



CIGNA MEDICAL COVERAGE POLICY

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Subject Lumbar Fusion for Spinal Instability and Degenerative Disc Conditions

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Coverage Policy

LUMBAR FUSION FOR INSTABILITY

CIGNA covers lumbar fusion as medically necessary for ANY of the following indications when there is an associated spinal instability:

- acute spinal fracture
- progressive neurological impairment
- neural compression after spinal fracture
- epidural compression or vertebral destruction from tumor
- spinal tuberculosis
- spinal debridement for infection
- spinal deformity (e.g., idiopathic scoliosis over 40°, progressive degenerative scoliosis)

- intraoperative excessive facet removal, associated radical discectomy, removal of pars interarticularis or pars fracture

CIGNA covers lumbar fusion for a single level (e.g., L4–L5) as medically necessary for the treatment of spinal stenosis when there is an associated spondylolisthesis (i.e., anterolisthesis), and ALL of the following criteria are met:

- back pain with neurogenic claudication symptoms or radicular pain
- failure of at least three consecutive months of conservative medical management (e.g., exercise, analgesics, nonsteroidal anti-inflammatory drugs[NSAIDS], physical therapy, activity/lifestyle modification)
- clinically significant functional impairment (e.g., inability to perform household chores or prolonged standing, interference with essential job functions)
- central, lateral recess or foraminal stenosis is demonstrated on imaging studies (e.g., radiographs, magnetic resonance imaging [MRI], computerized tomography [CT], myelography)
- radiographic evidence of at least 4 mm anterior translation (i.e., anterolisthesis, spondylolisthesis)

CIGNA covers lumbar fusion as medically necessary for spondylolysis (i.e., pars interarticular fracture), and isthmic spondylolisthesis, when ANY of the following criteria is met:

- progressive deformity
- neurologic compromise
- symptomatic high-grade (i.e., 50% or more anterior slippage) spondylolisthesis (i.e., anterolisthesis) demonstrated on plain x-rays
- multilevel spondylolysis
- symptomatic low-grade spondylolisthesis (i.e., anterolisthesis) after 6 to 12 months of conservative treatment (e.g., education, analgesics, NSAIDS, exercise)

LUMBAR FUSION WITHOUT INSTABILITY

CIGNA covers a single level lumbar fusion for degenerative disc disease (in the absence of instability) as medically necessary when there is unremitting pain and significant functional impairment for at least 12 months duration, and during which time ALL of the following criteria have been met:

- unremitting pain and significant functional impairment continues despite at least six (6) consecutive months of structured*, physician supervised conservative medical management, which includes **ALL** of the following components
 - exercise, including core stabilization exercises
 - analgesics, nonsteroidal anti-inflammatory medication, unless contraindicated
 - physical therapy, including passive and active treatment modalities
 - cognitive therapy
 - activity/lifestyle modification
- single level degenerative disc disease, demonstrated on appropriate imaging studies (i.e., computerized tomography [CT] scan, magnetic resonance imaging [MRI], or discography) as the likely cause of pain
- documentation from a primary care physician, neurologist, physiatrist, psychiatrist or psychologist, supports absence of untreated, underlying psychological conditions/issues (e.g., depression, drug and alcohol abuse) as a contributor to chronic pain
- the individual is a nonsmoker, or has refrained from smoking for at least 6 weeks prior to any planned surgery

***Note: Structured medical management consists of medical care that is delivered through regularly scheduled appointments, including follow-up evaluation, with licensed healthcare professionals.**

LUMBAR FUSION FOLLOWING PRIOR SPINAL SURGERY

CIGNA covers lumbar fusion as medically necessary for EITHER of the following post-surgical conditions:

- recurrent disc herniation
- adjacent segment degeneration

when it has been at least 6 months from the prior spinal surgery, there is an associated spondylolisthesis (i.e., anterolisthesis), and ALL of the following criteria are met:

- recurrent symptoms consistent with neurological compromise
- significant functional impairment
- neural compression is documented by recent appropriate post-operative imaging
- failure of three months of conservative management
- instability (i.e. > 4mm anterior translation) is documented by appropriate imaging (i.e., anterolisthesis)
- individual experienced some relief of pain symptoms following the prior spinal surgery

CIGNA covers lumbar fusion as medically necessary for the treatment of pseudoarthrosis (i.e., nonunion of prior fusion) at the same level when it has been at least 12 months from the prior surgery and ALL of the following criteria are met:

- imaging studies confirm evidence of a pseudoarthrosis (e.g., radiographs, CT)
- failure of three months of conservative management
- individual experienced some relief of pain symptoms following the prior spinal surgery
- if applicable, physician office notes indicate the individual has refrained from smoking for at least 6 weeks prior to surgery

Lumbar fusion may be performed using various surgical techniques and instrumentation. Surgical approaches used to perform spinal fusion include anterior, posterior, and lateral. For the intent of this Coverage Policy, CIGNA considers anterior lumbar interbody fusion, posterior lumbar interbody fusion, transforaminal lumbar interbody fusion and posterolateral fusion standard approaches to performing spinal fusion. Approaches such as lateral transpsoas, extreme lateral interbody fusion and direct lateral are considered a modification to a standard approach.

NOT COVERED

CIGNA does not cover lumbar fusion for the management of EITHER of the following conditions because it is considered not medically necessary:

- with initial primary laminectomy/discectomy for nerve root decompression or spinal stenosis, without documented spondylolisthesis
- multiple-level (i.e., >1 level) degenerative disc disease

CIGNA does not cover sacroiliac joint fusion, including minimally invasive and percutaneous sacroiliac joint fusion for the treatment of mechanical back pain because it is considered experimental, investigational or unproven.

CIGNA does not cover ANY of the following surgical techniques/devices used for lumbosacral surgery because each is considered experimental, investigational or unproven:

- anterior interbody fusion or implantation of intervertebral body fusion devices using a laparoscopic approach
- pre-sacral interbody approach, including axial interbody approach [AxiaLif[®]]
- dynamic spine stabilization device systems (e.g., Dynesys[®], Stabilimax NZ[®])
- total facet arthroplasty, including Total Facet Arthroplasty System[™]
- isolated facet fusion, with or without instrumentation, including allograft bone graft substitutes used exclusively as stand-alone stabilization devices (e.g., TruFuse[®] [any level], NuFix[™] [any level]) *
- posterior non-pedicle supplemental fixation devices (e.g., Aspen[™] Spinous Process Fixation System, Lanx Spinal Fixation System)

Note: Please refer to the CIGNA Medical Coverage Policy Bone Graft Substitutes for Use in Bone Repair for additional information regarding bone graft substitutes.

General Background

Low back pain affects approximately 90% of the U.S. population at some point in their lives and may be caused by a wide variety of conditions, although in some cases no specific etiology is identified. Age-related intervertebral disc degeneration, typically resulting in degeneration of the discs themselves, facet joint arthrosis and segmental instability, is a leading causative factor (Kwon, et al., 2003). Conservative management typically consists of rest, exercise, analgesics, local injections, lumbar bracing and physical therapy. Generally, conservative therapy is not recommended in the presence of progressive neurological deficits, when spinal fracture or dislocation is unstable or for progressive spinal deformity. When conservative management is attempted and fails, surgery may be required for conditions with underlying pathology as determined by radiological findings.

Lumbar fusion, also referred to as lumbar arthrodesis, is a well-established method of treatment for infectious conditions of the spine (e.g., spinal tuberculosis). It has also been considered the standard treatment for progressive spinal deformities and traumatic injuries. Lumbar fusion is currently a proposed method of surgery to control low back pain attributed to abnormal or unstable vertebrae and pain due to mechanical degeneration of the intervertebral disc. Additionally, lumbar fusion is performed for clearly defined spinal instability. Although somewhat controversial, these indications have been expanded to include pain from degenerative disorders without deformity or neurological deficit. The success rate of lumbar fusion surgery in patients with clearly identified pathology is 70% to 90%, the success rate outcomes are lower in patients who have fusion for backache and common degenerative changes alone (Firestein, 2008). A less stringent approach to patient selection is warranted for conditions where the literature clearly supports improvement in pain and disability, for controversial conditions patients should be more carefully selected.

Arthrodesis is usually performed for conditions that involve only one vertebral segment; however it is necessary to fuse two segments in order to stop movement, which is referred to as a single level fusion. The general consensus in the medical literature is that the addition of multiple levels increases the complexity of the surgery and risks compared to single-level fusion. It has been reported in the literature that rate of nonunion (pseudoarthrosis) increases with multilevel fusions. Lumbar fusion of more than two segments (single level), is not typically recommended, particularly for degenerative disease, and is unlikely to reduce pain, as it removes normal motion in the lower back and may cause strain on other remaining joints. Added stress on nearby vertebrae can accelerate the degenerative process.

Specific patient selection guidelines for lumbar fusion have not been well-defined in the medical literature. Factors to be considered are the patient's history, physical exam, and response to conservative measures, psychosocial profile, diagnostic test results, and the physician's expertise. Patients should be educated regarding alternative treatments, benefits and associated risks in order to allow for realistic expectations after surgery. Co-morbidities may adversely affect clinical outcomes and fusion success; as a result these conditions should be evaluated and treated prior to surgery. Procedures that result in minimal disruption of tissue, restore the normal mechanics and physiology of the spine, and are not associated with adverse short- or long-term effects should be considered as treatment options (Hanley, David, 1999).

