SURGICAL TREATMENT FOR SPINE PAIN

Policy Number: 2014T0547H
Effective Date: May 1, 2014

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Related Policies:

- Bone or Soft Tissue Healing and Fusion Enhancement Products
- Epidural Steroid and Facet Injections for Spinal Pain
- Total Artificial Disc Replacement for the Spine

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COVERAGE RATIONALE

Spinal fusion using extreme lateral interbody fusion (XLIF) or direct lateral interbody fusion (DLIF) is proven.

Coding Clarification

- The North American Spine Society (NASS) recommends that anterior or anterolateral approach techniques performed via an open approach should be billed with CPT codes 22554 – 22585. These codes should be used to report the use of extreme lateral interbody fusion (XLIF) and direct lateral interbody fusion (DLIF) procedures (NASS, 2010).
- Laparoscopic approaches should be billed with an unlisted procedure code.

For information regarding medical necessity review, when applicable, see the following MCG™ Care Guidelines, 18th edition, 2014:

- Cervical Diskectomy or Microdiskectomy, Foraminotomy, Laminotomy, S-310 (ISC)
- Lumbar Diskectomy, Foraminotomy, or Laminotomy S-810 (ISC)
- Cervical Laminectomy S-340 (ISC)
- Lumbar Laminectomy S-830 (ISC)

- Cervical Fusion, Anterior S-320 (ISC)
- Cervical Fusion, Posterior S-330 (ISC)
- Lumbar Fusion S-820 (ISC)

The following spinal procedures are unproven:

A. Spinal fusion, when performed via the following methods:

1. **Laparoscopic anterior lumbar interbody fusion (LALIF**)
2. **Transforaminal lumbar interbody fusion (TLIF)** which utilizes only endoscopy visualization (such as a percutaneous incision with video visualization)
3. **Axial lumbar interbody fusion (AxiaLIF)** Interlaminar lumbar instrumented fusion (for example ILIF)

This includes interbody cages (for example PEEK, titanium etc), screws or devices with any of the above procedures.

Clinical evidence is limited primarily to retrospective studies and case series. Randomized, controlled trials comparing these procedures to standard procedures are needed to determine impact on health outcomes and long-term efficacy.

B. Spinal Decompression

1. **Interspinous process decompression (IPD) systems**, such as the X-STOP for the treatment of spinal stenosis
2. **Minimally invasive lumbar decompression (MILD)**

Clinical evidence is limited to small, uncontrolled studies with lack of blinding and long-term follow-up. No controlled trials have been performed to compare the X-STOP IPD and MILD procedures with decompressive surgery.

C. Spinal Stabilization

1. **Stabilization systems**, such as the Dynesys® Dynamic Stabilization System or the DSS Stabilization System for the treatment of degenerative spondylolisthesis
2. **Total facet joint arthroplasty, including facetectomy, laminectomy, foraminotomy, vertebral column fixation**
3. **Percutaneous sacral augmentation (sacroplasty)** with or without a balloon or bone cement for the treatment of back pain

Clinical evidence is limited to small, uncontrolled studies with lack of blinding and long-term follow-up. Randomized, controlled trials comparing these procedures to standard procedures are needed to determine impact on health outcomes and long-term efficacy. The Total Facet Arthroplasty System™ (TFAS) has not been approved by the U.S. Food and Drug Administration (FDA). A single clinical trial is in progress, but no results have been published.

D. Stand alone facet fusion without an accompanying decompressive procedure. This includes procedures performed with or without bone grafting and/or the use of posterior intrafacet implants such as fixation systems, facet screw systems or anti-migration dowels. Clinical evidence is limited primarily to case series and nonrandomized studies. Randomized, controlled trials comparing facet fusion to standard procedures are needed to determine impact on health outcomes and long-term efficacy.

BACKGROUND

Spinal procedures with the goal of decompression and/or stabilization can be done with an open surgical approach or minimally invasively. Open procedures require larger incisions, muscle stripping, longer hospitalization and subsequent increased recovery time. There is no standard definition of minimally invasive surgical techniques. "Minimally invasive" may include the use of smaller incisions, stab incisions or portals for instrumentation. The advantages of using a smaller surgical incision are reduced postoperative pain, diminished blood loss, faster recovery and reduced hospital stays.

Spinal Fusion

Spinal fusion, also called arthrodesis, is a surgical technique that may be done as an open or minimally invasive procedure. There are many different approaches to spinal fusion, but all techniques involve removing the disc between two or more vertebrae and fusing the adjacent vertebrae together using bone grafts and/or spacers placed where the disc used to be. Spacers can be made of bone or bone substitutes, metal (titanium), carbon fiber, polymers or bioresorbable materials and are often supported by plates, screws, rods and/or cages. Several minimally invasive spinal fusion procedures have been developed and include the following:

- Laparoscopic anterior lumbar interbody fusion (LALIF) is a minimally invasive alternative to an open surgical approach to spinal fusion. The vertebrae are reached through an incision in the lower abdomen or side.

- Transforaminal lumbar interbody fusion (TLIF) is a modification of the posterior lumbar interbody fusion (PLIF) that gives unilateral access to the disc space to allow for fusion of the front and back of the lumbar spine. The front portion of the spine is stabilized with the use of an interbody spacer and bone graft. The back portion is secured with pedicle screws, rods and additional bone graft. TLIF is performed through a posterior incision over the lumbar spine and can be done as an open or percutaneous procedure.

- Axial lumbar interbody fusion (AxiaLIF), also called trans-sacral, transaxial or para-coccygeal interbody fusion, is a minimally invasive technique used in L5-S1 (presacral) spinal fusions. The technique provides access to the spine along the long axis of the spine, as opposed to anterior, posterior or lateral approaches. The surgeon enters the back through a very small incision next to the tailbone and the abnormal disc is taken out. Then a bone graft is placed where the abnormal disc was and is supplemented with a large metal screw. Sometimes, additional, smaller screws are placed through another small incision higher on the back for extra stability.

- Interlaminar lumbar instrumented fusion (ILIF) combines direct neural decompression with an allograft interspinous spacer to maintain the segmental distraction, and a spinous process fixation plate to maintain stability for eventual segmental fusion.

Williams and Park (2007) address the presumed superiority of one minimally invasive approach over another as follows: "At this time, no particular approach and no particular minimally invasive technique of stabilization has been shown to be superior to others, and there are several good studies that show statistical equivalency between anterior lumbar antibody [sic] fusion (ALIF), posterior lumbar antibody [sic] fusion (PLIF), and posterolateral fusion with instrumentation."

Spinal Decompression

The following minimally invasive procedures decompress (reduce) the pressure on the spinal or nerve root:

- **The X-STOP Interspinous Process Decompression (IPD) System** has been developed as part of a minimally invasive surgical method to treat lumbar spinal stenosis, an abnormal narrowing or constriction of spaces that provide pathways for spinal nerves.

For many patients, this device can be implanted by an orthopedic surgeon under local anesthesia as an outpatient procedure, although in some circumstances, the physician may prefer to admit the patient for an inpatient stay (Zucherman et al., 2004).

- **Image-guided minimally invasive lumbar decompression (MILD®)** is a percutaneous procedure for decompression of the central spinal canal in patients with lumbar spinal stenosis. After filling the epidural space with contrast medium, a cannula is clamped in place with a back plate and a rongeur, tissue sculpter and trocar are used to resect thickened ligamentum flavum and small pieces of lamina. The process may be repeated on the opposite side for bilateral decompression.

Spinal Stabilization

- **The Dynesys® Dynamic Stabilization System** was designed as a means to provide stability during spinal fusion to stabilize the spine; however, is currently being investigated as a substitute for spinal fusion. The Dynesys Dynamic Stabilization System is intended for use in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the lumbar or sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

- **Total facet joint arthroplasty, such as the Total Facet Arthroplasty System® (TFAS®)** is a non-fusion spinal implant developed to treat patients with moderate to severe spinal stenosis. TFAS replaces the diseased facets (and lamina, if necessary) following surgical removal.

- **Percutaneous sacroplasty** is a minimally invasive surgical treatment that attempts to repair sacral insufficiency fractures using polymethylmethacrylate (PMMA) bone cement. For this procedure, 2 thin, hollow tubes are placed in the lower back, over the left half and right half of the sacrum, guided by images from x-rays or computed tomography scans. The surgeon then advances a needle through each tube to the site of the sacral fracture and injects 2 to 5 mL of bone cement (Hayes, 2009).

Facet Fusion

Facet fusion is a procedure that uses an allograft to fuse the joint together to provide spinal column stability and pain reduction. Facet fusion has been proposed as a treatment option for individuals with facet joint pain that does not respond to conservative treatment.

