence of cervical radiculopathy or myelopathy); and
   F. Member's activities of daily living are limited by persistent neck or cervico-brachial pain.

II. Aetna considers thoracic laminectomy (and/or thoracic diskectomy and fusion) medically necessary for individuals with herniated discs or other causes of thoracic nerve root compression (osteophytic spurring, ligamentous hypertrophy) when all of the following criteria are met:
   A. All other reasonable sources of pain have been ruled out; and
   B. Presence of thoracic pain secondary to nerve root or spinal cord compression with findings of weakness, myelopathy, or sensory deficit; and
   C. Imaging studies (e.g., CT or MRI) indicate nerve root or spinal cord compression at the level corresponding with the clinical findings; and
D. Member has failed at least 6 weeks of conservative therapy (unless there is evidence of thoracic cord compression with progression, which requires urgent intervention); and
E. Member has physical and neurological abnormalities confirming the historical findings of nerve root or spinal cord compression (e.g., reflex change, sensory loss, weakness) at or below the level of the lesion and may have gait or sphincter disturbance (evidence of thoracic radiculopathy or myelopathy); and
F. Member's activities of daily living are limited by persistent pain.

III. Aetna considers lumbar laminectomy medically necessary for individuals with a herniated disc when all of the following criteria are met:

   A. All other reasonable sources of pain have been ruled out; and
   B. Imaging studies (e.g., CT or MRI) indicate nerve root compression that corresponds to the clinical findings of the specific affected nerve root; and
   C. Member has failed at least 6 weeks of conservative therapy (see background section); and
   D. Member's activities of daily living are limited by persistent pain radiating from the back down to the lower extremity; and
   E. Presence of neurological abnormalities (e.g., reflex change, positive straight leg raising, sensory loss, weakness) persist on examination and correspond to the specific affected nerve root.

IV. Aetna considers cervical, lumbar, or thoracic laminectomy medically necessary for any of the following:

   A. Spinal fracture, dislocation (associated with mechanical instability), locked facets, or displaced fracture fragment confirmed by imaging studies (e.g., CT or MRI); or
   B. Spinal infection confirmed by imaging studies (e.g., CT or MRI); or
   C. Spinal tumor confirmed by imaging studies (e.g., CT or MRI); or
   D. Epidural hematomas confirmed by imaging studies (e.g., CT or MRI); or
   E. Synovial cysts, or arachnoid cysts causing spinal cord or nerve root compression with unremitting pain, confirmed by imaging studies (e.g., CT or MRI) and with corresponding neurological deficit, where symptoms have failed to respond to six weeks of conservative therapy (unless there is evidence of cord compression, or progressive neurological deficit, which requires urgent intervention) or
   F. Severe spinal stenosis (recess, foraminal, central stenosis) with unremitting pain, with stenosis confirmed by imaging studies (e.g., CT or MRI) at the level corresponding to neurological findings, where symptoms have failed to respond to three months of conservative therapy (unless there is evidence of cord compression, or progressive neurological deficit, which requires urgent intervention); or
   G. Other mass lesions confirmed by imaging studies (e.g., CT or MRI), upon individual case review.

V. Aetna considers lumbar decompression with or without discectomy medically necessary for rapid progression of neurological impairment (e.g., foot drop, extremity
weakness, numbness or decreased sensation, saddle anesthesia, bladder
dysfunction or bowel dysfunction) confirmed by imaging studies (e.g., CT or MRI).

VI. Aetna considers cervical spinal fusion medically necessary for any of the following:

A. Cervical kyphosis associated with cord compression; or
B. Symptomatic pseudarthrosis (non-union of prior fusion), which is associated with radiological (e.g., CT or MRI) evidence of mechanical instability or deformity of the cervical spine; or
C. Spinal fracture, dislocation (associated with mechanical instability), locked facets, or displaced fracture fragment confirmed by imaging studies (e.g., CT or MRI), which may be combined with a laminectomy; or
D. Spinal infection confirmed by imaging studies (e.g., CT or MRI) and/or other studies (e.g., biopsy), which may be combined with a laminectomy; or
E. Spinal tumor, primary or metastatic to spine, confirmed by imaging studies (e.g., CT or MRI), which may be combined with a laminectomy; or
F. Nontraumatic atlantoaxial (C1-C2) subluxation (e.g., associated with congenital anomaly, os odontoideum, or rheumatoid arthritis) greater than 5 mm confirmed by imaging studies (e.g., CT or MRI); or
G. Spondylolisthesis with segmental instability confirmed by imaging studies (e.g., CT or MRI), when both of the following are met:
   1. Significant instability (sagittal plane translation more than 3.5 mm or more than 20 percent of vertebral body width or relative sagittal plane angulation greater than 11 degrees); and
   2. Symptomatic unremitting pain that has failed 3 months of conservative management; or
H. Severe spinal stenosis (recess, foraminal, central stenosis) with unremitting pain, with stenosis confirmed by imaging studies (e.g., CT or MRI) at the level corresponding to neurological findings, where symptoms have failed to respond to 3 months of conservative therapy (unless there is evidence of cord compression, or progressive neurological deficit, which requires urgent intervention).

VII. Aetna considers thoracic spinal fusion medically necessary for any of the following:

A. Scoliosis confirmed by imaging studies, with Cobb angle greater than 40 degrees in skeletally immature children and adolescents, or Cobb angle greater than 50 degrees associated with functional impairment in skeletally mature adults; or
B. Thoracic kyphosis resulting in spinal cord compression, or kyphotic curve greater than 75 degrees that is refractory to bracing; or
C. Symptomatic pseudarthrosis (non-union of prior fusion), which is associated with radiological (e.g., CT or MRI) evidence of mechanical instability or deformity of the thoracic spine that has failed 3 months of conservative management; or
D. Spinal fracture, dislocation (associated with mechanical instability), locked facets, or displaced fracture fragment confirmed by imaging studies (e.g., CT or MRI), which may be combined with a laminectomy; or
E. Spinal infection confirmed by imaging studies (e.g., CT or MRI) and/or other studies (e.g., biopsy), which may be combined with a laminectomy; or
F. Spinal tumor, primary or metastatic to spine, confirmed by imaging studies (e.g., CT or MRI), which may be combined with a laminectomy; or
G. Spondylolisthesis with segmental instability confirmed by imaging studies (e.g., CT or MRI), when both of the following criteria are met:
   1. Significant spondylolisthesis, grades II, III, IV, or V (see appendix); and
   2. Symptomatic unremitting pain that has failed 6 months of conservative management; or

H. Severe spinal stenosis with unremitting pain confirmed by imaging studies (e.g., CT or MRI) that has failed 3 months of conservative management when any of the following is met:
   1. Decompression is performed in an area of segmental instability as manifested by gross movement on flexion-extension radiographs; or
   2. Decompression coincides with an area of significant degenerative instability (e.g., scoliosis or any degree of spondylolisthesis (grades I, II, III, IV or V); or
   3. Decompression creates an iatrogenic instability by the disruption of the posterior elements where facet joint excision exceeds 50% bilaterally or complete excision of one facet is performed.

VIII. Aetna considers lumbar spinal fusion medically necessary for any of the following:

A. Adult scoliosis, kyphosis, or pseudarthrosis (non-union of prior fusion), which is associated with radiological (e.g., CT or MRI) evidence of mechanical instability or deformity of the lumbar spine that has failed 3 months of conservative management; or

B. Spinal fracture, dislocation (associated with mechanical instability), locked facets, or displaced fracture fragment confirmed by imaging studies (e.g., CT or MRI), which may be combined with a laminectomy; or

C. Spinal infection confirmed by imaging studies (e.g., CT or MRI) and/or other studies (e.g., biopsy), which may be combined with a laminectomy; or

D. Spinal tumor confirmed by imaging studies (e.g., CT or MRI), which may be combined with a laminectomy; or

E. Spondylolisthesis with segmental instability confirmed by imaging studies (e.g., CT or MRI), when both of the following criteria are met:
   1. Significant spondylolisthesis, grades II, III, IV, or V (see appendix); and
   2. Symptomatic unremitting pain that has failed 6 months of conservative management; or

F. Severe spinal stenosis with unremitting pain confirmed by imaging studies (e.g., CT or MRI) that has failed 3 months of conservative management when any of the following is met:
   1. Decompression is performed in an area of segmental instability as manifested by gross movement on flexion-extension radiographs; or
   2. Decompression coincides with an area of significant degenerative instability (e.g., scoliosis or any degree of spondylolisthesis (grades I, II, III, IV or V); or
3. Decompression creates an iatrogenic instability by the disruption of the posterior elements where facet joint excision exceed 50% bilaterally or complete excision of one facet is performed.

IX. Aetna considers lumbar spinal fusion experimental and investigational for degenerative disc disease and all other indications not listed above as medically necessary because of insufficient evidence of its effectiveness for these indications.

X. Aetna considers spinal surgery in persons with prior spinal surgery medically necessary when any of the above criteria (I - V) is met.

XI. Aetna considers cervical, thoracic and lumbar laminectomy and fusion experimental and investigational for all other indications not listed above as medically necessary because of insufficient evidence of its effectiveness for these indications.

* Certain fusion procedures are considered experimental and investigational: for interlaminar lumbar instrumented fusion (ILIF), Coflex-F implant for lumbar fusion, and minimally invasive transforaminal lumbar interbody fusion (MITLIF), see CPB 16 - Back Pain: Invasive Procedures. Also see CPB 772 - Axial Lumbar Interbody Fusion (AxiaLIF).

Notes: For use of mesenchymal stem cell therapy for spinal fusion, see CPB 0411 - Bone and Tendon Graft Substitutes and Adjuncts. For hybrid lumbar/cervical fusion with artificial disc replacement for the management of back and neck pain/spinal disorders, see CPB 0591 - Intervertebral Disc Prostheses. For use of evoked potentials in spinal surgery, see CPB 0181 - Evoked Potential Studies.

Background

The lifetime incidence of low back pain (LBP) in the general population is reported to be 60% to 90% with annual incidence of 5%. According to the National Center for Health Statistics (Patel, 2007), each year, 14.3% of new patient visits to primary care physicians are for LBP, and nearly 13 million physician visits are related to complaints of chronic LBP. The causes of LBP are numerous. For individuals with acute LBP, the precise etiology can be identified in only about 15% of cases (Lehrich et al, 2007).

The initial evaluation of patients with LBP involves ruling out potentially serious conditions such as infection, malignancy, spinal fracture, or a rapidly progressing neurologic deficit suggestive of the cauda equina syndrome, bowel or bladder dysfunction, or weakness, which suggest the need for early diagnostic testing. Patients without these conditions are initially managed with conservative therapy. The most common pathological causes of LBP are attributed to herniated lumbar discs (lumbar disc prolapse, slipped disc), lumbar stenosis and lumbar spondylolisthesis (Lehrich and Sheon, 2007).