Psychological assessment and treatment as part of a multi-disciplinary approach to conservative pain management is increasingly common. Authors have recommended psychological screening, and treatment if applicable, of patients with low back pain prior to surgery for identification of risk factors that may be associated with chronic disability. In some cases, risk factors, such as drug or alcohol abuse and depression, may aggravate the condition and act as a barrier to recovery following spinal fusion (Washington State Department of Labor and Industries, 2002; Hanley, David, 1999; Tang, et al., 2001).

There is no consensus in the published scientific literature regarding the optimal duration for conservative treatment prior to surgical intervention for low back pain; recommendations range from at least three months to greater than 12 months (Herkowitz, Sidhu, 1995; Hanley and David, 1999; Tang, et al., 2001; Washington State Department of Labor and Industry, 2002; Kwon, et al., 2003). Nevertheless, despite varying recommendations,

fusion for chronic degenerative discogenic related back pain, without instability and neural compression, is considered an option when all other established treatments have failed to improve the patient's symptoms.

Surgery for discogenic low back pain without instability or neural compression has lower success rates compared to those conditions with instability. Spinal instability generally implies a nonspecific mechanical failure of the spine that leads to back pain and is often the result of degenerative disc disease. While there is no consensus regarding the definition of lumbar spine instability it may be defined based on an interpretation of radiographs, some authors estimate instability as at least 3–4 mm or greater translation and greater than 10–15° of relative angulations between adjacent levels (Kwon, et al., 2003; Tang, et al., 2001; Hanley and David, 1999; Fritz, et al., 1998; Sonntag and Maricano, 1995). However, some authors stress the greater importance of defining the actual clinical significance of the instability and whether the fusion will relieve symptoms. According to the North American Spine Society (2001), most spinal surgeons agree that instability of one or more vertebral segments is an indication for fusion.

The primary tools utilized for diagnosing instability are a combination of plain radiographs with flexion and extension views, magnetic resonance imaging (MRI), computed tomography (CT) scans, and provocative discography.

Facet syndrome as a cause of low back pain is less common than degenerative disc disease and is not a clearly identified source of back pain. Facet joints are the articulations or connections between the vertebrae. Nociceptive nerve fibers have been identified in the facet joint capsules, in synovial tissue and in pericapsular tissue. It is hypothesized that increased motion and instability of the motion segments can lead to stress on the facet joint capsule, ultimately leading to the production of pain. Pain is characterized as worsening in extension and easing with flexion; it may radiate to the lateral buttock and thigh. Facet blocks have been the suggested treatment of choice and in some cases have been used as diagnostic criteria for patient selection. However, inconsistent outcomes have been reported (Esses, Moro, 1993; Lovely, Rastogi, 1997).

Indications: Lumbar Fusion for Instability

Conditions for which lumbar fusion has been proposed and have resulted in improved clinical outcomes include iatrogenic instability, lumbar stenosis, degenerative spondylolisthesis, progressive degenerative scoliosis, and pseudoarthrosis.

Iatrogenic Spinal Instability/Spinal Stenosis: Spinal instability may result from spinal stenosis that involves a narrowing of the spinal canal, nerve root canals, or intervertebral foramina due to spondylosis and degenerative disc disease, along with facet degeneration. It is a part of the aging process and is frequently seen in patients age 50 and older. Symptoms typically include low back pain, radiating leg pain and possible bladder and bowel difficulties. Central stenosis involves the area between the facet joints, the lateral recess involves the area at the lateral border of the dura and extends to the medial border of the pedicle, the foraminal region is ventral to the pars. Diagnostic imaging generally includes computed tomography (CT) scans, magnetic resonance imaging (MRI) and/or myelography. In the absence of a neurologic deficit, when conservative measures fail to relieve symptoms (back pain, sciatica), surgical treatment involves decompression (laminectomy) of the stenotic segments and correction of any associated deformity such as disc herniation, spondylolisthesis, scoliosis, or multidirectional malalignment. Neurological symptoms improve significantly following surgery however back pain may still be present, primarily due to pre-existing degenerative changes.

Fusion is indicated only if there is radiographic evidence of instability (e.g., spondylolisthesis). Cases of severe stenosis require more extensive decompression (i.e., complete facetectomy or resection of pars interarticularis), which may destabilize the spine. Lumbar spinal fusion may be necessary to stabilize the spine in these situations.

The North American Spine Society (NASS) published evidence based guidelines for the diagnosis and treatment of degenerative lumbar spinal stenosis in 2007 (NASS, 2007). According to the guidelines regarding the results of medical/interventional management of spinal stenosis:

- Of patients with mild to moderate lumbar spinal stenosis initially receiving medical/interventional treatment and followed for two to 10 years, approximately 20-40% will ultimately require surgical intervention. Of the patients who do not require surgical intervention, 50-70% will have improvement in their pain.

- In patients with severe symptoms of lumbar spinal stenosis, decompressive surgery alone is effective approximately 80% of the time.
- In patients with lumbar spinal stenosis and spondylolisthesis, decompression with fusion results in better outcomes than decompression alone.
- Of patients with lumbar spinal stenosis without spondylolisthesis or instability, there is no evidence to support the addition of a fusion.

Spondylolisthesis: Spondylolisthesis is a condition that involves the anterior translation of one vertebral segment over the next; more specifically anterolisthesis is an anterior translation of the vertebrae. It may be caused by chronic disc degeneration and/or facet degenerative changes (i.e., degenerative spondylolisthesis, most commonly L4-L5), segmental-rotational instability, or trauma (i.e., acute fracture). Isthmic spondylolisthesis typically occurs as a result of an anatomic defect in the pars, usually at level L5-S1. As the vertebra slips forward, the spinal nerves may be pinched, resulting in symptoms. Diagnosis is confirmed by radiography (standing, flexion-extension lateral views) which reveals instability when there is 4-5 mm of translation; CT and MRI (Canale, Beaty, 2007). The grade of spondylolisthesis is determined by the degree of slippage of the vertebral body and is as follows:

- Grade I: slippage 5% to 25%
- Grade II: slippage 26% to 50%
- Grade III: slippage 51% to 75%
- Grade IV: slippage > 75%
- Grade V: complete dislocation of adjacent vertebrae

The condition may be stable without neurological compromise. If neurological deficits do occur, or if slippage exceeds more than 4mm surgery is an option.

Spondylolysis: Spondylolysis is a bone defect in the pars interarticularis; the isthmus or bone bridge between the inferior and superior articular surfaces of the neural arch of a single vertebrae, most often the result of a stress fracture nonunion. The condition is an acquired condition, occurs commonly at a young age and may occur with or without spondylolisthesis. The main presenting symptom is back pain which is often nonspecific. In children conservative treatment involves orthotic bracing, activity modification and physical therapy. In adults treatment involves education, analgesics and NSAIDS, exercise and rapid return to activities. Once spondylolisthesis occurs healing of the pars is unlikely. Surgery is indicated when there is progressive neurological deficit, cauda equina compression, or persistent severe leg and back pain despite aggressive conservative management (Spinelli, Rainville, 2008).

Degenerative Scoliosis: Degenerative scoliosis is characterized by degeneration of the facets and discs, which leads to spinal curvature. Curve progression or lateral listhesis may imply instability and result in back and leg pain (e.g., claudication and radiculopathy). Although most patients can be treated conservatively, researchers agree that surgery is indicated when conservative measures fail and when there is progression of the deformity, neurogenic claudication and/or neurological deficits. In degenerative scoliosis, the curvature in the lumbar or thoracolumbar spine is often less than 40°. In cases of minimal stenosis (<25–30°), a simple laminectomy decompression yields favorable results. In cases of excessive resection of bone, fusion is recommended at the level of destabilization. If patients have more pronounced deformities with any degree of lateral listhesis, a fusion may be performed at the time of decompression (Gelalis, Kang, 1998).

Pseudoarthrosis: Pseudoarthrosis is failure of osseous bridging within the fusion mass. It is generally confirmed by radiograph or CT scan at least one year after the fusion. One factor associated with increased risk of pseudoarthrosis is smoking (Brown, et al., 1986). In addition, it has been reported in several studies that the incidence of nonunion increases with the greater number of segments fused. Tang et al. (2001) reported that the rate of nonunion for three-level arthrodesis may be higher in comparison to single-level arthrodesis. Pseudoarthrosis does not always cause symptoms but is generally suspected as a cause of intractable back pain in patients who initially had pain relief after a lumbar fusion. Radiographic studies typically indicate lucency and movement at the previous fusion site.