CLINICAL EVIDENCE

Spinal Fusion

In a review article by German et al. (2005) the author provides an overview of current minimally invasive lumbar fusion techniques. Pertinent literature and the authors' clinical experience were reviewed. Minimally invasive techniques have been developed for intertransverse process, posterior lumbar interbody, and transforaminal lumbar interbody fusions. It is emphasized that while these less-invasive procedures appear promising, the clinical results of these techniques remain preliminary with few long-term studies available for critical review. The author concluded that preliminary clinical evidence suggests that minimally invasive lumbar fusion techniques will benefit patients with spinal disorders. This study has a relatively short follow-up period. More long-term studies are still indicated.

Laparoscopic Anterior Lumbar Interbody Fusion (LALIF)

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. 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.

Frantzides et al. (2006) completed a retrospective analysis of consecutive patients who underwent L5-S1 laparoscopic ALIF between February 1998 and August 2003. Twenty-eight patients underwent L5-S1 LAIF (15 males and 13 females). The mean age was 43 years (range, 26 to 67). The authors concluded that ALIF is feasible and safe with all the advantages of minimally invasive surgery. Fusion rates and pain improvement were comparable to those with an open repair. However, the small numbers of patients in the study, and the specific experience of the surgeons with this procedure would make it difficult to generalize this result to a larger population

Inamasu and Guiot (2005) reviewed the literature on the outcomes of LALIF. Several comparative studies showed that at the L5-S1 disc level, there was no marked difference between LALIF and the open or mini-open ALIF in terms of short-term efficacy, i. e., operative time, blood loss and length of hospital stay. With regard to the complication rate, however, there was a higher incidence of retrograde ejaculation in LALIF. At the L4-L5 and L4-L5/L5-S1 disc levels, the complication rate and conversion rate to open surgery was high in LALIF, and many authors were not impressed with the LALIF at these levels. Several case series showed that the LALIF yielded excellent perioperative outcomes in the hands of experienced endoscopic spine surgeons at both the L5-S1 and L4-L5 disc levels. No conclusion regarding either the superiority or inferiority of LALIF to the open or mini-open ALIF can be drawn, because of the lack of data with a high-level of evidence.

Chung et al. (2003) compared perioperative parameters and minimum 2-year follow-up outcome for laparoscopic and open anterior surgical approach for L5-S1 fusion. The data of 54 consecutive patients who underwent anterior lumbar interbody fusion (ALIF) of L5-S1 from 1997 to 1999 were collected prospectively. More than 2-years' follow-up data were available for 47 of these patients. In all cases, carbon cage and autologous bone graft were used for fusion. Twenty-five patients underwent a laparoscopic procedure and 22 an open mini-ALIF. Three laparoscopic procedures were converted to open ones. For perioperative parameters only, the operative time was statistically different (P=0.001), while length of postoperative hospital stay and blood loss were not. The incidence of operative complications was three in the laparoscopic group and two in the open mini-ALIF group. After a follow-up period of at least 2 years, the two groups showed no statistical difference in pain, measured by visual analog scale, in the Oswestry Disability Index or in the Patient Satisfaction Index. The fusion rate was 91% in both groups. The laparoscopic ALIF for L5-S1 showed similar clinical and radiological outcome when compared with open mini-ALIF, but significant advantages were not identified.

In a multicenter study, prospective study by Regan et al. (1999), 240 patients underwent LALIF. This cohort was compared with 591 consecutive patients undergoing open anterior fusion using a retroperitoneal approach. The laparoscopy group had shorter hospital stays and reduced blood loss but had increased operative time. Operative time improved in the laparoscopy group as surgeons' experience increased. Operative complications were comparable in both groups, with an occurrence of 4.2% in the open approach and 4.9% in the laparoscopic approach. Overall, the device-related reoperation rate was higher in the laparoscopy group (4.7% vs. 2.3%), primarily as a result of intraoperative disc herniation. Conversion to open procedure in the laparoscopy group was 10%, with most cases predictable and preventable. The laparoscopic procedure is associated with a learning curve, but once mastered it is effective and safe when compared with open techniques of fusion.

Kaiser et al. (2002) conducted a retrospective review of 98 patients who underwent ALIF procedures between 1996 and 2001 in which either a mini-open or a laparoscopic approach was used. Patient demographics, intraoperative parameters, length of hospitalization, and technique-related complications associated with the use of these two approaches were compared. The subset of patients who underwent L5-S1 ALIF procedures was analyzed separately. A

laparoscopic approach was used in 47 of these patients, and the mini-open technique was used in the other 51 patients. The authors concluded that both the laparoscopic and mini-open techniques are effective approaches to use when performing ALIF procedures. On the basis of the data obtained in this retrospective review, the laparoscopic approach does not seem to have a definitive advantage over the mini-open exposure, particularly in an L5-S1 ALIF procedure. In the author's opinion, the mini-open approach possesses a number of theoretical advantages; however, the individual surgeon's preference ultimately is likely to be the dictating factor.

Endoscopic Transforaminal Lumbar Interbody Fusion
Transforaminal lumbar interbody fusion utilizing endoscopy, sometimes referred to as minimally invasive transforaminal interbody fusion (MITLIF), is essentially the same as an open transforaminal interbody fusion (TLIF) except that it is performed through smaller incisions using specialized retractors that gradually open an operative corridor through the muscles rather than pulling the muscles aside as with conventional open surgery. This approach requires a percutaneous incision with video visualization of the spine to perform TLIF. Specialized instruments are advanced through a retractor resulting in fewer traumas to soft tissues, which may result in reduced operative time and hospitalization.

A retrospective study by Villavicencio et al. (2010) compared minimally invasive (n=76) and open (n=63) approaches for transforaminal lumbar interbody fusion (TLIF) in patients with painful degenerative disc disease with or without disc herniation, spondylolisthesis, and/or stenosis at one or two spinal levels. Outcomes were measured using visual analog scale (VAS), patient satisfaction, and complications. Average follow-up was 37.5 months. Postoperative change in mean VAS was 5.2 in the open group and 4.1 in the minimally invasive group. Overall patient satisfaction was 72.1% in the open group versus 64.5% in the minimally invasive group. The total rate of neurological deficit was 10.5% in the minimally invasive TLIF group compared to 1.6% in the open group. The authors concluded that open and minimally invasive approaches for transforaminal lumbar interbody fusion have equivalent outcomes; however, the rate of neural injury related complications in the minimally invasive approach must be considered when selecting patients for surgery.

Park and Foley (2008) discussed their retrospective review study results in 40 consecutive patients who underwent MI-TLIF for symptomatic spondylolisthesis utilizing this approach. Thirty cases involved a degenerative spondylolisthesis while the remaining 10 were isthmic. The minimum follow-up was 24 months with a mean of 35 months. The authors conclude that MI-TLIF for symptomatic spondylolisthesis appears to be an effective surgical option with results that compare favorably to open procedures. Results are limited by study design, small patient numbers and lack of a control.

Scheufler et al. (2007) conducted a retrospective study which reports technique, clinical outcomes and fusion rates of percutaneous transforaminal lumbar interbody fixation (pTLIF). Results are compared with those of mini-open transforaminal lumbar interbody fixation (oTLIF) using a muscle splitting (Wiltse) approach. Percutaneous transforaminal lumbar interbody fixation (pTLIF) was performed in 43 patients with single-level and 10 patients with bi- or multilevel lumbar discopathy or degenerative pseudolisthesis resulting in axial back pain and claudication, pseudoradicular, or radicular symptoms. Postoperative pain was significantly lower after pTLIF after the second postoperative day ($P < 0.01$). The overall clinical outcome was not different from oTLIF at 8 and 16 months. The authors concluded that pTLIF allows for safe and efficient minimally invasive treatment of single and multilevel degenerative lumbar instability with good clinical results. Further prospective studies investigating long-term functional results are required to assess the definitive merits of percutaneous instrumentation of the lumbar spine.

Villavicencio et al. (2006) retrospectively compared outcomes in 167 consecutive patients with DDD treated with anterior-posterior lumbar interbody fusion MITLIF (73), open TLIF (51), or APLIF (43). MITLIF recipients had fewer previous surgeries (18%) compared with TLIF (39%) or APLIF (49%) recipients. Few details were provided as to surgical techniques or procedures.

Mean operative time was 255 min for MITLIF compared with 222 min in open TLIF versus 455 min in APLIF (P<0.0001 for both TLIF procedures versus APLIF). Mean estimated blood loss (EBL) was 231 mL for MITLIF patients, 424 mL for open TLIF patients, and 550 mL for APLIF patients (MITLIF was P<0.0001 versus APLIF and open TLIF was P<0.03 versus APLIF). The mean HLOS was 3.1 days for MITLIF, 4.1 for open TLIF, and 7.2 days for APLIF (both TLIF procedures were P<0.0001 versus APLIF). Only mean EBL showed a statistically significant decrease in MITLIF versus TLIF patients (P<0.006). For MITLIF, open TLIF, and APLIF, major complications occurred in 6 (8.2%), 0, and 27 (62.8%) patients respectively, with minor complications in 16 (21.9%), 18 (35.3%), and 6 (13.9%), respectively.15 This study is limited by its retrospective design.