Spondylolisthesis refers to the forward slippage of one vertebral body with respect to the one beneath it. This most commonly occurs at the lumbosacral junction with L5 slipping over S1, but it can occur at higher levels as well. It is classified based on etiology into 5 types: dysplastic, defect in pars interarticularis, degenerative, traumatic, and pathologic. The most common grading system for spondylolisthesis is the Meyerding grading system for severity of slippage, which categorizes severity based upon measurements on lateral X-ray of the
distance from the posterior edge of the superior vertebral body to the posterior edge of the adjacent inferior vertebral body. The distance is then reported as a percentage of the total superior vertebral body length (see appendix).

Guidelines for the approach to the initial evaluation of LBP have been issued by the Agency for Healthcare Research and Quality (1994) and similar conclusions were reached in systematic reviews (Jarvik et al, 2002; Chou et al, 2007; NICE, 2009). For adults less than 50 years of age with no signs or symptoms of systemic disease, symptomatic therapy without imaging is appropriate. For patients 50 years of age and older or those whose findings suggest systemic disease, plain radiography and simple laboratory tests can almost completely rule out underlying systemic diseases. Advanced imaging should be reserved for patients who are considering surgery or those in whom systemic disease is strongly suspected. Conservative care without immediate imaging is also considered appropriate for patients with radiculopathy, as long as symptoms are not bilateral or associated with urinary retention. Magnetic resonance imaging (MRI) should be performed if the latter symptoms are present or if patients do not improve with conservative therapy for 4 to 6 weeks. Ninety percent of acute attacks of sciatica will resolve with conservative management within 4 to 6 weeks; only 5% remain disabled longer than 3 months (Gibson and Waddell, 2007; Lehrich and Sheon, 2007; AHCPR 1994).

Conservative management for LBP includes:

- Avoidance of activities that aggravate pain
- Chiropractic manipulation in the first 4 weeks if there is no radiculopathy
- Cognitive support and reassurance that recovery is expected
- Education regarding spine biomechanics
- Exercise program
- Heat/cold modalities for home use
- Limited bed rest with gradual return to normal activities
- Low impact exercise as tolerated (e.g., stationary bike, swimming, walking)
- Pharmacotherapy (e.g., non-narcotic analgesics, NSAIDs (as second-line choices), avoid muscle relaxants, or only use during the first week, avoid narcotics)

In the American Pain Society/American College of Physicians Clinical Practice Guideline on "Nonpharmacologic Therapies for Acute and Chronic Low Back Pain," Chou and Huffman (2007) reached the following conclusions: "Therapies with good evidence of moderate efficacy for chronic or subacute low back pain are cognitive-behavioral therapy, exercise, spinal manipulation, and interdisciplinary rehabilitation. For acute low back pain, the only therapy with good evidence of efficacy is superficial heat."

According to a draft technology assessment prepared for the Agency for Healthcare Research and Quality (AHRQ) by the Duke Evidence-based Practice Center on spinal fusion for treatment of degenerative disease affecting the lumbar spine (AHRQ, 2006), conservative treatments are generally performed routinely before any surgery is considered in axial back pain. These include medical management (such as NSAIDs, etc.), pain management, injections, physical therapy, exercise and various forms of cognitive rehabilitation. Such conservative treatments are seldom applied in a comprehensive, well-organized rehabilitation program, although some such programs do exist. Conservative treatments are usually tried for at least 6 to 12 months before surgery for any form of lumbar fusion is considered. Several reviews of these therapies noted that there is no evidence about the effectiveness of any of these therapies for low back or radicular pain beyond about 6 weeks. In addition, the assessment stated that almost all lumbar spine surgery, including lumbar fusion, is performed...
to reduce the subjective individual symptoms of radiculopathy; thus, patient education to inform patients of their treatment options is considered critical. The other indications for lumbar fusion focus on improvement in axial lumbar pain (i.e., near the midline and not involving nerve roots or leg pain). These indications include lumbar instability, such as degenerative lumbar scoliosis, spondylolisthesis for axial pain alone, and for less common problems, such as discitis, lumbar flat back syndrome, neoplastic bone invasion and collapse, and chronic fractures, such as osteoporotic fractures which develop into burst fractures over time. The assessment concluded that, "The evidence for lumbar spinal fusion does not conclusively demonstrate short-term or long-term benefits compared with non-surgical treatment, especially when considering patients over 65 years of age, for degenerative disc disease; for spondylolisthesis, considerable uncertainty exists due to lack of data, particularly for older patients."

The National Institute for Clinical Excellence's (NICE, 2009) guidance on early management of people with non-specific LBP stated that it is important to help people with persistent non-specific LBP self-manage their condition. The guidance stated that one of the following treatment options should be offered to the patient: (i) an exercise program, (ii) a course of manual therapy (i.e., spinal manipulation, spinal mobilization, massage), (iii) a course of acupuncture, and (iv) pharmacological therapy. Referral to a combined physical and psychological treatment program may be appropriate for individuals who have received at least one less intensive treatment and have high disability and/or significant psychological distress. The guidance stated "[t]here is evidence that manual therapy, exercise and acupuncture individually are cost-effective management options compared with usual care for persistent non-specific low back pain. The cost implications of treating people who do not respond to initial therapy and so receive multiple back care interventions are substantial. It is unclear whether there is added health gain for this subgroup from either multiple or sequential use of therapies." In addition, the guidance stated that imaging is not necessary for the management of non-specific LBP. An MRI is appropriate only for people who have failed conservative care, including a combined physical and psychological treatment program, and are considering a referral for an opinion on spinal fusion.

The American Pain Society Clinical Practice Guideline Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain (Chou et al, 2009) stated "[r]ates of certain interventional and surgical procedures for back pain are rising. However, it is unclear if methods for identifying specific anatomic sources of back pain are accurate, and effectiveness of some interventional therapies and surgery remains uncertain or controversial." Included in the guideline are the following recommendations.

The APS guideline stated that, in patients with chronic non-radicul LBP, provocative discography is not recommended as a procedure for diagnosing LBP (strong recommendation, moderate-quality evidence) (Chou et al, 2009).

In patients with non-radicul LBP who do not respond to usual, non-interdisciplinary interventions, the APS guideline recommended that clinicians consider intensive interdisciplinary rehabilitation with a cognitive/behavioral emphasis (strong recommendation, high-quality evidence) (Chou et al, 2009).

In patients with non-radicul LBP, common degenerative spinal changes, and persistent and disabling symptoms, the APS guideline recommended that clinicians discuss risks and benefits of surgery as an option (weak recommendation, moderate-quality evidence) (Chou et al, 2009).
The guideline recommended that shared decision-making regarding surgery for non-specific LBP include a specific discussion about intensive interdisciplinary rehabilitation as a similarly effective option, the small to moderate average benefit from surgery versus non-interdisciplinary non-surgical therapy, and the fact that the majority of such patients who undergo surgery do not experience an optimal outcome (defined as minimum or no pain, discontinuation of or occasional pain medication use, and return of high-level function) (Chou et al, 2009).

The APS guideline explained that for persistent non-radicular LBP with common degenerative changes (e.g., degenerative disc disease), fusion surgery is superior to non-surgical therapy without interdisciplinary rehabilitation in 1 trial, but no more effective than intensive interdisciplinary rehabilitation in 3 trials (Chou et al, 2009). Compared with non-interdisciplinary, non-surgical therapy, average benefits are small for function (5-10 points on a 100-point scale) and moderate for improvement in pain (10-20 points on a 100-point scale). Furthermore, more than half of the patients who undergo surgery do not experience an "excellent" or "good" outcome (i.e., no more than sporadic pain, slight restriction of function, and occasional analgesics). Although operative deaths are uncommon, early complications occur in approximately 18% of patients who undergo fusion surgery in randomized trials. Instrumented fusion is associated with enhanced fusion rates compared with non-instrumented fusion, but insufficient evidence exists to determine whether instrumented fusion improves clinical outcomes, and additional costs are substantial. In addition, there is insufficient evidence to recommend a specific fusion method (anterior, posterolateral, or circumferential), though more technically difficult procedures may be associated with higher rates of complications.

In patients with persistent and disabling radiculopathy due to herniated lumbar disc or persistent and disabling leg pain due to spinal stenosis, the APS guideline recommended that clinicians discuss risks and benefits of surgery as an option (strong recommendation, high-quality evidence) (Chou et al, 2009). It is recommended that shared decision-making regarding surgery include a specific discussion about moderate average benefits, which appear to decrease over time in patients who undergo surgery.

The APS guideline explained that for persistent and disabling radiculopathy due to herniated lumbar disc, standard open discectomy and microdiscectomy are associated with moderate short-term (through 6 to 12 weeks) benefits compared to non-surgical therapy, though differences in outcomes in some trials are diminished or no longer present after 1 to 2 years (Chou et al, 2009). In addition, patients tend to improve substantially either with or without discectomy, and continued non-surgical therapy in patients who have had symptoms for at least 6 weeks does not appear to increase risk for cauda equina syndrome or paralysis.

If conservative management fails to relieve symptoms of radiculopathy and there is strong evidence of dysfunction of a specific nerve root confirmed at the corresponding level by findings demonstrated by CT or MRI, further evaluation and more invasive treatment, including spine surgery, may be proposed as a treatment option. The primary rationale of any form of surgery for disc prolapse is to provide decompression of the affected nerve root to relieve the individual's symptoms. It involves the removal of all or part of the lamina of a lumbar vertebra. The addition of fusion with or without instrumentation is considered when there are concerns about instability. Open discectomy, performed with or without the use of an operating microscope, is the most common surgical technique applied, but there are now a number of other less invasive surgical approaches. The surgical treatment of sciatica with discectomy is reportedly ineffective in a sizable percentage of patients, and re-herniation...
occurs after 5% to 15% of such procedures. Thus, it would be ideal to define the optimal type of treatment for the specific types of prolapse (Carragee et al, 2003).

Different fusion procedures, including anterior lumbar interbody fusion, posterolateral fusion, posterior lumbar interbody fusion and transfemoral lumbar interbody fusion, and anterior-posterior combined fusion, do not vary significantly in pain or disability outcomes, although there are qualitative differences in complications related to the surgical approach. Prior to the 1980’s both anterior and posterior non-instrumented lumbar fusions were commonly performed, using primarily bone graft. As pedicle screws became more widely used, it was noted that the rate of fusion increased from 65% with bone graft alone to nearly 95% with the instrumentation to provide internal support for the bone graft. The increased stiffness from the insertion of screws and rods has been hypothesized to lead to increased degeneration at spine segments adjacent to the fusion.