Lumbar Fusion in the Absence of Instability

Degenerative Disc Disease: Degenerative disc disease (DDD) is considered a normal part of the aging process. Clinical symptoms are typically consistent with mechanical back pain, which is aggravated by activity and relieved by rest. Determining if a disc is the primary source of pain is challenging and treatment, particularly surgical, is considered controversial for this indication (Tang, et al., 2001; Deyo, et al., 2004). Discography can be useful in determining the location of pain but does not determine instability, and some authors have questioned the diagnostic utility of this procedure. In contrast to conditions resulting in instability, DDD is described as axial spine pain with no or minimal abnormalities of spinal alignment or disc contour. Primary treatment is nonsurgical and involves education regarding the disease process, activity modification, muscle strengthening and analgesics (e.g., nonsteroidal anti-inflammatory, local injection) as needed. Surgery may be indicated if conservative measures fail and disc disease is limited to a few lumbar segments. Evidence supporting lumbar fusion however, as a method of treatment for DDD is limited, and few well-designed clinical studies have supported arthrodesis as superior to nonoperative therapy for improving clinical outcomes (Resnick, et al., 2005). Surgery leads to improvement in only 65% of cases, 35% are no better or worse with respect to axial spine pain. Moreover, despite improvement after surgical treatment patients continue to have activity limitations caused by pain and stiffness. Lumbar fusion is associated with more risks than conservative treatment, and when compared to structured rehabilitation and behavioral therapy programs there is no meaningful difference in clinical outcomes (e.g., pain relief, functional improvement). Authors stress the importance of accurate patient selection and identification of the source of pain.

Literature Review: Few randomized controlled clinical trials have compared lumbar fusion to nonoperative care in the published medical literature. There is limited evidence demonstrating patients with chronic low back pain treated with surgery have better clinical outcomes when compared to standard conservative management (Fritzell, et al., 2001). When comparing intense rehabilitation and cognitive therapy to lumbar fusion, the reported clinical outcomes demonstrate lumbar fusion is no more effective than intense rehabilitation combined with cognitive therapy (Brox, et al., 2010; Mirza, et al., 2007; Brox, et al., 2006; Fairbank, et al., 2005; Brox, et al., 2003; Ibrahim, et al., 2001). Follow-up within randomized controlled clinical trials and systematic reviews range from one to four years following surgery, with patient populations that range from 60 to 394 participants. One study was a merged RCT and reported on combined data from the Brox studies (2003, 2006) at four year follow-up (Brox, et al., 2010). The main outcome measured was the ODI score in most of the studies; some used VAS and SF-36 as a supplemental measure. The intensive rehabilitation program varied in length and type of treatment among studies; however it generally included regularly scheduled physical therapy, cognitive therapy, spine stabilization exercise, coping strategies, education regarding activity modification, and daily hydrotherapy (in some centers). Cognitive therapy within these studies generally included instructional sessions regarding the disease process, which included but was not limited to pain receptors, facet joints, and muscle involvement. Additionally, subjects were encouraged to use their backs, to bend and to not be too cautious. The information was reinforced through various types of sessions which included individual, group discussions and lectures at various points in time. In a more general sense, cognitive therapy typically includes instruction about the disease process, instruction regarding how choices related to stress, actual physical activity, and adherence impacts the disease process, as well as impacting pain, and disability. In addition, there is emphasis on developing specific strategies to successfully manage fear, anxiety and sadness related to the condition.

In 2001 Fritzell (n=294) reported that in a well-informed and carefully selected group of patients with chronic low back pain, at two year follow-up, lumbar fusion was significantly superior compared to nonsurgical treatments, which included physical therapy, education, treatment aimed at pain relief, cognitive and functional training, and coping strategies. The authors acknowledged there was still considerable pain at two years in the surgical group, although the pain was reduced. It is uncertain if the results at two years were maintained over time. The results of a meta-analysis (Ibrahim et al., 2001) indicate spinal fusion for chronic low back pain did show a marginal improvement in the ODI scores compared to nonsurgical intervention, however surgery was found to be associated with a significant risk of complications; the evidence did not support routine fusion for the treatment of chronic pain. When comparing lumbar fusion with cognitive intervention and exercise, Brox et al. (2003) reported at one year follow-up the ODI was significantly reduced from 41 to 26 after surgery, compared with 42 to 30 after cognitive intervention and exercise. The overall surgical success rate was 70% with the cognitive intervention with exercise success rate of 76%. The main outcome measure indicated equal improvement in both groups. In 2005 Fairbanks and colleagues compared lumbar fusion to intense rehabilitation. Both groups reported reduction in disability at two year follow-up. The surgery groups ODI score improved significantly more than in those allocated to rehabilitation, although clinically the difference was small when considering risks and additional costs of surgery. Brox et al. (2006) reported that ODI was significantly improved from 47 to 38 after fusion and from 45 to 32 after cognitive rehabilitation. The reported success rate in

the fusion group was 50% versus 48% in the cognitive intervention group. In the authors' opinion, lumbar fusion failed to show any benefit over cognitive intervention. When reporting four year follow-up from two merged RCTs, Brox and associates (2010) noted long-term improvement was not better after instrumented fusion; lumbar fusion was not superior when compared to cognitive intervention and exercise for relieving symptoms, improving function or return to work.

Carreon et al. (2008) published a systematic review of 25 studies and evaluated lumbar fusion and nonsurgical interventions for various degenerative spine disorders. Nonsurgical care included exercise, manual treatment cognitive intervention, facet injections, intradiscal steroid injections, and acupuncture. The authors noted that patients with DDD had the worst disability and had considerable improvement in ODI after surgery and minimal improvement after nonsurgical interventions. Patients with spondylolisthesis had more substantial improvement in ODI after posterior fusion, compared to other approaches. Patients with chronic low back pain in any study group did not improve as much as patients in any study group except for patients with DDD treated nonsurgically. In this group of patient's issues such as lack of definite cause to back pain, chronicity of the disease, and compensation and litigation may play a significant role in outcomes. The reviewed studies had variances in characteristics with potential for inherent bias regarding treatments. In the authors opinion proof of efficacy for fusion and nonsurgical treatment remains unclear.

In 2007 ECRI conducted a health technology assessment evaluating spinal fusion and discography for chronic back pain and uncomplicated lumbar DDD (ECRI, 2007). According to this assessment ECRI concluded the following:

- The evidence is insufficient to support lumbar fusion is more effective (to a clinically meaningful degree) than nonsurgical treatments (intensive exercise and rehabilitation plus cognitive behavioral therapy) in patients with and without prior surgery.
- Lumbar fusion leads to significantly higher rates of early adverse events compared to non-intensive physical therapy or intensive exercise/rehabilitation plus CBT.
- No adverse events occurred 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 adverse events most frequently reported included reoperation, infection, device related complications, neurologic complications, thrombosis, bleeding/vascular complications, and dural injury.
- The evidence was insufficient to determine what patient characteristics are associated with differences in the benefits and adverse events of lumbar fusion surgery.

Clinical outcomes for lumbar fusion as a method of treatment for uncomplicated DDD are comparable to those of intense rehabilitation including cognitive therapy. The goal of lumbar fusion is to improve function; reducing pain and disability. Fusion rates have not been clearly established, although evidence suggests the rate is lower for uncomplicated DDD. Individuals often continue to have some degree of back pain following surgery, and some require a second surgery. Nevertheless, for carefully selected individuals with an identified pain generator, lumbar fusion may be considered a viable treatment option for DDD when all other treatment options have failed to provide pain relief.

Sacroiliac Joint Fusion

The sacroiliac joint is located in the pelvis and links the iliac bones (pelvis) to the spine. Similar to other joints, the sacroiliac joint can become damaged by injury or by usual wear and tear on the joint surfaces. Whether or not the sacroiliac is a source of back pain is debatable. Physical examination is often inaccurate in confirming a diagnosis and the sensitivity and specificity of radiographs is low. It is generally agreed that fluoroscopically guided intra-articular injection of a local anesthetic helps to confirm or exclude the diagnosis. Symptoms associated with sacroiliac joint disease include pain in the upper legs, buttocks, and spine which is often aggravated by sitting, lifting, running or walking. Fusion of the sacroiliac joint, combined with bone grafts and other metal implant devices, is an extensive procedure; it is generally recommended as a salvage procedure when all other measures have failed to provide relief of pain.

Literature review: Evidence evaluating sacroiliac fusion for treatment of chronic back pain is limited to small case series and retrospective studies involving small sample populations and few published reviews (Buchowski, et al., 2005; Zelle, et al., 2005; Cohen, et al., 2005; Shutz and Grob, 2006). Reported clinical outcomes are mixed and therefore no strong conclusions can be made regarding safety and efficacy when performed for the treatment of mechanical back pain.

Standard Surgical Approaches

Standard surgical approaches, well-accepted in the scientific literature, which may or may not involve instrumentation, include posterior approach, anterior approach or a lateral approach.

Fusion may be performed alone or in combination with other procedures such as decompression (e.g., discectomy, corpectomy) or laminectomy. Discectomy involves removal of the intervertebral disc, either partial or complete. Corpectomy involves resection of the vertebral body, either partial or complete. According to NASS, a corpectomy of the lumbar spine, when performed with anterior spinal decompression, involves removal of at least one-third of the vertebral body (NASS, 2007). Laminectomy involves removal of the posterior arch of the vertebra.