In a case series, Deutsch and Musacchio (2006) prospectively evaluated 20 patients with DDD (all of whom had failed conservative therapy) who received MITLIF with unilateral pedicle screw placement. Mean operative time was 246 minutes, mean EBL was 100 mL and mean HLOS was 2.5 days. At follow-up from 6 to 12 months, a good result (> 20% decrease in ODI) was observed in 17/20 (85%) patients with no improvement in 3 (15%). Mean ODI decreased from 57% to 25%, VAS score decreased from 8.3 to 1.4 (P<0.005) and 13/20 (65%) patients displayed some degree of fusion at 6 months. Cerebrospinal fluid (CSF) leaks occurred in 2 patients, and one new postoperative radiculopathy was observed, which resulted in further surgery to readjust a pedicle screw.

Isaacs et al. (2005) retrospectively compared 20 patients receiving MITLIF with 24 patients receiving traditional PLIF. All patients had grade I or II spondylolisthesis or mechanical lower back pain and radiculopathy (pain involving the nerve root) and had failed conservative therapy. Two interbody grafts were placed with bilateral pedicle screws using Medtronic instrumentation in the MITLIF group. One senior surgeon supervised all MITLIF operations, while 5 surgeons performed the PLIF operations. Mean operative time was 300 min in MITLIF recipients versus 276 min in PLIF recipients. For the MITLIF and PLIF groups, respectively, the mean EBL was 226 and 1147 mL (P<0.001); mean HLOS was 3.4 versus 5.1 days (P<0.02) and complications occurred in 1 versus 6 patients in these groups, respectively. The retrospective nature of this design limits the ability to draw firm conclusions regarding efficacy.

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).

Axial Lumbar Interbody Fusion
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 clearly 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.

The AxiaLIF (Axial Lumbar Interbody Fusion) System includes surgical instruments for creating a safe and reproducible presacral access route to the L5-S1 vertebral bodies. The AxiaLIF technique features novel instrumentation to enable standard of care fusion principles, distraction and stabilization of the anterior lumbar column while mitigating the soft tissue trauma associated with traditional lumbar fusion through open surgical incisions. The lumbar spine is accessed through a percutaneous opening adjacent to the sacral bone. This atraumatic tissue plane alleviates the need for the surgeon to cut through soft tissues like muscles and ligaments, thus lessening patient pain and the likelihood of complications (TranS1 website).

In a 5-year post-marketing surveillance study, Gundanna et al. (2011) reported complications associated with axial presacral lumbar interbody fusion in 9152 patients. A single-level L5-S1 fusion was performed in 8034 patients (88%), and a two-level L4-S1 fusion was performed in 1118 patients (12%). Complications were reported in 1.3% of patients with the most commonly reported complications being bowel injury (0.6%) and transient intraoperative hypotension (0.2%). Other complications noted include superficial wound and systemic infections, migration, subsidence, presacral hematoma, sacral fracture, vascular injury, nerve injury and ureter injury. The overall complication rate was similar between single-level (1.3%) and two-level (1.6%) fusion procedures, with no significant differences noted for any single complication. The authors concluded that the overall complication rates compare favorably with those reported in trials of open and minimally invasive lumbar fusion surgery.

Tobler and Ferrara (2011) conducted a prospective evaluation study (n=26) to determine clinical outcomes, complications and fusion rates following axial lumbar interbody fusion. Single-level (L5-S1) fusions were performed in 17 patients and two-level (L4-S1) fusions were performed in 9 patients. Significant reductions in pain and disability occurred as early as three weeks postoperatively and were maintained. Fusion was achieved in 92% of patients at 12 months and in 96% of patients at 24 months. One patient underwent successful revision. The authors reported no severe adverse events and clinical outcomes and fusion rates comparable to other methods of interbody fusion. Further results from larger, prospective studies are needed to determine long-term efficacy.

Retrospective case series evaluating clinical outcomes and fusion rates following axial presacral interbody fusion reported an overall fusion rate ranging from 86% - 96% (Tobler et al., 2011; Patil et al., 2010; Bohinski et al., 2010; Stippler et al., 2009). Further results from larger, prospective studies are needed to determine long-term efficacy.

The National Institute for Health and Clinical Excellence (NICE) states that current evidence on the efficacy of transaxial interbody lumbosacral fusion is limited in quantity but shows symptom relief in the short term in some patients. Evidence on safety shows that there is a risk of rectal perforation. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. NICE encourages further research into transaxial interbody lumbosacral fusion (NICE, 2011).

Aryan et al. (2008) retrospectively reviewed 35 patients with L5-S1 degeneration who underwent percutaneous paracoccygeal axial fluoroscopically-guided interbody fusion (AxiaLIF). Twenty-one patients underwent AxiaLIF followed by percutaneous L5-S1 pedicle screw-rod fixation. Two patients underwent AxiaLIF followed by percutaneous L4-L5 extreme lateral interbody fusion (XLIF) and posterior instrumentation. Ten patients had a stand-alone procedure. Unfavorable anatomy precluded access to the L5-S1 disc space during open lumbar interbody fusion in 2 patients who subsequently underwent AxiaLIF at this level as part of a large construct. Thirty-two patients (91%) had radiographic evidence of stable L5-S1 interbody cage placement and fusion at the last follow-up. Average follow-up was 17.5 months. The authors concluded that this approach was safe to perform alone or in combination with minimally invasive or traditional open fusion procedures. While these results are promising, the study is limited by its retrospective design, small sample size and lack of randomization and control.

A technical note by Marotta et al. (2006) described a new paracoccygeal approach to the L5-S1 junction for interbody fusion with transsacral instrumentation. The authors report that this novel technique of interbody distraction and fusion via a truly percutaneous approach corridor allows for circumferential treatment of the lower lumbar segments with minimal risk to the anterior organs and dorsal neural elements.

In a review, Ledet et al. (2006) reported that preliminary results of a novel transaxial approach to lumbosacral fixation appear promising.

Cragg et al. (2004) reported preliminary results of cadaver, animal and human studies performed to determine the feasibility of axial anterior lumbosacral spine access using a percutaneous, presacral approach. Custom instruments were directed under fluoroscopic guidance along the midline of the anterior sacrum to the surface of the sacral promontory where an axial bore was created into the lower lumbar vertebral bodies and discs. Imaging and gross dissection were performed in cadavers and animals. The procedure was used for lumbosacral biopsy in human subjects guided by intraoperative imaging and clinical monitoring. All procedures were technically successful. The authors concluded that this study demonstrated the feasibility of the axial access technique to the anterior lower lumbar spine.

Interlaminar Lumbar Instrumented Fusion (ILIF)
NuVasive is conducting a clinical trial to evaluate interlaminar lumbar instrumented fusion in patients with single-level degenerative disc disease (DDD) of the lumbar spine. The study is still ongoing. Additional information is available at: http://clinicaltrials.gov/ct2/show/NCT01019057. Accessed October 31, 2013.

Professional Societies
American Association of Neurological Surgeons (AANS)/Congress of Neurological Surgeons (CNS)
AANS and CNS have jointly published a series of guidelines addressing fusion for degenerative disease of the lumbar spine. These guidelines are available at: http://www.spinesection.org/fusion_guidelines.php. Accessed October 31, 2013.

Spinal Decompression
Interspinous Process Decompression (IPD) Systems
Kabir et al. (2010) conducted a systematic review to evaluate the current biomechanical and clinical evidence on lumbar interspinous spacers (ISPs). The main outcome measure was clinical outcome assessment based on validated patient-related questionnaires. Biomechanical studies were analyzed to evaluate the effects of ISPs on the kinematics of the spine. The largest number of studies has been with the X-STOP device. The biomechanical studies with all the devices showed that ISPs have a beneficial effect on the kinematics of the degenerative spine. Apart from 2 randomized controlled trials, the other studies with the X-STOP device were not of high methodologic quality. Nevertheless, analysis of these studies showed that X-STOP may improve outcome when compared to nonoperative treatment in a select group of patients, aged 50 or over, with radiologically confirmed lumbar canal stenosis and neurogenic claudication. Studies on the other devices show satisfactory outcome to varying degrees. However, due to small number and poor design of the studies, it is difficult to clearly define indications for their use in lumbar degenerative disease. The authors concluded that lumbar ISPs may have a potential beneficial effect in a select group of patients with degenerative disease of the lumbar spine. However, further well-designed prospective trials are needed to clearly outline the indications for their use.

Anderson et al. (2006) conducted a randomized controlled study with a cohort of 75 patients with degenerative spondylolisthesis. 42 underwent surgical treatment and 33 control individuals were treated nonoperatively. In this study, they concluded that the X-STOP was more effective than nonoperative treatment in the management of NIC secondary to degenerative lumbar

spondylolisthesis.