Anterior spine procedures, through either the peritoneum or retroperitoneum, require no posterior muscle and ligamentous dissection and result in less post-operative axial back pain. This approach is generally recommended for the treatment of axial LBP in young individuals. The usual criteria for consideration of an anterior lumbar fusion (or anterior lumbar arthroplasty) include a young person (i.e., age 20 to 40 years), who on MRI scan has either one or two dark discs, a concordant discogram indicating the axial pain is likely arising from the degenerated joints, and failure of previous conservative measures to improve the back pain over a period of time, with a minimum of 6 month conservative treatment. However, according to AHRQ (2006), the discogram remains highly controversial, and recent reports suggest that relying on the MRI findings of a dark disc and limiting the discogram to just those levels may improve the definition of a “positive discogram”. The AHRQ assessment stated, “However, the high rate of false positives with normal disc spaces is problematic, as well as the high rate of prevalence of dark disc syndrome.” As patients age into their 40’s and 50’s the disc and facet degenerative processes slowly worsen, and it is less likely to find patients with isolated arthritis, thus, anterior fusion is less often recommended for older patients. Posterior fusion may be preferable for older individuals in order to stabilize facet joint disease. However, the posterior approach involves significant muscle dissection, resulting in severe back pain in the post-operative period, and is avoided by some surgeons.

The natural history of sciatica is favorable, with resolution of leg pain within 8 weeks from onset in the majority of patients (Peul et al, 2007). Dutch guidelines on the diagnosis and treatment of the lumbosacral radicular syndrome (Stam, 1996) recommended the option of lumbar-disk surgery in patients who have sciatica if symptoms do not improve after 6 weeks of conservative treatment. To determine the optimal timing of surgery, investigators (Peul et al, 2007) randomly assigned patients (n = 283) who had had severe sciatica for 6 to 12 weeks to early surgery or to prolonged conservative treatment with surgery if needed. The primary outcomes were the score on the Roland Disability Questionnaire, the score on the visual analog scale for leg pain, and the patient’s report of perceived recovery during the first year after randomization. Repeated-measures analysis according to the intention-to-treat principle was used to estimate the outcome curves for both groups. Of 141 patients assigned to undergo early surgery, 125 (89%) underwent microdiscectomy after a mean of 2.2 weeks. Of 142 patients designated for conservative treatment, 55 (39%) were treated surgically after a mean of 18.7 weeks. There was no significant overall difference in disability scores during the first year (p = 0.13). Relief of leg pain was faster for patients assigned to early surgery (p < 0.001). Patients assigned to early surgery also reported a faster rate of perceived recovery (hazard ratio, 1.97; 95% confidence interval [CI]: 1.72 to 2.22; p < 0.001). In both groups, however, the probability of perceived recovery after 1 year of follow-up was 95%. The
investigators concluded that the 1-year outcomes were similar for patients assigned to early surgery and those assigned to conservative treatment with eventual surgery if needed, but the rates of pain relief and of perceived recovery were faster for those assigned to early surgery.

A Cochrane systematic review (2007) on surgical interventions for lumbar disc prolapse identified 40 randomized controlled trials and 2 quasi-randomized trials on the surgical management of lumbar disc prolapse. However, the authors identified only 4 studies (Weber, 1983; Greenfield, 2003; Butterman, 2004; Weinstein, 2006) that compared discectomy with conservative management. The authors stated that these studies contain major design weaknesses, particularly on the issues of sample size, randomization, blinding, and duration of follow-up. Furthermore, outcome measures in clinical studies of LBP have not been standardized making it difficult to compare the results of clinical studies of similar treatment.

The first study (Weber, 1983) compared the results of surgical versus conservative treatment for lumbar disc herniation confirmed by radiculography (n = 126) with 10 years of follow-up observation. The author reported a significantly better result in the surgically treated group at the 1-year follow-up examination; however, after 4 years the difference was no longer statistically significant. Only minor changes took place during the last 6 years of observation. The trial was not blinded and 26% of the conservative group crossed-over to surgery.

In a prospective, randomized study, Buttermann (2004), evaluated the efficacy of epidural steroid injection versus discectomy in the treatment of patients with a large, symptomatic lumbar herniated nucleus pulposus (n = 100). The discectomy patients had the most rapid decrease in symptoms, with 92% to 98% of the patients reporting that the treatment had been successful over the various follow-up periods. Of the 50 patients who had undergone epidural steroid injection, 42% to 56% reported the treatment had been effective. Those who did not obtain relief from the injection had a subsequent discectomy (27 of 50 patients). The epidural steroid injection trial group did not appear to have any adverse outcomes as a result of their delay in receiving surgery. The author concluded that discectomy was more effective in reducing symptoms and disability associated with a large herniated lumbar disc than epidural steroid injection; however, the epidural steroid injection was found to be effective for the follow-up period of 3 years by nearly 50% of the patients who had not had improvement with 6 or more weeks of non-invasive care.

The Spine Patient Outcomes Research Trial (SPORT) was designed to compare the effectiveness of surgical and non-surgical treatment among participants with confirmed diagnoses of intervertebral disk herniation, spinal stenosis, and degenerative spondylolisthesis. The SPORT included 13 multi-disciplinary spine centers across the United States. To assess the efficacy of standard open diskectomy versus non-operative treatment individualized to the patient for lumbar intervertebral disk herniation, the SPORT observational cohort (Weinstein et al, 2006) conducted a randomized clinical trial (n = 501) with image-confirmed lumbar intervertebral disk herniation and persistent signs and symptoms of radiculopathy for at least 6 weeks. The authors reported limited adherence to the assigned treatment: 50% of patients assigned to surgery received surgery within 3 months of enrollment, while 30% of those assigned to non-operative treatment received surgery in the same period. Intent-to-treat analyses demonstrated substantial improvements for all primary and secondary outcomes in both treatment groups. Between-group differences in improvements were consistently in favor of surgery for all periods but were small and not statistically significant for the primary outcomes. The authors reported that both surgical and non-operative treatment groups improved substantially over a 2-year period. However, the
large numbers of patients who crossed over between assigned groups precluded any conclusions about the comparative effectiveness of operative therapy versus usual care.

The fourth study (Greenfield, 2003), available only as an abstract, compared microdiscectomy with a low-tech physical therapy regime and educational approach in patients with LBP and sciatica with a small or moderate disc prolapse. At 12 and 18 months there were statistically significant differences in pain and disability favoring the surgical group; however, by 24 months there was no difference between the 2 groups.

The Cochrane systematic review (2007) concluded: (i) most lumbar disc prolapses resolve naturally with conservative management and the passage of time; (ii) there is considerable evidence that surgical discectomy provides effective clinical relief for carefully selected patients with sciatica due to lumbar disc prolapse that fails to resolve with conservative management. It provides faster relief from the acute attack of sciatica, although any positive or negative effects on the long-term natural history of the underlying disc disease are unclear. There is still a lack of scientific evidence on the optimal timing of surgery. The amount of cross-over in these trials makes it likely that the intent-to-treat analysis underestimates the true effect of surgery; but the resulting confounding also makes it impossible to draw any firm conclusions about the efficacy of surgery.

In a randomized controlled study, Brox et al (2006) compared the effectiveness of lumbar fusion with posterior transpedicular screws and cognitive intervention and exercises on 60 patients aged 25 to 60 years with LBP lasting longer than 1 year after previous surgery for disc herniation. Cognitive intervention consisted of a lecture intended to give the patient an understanding that ordinary physical activity would not harm the disc and a recommendation to use the back and bend it. This was reinforced by 3 daily physical exercise sessions for 3 weeks. The primary outcome measure was the Oswestry Disability Index (ODI). The success rate was 50 % in the fusion group and 48 % in the cognitive intervention/exercise group. The authors concluded that for patients with chronic LBP after previous surgery for disc herniation, lumbar fusion failed to show any benefit over cognitive intervention and exercise.

The American Association of Neurological Surgeons/Congress of Neurological Surgeons (AANS/CNS) Guideline's for the Performance of Fusion Procedures for Degenerative Disease of the Lumbar Spine (Resnick, 2005), is a series of guidelines that deal with the methodology of guideline formation, the assessment of outcomes following lumbar fusion, recommendations that involve the diagnostic modalities helpful for the pre- and post-operative evaluation of patients considered candidates for or treated with lumbar fusion, followed by recommendations dealing with specific patient populations. Finally, several surgical adjuncts, including pedicle screws, intra-operative monitoring, and bone graft substitutes are discussed, and recommendations are made for their use.

In their review of the literature, the AANS/CNS committee found that several authors published their experience in the surgical management of patients with stenosis and spondylolisthesis treated with decompression with or without fusion. These results are variable and all studies involved nonvalidated outcome measures. Many of the published reviews presented flawed results due to poorly defined outcome measures, inadequate numbers of patients, and comparison of dissimilar treatment groups. As a result, most of the published studies on lumbar fusion were not included in their review. However, the committee stated that, "The aforementioned results do not detract from the importance of this document; rather, we can now clearly see the need for the neurosurgical community to design and complete prospective randomized controlled studies to answer the many lingering clinical questions with rigorous
scientific power." The guidelines concluded that "The precise definition of instability or kyphosis has varied among researchers and requires further study."

Investigators from the SPORT trial (Weinstein et al, 2007) compared surgical versus non-surgical treatment for lumbar degenerative spondylolisthesis. Candidates who had at least 12 weeks of symptoms and image-confirmed degenerative spondylolisthesis were offered enrollment in a randomized cohort (n = 304) or an observational cohort (n = 303). Eighty-six percent of patients had grade 1 slippage and 14 % had grade 2. However, all patients had neurogenic claudication or radicular leg pain with associated neurologic signs, spinal stenosis shown on cross-sectional imaging, and degenerative spondylolisthesis. Treatment was standard decompressive laminectomy (with or without fusion) or usual non-surgical care. The primary outcome measures were the 36-Item Short-Form General Health Survey (SF-36) bodily pain and physical function scores (100-point scales, with higher scores indicating less severe symptoms) and the modified ODI (100-point scale, with lower scores indicating less severe symptoms) at 6 weeks, 3 months, 6 months, 1 year, and 2 years. The investigators reported high 1 year cross-over rates in the randomized cohort (approximately 40 % in each direction) but moderate in the observational cohort (17 % cross-over to surgery and 3 % cross-over to non-surgical care). The intention-to-treat analysis for the randomized cohort showed no statistically significant effects for the primary outcomes. The as-treated analysis for both cohorts combined showed a significant advantage for surgery at 3 months that increased at 1 year and diminished only slightly at 2 years. The treatment effects at 2 years were 18.1 for bodily pain (95 % CI: 14.5 to 21.7), 18.3 for physical function (95 % CI: 14.6 to 21.9), and -16.7 for the ODI (95 % CI: -19.5 to -13.9). The investigators concluded that patients with degenerative spondylolisthesis and spinal stenosis treated surgically showed substantially greater improvement in pain and function during a period of 2 years than patients treated non-surgically. However, the investigators stated, "Often patients fear they will get worse without surgery, but the patients receiving nonsurgical treatment, on average, showed moderate improvement in all outcomes." No conclusion is drawn regarding selection criteria for percentage of vertebral slippage in individuals with spondylolisthesis considered for fusion.