Correlating laboratory findings with presence of symptoms, selection of appropriate candidates and determining the ideal surgical intervention are challenges addressed by several authors in the medical literature evaluating lumbar fusion. Much of the evidence consists of randomized trials, both prospective and retrospective case series, observational studies and published systematic reviews and meta-analysis (Hanley and David, 1999; Gibson, et al., 1999; Fritzell, et al., 2001; Fritzell, et al., 2002; Brox, et al., 2003; Sengupta, 2004; Gibson and Waddell, 2005; Weinstein, et al., 2007). In many of the studies the reported clinical outcomes, specifically improvements in pain and function, are mixed. There are some data however, to support a comparative benefit with surgical treatment (Fritzell, et al., 2001; Resnick, et al., 2005; Gibson, Waddell, 2005; Weinstein, et al., 2007). Successful fusion rates vary but have been reported to be as high as 100% postoperative; however, patients with successful fusion may still have continued pain and disability. After a spinal fusion, approximately 10% of all patients experience problems such as nonunion, loss of spinal curvature and loss of flexibility. Controversy regarding the subsequent degeneration of adjacent segments currently remains. Although efficacy for some indications is unclear, despite these confounding variables lumbar fusion using a standard approach is considered an established method of treatment for various spinal conditions.

Posterolateral Arthrodesis: Posterolateral arthrodesis with autograft is the most commonly performed technique. This method utilizes an approach from the back through a midline incision and involves placing bone graft in the posterolateral portion of the spine. In addition, posterolateral arthrodesis typically involves fusion of the facet joint. This area of the spine is very vascular and, as a result, bone regrowth is enhanced. As the bone graft grows, it adheres to the transverse processes and spinal fusion is achieved, stopping the motion that might stimulate a pain response. The outcomes of posterolateral arthrodesis for discogenic back pain have not been favorable, however. For discogenic back pain, interbody arthrodesis better addresses the site of the pain generator.

Posterior Lumbar Disc Excision and Interbody Arthrodesis: This method, which involves excision of the disc with interbody arthrodesis, is hypothesized to remove the source of pain and to prevent motion. It achieves spinal fusion with the insertion of an implant (e.g., cage) or bone graft directly into the disc space under a compression load which supports bone healing. The bone graft will ultimately stimulate a response that causes bone to grow between the two vertebral bodies. The bone growth then stops the motion at that particular segment. This type of fusion is often supplemented by a posterolateral fusion.

Transforaminal Lumbar Interbody Fusion: Transforaminal lumbar interbody fusion (TLIF), performed through an open technique, is also performed through a posterior approach. Access to the spine is through the foramen which is enlarged by removal of surrounding bone. The bone graft is inserted into the disc space from the side and includes removal of the facet joint and part of the lamina (on the side) promoting insertion of a biomechanical device or bone graft. In contrast to posterior lateral interbody fusion, this approach reduces the need for retraction of spinal nerves and may reduce the risk of scarring or damage to the nerves.

Anterior Lumbar Disc Excision and Interbody Fusion Arthrodesis: The anterior lumbar disc excision and interbody fusion is similar to the posterior approach, except that the disc space is fused by approaching the spine through the abdomen instead of the lower back. It is most often used in cases of one-level disc disease where there is minimal instability. This method has been associated with fairly high nonunion rates, although it does not disturb the back muscles or nerves. As in the posterior interbody fusion, the bone graft is placed in the intervertebral disc space under a compression load. Researchers have reported that placing the bone graft in front of the spine leads to better fusion. A stand-alone anterior interbody fusion is often supplemented with a

posterior fusion or anterior plate fixation secondary to limited pain relief that may occur with anterior interbody fusion alone.

Anterior/Posterior Lumbar Fusion: The anterior/posterior lumbar fusion is an approach from both the front and back of the spine. It is usually performed on patients who have a high degree of spinal instability (e.g., fractures) or for revision surgery, although it may be used as a primary technique in patients with disabling low back pain. Fusion of both the front and back eliminates all potential sources of pain and provides a high degree of stability and a large surface area for fusion to occur. While this method does lead to a very high fusion rate, there are increased risks as a result of the extensiveness of the surgery.

Lateral Interbody Fusion (Direct Lateral [DLIF], Extreme Lateral [XLIF[®]])

Open lateral approaches have historically been considered a well-established method of performing spinal surgery for indications such as treatment of spinal tumors or fractures. Lateral interbody fusion differs from standard approaches in that the spine is approached from the side (lateral), rather than through the abdominal cavity (anterior) or the back (posterior). During a direct lateral or extreme lateral approach, a narrow passageway is created through the underlying tissues and the psoas muscle using tubular dilators, without cutting the muscle; which is the major difference between the open approach and lateral approach. The interbody device and bone graft are inserted via the tubular dilator. Neuromonitoring is performed for identification of spinal nerve roots. In some cases, it is necessary to remove part of the iliac crest. The procedure is generally indicated for interbody fusion at the lower levels of the spine (e.g., L1-L5 levels) and is considered a modification to the lateral retroperitoneal approach utilized for other spinal surgery and an alternative to posterior lumbar interbody fusion (PLIF), transforaminal lumbar interbody fusion (TLIF). Only those vertebrae of the spine that have clear access from the side of the body can be approached using this technique. The procedure is generally contraindicated for L5-S1 levels. The XLIF and DLIF systems are instrumentation systems and not implantable devices.

Other terms seen in the medical literature in reference to this approach involve two retractor systems, DLIF (Sofamor Danek, Medtronic, Memphis, TN) and XLIF[®] (Nuvasive, San Diego, CA). Lateral interbody fusion may also be referred to as the trans-psoas approach or lateral extracavitary lumbar interbody fusion. In theory, a lateral interbody fusion is considered minimally invasive/disruptive, reduces complications, avoids the major blood vessels, and only requires small 3–4 cm incisions. Limitations of the approach include potential injury to the lumbar plexus.

Literature Review: Evidence in the published literature addressing the safety and efficacy of lateral interbody fusion for degenerative lumbar conditions is limited to feasibility studies (Bergey, et al, 2004; Ozgur, et al., 2006), a prospective chart review compared to a historical cohort (Knight, et al., 2009), prospective case series (Rodgers, et al., 2010b), retrospective reviews (Ozgur, et al., 2010; Rodgers, et al., 2010a) and few early case reports. Although limited, the published evidence lends some support to improved technical outcomes, such as shorter length of hospital stay, operative time and less blood loss. Some improvements in pain using VAS scores with XLIF procedures have been reported.

While the approach for lateral interbody fusion may be considered a modification to an accepted lateral approach for spinal surgery in general, there are few published studies examining clinical outcomes, such as functional ability and successful fusion rates, following DLIF/XLIF procedures. Rodgers et al. (2010b) reported the results of a prospective case series (n=66) evaluating radiographic and computed tomography (CT) assessment of interbody fusion 12 months following XLIF. A total of 97% of patients were judged fused by CT; by radiograph criteria 98.4% of patients were judged as fused. On average, there was an 80% reduction in pain, listhesis improved by 75%, and patient satisfaction was high at 89.4%. There were no reoperations due to pseudoarthrosis. This group of authors noted that with a traditional open approach fusion rates are 95% or better. In a retrospective review of prospectively collected outcomes, Ozgur et al. (2010) reported two year clinical and radiograph success of lateral interbody fusion (n=66) as a treatment for degenerative conditions. Clinical outcomes included VAS and ODI scores, radiographs were used to verify solid fusion. Pain scores decreased significantly by 37% at two years; functional ODI scores decreased significantly by 39% from preoperative, clinical success by ODI changes was achieved in 71% of patients. Radiograph success was achieved in 91% of patients; one patient developed pseudoarthrosis. In the authors opinion the lateral interbody fusion is a safe and effective treatment option. Rodgers et al. (2010a) compared the incidence of early complications and predictive factors affecting complication rates in obese (n=156) and non obese (n=157)

patients who underwent XLIF. The authors reported there was no greater risk in obese patients when compared to nonobese, complications were minimal and comparable in each group.

The extreme lateral approach has also been evaluated for the treatment of degenerative scoliosis. Evidence evaluating functional outcomes consists mainly of small retrospective case series (Anand, et al., 2010; Dawar, et al., 2010; Tormenti, et al., 2010). Tormenti et al., (2010) reported on eight patients who underwent a combined transpsoas and posterior approach; radiograph outcomes such as the Cobb angle and apical vertebral translation were significantly improved; the combination of XLIF and TLIF resulted in less blood loss however the authors also noted there were significant risks which in their study included motor radiculopathies, bowel injury and post-operative thigh paresthesias. Dakwar et al. (2010) reported on the results of 25 subjects who underwent the lateral transpsoas approach for thoracolumbar deformity. At an average follow-up of 11 months there was a mean improvement of 5.7 points on the VAS scale and 23.7% on the ODI. A total of 80% had radiograph evidence of fusion when evaluated at more than 6 months following surgery. Sagittal balance was not corrected in approximately one third of the patients. In the authors opinion the lateral transpsoas approach was a feasible alternative to other approaches. Anand et al. (2010) reported on 28 subjects who underwent minimally invasive approaches (transpsoas and interbody fusion, transsacral interbody fusion, and percutaneous screw fixation) correction of deformity and fusion for the treatment of scoliosis. The average follow-up was 22 months. All patients were noted to have correction of the deformity and solid fusion on plain radiographs, 21 were further confirmed on CT scan. VAS, SF-36 and ODI scores improved post-operatively compared to preoperative scores. Major complications included two quadriceps palsies which recovered, one renal hematoma and an unrelated cerebellar hemorrhage.