Zucherman et al. (2004) completed a prospective randomized multi-center study of the X-STOP IPD System. Results of additional follow-up were reported in a second article (Zucherman, 2005). Patients who had experienced back pain for an average of 4.1 years and who had neurogenic intermittent claudication secondary to lumbar spinal stenosis that was documented by computed tomography (CT) or magnetic resonance imaging (MRI) were randomized to received either the X-STOP (n=100) or non-operative therapy (n=91) as a control. The non-operative group received one or more epidural steroid injections and some also underwent treatment with NSAIDs, analgesics, and/or physical therapy. The primary outcome measure was the Zurich Claudication Questionnaire (ZCQ). At 2 years follow-up, mean ZCQ Symptom Severity scores had improved 45% for the X-STOP treatment group versus a 7% improvement for the control group. In addition, mean ZCQ Physical Function scores had improved 44% for the X-STOP treatment group versus no change for the control group. Concurrent with these findings, 73% of treatment group patients reported they were somewhat or more than somewhat satisfied with treatment versus 36% of control group patients. Differences between groups in ZCQ scores and patient satisfaction were statistically significant (P<0.001). During the 2-year follow-up period, 6% of X-STOP treatment group patients and 30% of control group patients underwent laminectomy for unresolved symptoms; however, it was not reported whether this difference was statistically significant. At 1 and 2 years follow-up, there were no significant differences between the treatment and control groups in any of eight spinal radiographic measurements. While these results are promising, additional studies are needed to further validate these results.

A prospective study by Siddiqui et al. (2006) concluded that the X-STOP device improves the degree of central and foraminal stenosis in vivo. This study was based on twenty-six patients with lumbar spine stenosis who underwent a one- or two-level X-STOP procedure. All had preoperative and postoperative positional MRI in standing, supine, and sitting flexion and extension. Measurements were carried out on the images acquired.

A study by Nandakumar et al. (2010) evaluated the effect of the X-stop device on the dural sac in 48 patients with spinal stenosis. MRI scans pre- and postoperatively showed a mean increase in the dural sac area that was maintained 24 months after surgery. There was also a reduction in mean anterior disc height, from 5.9 to 4.1 mm at the instrumented level in single-level cases, from 7.7 to 6.1 mm in double-level cases caudally, and from 8.54 to 7.91 mm cranially. This was thought to be a result of the natural progression of spinal stenosis with aging. The mean lumbar spine motion was 21.7 degrees preoperatively and 23 degrees at 24 months in single-level cases. In double-level cases, this was 32.1 degrees to 31.1 degrees. While these results show that the X-STOP device is effective in decompressing spinal stenosis, it does not significantly alter the range of motion of the lumbar spine at instrumented and adjacent levels.

In a comparison study, Kondrashov et al. (2006), presented 4-year follow up data on 18 patients with an average follow up of 51 months. Their results suggest that intermediate-term clinical outcomes of X-STOP IPD surgery are stable over time as measured by the Oswestry Disability index (ODI). However, they stated that lower disability at the start made it more difficult to achieve the 15 point-point ODI success criteria.

In a retrospective study by Verhoff et al. (2008) a cohort of 12 consecutive patients with symptomatic lumbar spinal stenosis caused by degenerative spondylolisthesis were treated with the X-STOP interspinous distraction device. All patients had low back pain, neuroclaudication and radiculopathy. Pre-operative radiographs revealed an average slip of 19.6%. MRI of the lumbosacral spine showed a severe stenosis. In 10 patients, the X-STOP was placed at the L4-5 level, whereas two patients were treated at both, L3-4 and L4-5 level. The mean follow-up was 30.3 months. In 8 patients a complete relief of symptoms was observed post-operatively, whereas the remaining 4 patients experienced no relief of symptoms. Recurrence of pain, neurogenic claudication, and worsening of neurological symptoms was observed in three patients within 24 months. Post-operative radiographs and MRI did not show any changes in the percentage of slip

or spinal dimensions. Finally, secondary surgical treatment by decompression with posterolateral fusion was performed in seven patients (58%) within 24 months. The authors concluded that the X-STOP interspinous distraction device showed an extremely high failure rate, defined as surgical re- intervention, after short term follow-up in patients with spinal stenosis caused by degenerative spondylolisthesis.

Siddiqui et al. (2005) performed a small, uncontrolled study of the X-STOP IPD System to evaluate changes in the lumbar spine after device implantation. This study involved preoperative and postoperative MRI studies of 12 patients, 5 of whom underwent implantation of X-STOP devices at two spinal levels. Six months after device implantation, at the sites of implantation, patients had statistically significant increases in posterior disc height while standing and in left and right exit foraminal dimensions during extension. These changes resulted in a mean overall increase in the cross-sectional area of the dural sac from 78 to 93 mm2 (P<0.01). Despite these changes, there were no significant changes in lumbar posture or in the overall range of lumbar spinal movements. Siddiqui et al. did not report any outcomes related to patients symptoms or physical function.

Another small, uncontrolled study of the X-STOP IPD System was performed by Lee et al. (2004). These investigators implanted 11 devices in 10 patients with lumbar spinal stenosis. At a mean of 11 months after implantation, 5 patients were very satisfied and 2 patients were somewhat satisfied with the results of the procedure. Based on the Swiss Spinal Stenosis (SSS) questionnaire, these patients had no improvement in mean symptom severity. Although mean SSS physical function scores improved from 2.71 at baseline to 2.20, the investigators did not report whether this change was statistically significant. Lee et al. also reported an increase in mean dural sac cross-sectional area from 74 to 90 mm2 (P<0.005) and other radiographic outcomes similar to those reported by Siddiqui et al. (2005).

A Hayes health technology brief found that while the results of available studies are promising, only one randomized controlled trial has been performed to determine whether X-STOP implantation provides better outcomes than conservative therapies. None of the studies involved more than 2 years of follow-up, and no controlled trials have been performed to compare the X-STOP IPD procedure with decompressive surgery (Hayes, 2010; updated 2012).

In an emerging technology report, ECRI outlined the quality and consistency of the current evidence base concerning the X-STOP (ECRI, 2009).

- Small evidence base. Only one RCT is available for analysis; results would need to be confirmed by other studies.
- Lack of blinding. Although surgical interventions present logistical barriers to blinding, a lack of blinding may impart a source of bias.
- Limited long-term follow-up. Two-year follow-up is inadequate to determine the durability of results associated with the X-STOP implant. Issues such as implant dislodgement or migration may require longer follow-up in greater numbers of patients. The durability of symptom relief is another concern, and longer follow-up is required to determine what percentage of patients either experience recurrent symptoms or ultimately convert to a conventional surgical decompression procedure. Furthermore, implanting an X-STOP spacer alters the biomechanics of the back, and longer follow-up could potentially reveal the emergence of new symptoms.
- Comparison to nonoperative treatment but not to other surgical options. The current clinical trial compares the X-STOP to nonoperative treatment. Comparison to conventional surgical decompression procedures will be required to clarify where the X-STOP procedure lies in the hierarchy of treatment options for spinal stenosis (i.e., will X-STOP implantation be considered an intermediate treatment option between nonoperative management and conventional surgical decompressive procedures or will X-STOP implantation emerge as a definitive surgical procedure?).

The National Institute for Health and Clinical Excellence states that current evidence on interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication (such as the X-STOP prosthesis) shows that these procedures are efficacious for carefully selected patients in the short and medium term, although failure may occur and further surgery may be needed. There are no major safety concerns. Therefore these procedures may be used provided that normal arrangements are in place for clinical governance, consent and audit. Patient selection should be carried out by specialist spinal surgeons who are able to offer patients a range of surgical treatment options (NICE, 2010).

Minimally Invasive Lumbar Decompression (MILD®)
A multicenter, non-blinded prospective study of 78 patients by Chopko and Caraway (2010) assessed the safety and functional outcomes of the MILD procedure in the treatment of symptomatic central canal spinal stenosis. Outcomes were measured by Visual Analog Score (VAS), Oswestry Disability Index (ODI), Zurich Claudication Questionnaire (ZCQ), and SF-12v2 Health Survey at baseline and 6 weeks post-treatment. At 6 weeks, the study showed a reduction in pain as measured by VAS, ZCQ, and SF-12v2. In addition, improvement in physical function and mobility as measured by ODI, ZCQ, and SF-12v2 was also seen. The authors concluded that the MILD procedure was safe and demonstrated efficacy in improving mobility and reducing pain associated with lumbar spinal canal stenosis. The study is limited by short term follow-up, small sample size and lack of a control group.