Vokshoor (2004) stated that before surgery is considered for adult patients with degenerative spondylolisthesis, minimal neurologic signs, or mechanical back pain alone, conservative measures should be exhausted, and a thorough evaluation of social and psychological factors should be undertaken. Indications for surgical intervention (fusion) include:

- Any high-grade slip (greater than 50 %)
- Iatrogenic spondylolisthesis
- Neurologic signs -- Radiculopathy (unresponsive to conservative measures), myelopathy, neurogenic claudication
- Traumatic spondylolisthesis
- Type 1 and type 2 slips, with evidence of instability and progression of listhesis
- Type 3 (degenerative) listhesis with gross instability and incapacitating pain

This is consistent with Wheeless (2008) who stated that for spondylolisthesis, posterior spine fusion should be limited to those patients who do not respond to conservative measures and whose slips are greater than 50 %.

Matsudaira and colleagues (2005) compared outcomes following decompression laminectomy combined with posterolateral fusion and pedicle screw instrumentation (n = 19) versus a laminoplasty technique without fusion (n = 18) in patients with grade I lumbar degenerative spondylolisthesis and reported no significant difference in the degree of clinical improvement between the 2 groups at the 2 year follow-up.
Randomized controlled trials have shown results of fusion to be equivalent to those of structured exercise and cognitive intervention. In a retrospective study on lumbar fusion outcomes among Washington State compensated workers with chronic back pain (n = 1,950), Maghout et al (2006) reported that fusions with cages increased from 3.6 % in 1996 to 58.1 % in 2001. Overall disability rate at 2 years after fusion was 63.9 %, the re-operation rate was 22.1 %, and the rate for other complications was 11.8 %. The use of cages or instrumentation was associated with an increased complication risk compared with bone-only fusions without improving disability or reoperation rates. Legal, work-related, and psychologic factors predicted worse disability. Discography and multi-level fusions predicted greater reoperation risk. The authors concluded that the use of intervertebral fusion devices rose rapidly after their introduction in 1996 and that this increased use was associated with an increased complication risk without improving disability or reoperation rates.

In a systematic review of randomized trials comparing lumbar fusion surgery to non-surgical treatment of chronic back pain associated with lumbar disc degeneration, Mirza et al (2007) compared outcomes in 4 trials that focused on non-specific chronic back. One study suggested greater improvement in back-specific disability for fusion compared to unstructured nonoperative care at 2 years, but the trial did not report data according to intent-to-treat principles. Three trials suggested no substantial difference in disability scores at 1-year and 2-years when fusion was compared to a 3-week cognitive-behavior treatment addressing fears about back injury. However, 2 of these trials were under-powered to identify clinically important differences. The third trial had high rates of cross-over (greater than 20 % for each treatment) and loss to follow-up (20 %); it is unclear how these affected results. The authors concluded that surgery may not be more efficacious than structured cognitive-behavior therapy, however, methodological limitations of the randomized trials prevent firm conclusions.

According to the American College of Physicians/American Pain Society Clinical Practice Guideline, Diagnosis and Treatment of Low Back Pain (2007), studies on LBP show large variations in practice patterns on diagnostic tests and treatments, although costs of care can differ substantially, patients seem to experience similar outcomes. The guideline makes the following recommendations:

**Recommendation 1**: A focused history and physical should be conducted to determine whether the back pain is: (i) non-specific; (ii) associated with radiculopathy or spinal stenosis; or (iii) due to another specific spinal cause. The history should include an assessment of psychosocial risk factors, which predict risk of chronic disabling back pain (strong recommendation, moderate-quality evidence).

**Recommendation 2**: For patients with non-specific LBP, imaging or other diagnostic tests should not be routinely obtained (strong recommendation, moderate-quality evidence).

**Recommendation 3**: For patients with LBP when severe or progressive neurologic deficits are present or when serious underlying conditions are suspected on the basis of history and physical examination, diagnostic imaging and testing should be obtained (strong recommendation, moderate-quality evidence).

**Recommendation 4**: For patients with persistent LBP and signs or symptoms of radiculopathy or spinal stenosis who are also considered candidates for surgery or epidural steroid injection (for suspected radiculopathy), MRI (preferred) or CT should be performed (strong recommendation, moderate-quality evidence).
Recommendation 5: Patients with LBP should be advised to remain active, and information about effective self-care options, including evidence-based information on the expected course of LBP, should be provided (strong recommendation, moderate-quality evidence).

Recommendation 6: For patients with LBP, the use of medications with proven benefits should be considered in conjunction with back care information and self-care. Severity of baseline pain, functional deficits, potential benefits, risks, and relative lack of long-term efficacy and safety data should be considered before initiating therapy (strong recommendation, moderate-quality evidence). First-line medication options for most patients are acetaminophen or non-steroidal anti-inflammatory drugs.

Recommendation 7: For patients with LBP who do not improve with self-care options, non-pharmacologic therapy with proven benefits should be considered. For acute LBP, spinal manipulation may be considered. For chronic or subacute LBP, intensive inter-disciplinary rehabilitation, exercise therapy, acupuncture, massage therapy, spinal manipulation, yoga, cognitive-behavioral therapy, or progressive relaxation may be considered (weak recommendation, moderate-quality evidence).

The Washington State Health Technology Assessment Program commissioned the ECRI Institute, an independent, non-profit health services research agency, to conduct an assessment of lumbar fusion and discography in patients with chronic uncomplicated degenerative disc disease (DDD) associated with chronic LBP. In a draft assessment (2007), the ECRI Institute stated that they did not find sufficient evidence that lumbar fusion surgery is more effective to a clinically meaningful degree than non-surgical treatments for any of the following patient populations, comparisons and outcomes:

Meta-analysis of post-operative changes in Oswestry disability scores from 2 moderate quality randomized controlled trials (RCTs) (n = 413) revealed no clinically meaningful difference between fusion and intensive exercise/rehabilitation plus cognitive behavioral therapy (CBT) in patients without prior back surgery, although the difference slightly favored fusion. Strength of evidence: Weak. The evidence was insufficient to determine whether lumbar fusion provides a greater improvement in back pain (1 moderate-quality RCT, n = 64) or quality of life (no acceptable evidence) compared to intensive exercise/rehabilitation plus CBT in patients without prior back surgery. The evidence from 1 moderate quality RCT (n = 60) was insufficient to determine the relative benefits of lumbar fusion compared to intensive exercise/rehabilitation in patients with prior back surgery. The evidence from 1 moderate quality RCT (n = 294) was insufficient to determine the relative benefits of lumbar fusion compared to conventional physical therapy in patients with or without prior back surgery.

The ECRI Institute assessed the rates of adverse events (peri-operative, long-term events, and reoperations) for lumbar fusion surgery and non-surgical treatments and reported the following:

Categories of adverse events most frequently reported in fusion studies include reoperation (0 - 46 %), infection (0 - 9 %), various device-related complication (0 - 17.8 %), neurologic complications (0.7 - 26 %), thrombosis (0 - 4 %), bleeding/vascular complications (0 - 13 %), and dural injury (0.5 - 29 %)
Lumbar fusion leads to significantly higher rates of early adverse events compared to non-intensive physical therapy or intensive exercise/rehabilitation plus CBT.
Lumbar fusion leads to significantly higher rates of late adverse events at 2-year follow-up compared to non-intensive physical therapy or intensive exercise/rehabilitation plus CBT.
None of the 4 RCTs comparing fusion to non-intensive physical therapy or intensive exercise/rehabilitation plus CBT reported any adverse events occurring in patients who only received non-operative care. Most of the reported adverse events could not have occurred in patients who did not undergo surgery.

The ECRI assessment stated that there is insufficient evidence to determine what patient characteristics are associated with differences in the benefits and adverse events of lumbar fusion surgery.

**Contraindications:**

The ECRI assessment identified one guideline citing absolute contraindications for lumbar fusion and 3 guidelines reporting relative contraindications.

The Washington State Department of Labor and Industries (2004) cited the following as an absolute contraindication for lumbar fusion:

Initial laminectomy/discectomy related to unilateral compression of a lumbar nerve root

The Washington State Department of Labor and Industries (2004) cited the following as relative contraindications for lumbar fusion:

- Current evidence of a factitious disorder
- Current smoking
- Greater than 12 months of disability (time-loss compensation benefits) prior to consideration of fusion
- High degrees of somatization on clinical or psychological evaluation
- Multiple level degenerative disease of the lumbar spine
- No evidence of functional recovery (return to work) for at least 6 months following the most recent spine surgery
- Presence of a personality disorder or major psychiatric illness
- Psychosocial factors that are correlated with poor outcome, such as history of drug or alcohol abuse
- Severe physical deconditioning.

The American Association of Neurological Surgeons reviewed evidence on lumbar fusion for the treatment of disc herniation and radiculopathy, and concluded: "There is insufficient evidence to recommend a treatment guideline." However, they did comment that lumbar spinal fusion is not recommended as a routine treatment following primary disc excision in patients with a herniated lumbar disc causing radiculopathy, though it may be of use for patients with herniated discs and evidence of preoperative lumbar spinal disability or deformity, for patients with significant chronic axial LBP and radiculopathy due to disc herniation, or for patients with recurrent lumbar disc herniation.

For patients with low back complaints in general, the American College of Occupational and Environmental Medicine (2005) stated that patients with co-morbidities including cardiac or respiratory disease, diabetes, or mental illness, are poor candidates for back surgery in general.
A cervical laminectomy (may be combined with an anterior approach) is sometimes performed when acute cervical disc herniation causes cord compression or in cervical disc herniations refractory to conservative measures. Studies have shown that an anterior discectomy with fusion is the recommended procedure for central or anterolateral soft disc herniation, while a posterior laminotomy-foraminotomy may be considered when technical limitations for anterior access exist (e.g., short thick neck) or when the individual has had prior surgery at the same level (Windsor, 2006).

Discectomy alone is regarded as a technique that most frequently results in spontaneous fusion (70 % to 80 %). Additional fusion techniques include the use of bone grafts (autograft, allograft or artificial) with or without cages and/or the use of an anterior plate. A Cochrane systematic review (2004) reported the results of 14 studies (n = 939) that evaluated three comparisons of different fusion techniques for cervical degenerative disc disease and concluded that discectomy alone has a shorter operation time, hospital stay, and post-operative absence from work than discectomy with fusion with no statistical difference for pain relief and rate of fusion. The authors concluded that more conservative techniques (discectomy alone, autograft) perform as well or better than allograft, artificial bone, and additional instrumentation; however, the low quality of the trials reviewed prohibited extensive conclusions and more studies with better methodology and reporting are needed.