Data comparing DLIF/XLIF to other traditional or minimally invasive approaches to interbody fusion is insufficient therefore no conclusions can be drawn regarding efficacy compared to other standard surgical approaches. While additional clinical trials are necessary to demonstrate impact on meaningful long-term clinical outcomes, the published evidence suggests in the short- to intermediate-term lateral interbody fusion is safe and effective as an alternative to anterior or posterior fusion approaches. In addition, although there are no formal professional society statements supporting lateral interbody fusion in the form of XLIF or DLIF, the North American Spine Society (NASS) indicates these methods are a modified standard approach for lateral interbody fusion.

Minimally Invasive and Emerging Approaches

Minimally invasive approaches to lumbar fusion are currently being investigated, which may include axial lumbar interbody fusion and laparoscopic fusion. Minimally invasive surgery is usually associated with less blood loss, less analgesic use and shorter hospitalizations and may be performed through smaller incisions with less soft tissue trauma or through smaller percutaneous incisions involving specialized instrumentation (e.g., endoscopic instruments). However, the benefits of these more minimally invasive approaches, including improvement in net health outcomes, compared to the standard open approach are not well-defined in the published scientific literature or textbooks. Regarding the superiority of minimally invasive approaches, according to Williams and Park (2007), "At this time, no particular approach and no particular technique of stabilization have been shown to be superior to others, and there are several good studies that show statistical equivalency between anterior lumbar interbody [sic] fusion (ALIF), posterior lumbar interbody [sic] fusion (PLIF), and posterolateral fusion with instrumentation. There has been no superiority proved for the various minimally invasive options."

Total Facet Arthroplasty, Posterior Facet Implants and Facet Fusion: Facet joints and discs connect the vertebrae and allow movement. Degenerated or diseased facet joints may require surgery such as a spinal fusion to restore function and stabilize the joint. Total facet arthroplasty refers to the implantation of a posterior spinal implant to restore structure and function and is proposed as an alternative to posterior spinal fusion for individuals with facet arthrosis, spinal stenosis, and spondylolisthesis. The objective of facet arthroplasty is to stabilize the spine while retaining normal intervertebral motion of the surgically removed segment following neural decompression. In theory, facet arthroplasty maintains the normal biomechanics of the adjacent vertebrae and if normal motion patterns are achieved, the risk of adjacent-level degeneration may be reduced.

Overall, a variety of implants have been investigated as alternatives to rigid interbody or posterolateral intertransverse process spinal fusion. One facet arthroplasty implant under investigation is the Total Facet Arthroplasty System™ (TFAS, Archus Orthopedics), an articulating joint prosthesis intended to restore normal motion and provide stabilization of spinal segments through replacement of the facet. It is intended for single

spinal level use and is implanted through an open posterior surgical approach. The device is manufactured from metal components; pedicle fixation is accomplished by a polymethylmethacrylate (PMMA) cement.

Literature Review: Although the device is undergoing a clinical trial sponsored by the manufacturer, at this time there are no FDA approved posterior facet joint implants. Evidence in the published peer-reviewed scientific literature consists of a biomechanical study (Zhu, et al., 2007), a pilot study and a human cadaveric study (Phillips, et al., 2009). Further well-designed studies supporting long term outcomes are needed to support safety and efficacy of this technology.

Isolated facet fusion as a treatment for mechanical back pain has not been proven effective in the published literature; however facet fusion is performed as part of a posterior lumbar fusion. Various types of fusion materials may be utilized during facet fusion procedures and include autograft, standard allograft, or prepared allograft bone dowel (e.g., TruFuse[®], [minSURG[™] Corp, Clearwater, FL]; NuFix, [Nutech Medical, Birmingham, AL]). Prepared allograft bone dowels are recommended for providing stabilization by employing wedge fixation and may be used as standalone facet fusion materials or as a supplement to other fusion procedures. Despite recent developments in available allograft materials, a comparative benefit has yet to be firmly established for these materials in comparison to autograft materials. Similar to other facet fusion materials and devices, although FDA approved, evidence in the medical literature is insufficient and does not support clinical utility.

Axial Lumbar Interbody Fusion: Axial lumbar interbody fusion has been investigated as a minimally invasive method of treatment for anterior L5–S1 interbody fusion. The procedure is performed by way of percutaneous access to the lumbar spine through the pre-sacral space (Cragg, et al., 2004). It is also referred to as paracoccygeal axial approach, trans-sacral approach, or a percutaneous pre-sacral approach. The patient is placed prone and a 4 mm incision is made lateral to the coccyx. Under fluoroscopic guidance, a trocar is advanced anterior to the sacrum up to the L5–S1 level. Once in proper position, the guide is removed and replaced with a drill bit for inserting rods or screws for stabilization. Theoretically, this approach avoids the viscera, blood vessels and nerves; preserves normal tissue at the treatment site; provides access to the disc space without interrupting the annulus; and allows for percutaneous longitudinal access to the anterior spine. Risks to the patient as a result of this approach may include perforation of the bowel, injury to the blood vessels and/or nerves, and infection.

The AxiaLif[®] System (Trans1[®] Inc, Wilmington, NC) was developed for creating a pre-sacral access in order to perform percutaneous fusion. The system is described by the U.S. Food and Drug Administration (FDA) as an anterior spinal fixation device composed of a multi-component system, including implantable titanium alloy devices and instrumentation made of titanium alloy and stainless steel. The device includes instruments for creating a small axial-track to the L5–S1 disc space. According to the FDA, the device is used for distracting the L5–S1 vertebral bodies and inserting bone graft material into the space. The device also includes an anterior fixation rod that is implanted through the same track.

Literature Review: Evidence in the medical literature evaluating the effectiveness of axial lumbar interbody fusion is limited to technical reports, case reports and a retrospective case series (Marotta, et al., 2006; Yuan, et al., 2006, Aryan, et al., 2008; Botolin, et al., 2010). The retrospective case series (Aryan, et al., 2008) involved 35 patients who underwent percutaneous paracoccygeal axial fluoroscopically-guided interbody fusion (axiaLif) and demonstrated that at an average of 17.5 months post-procedure, 32 subjects had radiographic evidence of stable cage placement and fusion. However, the authors acknowledged further investigation is warranted before recommending the routine use of this surgical technique. In a more recent study AxiaLif was extended to a two-level fusion at both L4-L5 and L5-S1; however this was a biomechanical study on cadaveric spine segments. Additionally, investigators have evaluated the adjunct use of computer navigation to improve technique with minimally invasive approaches such as AxiaLif.

Although this method may be considered an emerging minimally invasive surgical approach, no randomized controlled trials were found in the peer-reviewed, published, scientific literature supporting safety and efficacy. Improvement in net health outcomes has not been demonstrated when compared to standard surgical methods, and it remains unclear whether this surgical technique results in clinical benefits that are as good as or superior to standard surgical techniques. The evidence is insufficient to allow any conclusions regarding short- or long-term clinical benefits, possible complications, failure rates, relief of symptoms, improvement in functional levels, and the need for further surgery.

Laparoscopic Anterior Lumbar Interbody Fusion (LALIF): LALIF is a minimally invasive technique that has been proposed as an alternative to an open surgical approach to spinal fusion. This method employs a laparoscope to remove the diseased disc and insert an implant (i.e., rhBMP, autogenous bone, cages or fixation devices) into the disc space intended to stabilize and promote fusion. This technique is evolving as a method of minimizing soft-tissue injury and is associated with a learning curve. Proponents suggest that minimally invasive surgery results in decreased morbidity, less postoperative pain and shortened length of hospital stay (Thongtrangan, et al., 2004; Regan, et al., 1999).

Literature Review: Evidence in the peer-reviewed scientific literature evaluating laparoscopic anterior lumbar interbody fusion is primarily in the form of prospective and retrospective case series, comparative trials, and nonrandomized trials (Regan, et al., 1999; Lieberman, et al., 2000; Cowles, et al., 2000; Zdeblick and David, 2000; Chung, et al., 2003; Inamasu, Gulot, 2006). The average sample size of these studies varies but range on average from 40 to more than 200 patients. Some authors have reported higher intra- and postoperative morbidity and longer surgical time with laparoscopic fusions compared to open procedures (Regan, et al., 1999; Cowles, et al., 2000; Zdeblick and David, 2000). It has been reported in the literature that length of stay does not differ significantly between the laparoscopic and open approach (Lieberman, et al., 2000; Cowles, et al., 2000; Chung, et al., 2003). Furthermore, authors have commented on the technical difficulty of this method and the associated learning curve, although as the surgeons experience increases in most studies, the operative time decreases. There is some evidence to support less blood loss and a tendency toward shorter hospital stay when laparoscopic ALIF is performed for single-level anterior fusion; however, there is a paucity of evidence to support improved outcomes in multilevel procedures. Evidence supporting improved clinical outcomes such as relief of pain, functional improvement and successful rates of fusion is limited. Both open and laparoscopic approaches carry associated risks. In addition, it appears the laparoscopic approach is being used less frequently due to the development of other minimally invasive surgical techniques. Currently, the published, peer-reviewed scientific literature does not allow strong conclusions regarding the overall benefit and long-term efficacy of the laparoscopic approach compared to open spinal fusion.