One-year follow-up from an industry-sponsored multicenter study by Chopko and Carawaym, with patients who were treated with mild® devices, a set of specialized surgical instruments used to perform percutaneous lumbar decompressive procedures for the treatment of various spinal conditions, was reported in 2012. (10) All 78 patients had failed conservative medical management, with 75.9% of patients treated with conservative therapy for more than 6 months. Twenty-nine patients (50%) were discharged from the surgical facility on the same day as the procedure, and none of the patients stayed longer than 24 hours. There were no reports of major intraoperative or postoperative procedure-related adverse events. The primary outcome of patient success was defined as a 2-point improvement in VAS pain, but the percentage of patients who achieved success was not reported. VAS for pain improved from a mean of 7.4 at baseline to 4.5 at 1-year follow-up. The ODI improved from 48.6 to 36.7, and there was significant improvement on all domains of the Zurich Claudication Questionnaire and the SF-12 physical component score (from 27.4 to 33.5). The small number of study participants and its industry sponsorship limit the conclusions that can be drawn from this study.

A retrospective review by Lingreen and Grider (2010) evaluated the efficacy of minimally invasive lumbar decompression in 42 patients with spinal stenosis and ligamentum flavum hypertrophy. Patient self reported VAS, pre and post procedure functional assessments of activities of daily living (ADL), major and minor complication reports and need for follow-up procedures were evaluated. Patients self-reported improvement in function as assessed by ability to stand and ambulate for greater than 15 minutes, whereas prior to the procedure 98 % reported significant limitations in functioning. Visual analog pain scores were significantly decreased by 40% from baseline. No major adverse events were reported and of the minor adverse events, soreness lasting 3.8 days was most frequently reported. The authors concluded that the MILD procedure appears to be a safe and likely effective option for treatment of neurogenic claudication in patients who have failed conservative therapy and have ligamentum flavum hypertrophy as the primary distinguishing component of the stenosis. The study is limited by small sample size, reporting of subjective outcomes and comparison to other procedures for treating lumbar spinal stenosis.

Deer and Kapural (2010) conducted a retrospective survey to evaluate the safety of the MILD procedure in 90 consecutive patients with lumbar canal stenosis. Manual and electronic chart survey was conducted by 14 treating physicians located in 9 states within the United States. Complications and/or adverse events that occurred during or immediately following the procedure

prior to discharge were recorded. There were no major adverse events or complications related to the devices or procedure. No incidents of dural puncture or tear, blood transfusion, nerve injury, epidural bleeding or hematoma were observed. The authors concluded that MILD appears to be a safe procedure; however, additional studies are underway to establish complication frequency and longer-term safety. The study is limited by small sample, study design and lack of information on efficacy.

Spinal Stabilization

Dynamic stabilization system

Dynamic stabilization, also known as soft stabilization or flexible stabilization has been proposed as an adjunct or alternative to spinal fusion for the treatment of severe refractory pain due to degenerative spondylolisthesis, or continued severe refractory back pain following prior fusion, sometimes referred to as failed back surgery syndrome. Dynamic stabilization uses flexible materials rather than rigid devices to stabilize the affected spinal segment(s). These flexible materials may be anchored to the vertebrae by synthetic cords or by pedicle screws. Unlike the rigid fixation of spinal fusion, dynamic stabilization is intended to preserve the mobility of the spinal segment.

In a randomized controlled trial by Welch et al. (2007), the authors present the preliminary clinical outcomes of dynamic stabilization with the Dynesys spinal system as part of a multicenter randomized prospective Food and Drug Administration (FDA) investigational device exemption (IDE) clinical trial. This study included 101 patients from six IDE sites (no participants were omitted from the analysis) who underwent dynamic stabilization of the lumbar spine with the Dynesys construct. Patient participation was based on the presence of degenerative spondylolisthesis or retrolisthesis (Grade I), lateral or central spinal stenosis, and their physician's determination that the patient required decompression and instrumented fusion for one or two contiguous spinal levels between L-1 and S-1. Participants were evaluated preoperatively, postoperatively at 3 weeks, and then at 3-, 6-, and 12-month intervals. The 100-mm visual analog scale was used to score both lower limb and back pain. Patient functioning was evaluated using the Oswestry Disability Index (ODI), and the participants' general health was assessed using the Short Form-12 questionnaire. Overall patient satisfaction was also reported. One hundred one patients (53 women and 48 men) with a mean age of 56.3 years (range 27-79 years) were included. The mean pain and function scores improved significantly from the baseline to 12-month follow-up evaluation, as follows: leg pain improved from 80.3 to 25.5, back pain from 54 to 29.4, and ODI score from 55.6 to 26.3%.

The early clinical outcomes of treatment with Dynesys are promising, with lessening of pain and disability found at follow-up review. Dynesys may be preferable to fusion for surgical treatment of degenerative spondylolisthesis and stenosis because it decreases back and leg pain while avoiding the relatively greater tissue destruction and the morbidity of donor site problems encountered in fusion. However, long-term follow-up is still recommended. (Welch, 2007)

Stoll et al. (2002) conducted a clinical trial and is the largest of the three reviewed studies. Although these investigators enrolled 83 patients, only 39 (47%) of these patients had a diagnosis of degenerative spondylolisthesis, which was secondary. Primary indications for Dynesys device implantation were: spinal stenosis (60%), degenerative discopathy (24%), disc herniation (8%), revision surgery (6%), or not reported (1%). In addition to implantation of 1 or more Dynesys devices, 56 (75%) patients underwent direct decompression, 3 (4%) underwent nucleotomy, and 8 (10%) underwent other procedures that were not described. At a mean of 38 months after implantation, 8 (10%) patients had undergone implant removal, in some cases due to persistent pain. In the 73 patients who were available for follow-up, low-back pain on a 1 to 10 scale improved from 7.4 at baseline to 3.1 at final report. Likewise, Oswestry Disability Index scores improved from 55%to 23%. However, results were not reported separately for patients who had degenerative spondylolisthesis and 5 (6%) patients underwent additional procedures after Dynesys implantation including extension of implantation to an adjacent spinal level, decompression of an adjacent segment, spinal fusion, or laminectomy of the index segment.

The only available study in which all patients had degenerative spondylolisthesis was a clinical trial conducted by Schnake et al. (2006). These investigators enrolled 26 patients who had spinal stenosis that was treated with interlaminar decompression combined with implantation of a single Dynesys device. Outcomes were not reported for 1 (4%) patient who died of unrelated causes and 1 (4%) patient who fell and had a traumatic vertebral fracture. In the other 24 patients, pain on a 100-point scale improved from a mean score of 80 at baseline to a score of 23 at a mean of 26 months, a statistically significant difference (P<0.00001). Statistically significant improvements relative to baseline were also observed in mean walking distance, which improved from 250 meters to > 1000 meters (P<0.00001) and in number of patients using analgesics, which decreased from 19 to 6 (P<0.02). Of the 24 patients whose surgery outcomes were reported, 21 (88%) stated that they would undergo the operative procedure again. In spite of these improvements, the implant showed signs of failure in 4 (17%) patients, 5 (21%) patients still had claudication, 7 (29%) patients had degeneration of adjacent spinal segments, and mean overall spondylolisthesis increased by 2% (range 0% to 12%). Although this change in spondylolisthesis was not statistically significant, it did show a strong trend toward significance (P=0.056).

Scarfo and Muzii (2003) conducted a small, uncontrolled study of Dynesys device implantation for lumbar vertebral instability. These investigators enrolled 26 patients but 13 (50%) of these patients also underwent microsurgical decompression and only 14 (54%) of these patients had spondylolisthesis or pseudospondylolisthesis. Outcomes reported at an average of 24 months after surgery indicated that back pain ceased in 20 (77%) patients and decreased in the other 6 (23%) patients. Neurological symptoms decreased and nerve root pain disappeared; however, these improvements were not reported quantitatively. Moreover, pain and neurological outcomes do not seem to have been reported separately for patients with spondylolisthesis. Although standard radiographs indicated that spondylolisthesis disappeared in 9 (64%) patients and improved in the other 5 (36%), the extent of spondylolisthesis at baseline was not reported and it was not reported whether the overall improvement was statistically significant compared with baseline.

Results of these studies provide little evidence concerning the efficacy of the Dynesys Dynamic Stabilization System for degenerative spondylolisthesis. In all three available studies, 50% to 100% of the patients underwent surgical procedures other than Dynesys device implantation so it is not possible to determine which treatment effects could be attributed to the Dynesys device. Furthermore, in two of the reviewed studies, approximately half of the patients did not have spondylolisthesis and most or all of the outcomes were not reported separately for patients with and without spondylolisthesis. One of the three reviewed studies enrolled patients only if they had degenerative spondylolisthesis and this study found that overall, mean spondylolisthesis worsened by 2%. Although this change was not statistically significant, it did show a strong trend toward significance (Schnake, 2006). In contrast, an uncontrolled trial with a small number of patients who had spondylolisthesis and who underwent Dynesys device implantation reported that spondylolisthesis improved or disappeared in all patients; however, this study did not report the extent of spondylolisthesis at baseline, nor did it report whether improvements in spondylolisthesis were statistically significant (Scarfo, 2003). Controlled studies with adequate follow-up and thorough assessment of outcomes are needed to determine if the Dynesys Dynamic Stabilization System provides clinically significant benefits for patients who have degenerative spondylolisthesis.