To identify whether there is an advantage to instrumented or non-instrumented spinal fusion over decompression alone for patients with degenerative lumbar spondylolisthesis on the surgical management of degenerative lumbar spondylolisthesis, Martin et al (2007) reported the results of 13 studies in a systematic review; however, the studies were generally of low methodologic quality. Abstracted outcomes included clinical outcome, reoperation rate, and solid fusion status. Analyses were separated into: (i) fusion versus decompression alone, and (ii) instrumented fusion versus non-instrumented fusion. A satisfactory clinical outcome was significantly more likely with fusion than with decompression alone; however, the clinical benefit favoring fusion decreased when analysis was limited to studies where the majority of the patients reported neurologic symptoms (e.g., intermittent claudication and/or leg pain). The use of adjunctive instrumentation significantly increased the probability of attaining solid fusion, but no significant improvement in clinical outcome was reported. There was a non-significant trend toward lower repeat operations with fusion compared with both decompression alone and instrumented fusion. The authors concluded that spinal fusion may lead to a better clinical outcome than decompression alone. No conclusion about the clinical benefit of instrumenting a spinal fusion could be made; however, there is moderate evidence that the use of instrumentation improves the chance of achieving solid fusion.

Tsutsumimoto and colleagues (2008) retrospectively examined the surgical outcomes of un-instrumented posterolateral lumbar fusion for a minimum of 8 years (average of 9.5 years), by comparing cases exhibiting union with those exhibiting non-union. Un-instrumented posterolateral lumbar fusion was performed for the treatment of lumbar canal stenosis (LCS) with degenerative spondylolisthesis. The study included 42 patients, and the follow-up rate was 82.4 %. The mean age of the patients was 64.1 years (range of 46 to 77 years). Eight patients exhibited fusion at the L3-L4 level and 34 patients, at the L4-L5 level. The fusion status was assessed using plain radiographs. The clinical outcomes were evaluated using the Japanese Orthopaedic Association (JOA) scores. Non-union was noted in 26 % (11/42) of the patients. There were no statistically significant differences between the groups exhibiting union and non-union with respect to age, sex, pre-operative JOA score, or pre-operative lumbar instability. The union group achieved better operative results than the non-union group.
at the 5-year and final follow-up (p = 0.006 and 0.008, respectively), although there was no significant difference in the percent recovery at 1 and 3-year follow-up (p = 0.515 and 0.506, respectively). A stepwise regression analysis revealed that the best combination of predictors for recovery at the time of final follow-up included the fusion status and the presence of co-morbid disease.

A BlueCross BlueShield Association Technology Evaluation Center (BCBSA, 2007) assessment on the artificial lumbar disc commented on the evidence for spinal fusion for degenerative disc disease. The assessment stated that "The effectiveness of fusion for chronic degenerative disc disease is not well established. There are few clinical trials and results are inconsistent." One of the reasons the assessment concluded that the artificial disc is unproven is that the clinical studies compared it to spinal fusion, which is itself an unproven treatment for degenerative disc disease. The assessment stated that "Surgical arthrodesis, or fusion, is considered the current standard surgical treatment for degenerative disc disease which is not responsive to other treatments. Elimination of motion across the disc space and reduction of loads on disc tissues theoretically result in pain relief. Evidence supporting the efficacy of fusion is relatively sparse."

National survey data showed a rapid increase in the use of spinal fusion (i.e., annual numbers of procedures increased by 77% from 1996 to 2001) as a result of new technological advances (e.g., bone morphogenetic protein), financial incentives, and controversial expansion of indications (e.g., discogenic back pain without evidence of sciatica), and a high rate of re-operations. These increases were not associated with reports of clarified indications or improved efficacy of various fusion techniques for various indications (Deyo et al, 2004, 2005). The review of spinal fusion surgery by Deyo et al (2004) stated that, "Fundamental problems plague the study of spinal fusion, including the lack of definitive methods to confirm a solid fusion, a weak association between solid fusion and pain relief, and the placebo effect of surgery for pain relief." They further stated that, "Evidence-based practice for degenerative spine disorders might reserve the use of spinal fusions for spondylolisthesis and only rare cases of disk herniation or spinal stenosis without spondylolisthesis," and that "More evidence from clinical trials should be required for degenerative disk disease to be an accepted indication." Regarding the use of "emerging spinal implants," such as artificial discs, the review states that, "If ongoing trials suggest results equivalent to those of spinal fusion, it may be faint praise, given the paucity of evidence that spinal fusion is safe and effective for common indications."

A review of the literature by Turner et al (1992) found no randomized trials of fusion. Combining many studies of fusion performed for many different clinical indications, the authors found an average of 68% of patients reported a satisfactory outcome. A 1999 Cochrane review (Gibson et al) concluded that at that time there was no acceptable evidence of any form of fusion for degenerative lumbar spondylosis, back pain, or "instability." The authors could find no randomized clinical trials comparing fusion to a nonsurgical alternative, only trials which compared surgical techniques of fusion to each other.

Two published clinical trials comparing lumbar fusion to a non-surgical alternative treatment for patients with chronic back pain due to degenerative disc disease have been published since the Cochrane review. Fritzell et al (2001) conducted a multi-center randomized controlled trial comparing 3 techniques of lumbar fusion to non-surgical treatment. Enrollment criteria included patients (n = 294) with chronic pain, severe disability, pain attributed to degenerative disc disease, and no neurologic compromise due to herniated disc, spondylolisthesis, or spinal stenosis. There was no specified non-surgical treatment, but it
was described as commonly used physical therapies. In terms of patients' overall assessment, 63% of patients receiving fusion reported being better or much better, compared to 29% of control patients. Critics of the study have pointed to the modest effect of surgery (up to 30% mean score change), and the fact that control patients may not have received optimal nonsurgical treatment (Deyo et al, 2004).

The other randomized trial, by Brox et al (2003), assigned a specific cognitive and exercise regimen to the non-surgical patients. Enrollment criteria for this study were roughly similar to the other clinical trial, and outcomes were assessed at 1 year. In this study, patients receiving fusion reported improvements ranging from 36 to 49% on pain and disability scales, but patients in the control arm also reported similar improvements in these scores, resulting in differences which were not statistically significant for most outcomes. Although this trial was much smaller (n = 64) than the study by Fritzell et al (2001), the point estimates of effect for each arm are very similar to each other, and confidence intervals sufficiently narrow to rule out a large clinical benefit of surgery. The authors believed that the difference in results between the 2 studies was caused by the specific intervention used in the non-surgical group, which produced improvements similar to the surgical fusion group.

The relative sparseness of controlled clinical trial data regarding the effectiveness of fusion for degenerative disc disease makes the validity of it as a valid comparator to total disc replacement uncertain. It can not be ruled out that some of the improvements associated with lumbar fusion are due to natural history, placebo effects, or co-interventions such as rehabilitation and exercise programs. It would be difficult to compare retrospective studies of fusion with case series results of artificial disc because of the very restrictive selection criteria for the artificial disc. Complicating the evaluation of fusion is the variety of techniques and devices used to perform the procedure. Pedicle screws and intervertebral fusion cages are 2 types of devices implanted during some procedures. Clinical trial results comparing use of these devices have not produced consistent results (BCBSA, 2007).

Common complications of fusion reported by Deyo et al (2004) include instrument failure (7%), complications at the bone donor site (11%), neural injuries (3%), and failure to achieve a solid fusion or pseudarthrosis (15%). In addition, fusion is thought to cause increased rate of disc degeneration in spinal segments adjacent to the fusion.

The Washington State Health Technology Assessment Program commissioned Spectrum Research Inc., an independent, clinical research organization, to conduct a systematic review of the evidence on the safety, efficacy, and cost-effectiveness of artificial disc replacement (Dettori et al, 2008). One of the questions posed to the reviewers was whether there is evidence of the efficacy/effectiveness of artificial disc replacement compared with comparative therapies, including spinal fusion. The assessment reviewed the effectiveness of artificial disc replacement compared with spinal fusion in patients with degenerative disc disease and concluded that there is moderate evidence that the efficacy/effectiveness of lumbar artificial disc replacement is comparable with anterior lumbar interbody fusion or circumferential fusion up to 2 years following surgery; however, the authors stated that a non-inferiority trial requires that the reference treatment have an established efficacy or that it is in widespread use. For the lumbar spine, the authors noted that the efficacy of lumbar fusion for degenerative disc disease remains uncertain, especially when it is compared with non-operative care; thus, this limits the ability to fully answer the efficacy/effectiveness question of artificial disc replacement.

Four randomized controlled trials comparing lumbar fusion to non-surgical treatments found that nearly 15% (58/399) of patients receiving lumbar fusion experienced complications. The
most frequent complications reported included re-operation (with rates ranging from 0 % - 46.1 %), infection (0 % - 9 %), device-related complications (0 % - 17.8 %), neurologic complications (0.7 % - 25.8 %), thrombosis (0 % - 4 %), bleeding/vascular complications (0 % - 12.8 %), and dural injury (0.5 % - 29 %). In another study, a 12 % 2-year incidence rate of major complications following lumbar spinal fusion was reported, with a re-operation rate of 14.6 % for that population. Other complications reported in the literature include the potential for adjacent segment degeneration (development of disc degeneration, hypertrophic facets, dynamic instability, and/or spinal stenosis in adjacent levels), pseudoarthrosis, bone graft donor site pain and infection, instrumentation prominence or failure, neural injuries, and failure to relieve pain (Dettori et al, 2008).

Failed back surgery syndrome (FBSS), a condition in which there is failure to improve satisfactorily after back surgery, is characterized by intractable pain and various degrees of functional disability after lumbar spine surgery. A review of the literature on failed degenerative lumbar spine surgery (Diwan et al, 2003) estimated that 10 % to 15 % of patients who have undergone a spinal decompression procedure and 15 % to 20 % of patients who have had a spinal fusion procedure for degenerative disease of the lumbar spine undergo revision lumbar surgery within 3 to 5 years due to significant back and leg symptoms. However, most studies do not give the time to reoperation from the initial surgery. AHRQ (2006) reviewed studies that reported the incidence of adjacent segment disease requiring reoperation following lumbar or lombosacral fusion and reported that annualized reoperation rates ranged from 0 % to 3.7 % and 1.7 % to 3.4 % for non-fusion lumbar surgery based on the over-all reoperation rates of the studies and the average time to follow-up.

The major causes for reoperation include fibrosis and adhesions, spinal instability, recurrent herniated disk, and inadequate decompression (Skaf et al, 2005). Over time, recurrent lumbar stenosis may occur at the same level (due to persistent or even enhanced motion at that level) or at adjacent levels due to the natural course of disease progression. It is hypothesized that fusion at one level increases stress on joints at adjacent levels during ordinary spine motion, hence leading to accelerated degenerative joint disease at these adjacent levels, as compared to the natural history of disease progression. Whether an instrumented fusion may increase adjacent segment disease is another controversial point, but without much evidence (AHRQ, 2006).

The etiology of FBSS can be poor patient selection, incorrect diagnosis, sub-optimal selection of surgery, poor technique, failure to achieve surgical goals, and/or recurrent pathology. Successful intervention in this difficult patient population requires a detailed history to accurately identify symptoms, rule out extra-spinal causes, identify a specific spinal etiology, and assess the psychological state of the patient. Only after these factors have been assessed can further treatment be planned (Guyer et al, 2006).