Percutaneous Sacroiliac (SI) Joint Fusion: As an alternative to traditional sacroiliac fusion, percutaneous sacroiliac joint fusion is a minimally invasive approach in which instrumentation such as cages or screws, with or without bone graft, are placed percutaneously in order to achieve a fusion. The iFuse Implant System™ (SI Bone, Cupertino, CA) received FDA (510k) approval in 2008 and consists of porous plasma spray coated rigid titanium implants which are inserted across the SI joint to create fixation. According to the FDA the implant system is intended for fracture fixation of large bones and large bone fragments of the pelvis, for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. This device is recommended by the manufacturer for use as a fixation device for minimally invasive sacroiliac fusion with the proposed advantages of potential for earlier weight bearing, less invasive surgery and shorter length of hospital stay.

Literature review: Much of the peer-reviewed scientific evidence evaluating percutaneous sacroiliac fusion is in the form of small case series, case reports, and published reviews (Al-khayer, et al., 2008; Wise and Dall, 2008) and do not establish safety and efficacy of this method of treatment. Published studies evaluating the use of the iFuse implant system are lacking.

Spinal Instrumentation

Several types of instrumentation/stabilization devices have been developed as a method of improving the success of spinal fusion. Spinal instrumentation helps the fusion success by limiting motion at the fused segment to correct a deformity or to be used as a splint or load sharing while the bone grafts heal. Three types of spine instrumentation, often used in combination with bone grafting, include pedicle screws with rods, anterior interbody cages, and posterior lumbar cages. Bone grafts are commonly used to promote the union of adjacent vertebrae and may be used alone or together with devices such as spinal fusion cages. Authors have suggested that interbody fusion is less successful if structural support is not provided for the intervertebral space (Hanley, David, 1999). Resnick et al. (2005) recently reported that placement of an interbody graft is recommended as a treatment option to improve fusion rates and functional outcome in patients undergoing surgery for low back pain due to degenerative disc disease at one or two levels. They also noted that the surgeon should be cautioned that the marginal improvement in fusion rates and functional outcome with these techniques is associated with increased complication rates, particularly when combined approaches are used.

Posterior Non-Pedicle Supplemental Fixation Device: There has been recent interest in the use of posterior non-pedicle supplemental fixation devices as a method of temporary fixation of the thoracic, lumbar and sacral

spine while waiting for bony fusion to take place, as an alternative to pedicle screws. One such system is the Lanx Spinal Fixation System™ (SFS) (Lanx, Inc, Broomfield, CO) which is composed of screws, hooks, rods, connectors and spinous processes, plates and other instruments. This system is not intended for stand alone use. Lanx is used with bone graft material and acts as a temporary device; it should be removed after solid fusion has occurred. According to the manufacturer, the device is intended for plate fixation to spinous processes for the purpose of achieving supplemental fusion for conditions such as DDD, spondylolisthesis, trauma, and/or tumor.

A second device, the Aspen™ Spinous Process System (Lanx, Inc., Broomfield, CO) is a posterior, non-pedicle fixation device for placement in the lumbo-sacral spine (L1-S1). It is designed for plate attachment to spinous processes and used to achieve supplemental fusion in patients who suffer from degenerative disc disease and/or spondylolisthesis and is used with a minimally invasive approach. Similar to the Lanx device, this device is used with bone graft material and is not intended as a stand-alone device.

Literature review: Evidence in the published peer-reviewed scientific literature is lacking; safety and efficacy has not been established despite FDA approvals for these devices. Posterior non-pedicle supplemental fixation devices have not been proven to result in net health outcomes that are as good as or superior to those obtained with standard surgical approaches.

Bone Grafting: Spinal arthrodesis involves the use of bone grafts to stimulate growth between vertebral segments or levels. Both autologous and allograft bone graft material supplies a scaffold for the migration of cells involved in bone growth (osteoconductive). The graft process also requires growth factors and progenitor stem cells for osteoinduction and osteogenesis. Bone grafts for use with spinal fusion can be autograft (i.e., taken from the patient), allograft (i.e., taken from a donor) or bone graft substitutes (e.g., bone morphogenetic proteins [BMPs]). Autograft, having osteoconductive and osteoinductive properties, is currently the gold standard (North American Spine Society [NASS], 2000) and involves transplantation of bone from the iliac crest to the spine. Allograft also has both osteoconductive and osteoinductive properties, although the osteoinductive properties can be lessened with processing. Synthetic bone grafts have an osteoconductive role and are combined with autografts or allograft materials to augment the osteoinductive bone graft properties.

Alternatives to autograft and allograft include demineralized bone matrix (a product of processed allograft), ceramics, coral, graft composites (combinations of bone graft materials/growth factors), and bone morphogenetic proteins (NASS, 2006). For spinal surgery, demineralized bone matrix is commonly used to augment grafting material and increase the rate of spinal fusion and several substances (e.g., Osteofil, Grafton) are available for use. Cancellous bone grafts are used for osteogenesis and are particularly applicable to spinal fusion. Multiple chips of cancellous bone are frequently used for grafting procedures as well as cancellous bone graft substitutes which provide a scaffold for new bone formation (e.g., tricalcium phosphate). Recombinant BMP products are supported in the medical literature as a viable bone graft substitute for lumbar spinal fusion and primarily involve the use of spinal instrumentation. The safety and effectiveness rhBMP in the cervical spine has not been demonstrated and is not approved for this use by the U.S. Food and Drug Administration (FDA) (FDA, 2008). Numerous bone graft substitutes and extenders are available and commonly used; others, although FDA approved, continue to be investigated (e.g., Actifuse) for safety and efficacy. The use of mesenchymal stem cells is also currently being investigated to enhance spinal fusion although data is preliminary and primarily in the form of nonhuman trials.

Dynamic Stabilization Devices

Dynamic stabilization devices have been proposed by some authors as an adjunct or alternative to fusion. Dynamic stabilization devices use flexible material to stabilize the spine and alter load transmission without the purpose of fusing the segment. It leaves the spinal segment mobile and may be referred to as soft stabilization, semi-rigid stabilization, or flexible stabilization. In theory, the device controls abnormal motion and more physiologic load transmission to ease pain and prevent adjacent segment deterioration. Once this is achieved, the damaged disc may repair itself.

U. S. Food and Drug Administration (FDA): Pedicle screw spinal systems are prosthetic devices regulated by the FDA, some as Class II devices and some as Class III devices depending on the condition being treated and the particular device. In 2003, the FDA granted 510(k) approval for Dynesys® Spinal System (Centerpulse Spine-Tech, Inc, Minneapolis, MN). Since the approval of the Dynesys device, other dynamic stabilization systems have received FDA approval for spinal immobilization and stabilization during fusion and include the

CD Horizon® Spinal System (Medtronic Sofamor Danek, Inc., USA) and the N Fix II Dynamic Stabilization System (N Spine, Inc., San Diego, CA) to name a few.

Literature Review: The clinical utility of dynamic stabilization devices has not been proven in the peer-reviewed, scientific literature. Many of the studies evaluate the Dynesys Spinal System; few studies can be found evaluating other devices. The published evidence is not robust; a majority of the studies are retrospective or prospective case series and lack controls (Grob, et al., 2005; Schnake, et al., 2006; Welch, et al., 2007; Beastall, et al., 2007; Bothman, et al., 2007; Schaeren, et al., 2008). Length of follow-up extends to four years in a few studies but on average the follow-up period is two years. Sample populations are small ranging on average from 25 to 100 subjects. While some authors reported improvement in pain and function (Korovessis, et al., 2004; Schnake, et al., 2006; Welch, et al., 2007; Bothman, et al., 2007) adjacent segment degeneration has also been documented following insertion (Schnake, et al., 2006; Schaeren, et al., 2008). Adjacent segment motion following Dynesys was evaluated by Cakir et al. (2009) who reported that Dynesys had no beneficial effect on adjacent segment mobility compared with monosegmental instrumented fusion. Kumar et al. (2009) reported that disc degeneration at the bridged and adjacent segment continued despite Dynesys stabilization. Furthermore, some study participants have required reintervention—revision surgery and/or a need for removal of the device has been reported (Grob, et al., 2005; Welch, et al., 2007). Overall, the body of evidence does not permit strong scientific conclusions regarding safety and efficacy for these devices. In addition, there are some clinical trials that have been published reporting on the use of dynamic stabilization devices in the absence of fusion, however, none of these devices have received FDA approval for this indication.