A prospective case series by Kumar et al. (2008) of 32 patients who underwent the Dynesys procedure found that disc degeneration at the bridged and adjacent segment seems to continue despite Dynesys dynamic stabilization. This continuing degeneration could be due to natural disease progression.

Grob et al. (2005) reported on a retrospective case series involving 50 consecutive patients instrumented with Dynesys®. Patients were asked to respond to a questionnaire after Dynesys implantation, and 31 (64%) patients responded. After 2 years of follow-up, 19% were scheduled

for further surgical intervention. Only 50% of the patients indicated that the surgery had helped and improved overall quality of life and less than half reported improvement in functional capacity. The authors concluded that the results did not support the premise that semi-rigid fixation of the lumbar spine results in better patient-oriented outcomes than typical fusion.

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.

No practice guidelines or position statements from U.S. professional associations were found that recommend dynamic stabilization of the spine.

Total Facet Arthroplasty System™ (TFAS)
A clinical trial of the TFAS™ was initiated as a multi-center, randomized controlled clinical trial comparing the safety and efficacy of the TFAS™ to spinal fusion surgery in the treatment of moderate to severe degenerative lumbar spinal stenosis. The study planned to enroll 450 participants at approximately 20 investigative sites**.** The status of this study is unknown

Sacroplasty
The literature search identified a nonrandomized controlled study and 3 uncontrolled studies of percutaneous sacroplasty. Results of these studies provide preliminary evidence that percutaneous sacroplasty improves outcomes for patients who have sacral insufficiency fractures. The best evidence supporting use of this treatment was obtained in the nonrandomized controlled study and the largest available uncontrolled trial. Both of these studies enrolled patients who could not tolerate or failed to respond to conservative nonsurgical therapy. Comparing presurgery with postsurgery, percutaneous sacroplasty provided statistically significant reductions in pain and improvements in mobility and activities of daily living. Two smaller uncontrolled studies of percutaneous sacroplasty do not provide reliable evidence of efficacy since the investigators did not report whether patients underwent nonsurgical treatments for sacral insufficiency fractures before sacroplasty. Further controlled studies with long-term assessment of the results of percutaneous sacroplasty are needed to confirm that it is a safe and effective procedure for sacral insufficiency fractures (Hayes, 2009).

The only available controlled evaluation of percutaneous sacroplasty for sacral insufficiency fractures was a nonrandomized controlled study by Whitlow et al. (2007). For this study, 12 patients (1 man, 11 women; mean age 72±13 years; mean pain score 9.1) who had failure of conservative therapy underwent percutaneous sacroplasty and 21 patients (4 men, 17 women; mean age 74±13 years; mean pain score 9.1) underwent percutaneous vertebroplasty for vertebral fractures. There were no statistically significant differences between the sacroplasty group and the vertebroplasty group at baseline. At a mean of 21 months after treatment, mean pain scores had decreased to 3.1 for the sacroplasty group and 3 for the vertebroplasty group. Both procedures were associated with statistically significant decreases in pain compared with baseline (P<0.001); however, differences between the groups were not significant. Likewise, for measures of mobility and activities of daily living, statistically significant decreases were seen versus baseline for both procedures (P<0.001) but differences between the sacroplasty and vertebroplasty groups were not significant. The activities assessed were dressing, bathing, transferring to a chair, transferring to a bed, walking/moving, and housework/handiwork.

Facet Fusion
Gavaskar and Achimuthu (2010) conducted a prospective study of 30 patients with low-grade degenerative spondylolisthesis of the lumbar and lumbosacral spine who underwent facet fusion

using 2 cortical screws and local cancellous bone grafts. Visual analog scale and Oswestry disability assessment were used to measure outcomes which showed significant improvement at 1-year follow-up. The authors found that patients with degenerative spondylolisthesis with lower grade slips and normal anterior structures represent an ideal indication for facet fusion. The study is limited by short term follow-up, subjective outcomes and lack of comparison to other treatment modalities.

Park et al. (2002) studied 99 patients to assess the safety, efficacy, and complication rate associated with instrumented facet fusion of the lumbar and lumbosacral spine. Eighty-two patients underwent one-level fusion for degenerative spondylolisthesis and accompanying spinal canal stenosis (n=44) or recurrent disc herniation (n=38). Seventeen patients underwent two-level fusion for the treatment of either double instances of the above indications (n=7) or concurrent stenosis at the adjacent level (n=10). No complications were identified. The overall 2-year success rate of fusion was 96%; the success rates by fusion type were 99% in one-level fusions and 88% in two-level fusions. The authors concluded that instrumented facet fusion alone is a simple, safe, and effective surgical option for the treatment of patients with single-level disorders. The study is limited by lack of a control group for comparison to non-surgical options.

Evidence is limited primarily to case series and nonrandomized studies. No studies were found that discussed facet fusion when done alone without an accompanying decompressive procedure.

Professional Societies

American Association of Neurological Surgeons (AANS)

AANS published a technical assessment of TruFuse in 2009. The report concluded that there is insufficient objective information to evaluate the safety and utility of this device or to make recommendations regarding clinical usage.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

The FDA has approved numerous devices and instruments used in lumbar spinal fusion. Additional information, using product codes HRX, KWQ and MAX, is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Accessed October 31, 2013.

The FDA issued 510(k) approval (KI 12595) for the coflex-F Implant System on Feb 10, 2012. The coflex® Interlaminar Technology is an interlaminar functionally dynamic implant designed to impart a stabilization effect at the operative level(s). The coflex-F Implant System is a posterior, non-pedicle supplemental fixation device intended for use with an interbody cage as an adjunct to fusion at a single level in the lumbar spine (Li-SI). It is intended for attachment to the spinous processes for the purpose of achieving stabilization to promote fusion in patients with degenerative disc disease - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies - with up to Grade I spondylolisthesis. It consists of a single, Ushaped component, fabricated from medical grade titanium alloy (Ti6Al4V, per ASTM F136 and ISO 5832-3). In clinical use, the “U” is positioned horizontally, with its apex oriented anteriorly and the two long arms of the “U” paralleling the long axis of the spinal processes. The bone-facing surfaces are ridged to provide resistance to migration.

The FDA issued 510(k) approval (K050965) for the TranS1 AxiaLIF System on June 14, 2005. AxiaLIF is an anterior spinal fixation device intended for patients requiring spinal fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (Grade I or 2), or degenerative disc disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is not intended to treat severe scoliosis, severe spondylolisthesis (Grades 3 and 4), tumor or trauma. Its usage is limited to anterior supplemental fixation of the lumbar spine at L5-SI in conjunction with legally marketed facet and pedicle screw systems. 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.

Additional 510K approvals were received on January 11, 2008 (K073514) and April 28, 2008 (K073643). See the following web site for more information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Accessed October 31, 2013.

On March 14, 2011, the TranS1 AxiaLIF Plus (TranS1 Inc.) received FDA 510(k) clearance (K102334). According to the clearance summary: "…Indications and Intended use: TranS1 AxiaLIF® Plus System is intended to provide anterior stabilization of the L-5-S1 or L4-S1 spinal segment(s) as an adjunct to spinal fusion. The AxiaLIF® Plus System is indicated for patients requiring fusion to treat pseudoarthrosis (unsuccessful previous fusion) spinal stenosis, spondylolisthesis (Grade 1 or 2 if single-level; Grade 1 if two-level), or degenerative disc disease as defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic Studies, Its usage is limited to anterior supplemental Fixation of the lumbar spine at L-5-S1 or L-4-S1 in conjunction with use of legally marketed facet screw or pedicle screw systems at the same levels that are treated with AxiaLIF. Device Description: The TranS1® AxiaLIF® Plus system is a multi-component system including titanium alloy implantable devices and instrumentation made of titanium alloy and stainless steel. This device includes instruments for creating a small pre-sacral axial track to the L-5-S1 or L4-S1 disc space(s). The device's instruments are used for independently distracting the L-5-S1 or L4-S1 vertebral bodies and inserting bone graft material (DBM, autograft or autologous blood) into the disc space. The device includes an anterior fixation rod that is implanted through the same approach and is used to lock the construct together…"

On October 9, 2009, the FDA has issued 210(k) approval (K091623) for the NuVasive Laminoplasty Fixation System. The device is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The Laminoplasty Fixation System is used to hold the allograft material in place in order to prevent the allograft material from expulsion, or impinging the spinal cord. Additional information (product code NQW) is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf9/K091623.pdf. Accessed October 31, 2013.

The FDA regulates the X-STOP IPD System as a spinous process spacer/plate prosthesis. It received premarket approve (PMA) on November 21, 2005. No spinous process spacer/plate prosthesis other than the X-STOP IPD System has been approved by the FDA.