Relevant outcome studies are rarely diagnosis specific, and high level research studies comparing surgical and non-surgical approaches to FBSS studies have not been published to date. Surgical strategies focus on decompressing neural impingement or fusing unstable or putatively painful intervertebral discs. Non-surgical interventions range from nerve root specific blocks for pain relief to multi-disciplinary rehabilitation programs geared toward improving function (Hazard, 2006).

Herron (1994) reported the results of recurrent disc herniation treated by repeat laminectomy and discectomy. Fifty recurrences were treated in 46 patients, an average of 7 years and 1 month after the previous laminectomy. Thirty-four patients were treated for 37 recurrences at the same level, with 3 undergoing a third laminectomy and discectomy. Twelve patients were
treated for 13 recurrences at a different level. Four patients underwent a third laminectomy and discectomy for recurrent disc herniation. Forty-one patients had follow-up of at least 1 year and average follow-up was 4 years and 6 months. There were 28 good (69 %), 10 fair (24 %), and 3 poor (7 %) results. Patients with pending litigation or work-related injuries (5 good, 5 fair, and 3 poor) did less well overall than those without these issues (23 good, 5 fair, and 0 poor). Heron stated that, "Fusion is not routinely required in patients undergoing repeat laminectomy and discectomy for recurrent disc herniation. In the absence of objective evidence of spinal instability, recurrent disc herniation may be adequately treated by repeat lumbar laminectomy and discectomy alone".

Fritsch et al (1996) conducted a retrospective review of 182 revisions on FBSS from the years 1965 to 1990 and analyzed the reasons for failure of primary discectomy, the outcome of the revisions, and factors that influenced those outcomes. The reported re-intervention rates after lumbar discectomy ranged from 5 % to 33 % depending on the type of surgical procedure. The authors' former investigations reported a revision rate of 10.8 % in evaluating 1,500 lumbar discectomies. A total of 182 revisions were performed on 136 patients; 44 patients (34 %) were revised multiple times. Recurrent or un-influenced sciatic pain and neurologic deficiency or lumbar instability led to re-intervention. Recurrent lumbar disc herniation was mainly found at the first re-intervention. In multiple revision patients the rate of epidural fibrosis and instability increased to greater than 60 %. In 80 % of the patients the results were satisfactory in short-term evaluation, decreasing to 22 % in long-term follow up (2 to 27 years). Laminectomy performed in primary surgery could be detected as the only factor leading to a higher rate of revisions. The authors noted a trend toward poor results after recurrent disc surgery due to the development of epidural fibrosis and instability. In severe discotomy syndrome, a spinal fusion appeared to be more successful than multiple fibrinolyses.

Phillips and Cunningham (2002) conducted a review of the peer-reviewed publications that investigated etiologies and treatments for neurogenic pain in patients who have undergone previous spinal surgery. The authors recommended that in the absence of profound or progressive neurologic deficits, most patients with chronic back and leg pain who have undergone previous spinal surgery be treated non-operatively, however, additional decompressive surgical intervention may be justified in patients with well-defined, discrete pathology amenable to surgical correction who have been refractory to conservative care.

During a 2-year period, Duggal et al (2004) treated patients diagnosed with FBSS with anterior lumbar interbody fusion. Clinical and radiological outcomes were recorded in a prospective, non-randomized, longitudinal manner. Neurological, pain, and functional outcomes were measured pre-operatively and 12 months after surgery. Operative data, peri-operative complications, and radiological and clinical outcomes were recorded. Thirty-three patients with a pre-operative diagnosis of FBSS, with degenerative disc disease (n = 17), post-surgical spondylolisthesis (n = 13), or pseudarthrosis (n = 3), underwent anterior lumbar interbody fusion. Back pain, leg pain, and functional status improved significantly, by 76 % (p < 0.01), 80 % (p < 0.01), and 67 % (p < 0.01), respectively. The authors found anterior lumbar interbody fusion to be a safe and effective procedure for the treatment of FBSS for selected patients.

Skaf et al (2005) prospectively studied 50 patients with FBSS. The underlying pathology was identified and all the patients were treated surgically. Redo surgery was targeted at correcting the underlying pathology: removal of recurrent or residual disk, release of adhesions with neural decompression, and fusion with or without instrumentation. The post-surgical outcome
was studied using the ODQ. The average pre-operative ODQ mean score was 80.8; the average post-operative ODQ mean score was 36.6 at 1 month and 24.2 at 1 year. Best scores were obtained at 3 months of follow-up in most cases. Successful outcome (greater than 50 % pain relief) was achieved in 92 % of the patients at 1 year. The authors concluded that successful management of patients with FBSS could be achieved with proper patient selection, correct pre-operative diagnosis, and adequate surgical procedure targeting the underlying pathology.

Fu et al (2005) evaluated the long-term outcomes of repeat surgery for recurrent lumbar disc herniation and compared the results of disc excision with and without posterolateral fusion in a retrospective study. The sample included 41 patients who underwent disc excision with or without posterolateral fusion, with an average follow-up of 88.7 months (range of 60 to 134 months). Clinical symptoms were assessed based on the Japanese Orthopedic Association Back Scores. All medical and surgical records were examined and analyzed, including pain-free interval, intra-operative blood loss, length of surgery, and post-surgery hospital stay. Clinical outcome was excellent or good in 80.5 % of patients, including 78.3 % of patients undergoing a discectomy alone, and 83.3 % of patients with posterolateral fusion. The recovery rate was 82.2 %, and the difference between the fusion and non-fusion groups was insignificant (p = 0.799). The difference in the post-operative back pain score was also insignificant (p = 0.461). These 2 groups were not different in terms of age, pain-free interval, and follow-up duration. Intra-operative blood loss, length of surgery, and length of hospitalization were significantly less in patients undergoing discectomy alone than in patients with fusion. The authors concluded that repeat surgery for recurrent sciatica is effective in cases of true recurrent disc herniation.

Papadopoulos et al (2006) retrospectively reviewed a total of 27 patients who had undergone revision discectomies for recurrent lumbar disc herniations to assess their clinical outcomes. Patients were compared with a control group of 30 matched patients who had undergone only a primary discectomy. The spine module of the MODEMS outcome instrument was used to evaluate patients' satisfaction, pain and functional ability following discectomy, as well as quality of life. Patients were also asked whether they were improved or worsened with surgery. Those undergoing revision surgery were asked whether the improvement following the second surgery was more or less than the improvement following the first surgery. Improvement following the repeat discectomy was not statistically different from the improvement that occurred in patients who underwent just the primary operation. Differences in residual numbness/tingling in the leg and/or the foot as well as in frequency of back and/or buttock pain were identified. The authors concluded that revision discectomy is as efficacious as primary discectomy in selected patients.

An assessment of spinal fusion by the Andalusian Agency for Health Technology Assessment (AETSA) (Martinez Ferez et al, 2009) concluded that the available scientific evidence about spinal fusion is scarce and is based on low or moderate quality studies. The assessment found no clear evidence that fusion combined with spinal decompression provides some benefits in degenerative lumbar stenosis. The assessment found weak evidence in favor of spinal fusion in contrast with decompression for degenerative spondylolisthesis, but it is based on studies of low methodological quality. The report found that, for degenerative discopathies, spinal fusion does not provide clinical benefits compared to structured and intense conservative treatments with cognitive-behavioural therapy; on the contrary, it seems to provide benefits compared to less intensive treatments which are commonly used in practice. For degenerative discopathies with radicular compression, spinal fusion does not seem to provide a clear clinical benefit compared to decompression alone. The report found that total...
replacement of the degenerated discs by artificial discs such as Charité and Pro-Disc L shows results at least as good or better than those obtained by spinal fusion, which is considered the standard treatment in these cases. The report concluded that clinical trials of higher quality are necessary in order to get clear results about the real benefit which fusion provides for the treatment of the spinal degenerative pathologies which have been included in this report.

Anterior spinal fusion with instrumentation has been used for many years in the treatment of thoracolumbar and lumbar curves in adolescent idiopathic scoliosis (AIS). Tis et al (2010) reported the intermediate radiographical and pulmonary function testing (PFT) data from patients who underwent open instrumented anterior spinal fusion (OASF) using modern, rigid instrumentation for the treatment of primary thoracic (Lenke 1) adolescent idiopathic scoliosis (AIS). Of 101 potential patients who underwent OASF with a minimum 5-year follow-up, 85 (85 %) were studied. Standing radiographs were analyzed before surgery and at first standing erect, 2-year, and 5-year follow-up. Data on PFT were collected before surgery and at 5 years after surgery. Complete 5-year follow-up was obtained in 85 patients. Five years after surgery, the mean coronal correction was 26 degrees (51 %; p < 0.05) and the thoracolumbar/lumbar curve improved 16 degrees (51 %). There was a 9-degree (p < 0.001) increase in kyphosis, and there were 9 patients (11 %) in whom the C7 plumb line translated greater than 2 cm. There was a 6.7 % decrease in predicted forced expiratory volume in one second over the 5-year period, from 75.5 % +/- 13 % before surgery to 68.8 % +/- 2 % at 5-year follow-up (p = 0.007); however, there was no significant change in forced vital capacity. There were 3 significant adverse events: 1 implant breakage requiring re-operation and 2 cases of progression of the main thoracic curve requiring re-operation. The authors concluded that OASF is a reproducible and safe method to treat thoracic AIS. It provides good coronal and sagittal correction of the main thoracic and compensatory thoracolumbar/lumbar curves that is maintained with intermediate term follow-up. In skeletally immature children, this technique can cause an increase in kyphosis beyond normal values, and less correction of kyphosis should be considered during instrumentation. As with any procedure that employs a thoracotomy, pulmonary function is mildly decreased at final follow-up.

In a retrospective review, Kelly and colleagues (2010) evaluated a group of patients based on Scoliosis Research Society (SRS)-30 and Oswestry data as well as radiographical and MRI findings; and reported the results of long-term follow-up of anterior spinal fusion with instrumentation for thoracolumbar and lumbar curves in AIS. Eighteen patients were available for review. Average follow-up for this study was 16.97 years. Based on SRS-30 and the Oswestry Disability Index data, most patients had good function scores and acceptable pain levels. Radiographs demonstrated no progression of the thoracolumbar or thoracic curves. Implant failure was identified in 2 patients. Radiographical changes of early degenerative disc disease were identified in most patients but had no correlation with SRS or Oswestry data. These degenerative changes were evident on both radiographs and MRI. The authors concluded that the anterior approach in the treatment of thoracolumbar and lumbar curves in AIS offers good long-term functional outcomes for patients. Despite expected degenerative changes, patients scored well on the SRS and Oswestry tests, and were able to pursue careers and family activities.