Stabilimax NZ: Stabilimax NZ (Applied Spine Technologies Inc., New Haven, CT), is a posterior dynamic-stabilization system that has been designed to support an injured or degenerated spine. The manufacturer states Stabilimax NZ is a less invasive option for many patients undergoing fusion and requires no tissue removal or replacement. The device has a dual-spring mechanism with a variable dynamic feature that maximizes stiffness and support in the Neutral Zone (NZ).

The NZ is a region of high flexibility, either in flexion or extension, around the neutral posture position where there is little resistance of motion—it is an important measure of spinal stability. Alterations in the NZ have been associated with the presence of low back pain (Yue, et al., 2007). At present, clinical trials comparing posterior dynamic stabilization using Stabilimax NZ to patients receiving traditional fusion stabilization to treat degenerative lumbar spinal stenosis are underway under the investigational device exemption from the FDA. According to the FDA, an IDE allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification [510(k)] submission to the FDA.

Professional Societies/Organizations

American Academy of Orthopaedic Surgeons (AAOS): A formal position statement from the AAOS regarding spinal fusion was not found; however in a position statement regarding the effects of tobacco exposure on the musculoskeletal system the AAOS states, “Smokers have impaired bone healing, which can delay the healing of fractures and wounds, and has shown to negatively influence wound healing, bone surgery results and patient satisfaction when compared to nonsmokers. The American Academy of Orthopaedic Surgeons (AAOS) is concerned that the American public is not fully aware that the use and exposure to tobacco products has harmful effects on the musculoskeletal system. The AAOS strongly recommends avoiding use and exposure to tobacco products due to the severe and negative impact on the musculoskeletal system” (AAOS, 2010). Additionally, in 2010 the AAOS endorsed guidelines published by the American Pain Society (Chou, et al., 2009) for interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain.

Washington State Department of Labor and Industries (WSDLI): The WSDLI published guidelines in 2009 based on a health technology assessment report regarding lumbar fusion and discography in patients with chronic low back pain and uncomplicated degenerative disc disease. Uncomplicated disc disease excluded the following conditions: radiculopathy, functional neurologic deficits, spondylolisthesis, isthmic spondylosis, primary neurogenic claudication with stenosis, fracture, tumor, infection or inflammatory disease, and degenerative disease associated with significant deformity. Individuals with any of these listed conditions and no prior lumbar surgery may be considered a candidate for single level lumbar fusion surgery after failure of three months of conservative therapy and when other medical necessity criteria are met. If the patient has had prior surgery, criteria vary depending on the location and type of prior surgery. Because of potential risk for poor outcomes the following are considered relative contraindications and require additional consideration prior to surgery:

- current smoking
- severe physical deconditioning
- multiple level degenerative disease of the spine
- disability for one year or longer prior to consideration of fusion
- absence of evidence of functional recovery for at least 6 months after most recent spine surgery
- severe psychosocial problems, including, but not limited to: history of drug or alcohol abuse, personality disorder, or major psychiatric illness, current evidence of factitious disorder and high degrees of somatization on clinical or psychological evaluation.

For individuals with uncomplicated DDD after three months of failed conservative therapy, the individual should be referred for structured intense multidisciplinary management (SIMP) evaluation and treatment, as defined by the Healthcare Technology Clinical Committee. Treatment must be completed prior to surgery unless the patient cannot participate in the treatment program. Surgery can only be considered if pain is unresolved following completion of the SIMP. According to the guidelines, research supports SIMP for chronic pain management is as effective as fusion surgery, without the associated complications (WSDLI, 2009).

American Pain Society: Guidelines for interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain, published by the American Pain Society (Chou, et al., 2009), state that based on moderate quality evidence, for patients with nonradicular low back pain, common degenerative spinal changes, and persistent and disabling symptoms, it is recommended that clinicians discuss risks and benefits of surgery as an option. They further recommend that shared decision-making regarding surgery for nonspecific low back pain include a specific discussion about intensive interdisciplinary rehabilitation with a cognitive/behavioral emphasis, as a similarly effective option; the small to moderate average benefit from surgery versus noninterdisciplinary nonsurgical 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).

The American Association of Neurological Surgeons (AANS)/Congress of Neurological Surgeons (CNS) Joint Section on Disorders of the Spine and Peripheral Nerves: The AANS/CNS published guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine (Resnick, et al., 2005). Specific surgical treatments were analyzed and recommendations provided. Recommendations pertinent to patient selection and type of intervention vary, however the guidelines support the following:

- Lumbar fusion as a treatment for carefully selected patients with disabling low back pain due to one- or two-level degenerative disease without stenosis or spondylolisthesis
- Lumbar fusion as a possible adjunct in patients with herniated disc and preoperative lumbar deformity or instability, or significant chronic axial low back pain associated with radiculopathy due to herniated disc.
- Reoperative discectomy with fusion as a treatment option for recurrent disc herniation with lumbar instability, deformity or chronic axial low back pain.
- Posterolateral fusion for patients with lumbar stenosis and associated degenerative spondylolisthesis who require decompression.
- Pedicle screw fixation for spinal instability, kyphosis at the level of spondylolisthesis, or when iatrogenic instability is anticipated.
- Autologous bone or rhBMP-2 graft substitute in the setting of an ALIF in conjunction with a threaded titanium cage.

According to the AANS/CNS guidelines, due to insufficient evidence the following is not supported:

- A treatment standard or guideline for fusion following decompression in patients with stenosis without spondylolisthesis.
- A treatment standard for lumbar fusion using interbody techniques, in the case of single-level stand-alone ALIF or ALIF with posterior instrumentation, the addition of PLF is not recommended, as it increases operative time and blood loss while not influencing the likelihood of fusion or functional outcome.

- A treatment standard or guideline for pedicle screw fixation as an adjunct to posterolateral fusion for low back pain, although pedicle screw fixation is an option for patients who are at high risk of fusion failure being treated with PLF.

The American College of Occupational and Environmental Medicine (ACOEM): ACOEM practice guidelines second edition reports that surgery benefits fewer than 40% of patients with questionable physiologic findings, which is the rate of response of pain to placebo. Within the first 3 months after onset of acute low back symptoms, surgery is considered only for serious spinal pathology or nerve root compression not responsive to an adequate trial of conservative therapy. Moreover, surgery statistically increases the risk for future spine procedures with higher complication rate (ACOEM, 2008).

The Institute for Clinical Systems Improvement (ICSI): ICSI guidelines for adult low back pain (2008) states, “The decision to operate is a clinical decision based on the presence of severe, uncontrolled pain, profound or progressive neurological symptoms, or a failure to respond to conservative therapy.”

Summary

Evidence in the published scientific literature, textbooks and guidelines from professional organizations supports lumbar fusion as an established standard of treatment for a selected group of patients with low back pain. The procedure is associated with more complications than other types of spinal surgery, highlighted by relatively high rates of reoperation. Although additional data supporting long-term safety and efficacy would be helpful open lateral interbody approach is a well-established technique for spinal surgery, the literature supports XLIF and DLIF are considered a modification to this standard approach. There has been much interest in minimally invasive approaches and other emerging technologies for spinal fusion; however, these methods have not been proven to result in net health outcomes that are as good as those obtained with standard surgical approaches.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary when used to report lumbar fusion procedures:

CPT®* Codes	Description
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22534	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic or lumbar, each additional vertebral segment (List separately in addition to code for primary procedure)
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22585	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure)
22612	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with or without lateral transverse technique)
22614	Arthrodesis, posterior or posterolateral technique, single level; each additional vertebral segment (List separately in addition to code for primary procedure)
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar
22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (List separately in addition to code for primary procedure)

22800	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments
22802	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments
22804	Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments
22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments
22810	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments
22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments
22840	Posterior non-segmental instrumentation (e.g., Harrington rod technique, pedicle fixation across one interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)
22841	Internal spinal fixation by wiring of spinous processes (List separately in addition to code for primary procedure)
22842	Posterior segmental instrumentation (e.g., pedicle screw fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments (List separately in addition to code for primary procedure)
22843	Posterior segmental instrumentation (eg, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments (List separately in addition to code for primary procedure)
22844	Posterior segmental instrumentation (eg, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 13 or more vertebral segments (List separately in addition to code for primary procedure)
22845	Anterior instrumentation; 2 to 3 vertebral segments (List separately in addition to code for primary procedure)
22846	Anterior instrumentation; 4 to 7 vertebral segments (List separately in addition to code for primary procedure)
22847	Anterior instrumentation; 8 or more vertebral segments (List separately in addition to code for primary procedure)
22851	Application of intervertebral biomechanical device(s) (eg, synthetic cage(s), threaded bone dowel(s), methylmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure)

SPINAL INSTABILITY

Covered as medically necessary for the treatment of spinal instability:

ICD-9-CM Diagnosis Codes	Description
013.40- 013.46	Tuberculoma of spinal cord
013.50- 013.56	Tuberculous abscess of spinal cord
015.00- 015.06	Tuberculosis of vertebral column
213.2	Benign neoplasm of bone and articular cartilage, vertebral column, excluding sacrum and coccyx
213.6	Benign neoplasm of bone and articular cartilage, pelvic bones, sacrum and coccyx
225.3	Benign neoplasm of brain and other parts of nervous system, spinal cord
225.4	Benign neoplasm of brain and other parts of nervous system, spinal meninges