As stated in labeling approved by the FDA, the X-STOP implant is indicated for treatment of patients aged 50 or older suffering from pain or cramping in the legs (neurogenic intermittent claudication) secondary to a confirmed diagnosis of lumbar spinal stenosis. The X-STOP is indicated for those patients with moderately impaired physical function who experience relief in flexion from their symptoms of leg/buttock/groin pain, with or without back pain, and have undergone a regimen of at least 6 months of nonoperative treatment. The X-STOP may be implanted at one or two lumbar levels. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf4/P040001b.pdf. Accessed October 31, 2013.

The mild® tool kit (Vertos Medical) initially received 510(k) marketing clearance as the X-Sten MILD Tool Kit (X-Sten Corp.) from the U.S. Food and Drug Administration (FDA) in 2006, with intended use as a set of specialized surgical instruments to be used to perform percutaneous lumbar decompressive procedures for the treatment of various spinal conditions.

Vertos mild® instructions for use state that the devices are not intended for disc procedures but rather for tissue resection at the perilaminar space, within the interlaminar space and at the

ventral aspect of the lamina. These devices are not intended for use near the lateral neural elements and remain dorsal to the dura using image guidance and anatomical landmarks.

The DSS Stabilization System (Paradigm Spine, LLC) received 501(k) approval on May 2, 2008 as a Class III device. The rigid design, to be used with autograft and/or allograft, is intended as a single-level system for non-cervical pedicle fixation from the T4 to S1 vertebrae in skeletally mature patients to help provide immobilization and stabilization of spinal segments, as an adjunct to fusion. The slotted design is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities' of the thoracic, lumbar, and sacral spine. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf9/K090099.pdf. Accessed October 31, 2013.

The Dynesys Dynamic Stabilization System is classified by the FDA as a posterior metal/polymer spinal fusion system and it is regulated by the FDA as a Class II device. The Dynesys System received 510(k) approval on March 5, 2004 (Centerpulse Spine-Tech Inc., d/b/a Zimmer Spine; Minneapolis, MN). Zimmer acquired Centerpulse in October 2003. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf3/K031511.pdf. Accessed November 16, 2012.

The 510(k) approval letter from the FDA to Zimmer Spine was dated March 11, 2005. The indications of use for the Dynesys® Spinal System (#K043565) are as follows:
When used as a pedicle screw fixation system in skeletally mature patients, the Dynesys Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: Degenerative spondylolisthesis with objective evidence of neurologic impairment, and failed previous fusion (pseudarthrosis). Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf4/K043565.pdf. Accessed October 31, 2013.

In addition, when used as a pedicle screw fixation system, the Dynesys Spinal System is indicated for use in patients:

- Who are receiving fusions with autogenous graft only;
- Who are having the device fixed or attached to the lumbar or sacral spine;
- Who are having the device removed after the development of a solid fusion mass.

The Total Facet Arthroplasty System™ (Archus Orthopedics, Inc.) device is currently limited by the FDA to investigational use within the U.S.

Percutaneous sacroplasty involves injection of polymethylmethacrylate (PMMA) bone cement to repair the fracture. This type of cement is regulated as a Class II (moderate risk) device that is regulated via the FDA 510(k) process. Although the list of commercially available PMMA bone cements is too extensive for inclusion here, a recently approved cement that appears suitable for sacroplasty is Vertaplex Radiopaque Bone Cement (Stryker Instruments) (K072118), which was approved for vertebroplasty on December 7, 2007. See the following Web site for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf7/K072118.pdf. Accessed October 31, 2013.

Facet fusion systems include TruFuse and NuFix which the FDA classifies as biologics. Additional information is available at:
http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm. Accessed October 31, 2013.

Additional Medical Products
Spinal fusion: Atavi, MaXcess System, PathFinder

Cages - BAK Interbody Fusion System, INTERFIX RP, INFUSE Bone Graft/LT-CAGE, Lumbar I/F Cage, Ray TFC

Spinal Decompression and Stabilization: BioFlex System with Nitinol spring rod and memory loops; FASS (Fulcrum Assisted Soft Stabilization); Fixcet Spinal Facet Screw System; REVERE™ Stabilization System; Graf ligament Leeds-Keio Ligamentoplasty Loop system; NFlex™ Controlled Motion System (indicated for non-fusion only); Stabilmax NZ® Dynamic Spine Stabilization System; The X10 CROSSLINK® Plate Spinal System, ZYFUSE; OsteoLock; and FacetLinx.

The CoRoent interbody implant is also required for XLIF. The most recent version of this implant, the CoRoent No-Profile System, was cleared for marketing in 2011. According to FDA 510(k) documentation,

The CoRoent No-Profile System is a standalone system indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2 to S I). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved level(s). The CoRoent No-Profile System is intended for use with autograft. Patients must have undergone a regimen of at least six months of non-operative treatment prior to being treated with the CoRoent No-Profile System.

There are several spinal decompression devices such as The Wallis® System (Abbott Spine); the DIAM™ Spinal Stabilization System; and the ExtendSure (NuVasive) are used in Europe but are not currently FDA approved.

Stabilimax NZ: 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.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for spinal fusion procedures using the following methods: extreme lateral interbody fusion (XLIF) or direct lateral interbody fusion (DLIF), laparoscopic anterior lumbar interbody fusion (LALIF), transforaminal lumbar interbody fusion (TLIF) and the axial lumbar interbody fusion (AxiaLIF). Local Coverage Determinations (LCDs) do exist. Refer to the LCDs for Lumbar Spinal Fusion for Instability and Degenerative Disc Conditions, Category III CPT Codes, Non-Covered Category III CPT Codes, Noncovered Services and Services That Are Not Reasonable and Necessary.

Medicare does not have a National Coverage Determination (NCD) for spinal decompression procedures using interspinous process decompression (IPD) systems (i.e. X-STOP®) and minimally invasive lumbar decompression (MILD) methods. Local Coverage Determinations (LCDs) do exist. Refer to the LCDs for Interspinous Process Decompression, Category III CPT Codes and Services That Are Not Reasonable and Necessary. Local Coverage Articles (LCAs) do exist. Refer to the LCA for X STOP® Interspinous Process Decompression System.

Medicare does not have a National Coverage Determination (NCD) for spinal stabilization systems, total facet joint arthroplasty, facetectomy, laminectomy, foraminotomy, vertebral column fixation and percutaneous sacral augmentation (sacroplasty). Local Coverage Determinations (LCDs) do exist. Refer to the LCDs for Noncovered Services, Vertebroplasty, Vertebral

Augmentation; Percutaneous, Vertebroplasty/Vertebral Augmentation, Category III CPT Codes , Services That Are Not Reasonable and Necessary, Non-Covered Category III CPT Codes, Surgery: Vertebral Augmentation Procedures (VAPs) and Non-Covered Services.

Medicare does not have a National Coverage Determination (NCD) for stand-alone facet fusion without accompanying decompressive procedures. Local Coverage Determinations (LCDs) do exist. Refer to the LCDs for Category III CPT Codes, Noncovered Services and Non-Covered Services.

(Accessed November 14, 2013)

APPLICABLE CODES

The codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit document. This list of codes may not be all inclusive.

CPT® Code	Description
22100	Partial excision of posterior vertebral component (e.g., spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; cervical
22101	Partial excision of posterior vertebral component (e.g., spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; thoracic
22102	Partial excision of posterior vertebral component (e.g., spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; lumbar
22103	Partial excision of posterior vertebral component (e.g., spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; each additional segment (List separately in addition to code for primary procedure)
22110	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; cervical
22112	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; thoracic
22114	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; lumbar
22116	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; each additional vertebral segment (List separately in addition to code for primary procedure)
22206	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (eg, pedicle/vertebral body subtraction); thoracic
22207	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (eg, pedicle/vertebral body subtraction); lumbar
22208	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (eg, pedicle/vertebral body subtraction); each additional vertebral segment (List separately in addition to code for primary procedure)
22210	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; cervical

CPT® Code	Description
22212	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; thoracic
22214	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; lumbar
22216	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; each additional vertebral segment (List separately in addition to primary procedure)
22220	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; cervical
22222	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; thoracic
22224	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; lumbar
22226	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; each additional vertebral segment (List separately in addition to code for primary procedure)
22532	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic
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)
22548	Arthrodesis, anterior transoral or extraoral technique, clivus-C1-C2 (atlas-axis), with or without excision of odontoid process
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for separate procedure)
22554	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2
22556	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic
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)
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace
22590	Arthrodesis, posterior technique, craniocervical (occiput-C2)
22595	Arthrodesis, posterior technique, atlas-axis (C1-C2)
22600	Arthrodesis, posterior or posterolateral technique, single level; cervical below C2 segment
22610	Arthrodesis, posterior or posterolateral technique, single level; thoracic (with lateral transverse technique, when performed)