Lehman and Lenke (2007) reviewed the case of a 44-year-old woman who underwent long-segment fusion and an artificial disc replacement (ADR). There have been many reported advantages and disadvantages of stopping the fusion at L5, with the theoretical benefits being preserved motion, shorter operative time, allowing the remaining disc to compensate for curve correction cephalad in the lumbar spine, and a decreased likelihood for the development of a pseudarthrosis at that distal level. As the issue of the fate of the L5 to S1 motion segment
continues to be debated, these investigators presented the case of a medium-segment thoraco-lumbar fusion carried down to the L4 stable vertebra, an intervening healthy L4 to L5 disc space, with the placement of an artificial disc arthroplasty at the L5 to S1 level for a degenerative and discographically positive pain generator. At 2-year follow-up, her L5 to S1 artificial disc replacement level shows 11 degrees range of motion (ROM) and consolidated fusion from T12 to L4 with complete resolution of her axial back pain. Her T12 to L4 construct is stable, and the L4 to L5 level is unaffected at the latest follow-up. Her clinical outcome has been excellent with her return to a very active lifestyle. The authors concluded that ADR below a long-segment fusion is a viable alternative to performing fusion to additional motion segments.

In an in-vitro human cadaveric biomechanical study, Erkan et al (2009) compared the biomechanical properties of a 2-level Maverick disc replacement at L4 to L5, L5 to S1, and a hybrid model consisting of an L4 to L5 Maverick disc replacement with an L5 to S1 anterior lumbar interbody fusion using multi-directional flexibility test. A total of 6 fresh human cadaveric lumbar specimens (L4 to S1) were subjected to unconstrained load in axial torsion (AT), lateral bending (LB), flexion (F), extension (E), and flexion-extension (FE) using multi-directional flexibility test. Four surgical treatments -- intact, 1-level Maverick at L5 to S1, 2-level Maverick between L4 and L5, and the hybrid model (anterior fusion at L5 to S1 and Maverick at L4 to L5) were tested in sequential order. The ROM of each treatment was calculated. The Maverick disc replacement slightly reduced intact motion in AT and LB at both levels. The total FE motion was similar to the intact motion. However, the E motion is significantly increased (approximately 50 % higher) and F motion is significantly decreased (30 % to 50 % lower). The anterior fusion using a cage and anterior plate significantly reduced spinal motion compared with the condition (p < 0.05). No significant differences were found between 2-level Maverick disc prosthesis and the hybrid model in terms of all motion types at L4 to L5 level (p > 0.05). The authors concluded that the Maverick disc preserved total motion but altered the motion pattern of the intact condition. This result is similar to unconstrained devices such as Charité. The motion at L4 to L5 of the hybrid model is similar to that of 2-level Maverick disc replacement. The fusion procedure using an anterior plate significantly reduced intact motion. The authors concluded that clinical studies are recommended to validate the effectiveness of the hybrid model.

On behalf of the American Pain Society, Chou et al (2009) systematically evaluated benefits and harms of surgery for non-radiculopathic back pain with common degenerative changes, radiculopathy with herniated lumbar disc, and symptomatic spinal stenosis. For non-radiculopathic LBP with common degenerative changes, these researchers found fair evidence that fusion is no better than intensive rehabilitation with a cognitive-behavioral emphasis for improvement in pain or function, but slightly to moderately superior to standard (non-intensive) non-surgical therapy. Less than half of patients experience optimal outcomes (defined as no more than sporadic pain, slight restriction of function, and occasional analgesics) following fusion. Clinical benefits of instrumented versus non-instrumented fusion are unclear. For radiculopathy with herniated lumbar disc, these investigators found good evidence that standard open discectomy and microdiscectomy are moderately superior to non-surgical therapy for improvement in pain and function through 2 to 3 months. For symptomatic spinal stenosis with or without degenerative spondylolisthesis, they found good evidence that decompressive surgery is moderately superior to non-surgical therapy through 1 to 2 years. For both conditions, patients on average experience improvement either with or without surgery, and benefits associated with surgery decrease with long-term follow-up in some trials. Although there is fair evidence that ADR is similarly effective compared to fusion for single level degenerative disc disease and that an inter-spinous spacer device is superior to
non-surgical therapy for 1- or 2-level spinal stenosis with symptoms relieved with forward flexion, insufficient evidence exists to judge long-term benefits or harms. The authors concluded that surgery for radiculopathy with herniated lumbar disc and symptomatic spinal stenosis is associated with short-term benefits compared to non-surgical therapy, although benefits diminish with long-term follow-up in some trials. For non-radicular back pain with common degenerative changes, fusion is no more effective than intensive rehabilitation, but associated with small-to-moderate benefits compared to standard non-surgical therapy. This review did not mention the hybrid use of lumbar fusion and ADR for the management of LBP/spinal disorders.

Brox et al (2010) compared the long-term effectiveness of surgical and non-surgical treatment in patients with chronic LBP. The study was conducted at 4 university hospitals in Norway. The limitations on study enrollment ensured that patients with more significant symptoms and findings were not included in the protocol. All participants had LBP for at least 1 year, moderate disability, and evidence of disk degeneration at L4-L5 or L5-S1; those with symptomatic spinal stenosis were excluded from study participation. Similarly, patients with disk herniation or lateral recess stenosis plus signs of radiculopathy were excluded, as were those with generalized disk degeneration, ongoing serious somatic or psychiatric disease, or "reluctance" (term not defined) to undergo one of the study treatments. Participants were randomized to receive instrumented transpedicular fusion or non-surgical therapy. The non-surgical therapy was very intensive and included initial education, support, and physical training sessions that lasted an average of 25 hours per week over 3 weeks. There were 4 to 7 participants assigned to this training at a time, and they stayed in a hotel for patients during the 3 weeks. Specialists in physical medicine and rehabilitation guided the program, and participants also met with a peer who had previously completed the non-surgical program. At the end of the 3 weeks, participants were prescribed a home exercise program. The primary study outcome was the Oswestry disability index, which measures both pain and disability. Researchers also followed participants' ratings of treatment effectiveness, quality of life, and effects of the interventions on medication use and time missed from work. The study focused on these results measured at 4 years after randomization, and results were adjusted to account for sex, age, previous surgery for disk herniation, and baseline pain and disability scores. Of 234 eligible patients, 124 were enrolled in the trials. Baseline data were similar for the 2 groups. The mean age of participants was 42 years, and 72 % were women. The average duration of LBP was 9 years, and the mean severity of back pain was 64 on a scale of 0 to 100, with 100 being the most severe pain. Both treatment groups professed stronger beliefs in surgical versus non-surgical treatment of chronic LBP at baseline. In the surgical group, the rates of undergoing surgery were 88 % at 1 year and 91 % at 4 years. The respective rates of surgery in the non-surgical group were 5 % and 24 %. Study follow-up was excellent, with rates of 92 % and 86 % in the surgical and non-surgical groups at 4 years. Beyond comparing surgical and non-surgical treatment for chronic LBP, the study also gave some insight into the use of healthcare and other resources by these patients. Only a slight majority of patients saw a physician for back pain in the year before study follow-up at year 4. Less than 25 % received physical therapy. However, the rate of repeat surgery after the initial study surgery was 25 % over 4 years. This high repeat surgery rate was recorded despite the fact that no major adverse events related to surgery occurred through year 1 of the study.

Participants who received surgery were more than twice as likely to receive a disability pension, regardless of their randomized group. However, it would be wrong to infer that surgery itself promoted a higher rate of disability. These patients had surgery in response to more severe symptoms, and were therefore more likely to receive a disability pension in the first place. Moreover, applications for disability pension from patients who had received
surgery could have received more favorable reviews. There were no differences between randomized groups in the outcomes of pain and disability in either intent-to-treat or as-treated analyses at 4 years. The mean Oswestry disability index score declined in both groups from an approximate mean of 44 at baseline to 28 at 4 years. Among secondary outcomes, the only difference between treatment groups was a reduction in fear and avoidance of physical activity, favoring the non-surgical group. Measurements of general function improved by approximately 40% in both groups, and life satisfaction also improved. The number of participants returning to work improved with both treatments to a similar degree, and the proportions of participants rating their treatment as successful at 1 year were 61% and 65% in the surgical and non-surgical cohorts, respectively. Use of pain medication was higher among participants who received surgery, but any difference between treatment groups was not significant on intent-to-treat analysis.

Appendix

Types of Spondylolisthesis Description

The following types of spondylolisthesis are based on etiology:

Type 1: The dysplastic (congenital) type represents a defect in the upper sacrum or arch of L5. A high rate of associated spina bifida occulta and a high rate of nerve root involvement exist.

Type 2: This results from a defect in pars interarticularis, which permits forward slippage of the superior vertebra, usually L5.

The following 3 subcategories are recognized:

  Acutely fractured pars
  Elongated yet intact pars
  Lytic (i.e., spondylolysis) or stress fracture of the pars

Type 3: The degenerative (late in life) type is an acquired condition resulting from chronic disc degeneration and facet incompetence, leading to long-standing segmental instability and gradual slippage, usually at L4-L5. Spondylosis is a general term reserved for acquired age-related degenerative changes of the spine (i.e., discopathy or facet arthropathy) that can lead to this type of spondylolisthesis.

Type 4: The traumatic (any age) type results from fracture of any part of the neural arch or pars that leads to listhesis.

Type 5: The pathologic type results from a generalized bone disease, such as Paget disease or osteogenesis imperfecta.