237.5	Neoplasm of uncertain behavior of endocrine glands and nervous system, brain and spinal cord
237.6	Neoplasm of uncertain behavior of endocrine glands and nervous system, meninges
238.0	Neoplasm of uncertain behavior of other and unspecified sites and tissues, bone and articular cartilage
324.1	Intraspinal abscess
344.60-344.61	Cauda equine syndrome
721.7	Traumatic spondylopathy
724.2	Lumbago
724.3	Sciatica
724.4	Thoracic or lumbosacral neuritis or radiculitis, unspecified
724.5	Backache, unspecified
724.6	Disorders of sacrum
724.9	Other unspecified back disorders
730.08	Acute osteomyelitis, other specified site
730.18	Chronic osteomyelitis, other specified sites
730.28	Unspecified osteomyelitis, other specified sites
730.78	Osteopathy resulting from poliomyelitis, other specified sites
730.88	Other infections involving bone diseases classified elsewhere, other specified sites
730.98	Unspecified infection of bone of other specified site
733.13	Pathologic fracture of vertebrae
737.10	Kyphosis (acquired) (postural)
737.30-737.9	Scoliosis and other spinal curvatures
738.5	Other acquired deformity of back or spine
756.15	Anomalies of spine, fusion of spine [vertebra], congenital
756.19	Anomalies of spine, other
805.4	Fracture of vertebral column without mention of spinal cord injury, lumbar, closed
805.5	Fracture of vertebral column without mention of spinal cord injury, lumbar, open
806.4	Fracture of vertebral column with spinal cord injury, lumbar, closed
806.5	Fracture of vertebral column with spinal cord injury, lumbar, open
839.20	Other, multiple, and ill-defined dislocations, lumbar vertebra, closed
839.30	Other, multiple, and ill-defined dislocations, lumbar vertebra, open
953.2	Injury to nerve roots and spinal plexus, lumbar root
953.3	Injury to nerve roots and spinal plexus, sacral root
953.5	Injury to nerve roots and spinal plexus, lumbosacral plexus

SPINAL STENOSIS WITH ASSOCIATED SPONDYLOLISTHESIS

Covered as medically necessary for the treatment of spinal stenosis when there is an associated spondylolisthesis (i.e., anterolisthesis):

ICD-9-CM Diagnosis Codes	Description
724.02	Spinal stenosis, other than cervical, lumbar region, without neurogenic claudication (Code revised 10/1/2010)
724.03	Spinal stenosis, other than cervical, lumbar region, with neurogenic claudication (Code effective 10/1/2010)
724.2	Lumbago
724.3	Sciatica
724.4	Thoracic or lumbosacral neuritis or radiculitis, unspecified
724.5	Backache, unspecified
724.6	Disorders of sacrum

724.9	Other unspecified back disorders
738.4	Acquired spondylolisthesis
756.12	Congenital spondylolisthesis
953.2	Injury to nerve roots and spinal plexus, lumbar root
953.3	Injury to nerve roots and spinal plexus, sacral root
953.5	Injury to nerve roots and spinal plexus, lumbosacral plexus

SPONDYLOSIS AND ISTHMIC SONDYLOLISTHESIS

Covered as medically necessary for spondylolysis (i.e., pars interarticular fracture), and isthmic spondylolisthesis:

ICD-9-CM Diagnosis Codes	Description
721.3	Spondylosis and allied disorders, lumbosacral spondylosis without myelopathy
721.42	Lumbar spondylosis with myelopathy, lumbar region
721.8	Lumbar spondylosis with myelopathy, other allied disorders of spine
721.90	Spondylosis of unspecified site, without mention of myelopathy
721.91	Spondylosis of unspecified site, with myelopathy
724.2	Lumbago
724.3	Sciatica
724.4	Thoracic or lumbosacral neuritis or radiculitis, unspecified
724.5	Backache, unspecified
724.6	Disorders of sacrum
724.9	Other unspecified back disorders
738.4	Acquired spondylolisthesis
756.11	Anomalies of spine, spondylolysis, lumbosacral region
756.12	Congenital spondylolisthesis
953.2	Injury to nerve roots and spinal plexus, lumbar root
953.3	Injury to nerve roots and spinal plexus, sacral root
953.5	Injury to nerve roots and spinal plexus, lumbosacral plexus

DEGENERATIVE DISC DISEASE WITHOUT INSTABILITY

Covered as medically necessary for the treatment of degenerative disc disease in the absence of instability ONLY when ALL of the associated medical necessity criteria are met:

ICD-9-CM Diagnosis Codes	Description
721.42	Lumbar spondylosis with myelopathy, lumbar region
721.3	Spondylosis and allied disorders, lumbosacral spondylosis without myelopathy
722.10	Lumbar intervertebral disc without myelopathy
722.2	Displacement of intervertebral disc, site unspecified, without myelopathy
722.52	Degeneration of lumbar intervertebral disc
722.6	Degeneration of intervertebral disc, site unspecified
722.73	Intervertebral disc disorder with myelopathy, lumbar region
722.90	Other and unspecified disc disorder, unspecified region
722.93	Other and unspecified disc disorder, lumbar region
724.2	Lumbago
724.3	Sciatica
724.4	Thoracic or lumbosacral neuritis or radiculitis, unspecified
724.5	Backache, unspecified
724.6	Disorders of sacrum
724.9	Other unspecified back disorders

953.2	Injury to nerve roots and spinal plexus, lumbar root
953.3	Injury to nerve roots and spinal plexus, sacral root
953.5	Injury to nerve roots and spinal plexus, lumbosacral plexus

FOLLOWING PRIOR SPINAL SURGERY

Covered as medically necessary for recurrent disc herniation or adjacent segment disease and when it has been at least 6 months from the prior spinal surgery and there is an associated spondylolisthesis (i.e., anterolisthesis):

ICD-9-CM Diagnosis Codes	Description
722.80	Postlaminectomy syndrome, unspecified region
722.83	Postlaminectomy syndrome, lumbar region
722.93	Other and unspecified disc disorder, lumbar region
724.2	Lumbago
724.3	Sciatica
724.4	Thoracic or lumbosacral neuritis or radiculitis, unspecified
724.5	Backache, unspecified
724.6	Disorders of sacrum
724.9	Other unspecified back disorders
738.4	Acquired spondylolisthesis
738.5	Other acquired deformity of back or spine
756.11	Anomalies of spine, spondylolysis, lumbosacral region
756.12	Congenital spondylolisthesis
756.15	Anomalies of spine, fusion of spine [vertebra], congenital
756.19	Anomalies of spine, other
953.2	Injury to nerve roots and spinal plexus, lumbar root
953.3	Injury to nerve roots and spinal plexus, sacral root
953.5	Injury to nerve roots and spinal plexus, lumbosacral plexus

PSEUDOARTHROSIS

Covered as medically necessary for the treatment of pseudoarthrosis (i.e., nonunion of prior fusion) at the same level when it has been at least 12 months from the prior surgery:

ICD-9-CM Diagnosis Codes	Description
724.2	Lumbago
724.3	Sciatica
724.4	Thoracic or lumbosacral neuritis or radiculitis, unspecified
724.5	Backache, unspecified
724.6	Disorders of sacrum
724.9	Other unspecified back disorders
733.82	Nonunion of fracture
733.90	Disorder of bone and cartilage, unspecified
V45.4	Arthrodesis status

Experimental/Investigational/Unproven/Not Covered for ANY indication:

CPT* Codes	Description
0195T	Arthrodesis, pre-sacral interbody technique, including instrumentation, imaging (when performed), and discectomy to prepare interspace, lumbar; single interspace

0196T	Arthrodesis, pre-sacral interbody technique, including instrumentation, imaging (when performed), and discectomy to prepare interspace, lumbar; each additional interspace (List separately in addition to code for primary service)
0202T	Posterior vertebral joint(s) arthroplasty (e.g. facet joint(s) replacement) inc facetectomy, laminectomy, foraminotomy and vertebral column fixation, with or without injection of bone cement, inc fluoroscopy, single level, lumbar spine
0219T	Placement of posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical
0220T	Placement of posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; thoracic
0221T	Placement of posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; lumbar
0222T	Placement of posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; each additional vertebral segment (List separately in addition to code for primary procedure)

ICD-9-CM Diagnosis Codes	Description
	All Codes

Experimental, investigational, unproven and not covered when used to represent posterior non-pedicle supplemental fixation devices (e.g., Aspen™ Spinous Process Fixation System, Lanx Spinal Fixation System):

CPT* Codes	Description
22899	Unlisted procedure, spine

Experimental, investigational, unproven and not covered when used to represent sacroiliac joint fusion, including minimally invasive and percutaneous sacroiliac joint fusion, for the treatment of mechanical back pain:

CPT* Codes	Description
27280	Arthrodesis, sacroiliac joint (including obtaining graft)

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Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	12/15/2007	0303	Lumbar Fusion for Spinal Instability and Degenerative Disc Condition

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