CPT® Code	Description
22612	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)
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)
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar
22634	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; each additional interspace and segment (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
22818	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); single or 2 segments
22819	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); 3 or more segments
22830	Exploration of spinal fusion
22840	Posterior non-segmental instrumentation (e.g., Harrington rod technique, pedicle fixation across 1 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 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 (e.g., pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments (List separately in addition to code for primary procedure)

CPT® Code	Description
22844	Posterior segmental instrumentation (e.g., 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)
22848	Pelvic fixation (attachment of caudal end of instrumentation to pelvic bony structures) other than sacrum (List separately in addition to code for primary procedure)
22849	Reinsertion of spinal fixation device
22850	Removal of posterior nonsegmental instrumentation (e.g., Harrington rod)
22851	Application of intervertebral biomechanical device(s) (e.g., synthetic cage(s), methylmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure)
22852	Removal of posterior segmental instrumentation
22855	Removal of anterior instrumentation
22899	Unlisted procedure, spine
63001	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), 1 or 2 vertebral segments; cervical
63003	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), 1 or 2 vertebral segments; thoracic
63005	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), 1 or 2 vertebral segments; lumbar, except for spondylolisthesis
63011	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), 1 or 2 vertebral segments; sacral
63012	Laminectomy with removal of abnormal facets and/or pars inter-articularis with decompression of cauda equina and nerve roots for spondylolisthesis, lumbar (Gill type procedure)
63015	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), more than 2 vertebral segments; cervical
63016	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), more than 2 vertebral segments; thoracic
63017	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), more than 2 vertebral segments; lumbar
63020	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, including open and endoscopically-assisted approaches; 1 interspace, cervical
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, including open and endoscopically-assisted approaches; 1 interspace, lumbar

CPT® Code	Description
63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, including open and endoscopically-assisted approaches; each additional interspace, cervical or lumbar (List separately in addition to code for primary procedure)
63040	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; cervical
63042	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; lumbar
63043	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional cervical interspace (List separately in addition to code for primary procedure)
63044	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional lumbar interspace (List separately in addition to code for primary procedure)
63045	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; cervical
63046	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; thoracic
63047	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; lumbar
63048	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; each additional segment, cervical, thoracic, or lumbar (List separately in addition to code for primary procedure)
63050	Laminoplasty, cervical, with decompression of the spinal cord, 2 or more vertebral segments;
63055	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (e.g., herniated intervertebral disk), single segment; thoracic
63056	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (e.g., herniated intervertebral disk), single segment; lumbar (including transfacet, or lateral extraforaminal approach) (e.g., far lateral herniated intervertebral disk)
63057	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (e.g., herniated intervertebral disk), single segment; each additional segment, thoracic or lumbar (List separately in addition to code for primary procedure)
63064	Costovertebral approach with decompression of spinal cord or nerve root(s), (e.g., herniated intervertebral disk), thoracic; single segment
63066	Costovertebral approach with decompression of spinal cord or nerve root(s), (e.g., herniated intervertebral disk), thoracic; each additional segment (List separately in addition to code for primary procedure)

CPT® Code	Description
63075	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, single interspace
63076	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, each additional interspace (List separately in addition to code for primary procedure)
63077	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; thoracic, single interspace
63078	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; thoracic, each additional interspace (List separately in addition to code for primary procedure)
63081	Vertebral corpectomy (vertebral body resection), partial or complete, anterior approach with decompression of spinal cord and/or nerve root(s); cervical, single segment
63082	Vertebral corpectomy (vertebral body resection), partial or complete, anterior approach with decompression of spinal cord and/or nerve root(s); cervical, each additional segment (List separately in addition to code for primary procedure)
63085	Vertebral corpectomy (vertebral body resection), partial or complete, transthoracic approach with decompression of spinal cord and/or nerve root(s); thoracic, single segment
63086	Vertebral corpectomy (vertebral body resection), partial or complete, transthoracic approach with decompression of spinal cord and/or nerve root(s); thoracic, each additional segment (List separately in addition to code for primary procedure)
63087	Vertebral corpectomy (vertebral body resection), partial or complete, combined thoracolumbar approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic or lumbar; single segment
63088	Vertebral corpectomy (vertebral body resection), partial or complete, combined thoracolumbar approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic or lumbar; each additional segment (List separately in addition to code for primary procedure)
63090	Vertebral corpectomy (vertebral body resection), partial or complete, transperitoneal or retroperitoneal approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic, lumbar, or sacral; single segment
63091	Vertebral corpectomy (vertebral body resection), partial or complete, transperitoneal or retroperitoneal approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic, lumbar, or sacral; each additional segment (List separately in addition to code for primary procedure)
63101	Vertebral corpectomy (vertebral body resection), partial or complete, lateral extracavitary approach with decompression of spinal cord and/or nerve root(s) (e.g., for tumor or retropulsed bone fragments); thoracic, single segment
63102	Vertebral corpectomy (vertebral body resection), partial or complete, lateral extracavitary approach with decompression of spinal cord and/or nerve root(s) (e.g., for tumor or retropulsed bone fragments); lumbar, single segment
63103	Vertebral corpectomy (vertebral body resection), partial or complete, lateral extracavitary approach with decompression of spinal cord and/or nerve root(s) (e.g., for tumor or retropulsed bone fragments); thoracic or lumbar, each additional segment (List separately in addition to code for primary procedure)

CPT® Code	Description
63170	Laminectomy with myelotomy (e.g., Bischof or DREZ type), cervical, thoracic, or thoracolumbar
63172	Laminectomy with drainage of intramedullary cyst/syrinx; to subarachnoid space
63173	Laminectomy with drainage of intramedullary cyst/syrinx; to peritoneal or pleural space
63180	Laminectomy and section of dentate ligaments, with or without dural graft, cervical; 1 or 2 segments
63182	Laminectomy and section of dentate ligaments, with or without dural graft, cervical; more than 2 segments
63185	Laminectomy with rhizotomy; 1 or 2 segments
63190	Laminectomy with rhizotomy; more than 2 segments
63191	Laminectomy with section of spinal accessory nerve
63194	Laminectomy with cordotomy, with section of 1 spinothalamic tract, 1 stage; cervical
63195	Laminectomy with cordotomy, with section of 1 spinothalamic tract, 1 stage; thoracic
63196	Laminectomy with cordotomy, with section of both spinothalamic tracts, 1 stage; cervical
63197	Laminectomy with cordotomy, with section of both spinothalamic tracts, 1 stage; thoracic
63198	Laminectomy with cordotomy with section of both spinothalamic tracts, 2 stages within 14 days; cervical
63199	Laminectomy with cordotomy with section of both spinothalamic tracts, 2 stages within 14 days; thoracic
63200	Laminectomy, with release of tethered spinal cord, lumbar
63250	Laminectomy for excision or occlusion of arteriovenous malformation of spinal cord; cervical
63251	Laminectomy for excision or occlusion of arteriovenous malformation of spinal cord; thoracic
63252	Laminectomy for excision or occlusion of arteriovenous malformation of spinal cord; thoracolumbar
63265	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; cervical
63267	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar
63268	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; sacral
63270	Laminectomy for excision of intraspinal lesion other than neoplasm, intradural; cervical
63271	Laminectomy for excision of intraspinal lesion other than neoplasm, intradural; thoracic
63272	Laminectomy for excision of intraspinal lesion other than neoplasm, intradural; lumbar
63286	Laminectomy for biopsy/excision of intraspinal neoplasm; intradural, intramedullary, thoracic
63300	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; extradural, cervical
63301	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; extradural, thoracic by transthoracic approach
63302	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; extradural, thoracic by thoracolumbar approach

CPT® Code	Description
63303	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; extradural, lumbar or sacral by transperitoneal or retroperitoneal approach
63304	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; intradural, cervical
63305	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; intradural, thoracic by transthoracic approach
63306	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; intradural, thoracic by thoracolumbar approach
63307	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; intradural, lumbar or sacral by transperitoneal or retroperitoneal approach
63308	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; each additional segment (List separately in addition to codes for single segment)

CPT® Code (Unproven)	Description
0171T	Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; single level
0172T	Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; each additional level (List separately in addition to code for primary procedure)
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 procedure)
0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device (if utilized), one or more needles
0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device (if utilized), two or more needles
0202T	Posterior vertebral joint(s) arthroplasty (e.g., facet joint[s] replacement) including facetectomy, laminectomy, foraminotomy and vertebral column fixation, with or without injection of bone cement, including fluoroscopy, single level, lumbar spine
0219T	Placement of a 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 a 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 a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; lumbar

CPT® Code (Unproven)	Description
0222T	Placement of a 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)
0274T	Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; cervical or thoracic
0275T	Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar
0309T	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft, when performed, lumbar, L4-L5 interspace (List separately in addition to code for primary procedure)

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
05/01/2014	• Replaced references to "MCG™ Care Guidelines, 17th edition, 2013" with "MCG™ Care Guidelines, 18th edition, 2014" (effective 05/01/14) • Archived previous policy version 2014T0547G