The Myerding Grading System

The Myerding grading system measures the percentage of vertebral slip forward over the body beneath:

<table>
<thead>
<tr>
<th>grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>25% of vertebral body has slipped forward</td>
</tr>
<tr>
<td>2</td>
<td>25% to 49% of vertebral body has slipped forward</td>
</tr>
</tbody>
</table>
### Spinal Surgery: Laminectomy and Fusion

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>grade 3</td>
<td>50% to 74% of vertebral body has slipped forward</td>
</tr>
<tr>
<td>grade 4</td>
<td>75% to 99% of vertebral body has slipped forward</td>
</tr>
<tr>
<td>grade 5</td>
<td>Vertebral body has completely fallen off (i.e., spondyloptosis)</td>
</tr>
</tbody>
</table>


### CPT Codes / HCPCS Codes / ICD-9 Codes

**Lumbar laminectomy for herniated disc:**

**CPT codes covered if selection criteria are met:**

- 63030
- 63042
- + 63044
- 63047
- 63056

**Other CPT codes related to the CPB:**

- + 63035
- + 63048
- + 63057

**ICD-9 codes covered if selection criteria are met:**

- 722.10  Displacement of lumbar intervertebral disc without myelopathy
- 722.73  Intervertebral disc disorder with myelopathy, lumbar region

**Other ICD-9 codes related to the CPB:**

- 722.83  Postlaminectomy syndrome, lumbar region
- 724.2  Lumbago
- 724.3  Sciatica
- 724.4  Thoracic or lumbosacral neuritis or radiculitis, unspecified
- 724.5  Backache, unspecified
- 724.8  Other symptoms referable to back
724.9  Other unspecified back disorders
729.2  Neuralgia, neuritis, and radiculitis, unspecified
729.5  Pain in limb
780.79  Other malaise and fatigue
782.0  Disturbance of skin sensation
796.1  Abnormal reflex
839.20  Dislocation of lumbar vertebra, closed
839.30  Dislocation of lumbar vertebra, open

Cervical laminectomy(and/or an anterior cervical disectomy and cervical fusion) for herniated disc:

CPT codes covered if selection criteria are met:
22548
22551
22552
22554
63020
63040
+ 63043
63075
+63076

Other CPT codes related to the CPB:
+ 63035

ICD-9 codes covered if selection criteria are met:
722.0  Displacement of cervical intervertebral disc without myelopathy
722.71  Intervertebral disc disorder with myelopathy, cervical region
723.4  Brachial neuritis or radiculitis NOS [cervical nerve root compression]
726.91  Exostosis of unspecified site [of spine causing spinal cord or nerve root compression, confirmed by imaging studies]

Other ICD-9 codes related to the CPB:
596.55  Detrusor sphincter dyssynergia
722.81  Postlaminectomy syndrome, cervical region
723.1  Cervicalgia
723.8  Other syndromes affecting cervical region
729.2  Neuralgia, neuritis, and radiculitis, unspecified
729.5  Pain in limb
780.79  Other malaise and fatigue
781.2  Abnormality of gait
782.0  Disturbance of skin sensation
796.1  Abnormal reflex

**Thoracic laminectomy (and/or thoracic diskectomy and fusion):**

**CPT codes covered if selection criteria are met:**

22222
22532
+22534
22556
+22585
63003
63016
63046
+63048
63077
+63078

**ICD-9 codes covered if selection criteria are met:**

721.41  Spondylosis with myelopathy, thoracic region [Spondylogenic compression of thoracic spinal cord]
721.8  Other allied disorders of spine [spinal exostosis]
722.11  Displacement of thoracic intervertebral disc without myelopathy
722.72  Intervertebral thoracic disc disorder with myelopathy, thoracic region
722.82  Postlaminectomy syndrome, thoracic region
724.4  Thoracic or lumbosacral neuritis or radiculitis, unspecified [nerve root compression]

724.8  Other symptoms referable to back [spinal ligament hypertrophy]

839.21, 839.31  Closed and open dislocation, thoracic vertebra

953.8 - 953.9  Injury to multiple and unspecified sites of nerve roots and spinal plexus

**Lumbar decompression:**

**CPT codes covered if selection criteria are met:**

62287

63005

63012

63017

63030

**Other CPT codes related to the CPB:**

+ 63035

+63048

+63057

**ICD-9 codes covered if selection criteria are met:**

344.60 - 344.61  Cauda equina syndrome

736.79  Other acquired deformities of ankle and foot [foot drop]

**Other ICD-9 codes related to the CPB:**

564.89  Other functional disorders of intestine

596.59  Other functional disorder of bladder

780.79  Other malaise and fatigue

782.0  Disturbance of skin sensation

**Cervical, thoracic, or lumbar laminectomy other than for herniated disc:**

**CPT codes covered if selection criteria are met:**

63001

63003

63005
ICD-9 codes covered if selection criteria are met:

170.2  Malignant neoplasm of vertebral column, excluding sacrum and coccyx
192.2  Malignant neoplasm of spinal cord
192.3  Malignant neoplasm of spinal meninges
198.3  Secondary malignant neoplasm of brain and spinal cord
198.4  Secondary malignant neoplasm of other parts of nervous system
198.5  Secondary malignant neoplasm of bone and bone marrow
213.2  Benign neoplasm of vertebral column, excluding sacrum and coccyx
225.3  Benign neoplasm of spinal cord
225.4  Benign neoplasm of spinal meninges
237.5 Neoplasm of uncertain behavior of brain and spinal cord
237.6 Neoplasm of uncertain behavior of meninges
238.0 Neoplasm of uncertain behavior of bone and articular cartilage
324.1 Intraspinal abscess
348.0 Cerebral cysts
432.0 Nontaumatice extradural hemorrhage
432.1 Subdural hemorrhage
723.0 Spinal Stenosis of cervical region
724.00 - 724.03 Spinal stenosis, other than cervical
723.0 Spinal stenosis of cervical region
724.02 Lumbar region, without neurogenic claudication
727.40 Synovial cyst, unspecified [of spine causing spinal cord or nerve root compression, confirmed by imaging studies (e.g., CT or MRI) and with corresponding neurological deficit]
730.08, 730.18, 730.28, 730.78, 730.88, 730.98 Osteomyelitis, periostitis, and other infections involving bone, other specified sites [spinal]
805.4 - 805.5 Fracture of vertebral column without mention of spinal cord injury, lumbar
806.4 - 806.5 Fracture of vertebral column with spinal cord injury, lumbar
839.20 Dislocation of lumbar vertebra, closed
839.30 Dislocation of lumbar vertebra, open
952.00 - 952.9 Spinal cord injury without evidence of spinal bone injury [causing spinal cord or nerve root compression, confirmed by imaging studies (e.g., CT or MRI) and with corresponding neurological deficit]

Thoracic spinal fusion:

CPT codes covered if selection criteria are met:

22532
+22534
22556
22610
+22614
ICD-9 codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>170.2</td>
<td>Malignant neoplasm of vertebral column, excluding sacrum and coccyx</td>
</tr>
<tr>
<td>192.2</td>
<td>Malignant neoplasm of spinal cord</td>
</tr>
<tr>
<td>198.3</td>
<td>Secondary malignant neoplasm of brain and spinal cord [thoracic spinal cord]</td>
</tr>
<tr>
<td>198.5</td>
<td>Secondary malignant neoplasm of bone and bone marrow [spine, spinal (column)]</td>
</tr>
<tr>
<td>213.2</td>
<td>Benign neoplasm of vertebral column, excluding sacrum and coccyx</td>
</tr>
<tr>
<td>225.3</td>
<td>Benign neoplasm of spinal cord</td>
</tr>
<tr>
<td>237.5</td>
<td>Neoplasm of uncertain behavior of brain and spinal cord</td>
</tr>
<tr>
<td>238.0</td>
<td>Neoplasm of uncertain behavior of bone and articular cartilage [spine, spinal (column)]</td>
</tr>
<tr>
<td>239.2</td>
<td>Neoplasms of unspecified nature of bone, soft tissue, and skin [spine, spinal (column)]</td>
</tr>
<tr>
<td>239.7</td>
<td>Neoplasm of unspecified nature of endocrine glands and other parts of nervous system [thoracic spinal cord]</td>
</tr>
<tr>
<td>324.1</td>
<td>Intraspinal abscess</td>
</tr>
<tr>
<td>721.41</td>
<td>Spondylosis with myelopathy, thoracic region</td>
</tr>
<tr>
<td>722.11</td>
<td>Displacement of thoracic intervertebral disc without myelopathy</td>
</tr>
<tr>
<td>722.72</td>
<td>Intervertebral thoracic disc disorder with myelopathy, thoracic region</td>
</tr>
<tr>
<td>724.01</td>
<td>Spinal stenosis of thoracic region</td>
</tr>
<tr>
<td>724.4</td>
<td>Thoracic or lumbosacral neuritis or radiculitis, unspecified</td>
</tr>
<tr>
<td>733.82</td>
<td>Nonunion of fracture [spine, spinal (column)]</td>
</tr>
<tr>
<td>737.0</td>
<td>Adolescent postural kyphosis</td>
</tr>
<tr>
<td>737.10-737.19</td>
<td>Kyphosis (acquired)</td>
</tr>
<tr>
<td>737.30 737.39</td>
<td>Kyphoscoliosis and scoliosis</td>
</tr>
<tr>
<td>737.41</td>
<td>Kyphosis associated with other condition</td>
</tr>
<tr>
<td>737.43</td>
<td>Scoliosis associated with other condition</td>
</tr>
<tr>
<td>738.4</td>
<td>Acquired spondylolisthesis</td>
</tr>
<tr>
<td>805.2</td>
<td>Closed fracture of dorsal (thoracic) vertebra without mention of spinal cord injury</td>
</tr>
</tbody>
</table>
805.3  Open fracture of dorsal (thoracic) vertebra without mention of spinal cord injury

806.20 - 806.29  Closed fracture of dorsal (thoracic) vertebra with spinal cord injury

806.30 - 806.39  Open fracture of dorsal vertebra with spinal cord injury

839.21  Closed dislocation, thoracic vertebra

839.31  Open dislocation, thoracic vertebra

952.10 - 952.19  Dorsal (thoracic) spinal cord injury without evidence of spinal bone injury

V45.4  Arthrodesis status [non-union of prior fusion]

**Lumbar spinal fusion:**

**CPT codes covered if selection criteria are met:**

22533

22558

22612

+ 22614

22630

+22632

22633

22634

**ICD-9 codes covered if selection criteria are met:**

170.2  Malignant neoplasm of vertebral column, excluding sacrum and coccyx

192.3  Malignant neoplasm of spinal meninges

198.3  Secondary malignant neoplasm of brain and spinal cord

198.4  Secondary malignant neoplasm of other parts of nervous system

198.5  Secondary malignant neoplasm of bone and bone marrow

225.3  Benign neoplasm of spinal cord

225.4  Benign neoplasm of spinal meninges

237.5  Neoplasm of uncertain behavior of brain and spinal cord

237.6  Neoplasm of uncertain behavior of meninges

238.0  Neoplasm of uncertain behavior of bone and articular cartilage
324.1  Intraspinal abscess
724.02  Spinal stenosis, lumbar region
730.08  Acute osteomyelitis, other specified sites [spinal]
730.18  Chronic osteomyelitis, other specified sites [spinal]
730.28  Unspecified osteomyelitis, other specified sites [spinal]
730.78  Osteopathy resulting from poliomyelitis, other specified sites [spinal]
730.88  Other infections involving bone in disease classified elsewhere, other specified sites [spinal]
730.98  Unspecified infection of bone of other specified sites [spinal]
733.13  Pathologic fracture of vertebrae
733.82  Nonunion of fracture
737.30 - 737.39  Kyphoscoliosis and scoliosis
737.42  Lordosis, curvature of spine associated with other conditions
738.4  Acquired spondylolisthesis
756.12  Spondylolisthesis
805.4 - 805.5  Fracture of vertebral column without mention of spinal cord injury, lumbar
806.4 - 806.5  Fracture of vertebral column with spinal cord injury, lumbar
839.20  Dislocation of lumbar vertebra, closed
839.30  Dislocation of lumbar vertebra, open
V45.4  Arthrodesis status

ICD-9 codes not covered for indications listed in the CPB (not all inclusive):
722.51  Degeneration of thoracic or thoracolumbar intervertebral disc
722.52  Degeneration of lumbar or lumbosacral intervertebral disc

The above policy is based on the following references:


