Minimally Invasive Spine Surgery Procedures ~~Surgical Treatment for Spine Pain~~ (for Louisiana Only)

Policy Number: ~~CS115LA.X~~ **CS364LA.A**
Effective Date: ~~July 1, 2022~~**TBD**

➲ Instructions for Use

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Application

This Medical Policy only applies to the state of Louisiana.

Coverage Rationale

~~**Spinal procedures for the treatment of spine pain are proven and medically necessary in certain circumstances.**~~

~~For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures:~~

- ~~Decompression +/- Fusion, Cervical~~
- ~~Decompression +/- Fusion, Lumbar~~
- ~~Decompression +/- Fusion, Thoracic~~
- ~~Fusion, Cervical Spine~~
- ~~Fusion, Lumbar Spine~~
- ~~Fusion, Thoracic Spine~~

~~Click here to view the InterQual® criteria.~~

~~**The following techniques for lumbar interbody fusion (LIF) are proven and medically necessary:**~~

- ~~Anterior LIF (ALIF) including lateral approaches [e.g., extreme lateral interbody fusion (XLIF®), Direct Lateral Interbody Fusion (DLIF)]~~

- ~~Posterior LIF (PLIF), including Transforaminal Lumbar Interbody Fusion (TLIF)~~

The following spinal procedures are unproven and not medically necessary due to insufficient evidence of efficacy: ~~(this includes procedures that utilize interbody cages, screws, and pedicle screw fixation devices):~~

- **Axial Lumbar Interbody Fusion (AxiaLIF®), a percutaneous pre-sacral access route to the L5 - S1 vertebral bodies**
- **Percutaneous image-guided lumbar decompression (PILD)**
- **Percutaneous sacral augmentation (sacroplasty) with or without a balloon or bone cement**
- **Automated percutaneous and percutaneous endoscopic discectomy (APLD) for intervertebral disc decompression**
- **Minimally Invasive Lumbar Decompression (mild®)**
- Laparoscopic Anterior Lumbar Interbody Fusion (LALIF)
- Transforaminal Lumbar Interbody Fusion (TLIF) which utilizes only endoscopy visualization (such as a percutaneous incision with video visualization)
- ~~Axial Lumbar Interbody Fusion (AxiaLIF®)~~
- ~~Interlaminar Lumbar Instrumented Fusion (ILIF)~~
- ~~Spinal decompression and Interspinous Process Decompression systems for the treatment of Lumbar Spinal Stenosis [e.g., Interspinous Process Decompression (IPD), Minimally Invasive Lumbar Decompression (mild®)]~~
- ~~Spinal Stabilization systems:~~
  - ~~Stabilization systems for the treatment of degenerative Spondylolisthesis~~
  - ~~Total Facet Joint Arthroplasty, including facetectomy, laminectomy, foraminotomy, vertebral column fixation~~
  - ~~Percutaneous sacral augmentation (Sacroplasty) with or without a balloon or bone cement for the treatment of back pain~~
- ~~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~~

~~Documentation Requirements~~

~~Provide medical notes documenting the following:~~

- ~~Condition requiring procedure~~
- ~~History and co-morbid medical condition(s)~~
- ~~Member's symptoms, pain, location, and severity including functional impairment that is interfering with activities of daily living (meals, walking, getting dressed, driving)~~
- ~~Failure of Conservative Therapy through lack of clinically significant improvement between at least two measurements, on a validated pain or function scale or quantifiable symptoms despite concurrent Conservative Therapies (see definition), if applicable~~
- ~~Progressive deficits with clinically significant worsening based on at least two measurements over time, if applicable~~
- ~~Disabling Symptoms~~, if applicable

- ~~Specific diagnostic image(s) that shows the abnormality for which surgery is being requested which may include MRI, CT scan, X-ray, and/or bone scan; consultation with requesting surgeon may be needed to select the optimal image(s)~~
  ~~**Note:**~~
  - ~~Diagnostic images must be labeled with the:~~
    - ~~Date taken~~
    - ~~Applicable case number obtained at time of notification, or the member's name and ID number on the image(s)~~
  - ~~Submission of diagnostic imaging is required via the external portal at www.uhcprovider.com/paan; faxes will not be accepted~~
- ~~Diagnostic image(s) report(s)~~
- ~~Physical exam, including neurologic exam, including degree and progression of curvature (for scoliosis), if applicable~~
- ~~Whether the surgery will be performed with direct visualization or only with endoscopic visualization~~
- ~~Complete report(s) of diagnostic tests~~
- ~~Describe the surgical technique(s) planned [e.g., AxiaLIF®, XLIF, ILIF, OLIF, LALIF, image-guided minimally invasive lumbar decompression (mild®), percutaneous endoscopic discectomy with or without laser, etc.]~~

Definitions

Automated Percutaneous Lumbar Discectomy (APLD): Is a minimally invasive surgical technique for treatment of herniated lumbar intervertebral discs. For this procedure, a thin, blunt-tipped suction and cutting probe is inserted through the skin, and the end of the probe is placed into the middle of the herniated disc under fluoroscopic guidance. This device is then used to remove some or all of the degenerated portion of the center of the disc. The goal of this procedure is to relieve pressure on nerve roots without damaging surrounding tissues, thereby minimizing postoperative complications and morbidity. APLD is intended as an alternative to chemonucleolysis, open discectomy, or other types of percutaneous discectomy for individuals who have a relatively small degree of lumbar disc protrusion without fragmentation or complete extrusion of disc material and who have failed conservative therapy. (Vertos Medical, 2018)

~~**Anterior Lumbar Spine Surgery:** Performed by approaching the spine from the front of the body using a traditional front midline incision (i.e., through the abdominal musculature and retroperitoneal cavity) or by lateral approaches from the front side of the body (e.g., eXtreme lateral interbody fusion [XLIF]; direct interbody fusion [DLIF]; oblique interbody fusion [OLIF]).~~

~~**Arthrodesis:** A surgical procedure to eliminate motion in a joint by providing a bony fusion. The procedure is used for several specific purposes: to relieve pain; to provide stability; to overcome postural deformity resulting from neurologic deficit; and to halt advancing disease.~~

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) **s**~~S~~pinal **f**~~F~~usions. 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 (Cragg, et al., 2004).

Endoscope: A thin, fiberoptic tube with a light and lens, used to examine the interior of the patient's body; provides minimally invasive access for diagnostic and surgical procedures. (AANS, 2022)

~~**Conservative Therapy:** Consists of an appropriate combination of medication (i.e., NSAIDs, analgesics, etc.) in addition to physical therapy, spinal manipulation therapy, cognitive behavioral therapy (CBT) or other interventions based on the individual's specific presentation, physical findings, and imaging results (AHRQ 2013; Qaseem 2017; Summers 2013).~~

~~**Direct Lateral Interbody Fusion (DLIF):** Uses a similar approach as XLIF. 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. 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).~~

~~**Disabling Symptoms:** Are defined as in a pivotal study demonstrating benefit of surgery (Weinstein, 2009) where the participants with an Oswestry Disability Index score of more than 8, or an SF-36 Bodily Pain Score of less than 70 or a Physical Function Score of less than 78 were the ones that demonstrated benefit. These scores are equal to or more severe than the majority of participants, meaning those participants within two standard deviations (+ /-) of the mean for such scores.~~

~~**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.~~

Endoscopic Discectomy: Involves the percutaneous placement of a working channel under image guidance, followed by visualization of the working space and instruments through an endoscope, and aspiration of disc material. (Vertos Medical, 2018)

Fluoroscopy: Imaging technique to obtain real-time moving images of the internal structures of the body; this imaging uses an x-ray source and fluorescent screen; modern fluoroscopes couple the screen to an x-ray image intensifier and video camera allowing the images to be recorded and shown on a monitor. (Vertos Medical, 2018)

~~**Facet Arthroplasty:** The implantation of a spinal prosthesis to restore posterior element structure and function, as an adjunct to neural decompression.~~

~~**Facet Fusion:** A minimally invasive back procedure that uses specially designed bone dowels made from allograft material (donated cortical bone) that are inserted into the~~

~~facet joints. The procedure is designed to stop facet joints from moving and is intended to eliminate or reduce back pain caused by facet joint dysfunction (Gellhorn, 2013).~~

~~**Facet Syndrome:** A condition in which arthritic change and inflammation occur and the nerves to the facet joints convey severe and diffuse pain.~~

Image-Guided Minimally Invasive Lumbar Decompression (~~M~~mild®): A percutaneous procedure for decompression of the central spinal canal in individuals with ~~L~~llumbar ~~S~~sspinal ~~S~~sstenosis. In this procedure, a specialized cannula and surgical tools are used under fluoroscopic guidance for bone and tissue sculpting near the spinal canal (Vertos Medical, 2018).

Interbody Fusion: A surgical procedure that fuses 2 adjacent vertebral bodies of the spine. Lumbar interbody fusion may be performed in patients with spinal stenosis and instability, spondylolisthesis, scoliosis, following a discectomy, or for adjacent-level disc disease. (Ortho Info, 2021)

Interlaminar Lumbar Instrumented Fusion (ILIF): During the ILIF procedure, the surgeon makes an incision in the lower back and an opening is created through the ligaments. This allows access to the spinous processes. The bone, ligament or disc that is causing compression is removed to release pressure on the nerves. Allograft bone may be placed in the disc space. Bone, either autograft and / or allograft, is placed between the spinous processes and on the remaining lamina. An implant is inserted to stabilize the spine and secure the spinous processes until the fusion takes place**. (Veritas Health, 2022)**

~~**Interlaminar Stabilization Device:** An implantable titanium interspinous process device (IPD) that reduces the amount of lumbar spinal extension possible while preserving range of motion in flexion, axial rotation, and lateral bending. CoFlex® is a U-shaped device with two pair of serrated wings extending from the upper and lower long arms of the U. The U portion is inserted horizontally between two adjacent spinous processes (bones) in the back of the spine, and the wings are crimped over bone to hold the implant in place. The device is implanted after decompression of stenosis at the affected level(s) (Paradigm Spine, 2013).~~

~~**Interspinous Process Decompression (IPD):** Minimally invasive surgical procedure used to treat Lumbar Spinal Stenosis when conservative treatment measures have failed to relieve symptoms. IPD involves surgically implanting a spacer between one or two affected spinous processes of the lumbar spine. After implantation the device is opened or expanded to distract (open) the neural foramen and decompress the nerves. Spacers are implanted midline between adjacent lamina and spinous processes to provide dynamic stabilization following decompressive surgery. IPD is purported to block stenosis-related lumbar extension and, thus, relieve associated pain and allow resumption of normal posture.~~

Laparoscopic Anterior Lumbar Interbody Fusion (LALIF): Minimally invasive alternative to an open surgical approach to ~~S~~sspinal f~~F~~fusion. The vertebrae are reached through an incision in the lower abdomen or side. This method employs a laparoscope to remove the diseased disc and insert an implant (i.e., rhBMP, autogenous bone, cages, or fixation devices) into the disc space intended to stabilize and promote fusion**. (Veritas Health, 2022)** ~~.~~

~~**Lumbar Spinal Stenosis (LSS):** Narrowing or constriction of the lumbar spinal canal that may result in painful compression of a nerve and/or blood vessel(s) supplying the nerve.~~

~~**Neurogenic Claudication (also known as Pseudoclaudication):** A common indicator of lumbar spinal stenosis caused by an inflamed nerve coming from the spinal column. Symptoms include the sensation of pain in the buttock, thigh, or leg or weakness in the legs that is relieved with a change in position or leaning forward and improves with rest (Ammendolia, 2014).~~

~~**Note:** Neurogenic claudication should be differentiated from vascular claudication.~~ **Nucleoplasty: Also known as percutaneous disc decompression (PDD) or percutaneous plasma discectomy] uses x-ray images (fluoroscopy) for guidance to insert a specialized catheter to reach the disc nucleus. Radiofrequency energy is used to ablate nuclear material and create small channels within the disc. This is thought to decompress the disc, reducing the pressure both inside the disc and on nerve roots.**

Open Spine Surgery: Unlike the minimally invasive approach, traditional open spinal surgery relies on longer skin incisions and more extensive tissue dissection to expose the surgical field.

Percutaneous Endoscopic Lumbar Diskectomy (PELD): PELD is a minimally invasive procedure in which indirect access to the herniated disc is made under fluoroscopic guidance using an endoscope and specialized instruments ; removal of the disc occurs using laser or other mechanical means. (Veritas Health, 2022)

Percutaneous or Endoscopic Lumbar Fusion: During a percutaneous endoscopic procedure the surgeon does not have direct visualization of the operative field, in contrast to an open approach. Visual guidance is obtained using either fluoroscopy or a video monitor. Specialized instruments are typically used and advanced through a retractor, avoiding major soft tissue injury. The approach is associated with a steep learning curve, risk of radicular trauma with insertion of cages, and in some cases postoperative migration of the devices. **(Veritas Health, 2022)**

Percutaneous image-guided lumbar decompression (PILD): A posterior decompression of the lumbar spine performed under indirect image guidance without any direct visualization of the surgical area. (Veritas Health, 2022)

Posterior Lumbar Spine Surgery: Performed by approaching the spine through the individual's back by a traditional back midline incision or transforaminally through the opening between two spinal vertebrae (i.e., the foramen) where the nerves leave the spinal canal to enter the body (i.e., Transforaminal Lumbar Interbody Fusion [TLIF]) ~~.~~(Veritas Health, 2022)

Presacral: Anterior to the sacrum. (Ortho Info, 2021)

~~**Progressive:** Significant worsening of deficits or symptoms based on at least two measurements over days or weeks (rapidly progressive) or over months (progressive) on a validated pain or function scale or quantifiable symptoms.~~

~~**Radicular Pain:** Pain which radiates from the spine into the extremity along the course of the spinal nerve root. The pain should follow the pattern of a dermatome associated with the irritated nerve root identified (Lenahan, 2018).~~

- ~~Presenting symptoms should include a positive nerve root tension sign (positive straight leg raise test or femoral tension sign), or a reflex (asymmetric depressed reflex), sensory (asymmetric decreased sensation in a dermatomal distribution), or~~

~~motor (asymmetric weakness in a myotomal distribution) deficit that correspond to the specific affected nerve root. (Birkmeyer, 2002).~~

- ~~As surgery is meant to relieve radicular pain from nerve root compression, imaging should show compression of the corresponding nerve root.~~

Sacroplasty: A minimally invasive surgical treatment that attempts to repair sacral insufficiency fractures using bone cement. Sacral insufficiency fractures have traditionally been treated with conservative measures, including bed rest, analgesics, orthoses/corsets, and physical therapy. In some cases, pain persists and is refractory to these measures. For this procedure, two 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, 2018**; updated January 2021**).

~~**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.~~

~~**Spinal Instability of the Lumber Spine:**~~

- ~~Spinal instability is documented by at least 4 mm of translation or 10 degrees of angular motion on dynamic imaging (flexion – extension x-ray). Iatrogenic instability can be created by the disruption of the anterior spinal column or posterior elements when complete excision of one facet is performed or when bilateral facet joint excision is in excess of 50%.~~
- ~~Spinal instability could result in neurological deficit or pain referable to the site of instability.~~

~~**Spinal Stabilization:** These spinal devices are fixed in place using pedicle screws which are attached to the vertebral bodies adjacent to the intervertebral space being fused. Unlike standard frames, these devices are designed using flexible materials which purport to stabilize the joint while still providing some measure of flexibility.~~

~~**Spondylolisthesis:** An acquired condition that involves the anterior displacement of one vertebral segment over subjacent vertebrae (NASS, 2014a). The causes can be congenital, due to stress fractures, facet degeneration, injury, or after decompression surgery. The condition may be asymptomatic or cause significant pain and nerve-related symptoms. If the slippage occurs backwards, it is referred to as retrolisthesis and lateral slippage is called listhesis (NASS, 2014a). Listhesis demonstrated on imaging is considered clinically significant (as opposed to a normal age-related change without clinical implication) if sagittal plane displacement is at least 3 mm on flexion and extension views or relative sagittal plane angulation greater than 11 degrees. (Chogawala et al, 2016).~~

~~**Spondylolysis:** A bone defect in the pars interarticularis; the isthmus or bone bridges between the inferior and superior articular surfaces of the neural arch of single vertebrae, most often the result of a stress fracture nonunion. The condition is an acquired condition, occurs commonly at a young age and may occur with or without Spondylolisthesis. The main presenting symptom is back pain which is often children~~

~~conservative treatment involves orthotic bracing, activity modification and physical therapy. In adults, treatment involves education, analgesics, and NSAIDS, with exercise and rapid return to activities. Once Spondylolisthesis occurs healing of the pars is unlikely. Surgery is indicated when there is progressive neurological deficit, cauda equina compression, or persistent severe leg and back pain despite aggressive conservative management (Spinelli, 2008).~~

Spinal decompression: Spinal stenosis, which is a narrowing of the vertebral canal, is a common condition that can result in compression of the nerves. This can produce a variety of symptoms, including pain, numbness and muscle weakness. If surgery is recommended, it may be possible to remove the bone and soft tissues causing the nerve compression through an MIS approach using tubular dilators and a microscope or endoscope. The more common decompressive procedures include laminectomy and foraminotomy. (AANS,2022)

Transforaminal (TESSYS®) and Interlaminar Endoscopic Surgical Systems: The TESSYS® approach focuses on the endoscopic visualization of the foramen and a transforaminal approach in order to resect the herniated disc. The surgeon performs a foraminoplasty through which neural elements can be decompressed. Disc material is removed completely and directly through the foramen, which is gradually widened using specialized reamers and instruments. The iLESSYS® method uses endoscopic interlaminar access for the removal of herniated discs or the treatment of lumbar spinal stenosis. Generally, all lumbar levels can be treated with either approach.

Tubular Retractor: This technique involves progressive dilation of the soft tissues, as opposed to cutting directly through the muscles. By using tubes to keep the muscles out of the way, the surgeon works through the incision without having to expose the area widely. Sometimes, the surgeon will also utilize an endoscope or microscope focused down the tube to assist with performing the surgery Once the procedure is complete, the tubular retractor can be removed, allowing the dilated tissues to come back together. Depending on the extent and type of surgery necessary, incisions can often be small. (AANS,2022)

~~**Total Facet Joint Arthroplasty:** A non-fusion spinal implant developed to treat individuals with moderate to severe spinal stenosis.~~

~~**Transforaminal Lumbar Interbody Fusion (TLIF):** 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.~~

~~**Unremitting:** Constant and unrelieved by Conservative Therapy (refer to the definition of Conservative Therapy).~~

~~**X-STOP Interspinous Process Decompression (IPD) System:** A minimally invasive surgical method to treat neurogenic intermittent claudication secondary to Lumbar Spinal Stenosis (Zucherman et al., 2004).~~

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not

imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

~~**Coding Clarifications:**~~

- ~~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.~~

CPT Code	Description
*0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles, includes imaging guidance and bone biopsy, when performed
*0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, 2 or more needles, includes imaging guidance and bone biopsy, when performed
~~0202T~~	~~Posterior vertebral joint(s) arthroplasty (e.g., facet joint[s] replacement) including facetectomy, laminectomy, foraminotomy, and vertebral column fixation, injection of bone cement, when performed 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~~
~~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 (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method, under indirect image guidance (e.g., fluoroscopic, CT), single or multiple levels, unilateral or bilateral; cervical or thoracic~~
*0275T	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method, under indirect image guidance (e.g., fluoroscopic, CT), single or multiple levels, unilateral or bilateral; lumbar

CPT Code	Description
~~0719T~~	~~Posterior vertebral joint replacement, including bilateral facetectomy, laminectomy, and radical discectomy, including imaging guidance, lumbar spine, single segment~~
~~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 (e.g., pedicle/vertebral body subtraction); thoracic~~
~~22207~~	~~Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (e.g., pedicle/vertebral body subtraction); lumbar~~
~~22208~~	~~Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (e.g., 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~~
~~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)~~

CPT Code	Description
~~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 interspace; cervical below C2 segment~~
~~22610~~	~~Arthrodesis, posterior or posterolateral technique, single interspace; thoracic (with lateral transverse technique, when performed)~~

CPT Code	Description
~~22612~~	~~Arthrodesis, posterior or posterolateral technique, single interspace; lumbar (with lateral transverse technique, when performed)~~
~~22614~~	~~Arthrodesis, posterior or posterolateral technique, single interspace; each additional interspace (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; 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; 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)~~

CPT Code	Description
~~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)~~
~~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)~~
~~22852~~	~~Removal of posterior segmental instrumentation~~
~~22853~~	~~Insertion of interbody biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)~~
~~22854~~	~~Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)~~
~~22855~~	~~Removal of anterior instrumentation~~
~~22859~~	~~Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)~~
~~22867~~	~~Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level~~
~~22868~~	~~Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure)~~

CPT Code	Description
~~22869~~	~~Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level~~
~~22870~~	~~Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)~~
22899	Unlisted procedure, spine
62287	**Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar**
62380	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar
~~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; 1 interspace, cervical~~
~~63030~~	~~Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 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; 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 vertebral 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;~~
~~63051~~	~~Laminoplasty, cervical, with decompression of the spinal cord, 2 or more vertebral segments; with reconstruction of the posterior bony elements (including the application of bridging bone graft and non-segmental fixation devices [e.g., wire, suture, mini-plates], when performed)~~
~~63052~~	~~Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [e.g., spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; single vertebral segment (List separately in addition to code for primary procedure)~~

CPT Code	Description
~~63053~~	~~Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [e.g., spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; each additional segment (List separately in addition to code for primary procedure)~~
~~63055~~	~~Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (e.g., herniated intervertebral disc), single segment; thoracic~~
~~63056~~	~~Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (e.g., herniated intervertebral disc), single segment; lumbar (including transfacet, or lateral extraforaminal approach) (e.g., far lateral herniated intervertebral disc)~~
~~63057~~	~~Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (e.g., herniated intervertebral disc), 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 disc), thoracic; single segment~~
~~63066~~	~~Costovertebral approach with decompression of spinal cord or nerve root(s), (e.g., herniated intervertebral disc), thoracic; each additional segment (List separately in addition to code for primary procedure)~~
~~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)~~

CPT Code	Description
~~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)~~
~~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~~
~~63185~~	~~Laminectomy with rhizotomy; 1 or 2 segments~~
~~63190~~	~~Laminectomy with rhizotomy; more than 2 segments~~
~~63191~~	~~Laminectomy with section of spinal accessory nerve~~
~~63197~~	~~Laminectomy with cordotomy, with section of both spinothalamic tracts, 1 stage, 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~~

CPT Code	Description
~~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~~
~~63266~~	~~Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; thoracic~~
~~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~~
~~63275~~	~~Laminectomy for biopsy/excision of intraspinal neoplasm; extradural, cervical~~
~~63277~~	~~Laminectomy for biopsy/excision of intraspinal neoplasm; extradural, lumbar~~
~~63280~~	~~Laminectomy for biopsy/excision of intraspinal neoplasm; intradural, extramedullary, cervical~~
~~63282~~	~~Laminectomy for biopsy/excision of intraspinal neoplasm; intradural, extramedullary, lumbar~~
~~63285~~	~~Laminectomy for biopsy/excision of intraspinal neoplasm; intradural, intramedullary, cervical~~
~~63286~~	~~Laminectomy for biopsy/excision of intraspinal neoplasm; intradural, intramedullary, thoracic~~
~~63287~~	~~Laminectomy for biopsy/excision of intraspinal neoplasm; intradural, intramedullary, thoracolumbar~~
~~63290~~	~~Laminectomy for biopsy/excision of intraspinal neoplasm; combined extradural-intradural lesion, any level~~
~~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~~
~~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~~

CPT Code	Description
~~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)~~

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HCPCS Code	Description
***G0276**	**Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial**

Codes labeled with an asterisk (*) are not on the Louisiana Medicaid Fee Schedule and therefore may not be covered by the state of Louisiana Medicaid Program.

Description of Services

Back pain or radiculopathy related to herniated discs is an extremely common condition and a frequent cause of chronic disability. Although many cases of acute low back pain and radiculopathy will resolve with conservative care, a surgical decompression is often considered when the pain is unimproved after several months and is clearly neuropathic in origin, resulting from irritation of the nerve roots. Open surgical treatment typically consists of discectomy, in which the extruding disc material is excised. When performed with an operating microscope the procedure is known as microdiscectomy. Minimally invasive options have also been researched, in which some portion of the disc is removed or ablated, although these techniques are not precisely targeted at the offending extruding disc material.

In an attempt to alleviate many of the limitations of previous techniques, a pre-sacral approach to the lumbosacral junction has been investigated. Transaxial anterior lumbar interbody fusion is an emerging minimally invasive spinal fusion procedure used to treat patients with chronic lower back pain. This procedure is an alternative to traditional fusion techniques that utilize anterior or posterior approaches to directly expose the lumbosacral spine. In the case of transaxial anterior lumbar interbody fusion the spine is accessed percutaneously via the anterior surface of the sacrum. (Ollendorf, et al., 2011)

~~Lumbar spinal stenosis (LSS) is a narrowing of the spinal canal that compresses the neural elements in the lower back. It may be caused by trauma, tumor, infection, or congenital defects but is predominately caused by degenerative changes in the intervertebral discs and the ligaments and bone structures of the spine. These changes typically begin with a breakdown of the discs with consequent collapse of disc space, which leads to disc bulge and herniation, and transference of weight to the facet joints.~~

~~This in turn leads to cartilage erosion and compensatory growth of new bone (bone spurs) over the facet joints as well as thickening of ligaments around the facet joints to help support the vertebrae. Surgery may be performed if symptoms do not respond adequately to nonsurgical approaches and continue to cause poor quality of life (AANS, 2014; AAOS, 2013).~~

~~First-line treatments for symptomatic lumbar spinal stenosis include rest, NSAIDs, muscle relaxants, corset use, physical therapy, and lumbar epidural steroid injections. For persons with moderate to severe symptoms, surgical decompression with or without spinal fusion and discectomy may be indicated but are associated with serious complications and high operative risk, particularly for elderly patients. The effectiveness of nonsurgical treatments, the extent of pain, and patient preferences may all factor into the decision to have surgery (National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), 2016).~~

~~Posterior decompression for LSS has been evolving toward increasingly minimally invasive procedures in an attempt to reduce postoperative morbidity and spinal instability. Unlike conventional surgical decompression, the percutaneous mild® decompressive procedure is performed solely under fluoroscopic guidance (e.g., without endoscopic or microscopic visualization of the work area). This procedure is indicated for central stenosis only, without the capability of addressing nerve root compression or disc herniation, should either be required.~~

~~Interspinous fixation (fusion) devices are being developed to aid in the stabilization of the spine. They are evaluated as alternatives to pedicle screw and rod constructs in combination with interbody fusion. Interspinous fixation devices (IFDs) are also being evaluated for stand-alone use in patients with spinal stenosis and/or spondylolisthesis.~~

Clinical Evidence

Automated Percutaneous Lumbar Discectomy (APLD)

Systematic reviews have assessed automated percutaneous discectomy compared to other interventions; however, the majority of these reviews contained observational studies published more than a decade ago with generally small patient populations and inconsistent results. There is insufficient evidence obtained from well-designed and executed randomized controlled trials to evaluate the impact of automated percutaneous discectomy on net health outcome.

Manchikanti et al. (2013c) conducted a systematic review of APLD for the contained herniated disc. Pain relief was the primary outcome measure. Other outcome measures were functional improvement, improvement of psychological status, opioid intake, and return to work. Short-term effectiveness was defined as one year or less, whereas long-term effectiveness was defined as greater than one year. Nineteen observational studies and no randomized controlled trial were included and met inclusion criteria for methodological quality assessment. Overall, 5,515 patients were studied with 4,412 patients (80%) showing positive results lasting one year or longer. Based on USPSTF criteria, the indicated evidence for APLD is limited for short- and long-term relief. A study limitation is the paucity of RCTs in the literature describing APLD.

A number of systematic reviews (SRs) have been published since 2007. A review of these trials suggested that APD produced inferior results to either of the established procedures. The authors of the systematic reviews reached similar conclusions, that while

there is considerable evidence of efficacy for conventional surgical discectomy, there is insufficient evidence on percutaneous discectomy techniques including APD to draw firm conclusions. Large, blinded, randomized controlled trials (RCTs) with long-term follow-up are necessary to establish the safety and efficacy of automated percutaneous and percutaneous endoscopic discectomy compared with open surgical discectomy, the current standard of care for surgical removal of damaged intervertebral disc material. These comparisons are necessary to determine whether any beneficial treatment effects of percutaneous and endoscopic discectomy outweigh any risks and provide a significant advantage over conventional open discectomy techniques.

The 2005 National Institute for Health and Excellence guidance for automated percutaneous mechanical lumbar discectomy concluded, "There is limited evidence of efficacy based on uncontrolled case series of heterogeneous groups of patients, but evidence from small randomized controlled trials shows conflicting results. In view of the uncertainties about the efficacy of the procedure, it should not be used without special arrangements for consent and for audit or research."

The 2002 Lumbar Automated Percutaneous Discectomy Outcomes Group (LAPDOG) trial, (Haines et al.) is a RCT to compare automated percutaneous discectomy with open discectomy in patients with lumbar disc herniation. No additional RCTs have been identified since the 2002 LAPDOG trial. The trial was designed to recruit 330 patients but enrolled 36 patients for reasons not readily apparent. Twenty-seven patients were available at follow-up, with efficacy reported by 41% of those undergoing automated percutaneous discectomy and by 40% of those undergoing conventional discectomy. The trialists concluded that "It is difficult to understand the remarkable persistence of percutaneous discectomy in the face of a virtually complete lack of scientific support for its effectiveness in treated lumbar disc herniation."

Clinical Practice Guidelines

American Society of Interventional Pain Physicians (ASIPP)

In the section on percutaneous disc decompression, in the evidence-based guideline, the ASIPP found limited evidence for the use of automated percutaneous lumbar discectomy for the treatment of lumbar disc compression. (Manchikanti et al., 2013).

North American Spine Society (NASS)

The 2014 practice guidelines from the NASS on the diagnosis and treatment of lumbar disc herniation with radiculopathy recommended that percutaneous discectomy could be considered for the treatment of these patients. Both recommendations were grade C recommendations (poor quality evidence). However, a separate recommendation stated that evidence is insufficient to recommend for or against use of automated percutaneous discectomy compared with open discectomy.

Axial Lumbar Interbody Fusion (AxiaLIF)

Although this method may be considered an emerging minimally invasive surgical approach, no randomized controlled trials evaluating axial LIF as a minimally invasive or percutaneous surgical procedure for the treatment of L5-S1 conditions 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 is as beneficial as other surgical approaches to lumbosacral interbody fusion. .

~~Evidence from case series in one systematic review and one additional case series (not in the systematic review) is at too high a risk of bias to support conclusions on safety and effectiveness of one-level lumbar interbody fusion or L5-S1 spondylolisthesis or spondylosis with AxiaLIF. Multicenter randomized controlled trials (RCTs) comparing AxiaLIF to traditional interbody approaches are needed to assess AxiaLIF for one- and two-level interbody fusions and to compare axial lumbar interbody fusion with other surgical approaches. 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. (ECRI, 2018; updated 2020)~~

An ECRI report for the AxiaLIF Plus System indicated that the evidence from case series in one systematic review and one additional case series (not in the systematic review) is at too high a risk of bias to support conclusions on safety and effectiveness of one-level lumbar interbody fusion or L5-S1 spondylolisthesis or spondylosis with AxiaLIF. Randomized controlled trials (RCTs) comparing patient-oriented outcomes (e.g., pain, functional status, reoperation rates) of AxiaLIF with other interbody fusion surgical approaches are needed to assess AxiaLIF's comparative effectiveness (ECRI, 2020).
~~Hayes performed a literature review of the AxiaLIF system. The overall quality of the evidence was low. The published studies included small study populations, lacked control groups, and reported on relatively short-term outcomes. Due to the lack of comparative studies, there is no evidence to determine if AxiaLIF confers any health benefits compared with standard open and other minimally invasive fusion procedures. In addition, questions regarding long-term improvement in functional status and quality of life have not been adequately addressed. Randomized controlled trials are needed to better define patient selection criteria and the optimal clinical role of AxiaLIF compared with other fusion techniques. The evidence is currently insufficient to allow conclusions regarding the long-term health benefits, relief of symptoms, improvement in functional levels, complication and failure rates, and the need for additional surgery. (Hayes, 2015, archived 2020)~~

Schroeder et al. (2015) performed a systematic review of seventy-four articles discussing safety profile of axial interbody arthrodesis, but only 15 (13 case series and two retrospective cohort studies) met the study inclusion criteria. The authors concluded that review of the literature indicates that an axial interbody fusion performed at the lumbosacral junction is associated with a high fusion rate (93.15%) and an acceptable complication rate (12.90%). However, these results are based mainly on retrospective case series by authors with a conflict of interest. The limited prospective data available indicate that the actual fusion rate may be lower, and the complication rate may be higher than currently reported.

Zeilstra et al (2013) reported their 6-year single-center experience with L5-S1 axial lumbar interbody fusion (AxiaLIF). A total of 131 patients with symptomatic degenerative disc disease refractory to non-surgical treatment were treated with AxiaLIF at L5-S1 and were followed for a minimum of 1 year. Main outcomes included back and leg pain severity,

Oswestry Disability Index score, working status, analgesic medication use, patient satisfaction, and complications. Back and leg pain severity decreased by 51% and 42%, respectively, during the follow-up period. Back function scores improved 50% compared to baseline. The authors concluded that single-level AxiaLIF is a safe and effective means to achieve lumbosacral fusion in patients with symptomatic degenerative disc disease. Moreover, they noted that "Our study is limited by the retrospective nature of the analysis. Additionally, all patients underwent fusion at L5 to S1 and, therefore, no conclusions can be drawn regarding the effectiveness or safety of 2-level AxiaLIF from this report. Lastly, mean patient follow-up was 21 months. Although this represents one of the longest follow-up reports following AxiaLIF surgery, long-term clinical and radiographic outcomes are unknown."

In a 5-year post-marketing surveillance study, Gundanna et al. (2011) reported complications associated with axial presacral lumbar interbody fusion in 9,152 patients. A single-level L5-S1 fusion was performed in 8,034 patients (88%), and a two-level L4-S1 fusion was performed in 1,118 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.

~~*Professional Societies/Position Statements*~~*Clinical Practice Guidelines*

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 (2014). Surgical decompression is recommended for patients with symptomatic neurogenic claudication due to lumbar stenosis without spondylolisthesis who elect to undergo surgical intervention. In the absence of deformity or instability, lumbar fusion has not been shown to improve outcomes in patients with isolated stenosis, and therefore it is not recommended.

National Institute for Health and Clinical Excellence (NICE)

The National Institute for Health and Clinical Excellence (NICE) guidance stated that the evidence on the safety of transaxial interbody lumbosacral fusion for severe chronic low back pain shows that there are serious but well-recognized complications. 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, 2018).

North American Spine Society (NASS)

NASS published guidelines on the treatment of degenerative spondylolisthesis in 2014. NASS has stated that there is insufficient evidence to make a recommendation for or against the cost-effectiveness of minimal access-based surgical treatments compared to traditional open surgical treatments for degenerative lumbar spondylolisthesis. This guideline did not specifically address axial lumbosacral interbody fusion (AxiaLIF).

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. The average sample size of these studies varies but range on average from 40 to more than 200 patients. Many studies are outdated with average being over twenty years ago. 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.

Minimally Invasive Lumbar Decompression (MILD®)

Available studies have limitations that include non-controlled trials, case series, non-blinded studies, and small number of participants. Well-designed studies that include a larger number of participants at multi-centers, use of clear patient selection criteria, measures of outcome using standardized tools, comparison to conservative management, comparison with and without an anesthetic agent and longer-term outcomes are needed to validate the use/safety/effectiveness of this technology.

~~The literature search identified six studies published in 11 publications that met the inclusion and exclusion criteria and evaluated the Vertos mild device kit and associated procedure (referred to as the Vertos mild procedure) for the treatment of LSS and ligamentum flavum hypertrophy. The authors concluded that the low-quality body of evidence suggested statistically significant reductions in pain intensity and function, but that long-term durability and safety of more than 2 years is needed for the Vertos mild procedure. In addition, studies addressing appropriate patient selection criteria are needed to discern for whom the Vertos mild procedure may be most effective. Trials comparing the Vertos mild procedure with other minimally invasive procedures or open lumbar decompression are also needed. In addition, manufacturer support occurred in half of the studies. Limitations of the individual studies included limited follow-up, lack of blinding, high attrition, absence of power analyses, and missing data for some outcomes and endpoints. (Hayes, 2019)~~

~~ECRI (2018) performed a literature review of the Vertos mild device kit. Despite the large amount of available data, some evidence gaps remain. These nonrandomized comparative studies are at high risk of bias from lack of controls and randomization. Additional RCTs are needed to verify findings and assess mild's effectiveness compared with other decompression procedures.~~

ECRI (2021) performed a literature review of the Vertos mild device kit. Evidence from studies synthesized in systematic reviews shows the mild procedure is safe and relieves LSS symptoms at up to one-year follow-up. Evidence from additional studies suggests the mild procedure may be as effective but safer than laminectomy (three nonrandomized studies) and may be more effective than epidural steroid injections (one randomized controlled trial), but these findings need validation in additional RCTs to permit conclusions. Despite the large amount of available data, some evidence gaps remain. Additional RCTs are needed to verify findings and assess mild's effectiveness compared with other decompression procedures. Large, multicenter studies that assess the mild procedure's long-term effectiveness (i.e., five years or longer) are also needed.

Mekhail and associates (2021) published the results of a retrospective observational cohort study evaluating mild® for treatment of lumbar spinal stenosis, with hypertrophic ligamentum flavum as a contributing factor (n=75). The primary outcome measure was the incidence of open lumbar decompression surgery at the same level (s) as the mild

procedure during a five-year follow-up period. Secondary outcome measures included change in patient reported pain levels using the Numeric Rating Scale (NRS), and opioid medication use using the Morphine Milligram Equivalent does per day from baseline to 3, 6, and 12 months post procedure. The mean patient age was 74.4 years, all had continued pain despite conservative management for an average of 6.8 years. Nineteen subjects had mild performed at two levels, all others had single level surgery with the most frequent level treated being L4-L5. No major complications were reported, minor complications included post procedural soreness and ecchymosis, with one case of allergic dermatitis at the surgical site. The authors reported a significant difference in the NRS pain scores from baseline and all three time points, 73.8%, 69.5% and 60.3% respectively for 3, 6 and 12 months post procedure. Within five years nine subjects required open surgical decompression (2.4% annually), women had an odds ratio of 0.175 of having subsequent surgery compared with men. Only three had surgery at the exact same level as the mild procedure, seven had surgery which involved more levels than the mild. Only two subjects reported improvement in neurogenic claudication following the open procedure, three reported no improvement following open surgery, and three subjects did not have follow-up visits. In the author opinion mild was durable over five years and may allow elderly patients the avoidance of open lumbar surgery. The study is limited by its retrospective design, lack of control group, and small sample population.

Merkow and colleagues (2020) published results of a systematic review evaluating outcomes of both MILD and Superion (intraspinous process device) separately, as treatment of lumbar spinal stenosis. Regarding MILD the authors review included eight studies; two RCTs, three prospective observational trials, and three retrospective observational trials. The authors concluded that MILD is modestly safe and effective for treatment of lumbar spinal stenosis, based primarily on the study by Staats, et al. 2018 showing two year outcomes.

Aldahshory et al. (2020) evaluated and compared the clinical outcomes of two different treatment modalities for degenerative lumbar canal stenosis (LCS): the classic laminectomy with posterolateral transpedicular screw fixation and MILD. This was a randomized study of 50 patients with degenerative LCS. The study compared two cohorts: Group A – 25 patients underwent classic lumbar laminectomy with posterolateral transpedicular fixation and Group B – 25 patients underwent MILD. There were no statistically significant differences between both treatment modalities in the Visual analogue score (VAS) for leg pain and back pain, the patient satisfaction index, and the Oswestry disability index after 1 year. The fusion operations were associated with higher estimates of blood loss and longer hospital stay. The authors concluded that MILD has the same satisfactory results as classic laminectomy with posterolateral fixation for the treatment of degenerative LCS with less bleeding loss and shorter hospitalization. The study limitations included a 1-year follow-up that is not sufficient to assess the reoperation rate in case of adding fusion. Other limitations include small sample size and lack of information about the body mass index of each patient and the associated comorbidities.

In 2018 Deer and associates published consensus guidelines for minimally invasive spine treatment (MIST) for lumbar spinal stenosis. The United States Preventive Task Force (USPTF) criteria for evidence level and degree of recommendation was used along with strength of consensus for development of the guidelines. Within this guideline regarding percutaneous image guided lumbar decompression, the authors concluded the available evidence is level 1 and is supportive of PILD. In addition to retrospective and prospective studies reviewed by the consensus group, there were two comparative prospective trials that led to reimbursement approval by CMS, noted as being both Level 1

(Brown, et al., 2012; Staats, et al., 2016, detailed below), both compare PILD to lumbar ESI and not to open decompression. The recommendation by the authors is Grade A (good evidence the measure is effective and that benefits outweigh harms), Level1 (at least 1 controlled and randomized trial, properly designed), Consensus strong (>80% consensus).

Staats ~~and colleagues~~et al. (2018, included in ECRI above) reported results of a prospective, multicenter, randomized controlled clinical study. This study evaluated the long-term durability of the minimally invasive lumbar decompression (mild®~~MILD~~) procedure in terms of functional improvement and pain reduction for patients with lumbar spinal stenosis and neurogenic claudication due to hypertrophic ligamentum flavum. Follow-up occurred at 6 months and at 1 year for the randomized phase and at 2 years for mild®~~MILD~~ subjects only. Oswestry Disability Index, Numeric Pain Rating Scale, and Zurich Claudication Questionnaire were used to evaluate function and pain. Safety was evaluated by assessing incidence of device-/procedure-related adverse events. The authors concluded that mild®~~MILD~~ showed excellent long-term durability, and there was no evidence of spinal instability through 2-year follow-up. Given the minimally invasive nature of this procedure, its robust success rate, and durability of outcomes, mild® ~~MILD~~ is an excellent choice for first-line therapy for select patients with central spinal stenosis suffering from neurogenic claudication symptoms with hypertrophic ligamentum flavum. Despite the above findings that study did have the following limitations, lack of a control group at 2-year follow-up. The randomized controlled portion of the study concluded at the primary end point of 1 year, and supplementary follow-up through 2 years was conducted for the mild®~~MILD~~ patient group only. This study did not compare efficacy directly with open surgical approaches, including lumbar decompression, fusion, or spacers.

In another study, Chopko (2013) evaluated the long-term effectiveness and safety of mild as a treatment of neurogenic claudication associated with lumbar spinal stenosis. The 2-year data are reported for 45 participants that were treated with mild at 11 US facilities. Outcome measurements included the VAS, ODI, and ZCQ. Interim data on the participants are included for 1 week, 6 months, and 1-year follow-up. The authors reported that at 2 years, the subjects demonstrated a statistically significant reduction of pain as measured by VAS, and significant improvement in physical function and mobility as measured by ZQC and ODI. The authors also reported major improvement occurred by 1-week follow-up and showed no difference between each subsequent follow-up, suggesting considerable stability and durability of the initial result over time. There were no major adverse events or complications related to the procedure. Limitations of this study include its uncontrolled design and small size.

Brown et al. (2012) reported the results of a double-blind, randomized, prospective study of epidural steroid injections (ESI) and the mild procedure at a single pain management center. A total of 38 individuals with symptomatic lumbar spinal stenosis (LSS) participated in the study and were randomized into two treatment groups: 21 participants in the mild arm and 17 individuals in the ESI arm. Outcome measures were reported using the visual analog scale (VAS), the Oswestry Disability Index (ODI) and Zurich Claudication Questionnaire (ZCQ) patient satisfaction score. The authors reported that at 6 weeks, the mild participants improved from an average VAS baseline of 6.3 to a mean of 3.8). The ESI group had a mean VAS score of 6. at baseline compared with 6.3 at 6 weeks follow-up. Using the ODI, at 6 weeks follow-up, participants in the mild®~~mild~~ group demonstrated a decrease from a baseline mean ODI from 38.8 to 27.4. In the ESI group, the initial ODI was 40.5 and at 6 weeks follow-up, the ODI was 34.8. In the mild group, there was no significant change in the VAS and ODI scores from weeks 6 to 12. Participants in the ESI group were not measured at week 12. Participants were allowed to cross over from the ESI group to the mild group before 12 weeks and eventually, all of the participants

in the ESI group had the mild procedure. A total of 14 of the 17 participants in the cross-over ESI group experienced an improvement in their VAS scores after the mild procedure. Limitations of the study include its small size and short follow-up.

In 2010, Chopko et al, reported on a one-year follow-up from an industry-sponsored multicenter study, with patients who were treated with mild devices. 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.

Clinical Practice Guidelines

International Society for the Advancement of Spine Surgery

In 2016, the International Society for the Advancement of Spine Surgery (ISASS) published recommendations for decompression with interlaminar stabilization. ISASS concluded, based in part on a conference presentation of a study, that an interlaminar spacer in combination with decompression can provide stabilization in patients who do not present with greater than grade 1 instability. Recommended indications and limitations were described in the article. The document did not address interspinous and interlaminar distraction devices without decompression (Guyer et al., 2016).

National Institute for Health and Clinical Excellence

The National Institute for Health and Care 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).

North American Spine Society (NASS)

The 2014 revised NASS clinical guideline on interspinous process spacing devices concluded that there is insufficient evidence to make a recommendation for or against the placement of an interspinous process spacing device in patients with lumbar spinal stenosis (LSS).

~~One-year follow-up from an industry-sponsored multicenter study by Chopko and Caraway, 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. 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.~~

Percutaneous Image-guided Lumbar Decompression (PILD, PLDD)

This evidence review addresses posterior decompression of lumbar spinal stenosis with percutaneous treatment performed under fluoroscopic guidance. The primary literature on image-guided minimally invasive lumbar decompression includes a large RCT , a small RCT, and a number of prospective and retrospective cohort studies and case series. Relevant outcomes are symptoms, functional outcomes, health status measures, and treatment-related morbidity. The trial was unblinded and there is evidence of differing expectations and follow-up in the 2 groups, suggesting a high-risk of bias. The available evidence is insufficient to determine the efficacy of mild compared with placebo or to determine the efficacy of image-guided minimally invasive lumbar decompression compared with open decompression. Trials with relevant control groups could provide greater certainty on the risks and benefits of this procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

In a health technology assessment, a small body of very limited low-quality evidence is considered insufficient to determine the safety and efficacy of PLDD for lower back disc herniation (Hayes 2018, updated 2021). The assessment also suggests uncertainty regarding the comparative and long-term effectiveness of PLDD and the need for subsequent surgeries.

Brouwer and colleagues (2015, included in Hayes report above) conducted a RCT with non-inferiority study design (N=115) to evaluate PLDD compared with conventional surgery for the treatment of LBP. The non-inferiority analysis showed that PLDD resulted in non-inferior outcomes compared with conventional surgery; however, the number of reoperations required was significantly higher in the PLDD group (38%) compared with conventional surgery group (16%). At the two year follow up, Brower and his colleagues (2017) demonstrated that although the rate of reoperation in the PLDD group was higher than expected, surgery could be avoided in 48% of those patients that were original candidates for surgery. The authors concluded the results justify the need for additional studies into the value of PLDD as an alternative to conservative treatment.

In a retrospective observational study, Klessinger (2018c) reported on the re surgery frequency of 73 patients that received percutaneous lumbar disc decompression (PLDD) using DeKompressor. Patient data were drawn from an electronic medical record system of patients receiving PLDD between January 2005 and December 2007. A history of pain for a minimum of 3 months was mandatory. Patients had either low back pain or radicular pain with or without a sensory loss. Patients with a lumbar spine surgery in their history were excluded. All patients were seen in the practice one month after the operation for follow-up and subsequent follow up was according to the needs of the patient. In 22 patients (30.1%), the follow-up was longer than 5 years, and in five patients (6.8%) it was longer than 10 years. The mean follow-up time was 35.6 months. The results showed that one month after the intervention, excellent results were achieved in 17 patients and

good results, in 32 patients, giving a short-term success rate of 67.1%, however subsequent open surgery at the index level was necessary in 19 patients (26.0%). Most reoperations (15 patients) had to be performed during the first year after PLDD (20.5% of all patients, 78.9% of all resurgeries). These patients had a statistically significant worse outcome (26.7% versus 75.0% satisfied patients. Radicular pain was present in all patients with an early subsequent surgery, but only in 50% of patients with late surgery. The mean time between PLDD and the additional surgery was at 10.8 ± 17.9 months. The author concluded that despite an initial success rate of 67%, the resurgery rate of 26% offsets that, and suggests that PLDD is not a replacement for open discectomy. Further studies are needed to compare the outcome and rate of subsequent surgery in patient populations with and without radicular symptoms to find the ideal indications for PLDD.

In a prospective cohort study, McCormick et al. (2016) determined long-term outcomes of Dekompressor percutaneous lumbar disc decompression (PLDD) for discogenic radicular pain. Consecutive patients (n=70) with discogenic lumbosacral radicular pain who underwent PLDD with Dekompressor were included in the study. Numerical Rating Scale (NRS) leg pain score and Oswestry Disability Index (ODI) score data were collected at 6 months and 1 year. These 2 measures, 5-point Likert scale patient satisfaction, and surgical rate data were also collected at 8 years when possible. Forty and twenty-five patients were successfully contacted at 1-year and 8-year follow-up, respectively. At 1 year and 8 years, NRS leg pain scores were reduced greater than 50% in 47% and 29% of patients, respectively; ODI score improved greater than 30% in 43% and 26% of patients, respectively. Of the patients who were followed-up at 8 years, 36% had undergone surgery and the median satisfaction was "4" (interquartile range of 2 to 5). The authors concluded that while limited by loss-to-follow-up, the findings of this study suggested that treatment of discogenic lumbosacral radicular pain with Dekompressor resulted in decreased leg pain and disability and favorable satisfaction at long-term follow-up. They stated that further study with adequate follow-up retention is needed to confirm that Dekompressor spares open spinal surgery. The findings are limited by lack of comparison group and large loss to follow up.

Cong et al. (2016) conducted a systematic review to compare the effectiveness and safety of endoscopic discectomy (ED) with open discectomy (OD) for the treatment of symptomatic LDH. A search was used to identify all published RCTs up to August 2014. Cochrane methodology was used for the results of this meta-analysis. Nine relevant RCTs involving 1,092 patients were identified. Compared with OD, ED results in slightly better clinical outcomes which were evaluated by the Macnab criteria without clinical significance (ED group: 95.76%; OD group: 80%; P = 0.10), a significantly greater patient satisfaction rate (ED group: 93.21%; OD group: 86.57%; P = 0.03), lower intraoperative blood loss volume, and shorter length of hospital stay. The authors concluded that from the existing outcomes, ED surgery could be viewed as a sufficient and safe supplementation and alternative to standard open discectomy. The cost-effectiveness analyses still remain unproved from the existing data. More independent high-quality RCTs using sufficiently large sample sizes are needed.

Manchikanti et al. (2013b) conducted a systematic review on patients with radicular pain to determine effectiveness of mechanical lumbar disc decompression with nucleoplasty. Fifteen studies met the inclusion criteria, but only one was an RCT thus no meta-analysis could be performed. A total of 2,429 patients were evaluated with at least 50 patients in each study and a follow up period of one year. Patients had an average improvement of 62% in pain relief. In this limited to fair evidence, the authors concluded nucleoplasty may provide relief in patients with disc herniation. Limitations included lack of RCTs,

patient loss, publication bias and a large number of placebo-control groups where utilization of local anesthetic injection was performed thus mimicking a facet joint injection.

Nucleoplasty

Klessinger (2018a) conducted a retrospective case series to investigate the frequency of an additional open surgery after percutaneous cervical nucleoplasty (PCN) up to 10 years. The follow-up time was longer than 5 years in 31.6% of patients and longer than 10 years in 6.0% of patients. One hundred thirty-three patients who underwent PCN between 2005 and 2007 were included. Patient satisfaction was evaluated using McNab's outcome criteria. The necessity of an additional open surgery at the cervical spine, the period between PCN and the fusion, and the treated levels were analyzed. The results showed a short-term success rate (1 month) of 70.7%; however, subsequent surgery was performed in 19.5% of patients. Overall, 57.7 % of reoperations were performed during the first year after PCN. In patients with a good result after PCN, subsequent surgery was less frequent, and the interval between PCN and additional surgery was longer. The data from this study suggest that PCN is a poor replacement for conventional open surgery. Degeneration of the disc is progressive despite or because of PCN. Findings are limited by the lack of comparison group.

Klessinger (2018b) conducted a retrospective observational study of 203 patients who underwent percutaneous disc nucleoplasty (PDN) using the Perc-DLG Spine Wand (Arthrocare Corporation, Austin, Texas), to report the frequency of re-operation at the same level. Patient data were drawn from an electronic medical record system of patients who underwent PDN at a single level (L4-5 or L5-S1) in an outpatient procedure. The indications for PDN was either a discogenic low back pain, or a contained disc herniation with back pain with or without radiating pain and with or without a sensory loss. All patients had a history of pain for a minimum of three months. Level L4-5 was treated in 117 patients (57.6%), and level L5- S1 was treated in all other patients. In 43.3% of patients, the left side was treated, in 46.3% of the patients, the right side was treated; and in
21 patients (10.3%), both sides were treated. There were no PDN-related complications. Patients were seen one month after the procedure and subsequent follow up was dependent on patients complaints of pain. In 41 patients (20.2%), the
follow-up was longer than 5 years, and in 16 patients (7.9%), it was longer than 10 years with a mean follow up time of 28.8 months. One month after the PDN, the success rate was 63.5%, and subsequent surgery at the index level was required in 18.7% of patients. These patients either had poor pain relief after PDN or a new onset of similar pain. 50% of the re-surgeries had to be performed during the first three months after the PDN. In a five-year follow-up of 172 patients, excellent or good patient satisfaction was achieved in 87.9% of patients after one week, and 63.4% was achieved at the last follow-up. The authors concluded that while the initial patients satisfaction rate appears good, this is offset by the high re-surgery rate, and Indications for nucleoplasty should be reconsidered.

Nie et al. (2018) reported in a retrospective cohort study 5-year outcomes from a comparison of therapeutic efficacy of radiofrequency target disc decompression and nucleoplasty for LDH. Two hundred sixty patients with LDH were divided into two groups: target disc decompression group (group T, N=147) and nucleoplasty group (group N, N=113). VAS and functional rating index (FRI) were measured at one, three, six, 12, 24, and 60 months after the surgery. Hospitalization time, operation time, complications, and recurrence/invalid were compared between the two groups. Compared with the pre-operation,

the VAS and FRI in both groups were significantly decreased in post-operation (P < 0.01). There was no significant difference of the occurrence of complications and disease recurrence/invalid during the follow-up between the two groups. Logistic regression analysis showed that operation time was an independent factor in the prognosis. The authors concluded there was no significant difference between the two methods used and that both can significantly alleviate pain and improve quality of life. The study is limited by lack of randomization and a retrospective design.

Wu et al. (2015) conducted a RCT to compare CT-guided nucleoplasty, CT-guided nucleoplasty combined with nerve root injection, and CT-guided transforaminal lumbar epidural injections in 97 patients with lumbar disk herniation and leg pain. Results of the study demonstrated that the combination of nucleoplasty with nerve root injection produced a significantly greater reduction in the pain score and disability score when compare with only nucleoplasty in the short term, at 1 week, as well at 1 month. The study limitations included lack of blinding and relatively small patient populations.

Ren et al. (2015) evaluated the efficacy of percutaneous nucleoplasty using coblation technique for the treatment of chronic nonspecific LBP after 5 years of follow-up. Forty-one patients who underwent percutaneous nucleoplasty for chronic LBP were assessed preoperatively and at 1 week, 1 year, 3 years, and 5 years postoperatively in this case series. Pain was graded using a 10-cm VAS and the percentage reduction in pain score was calculated at each postoperative visit. The ODI was used to assess disability related to lumbar spine degeneration, and patient satisfaction was assessed using the modified MacNab criteria. There were significant differences between the preoperative, 1-week postoperative, and 3-year postoperative VAS and ODI scores, but not between the 3-and 5-year postoperative scores. Excellent or good patient satisfaction was achieved in 87.9% of patients after 1 week, 72.4% after 1 year, 67.7% after 3 years, and 63.4% at the last follow-up. The authors concluded although previously published short and medium-term outcomes after percutaneous nucleoplasty appeared to be satisfactory, the long-term follow-up results showed a significant decline in patient satisfaction over time. This is an uncontrolled study with a small sample size.

In a retrospective review, Liliang et al. (2016) reported outcomes from a case series of 47 patients who underwent nucleoplasty for degenerative LBP using VAS scores. At 10-months, 21 patients (67.7%) experienced substantial pain relief. The most common side effects following nucleoplasty were soreness at the needle puncture site (64.5%), numbness in the lower leg (12.9%), and increased intensity of back pain (9.7%). All side effects were transient. Multivariate analysis revealed that the discography results were the most critical predictor for substantial pain relief of nucleoplasty (*P*=0.03). The sensitivity and specificity of discography were 92.8% and 62.5%, respectively. Limitations of this study include lack of comparison to a different intervention, non-randomization, small sample size, and short follow-up period.

Kumar et al. (2014) evaluated the safety and efficacy of annul-nucleoplasty using Disc-FX for the treatment of lumbar disc pathology (N=24). All patients in this case series were non-responsive to non-operative treatment measures. A total of 12 patients had degenerative disc disease and 12 patients had contained LDH. Health outcomes included the VAS, ODI, and the SF-36 scores evaluated before and after the procedure. Study authors reported significant improvement in outcomes relative to baseline. The overall rate of re-intervention for symptoms that continued to persist was about 18%; in the group of patients with LDH, the rate was about 36%. The study was limited by lack of appropriate comparator groups, lack of randomization, and relatively limited follow-up.

Zhu et al. (2011) evaluated longer-term efficacy over a 2-year follow-up of coblation nucleoplasty treatment for protruded lumbar intervertebral disc in a case series. A total of 42 cases of protruded lumbar intervertebral disc treated by coblation nucleoplasty followed-up for 2 years were analyzed. Relief of LBP, leg pain and numbness after the operation were assessed by VAS. Function of lower limb and daily living of patients were evaluated by the ODI. The authors concluded that coblation nucleoplasty may have satisfactory clinical outcomes for treatment of protruded lumbar intervertebral disc for as long as 2-year follow-up, but longer-term benefit still needs verification. The findings are limited by lack of relevant comparison group.

NICE (2016a) evaluated percutaneous coblation of the intervertebral disc for LBP and concluded that this procedure may be used for patients with pain caused by contained herniated discs that have not responded to conservative treatment, when open surgery is not suitable.

Percutaneous Endoscopic Discectomy (PELD)

The primary beneficial outcomes of interest for treatment of spinal pain are relief of pain and improved function. Both outcomes are subjective and can be influenced by nonspecific effects, placebo response, and the variable natural history of the disease. Therefore, large, blinded, randomized controlled trials (RCTs) with long-term follow-up are necessary to establish the safety and efficacy of percutaneous endoscopic discectomy compared with open surgical discectomy, the current standard of care for surgical removal of damaged intervertebral disc material. These comparisons are necessary to determine whether any beneficial treatment effects of percutaneous endoscopic discectomy outweigh any risks and provide a significant advantage over conventional open discectomy techniques.

Xu et al. (2020) conducted a meta-analysis on the efficacy of percutaneous endoscopic lumbar discectomy (PELD) versus micro endoscopic discectomy (MED); the authors specifically focused on the midterm and long-term outcomes. A total of 487 studies were identified with only 9 articles meeting the inclusion criteria and high-quality standards. Only one of these was a randomized controlled trial, the other were observational studies. In the results analysis, both PELD and MED obtained satisfactory midterm and long-term clinical efficacy, however the PELD group obtained better outcomes in scores for low back pain after 2 years postoperatively compared with the MED group. The authors concluded that the PELD patients exhibited overwhelming superiority in length of incision, postoperative time in bed and hospital length of stay which supported PELD as less invasive and faster rehabilitation. Further well-defined large, randomized trials are needed to validate and increase the strength of these findings. Limitations included lack of randomization in most included studies, lack of detailed surgical methods for several studies thus limiting additional subgroup analysis and high heterogeneity.

Ruan et al. (2016) conducted a systematic review and meta-analysis to compare PELD and open lumbar microdiscectomy (OLM) for the treatment of LDH. A total of 7 studies (1389 patients) were included (2 RCTs and 5 observational studies). The authors concluded that existing evidence indicates that no superiority exists between the two surgical approaches for the treatment of LDH in terms of functional outcome, complication rate and reoperation rate, in spite of the PELD surgical group can achieve shorter operation time and hospital stay than OLM surgical group. This review is limited by a low number of RCTs, and unknown follow-up periods.
The results of a recent meta-analysis investigating the effect of PELD in comparison to other surgeries for treatment of lumbar disc herniation supports that similar

complications occurred with PELD in comparison, however it was also associated with a significantly higher rate of recurrent disc herniation (Bai, et al., 2021). The author's analysis included 14 studies involving 2528 subjects (ten cohorts, four RCTs), the other surgeries for comparison included open lumbar Page 11 of 46 Medical Coverage Policy: 0139 microdiscectomy, microendoscopic discectomy, minimally invasive transforaminal lumbar interbody fusion, and percutaneous endoscopic lumbar discectomy. Success rates in the PELD and other surgical intervention groups were 90.1% and 88.0%, respectively, recurrence rates in the PELD and other surgical intervention groups were 7.57% and 4.38%, respectively. The authors acknowledged additional large-scale, well-performed randomized trials are needed to verify their findings.

An ECRI report for the Vertebris System for Interlaminar Endoscopic Lumbar Discectomy indicated that the Interlaminar endoscopic lumbar discectomy with the Vertebris system reduces pain and improves functional status in patients with lumbar disc herniation, based on evidence from three nonrandomized comparison studies and four before-and-after studies; however, the studies are at too high a risk of bias to be conclusive about how well the system works or how it compares with other lumbar discectomy approaches. (ECRI, 2021).

Within a Health Technology Brief document published by Hayes, eight studies were reviewed evaluating safety and efficacy of PELD as treatment of primary lumbar disc herniation Hayes concluded that although overall the body of evidence was low-quality, the evidence consistently suggests PELD performs similarly to other surgical alternatives for decompression when there was failure of conservative management. However, Hayes acknowledged "substantial uncertainty exists due to the overall quality of the body of evidence and additional studies are needed to evaluate comparative effectiveness and determine patient selection criteria when employed for primary disc herniation". In a second Health Technology Brief document Hayes evaluated PELD as treatment of recurrent lumbar disc herniation. A total of six studies were included in the review. According to the report, a low quality body of evidence suggests PELD may be inferior to comparison treatments for decreasing back pain and that PELD may have higher recurrence rates than comparison treatments (Hayes, 2019c).

Alvi (2018) conducted a meta-analysis which included 14 RCTs or quasi-randomized trials and compared open discectomy (OD), with microdiscectomy(MD) to minimally invasive procedures including percutaneous discectomy, percutaneous endoscopic discectomy (PED), and tubular discectomy (TD) for lumbar disc herniation. All of the studies were determined to have a serious risk of bias and were judged to be of low or very low quality. No differences were seen between groups for VAS score. Open procedures were also associated with longer hospital stays and greater blood loss.

Clinical Practice Guidelines

American Society of Interventional Pain Physicians (ASIPP)

In 2013, a task force of the ASIPP published updated guidelines for interventional techniques in the management of chronic spinal pain. The evidence for percutaneous lumbar discectomy was rated as limited for short- and long-term relief based on all observational studies. An evidence rating of "limited" is defined as evidence insufficient to assess effects on health outcomes because of limited number or inadequate power of studies, large and unexplained inconsistency between higher-quality trials, important flaws in trial design or execution, gaps in the chain of evidence, or lack of information on important health outcomes. The ASIPP concluded that this technique may be performed when indicated but did not provide patient selection criteria. Nor was the

recommendation graded; the authors indicated only that this recommendation was based on "individual experience and the large amount of literature." Therefore, this recommendation is not considered evidence-based.

North American Spine Society (NASS)

The 2014 practice guidelines from the NASS on the diagnosis and treatment of lumbar disc herniation with radiculopathy recommended that endoscopic percutaneous discectomy or automated percutaneous discectomy could be considered for the treatment of these patients. Both recommendations were grade C recommendations (poor quality evidence). However, a separate recommendation stated that evidence is insufficient to recommend for or against use of automated percutaneous discectomy compared with open discectomy.

Percutaneous Sacroplasty

A Hayes report for percutaneous sacroplasty for treatment of sacral insufficiency fractures published in 2018 indicates that the literature search identified a nonrandomized controlled study and a few 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 pre surgery with post-surgery, 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. The January 2021 Hayes update indicates that the evidence regarding efficacy is unchanged since publication of the 2018 Health Technology Brief (Hayes, 2018; updated January 2021).

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Frey et al. (2017) reported on patients treated with percutaneous sacroplasty, particularly the long-term efficacy of sacroplasty vs nonsurgical management. This prospective, observational cohort study spanned ten years and comprised 240 patients with sacral insufficiency fractures. Thirty-four patients were treated with nonsurgical methods, and 210 patients were treated with sacroplasty. Pain, as measured by VAS, was recorded before treatment and at several follow-ups. Mean pretreatment VAS for the

sacroplasty group was 8.29; for the nonsurgical treatment group, it was 7.47. Both forms of treatment resulted in significant VAS improvement from pretreatment to the 2-year follow-up. However, the sacroplasty treatment group experienced significant VAS score improvement consistently at many of the follow-up points (pretreatment to post; posttreatment through 2 weeks; 12 weeks through 24 weeks; 24 weeks through 1 year. Meanwhile, the group with nonsurgical treatment only experienced one significant pain improvement score—at the 2-week follow-up posttreatment. One major limitation of this study was that the nonsurgical treatment group was not followed up with at the 10-year mark whereas the sacroplasty group did receive follow-up.

Dougherty et al. (2014) retrospectively evaluated outcomes of consecutive patients with SIF treated by percutaneous sacroplasty in an electronic database. The study included 57 patients (75% women; age 61 to 85 years, median 74 for men or 75 for women; duration of pain 2 to 5 weeks. Pain was measured at rest and, sometimes, during activity on an 11-point NRS (higher values = greater pain) or described by patients, opioid use was also evaluated before and at 1 to 5 weeks (median, 2.5) after sacroplasty. The study is limited by retrospective design, small sample size, lack of a control group, subjective outcome measures, inconsistent evaluation of pain, and short follow-up.

Kortman et al. (2013, included in Hayes report above) retrospectively examined outcomes of patients with painful SIF or symptomatic sacral lesions treated by percutaneous sacroplasty at any of six participating U.S. centers. Patients were included in the study if they had severe sacral pain refractory to standard conservative management (defined as any combination of bed rest, analgesics, partial weight bearing, and orthosis), imaging evidence of bilateral or unilateral SIF or focal or infiltrating sacral lesions, and symptoms attributable to sacral pathology. The SIF group consisted of 204 patients. The group with sacral lesions (SL group) included 39 patients. Sacroplasty entailed the long- or short-axis approach and PMMA or bioceramic cement, but the rate of each approach and the trade names for cement and other devices were not reported. Pain was evaluated by self-report, a VAS, and analgesic use before and at 1 month after sacroplasty. All patients with SIF were followed for ≥ 1 year. Compared with pretreatment values, mean VAS scores improved significantly after sacroplasty in patients with bilateral SIF, patients with unilateral SIF, and patients with sacral lesions. In the entire group with SIF and the group with sacral lesions, respectively, 31% and 18% experienced complete pain relief and 3.0% and 10% experienced no significant pain relief. Use of narcotic, non-narcotic, and over-the-counter analgesics decreased markedly after versus before sacroplasty in both groups but data for analgesic use were not reported. The study is limited by retrospective design, lack of a control group, and use of subjective outcome measures.

Percutaneous Endoscopic Transforaminal Discectomy (PETD)

Jiang et al. (2021) conducted a retrospective analysis of 48 patients with recurrent lumbar disc herniation (RLDH) to compare the clinical efficacy of percutaneous transforaminal endoscopic discectomy (PTED) and traditional laminectomy (TL). Perioperative evaluation indicators included operation time, the intraoperative blood loss, length of incision and hospitalization time. Clinical outcomes were measured preoperatively, and at 1 day, 3 months, and 12 months postoperatively using the Oswestry disability index (ODI) and visual analog scale (VAS) scores. The results showed that compared with the TL group, the operation time, postoperative bed-rest time, and hospitalization time of the PTED group were significantly shorter, and the intraoperative blood loss was also reduced. There were no significant differences in VAS or ODI scores between the two groups before or after surgery. The authors concluded that PTED and TL have similar clinical efficacy in the treatment of RLDH, but PTED can shorten the

operation time, postoperative bedrest time and hospitalization time, and reduce intraoperative blood loss, and PTED is a safe and effective surgical method for the treatment of RLDH. but more randomized controlled trials are still required to further verify these conclusions. This study is limited by the retrospective design and a small number of participants.

Tacconi et al. (2020) compared surgical invasiveness between two procedures: transforaminal full endoscopic lumbar discectomy (FELD) and open discectomy (OD). 50 patients with a single-level lumbar foraminal herniation were randomly assigned to either have a FELD or OD procedure. Pre- and postoperative leg and back pain data were collected using a visual analog scale (VAS). A satisfactory postoperative outcome was defined by a decrease in the leg pain score by ≥3 points from the preoperative leg VAS score. The VAS scores for back pain were recorded ≥6 hours after the procedure or at mobilization. Additional assessment of back pain was not performed later during follow-up period due to potential risk of back pain occurring secondarily to spinal instability or a degenerative disc. There were no intraoperative or postoperative surgical complications. For the OD group, the median VAS score for leg pain had decreased from 7 preoperatively to 2 at six months postoperatively. In the FELD group, the median VAS score for leg pain had decreased from 8 preoperatively to 2 at six months postoperatively. The authors concluded even though the VAS scores for leg pain were not significantly different between the two groups, the period for patient mobilization along with the VAS scores for back pain immediately postoperatively were significantly lower for the FELD group. Limitations included a relatively small number of participants.

In a 2019 meta-analysis, Huang et al. sought to systematically review and compare the safety and effectiveness of PETD versus percutaneous endoscopic interlaminar discectomy (PEID) for the treatment of LDH. A total of 13 studies with 974 cases consisting of 3 RCTs, 3 prospective studies and 7 retrospective studies were included. The agrate results, based on observational studies and randomized controlled trials, suggest that patients treated with PEID experienced significant advantages with shorter operation time, less intraoperative blood loss and less intraoperative fluoroscopy times but more complications than those treated with PETD; however, the two operative approaches did not significantly differ in terms of LDH recurrence, hospital stay, ODI scores, VAS scores, Japanese Orthopedic Association (JOA) scores and MacNab criteria at the final follow-up. The authors concluded that PEID may be superior to PETD in certain ways, some of its advantages have yet to be verified and the two interventions were not significantly different in terms of relief of symptoms and functional recovery. They also concluded that PEID would be recommended for treating LDH especially at L5/S1 under certain conditions, but a prudent attitude is necessary to choose between the two operative approaches before a large sample and high quality RCTs have been performed. Limitations included lack of separation between randomized and non-randomized studies in the aggregate estimates, which could introduce biases, clinical heterogeneity and short-term follow-up.

Mo et al. (2019) evaluated percutaneous endoscopic transforaminal diskectomy (PETD) in comparison with percutaneous endoscopic interlaminar diskectomy (PEID) for herniation at L5-S1. 80 participants were recruited and randomly assigned to two different groups - either PETD or PEID. All procedures were performed by the same physician. Even though the operation time in the PEID group was significantly shorter than the PETD group, no significant differences were noticed during the postoperative period. All patients were followed for 9-22 months, with an average follow-up of 16.59 ± 4.10 months in the PETD group and 16.71± 3.72 months in the PEID group. The Oswestry Disability Index (ODI) and visual analog scale (VAS) scores with similar with no significant differences between the

two groups. The authors concluded PETD has a similar clinical effect to that of PEID. Limitations included single-center study, low number of participants and analysis based on as-treated rather than intent-to-treat approach. Larger sample size and tracking of long-term results are still warranted.

Yu et al. (2019) compared the clinical outcomes for percutaneous transforaminal endoscopic discectomy (PTED) and micro-endoscopic discectomy (MED) as alternative minimally invasive procedures for lumbar disc herniation. A literature search provided eight studies in the final analysis totaling 805 patients. Only one of these studies was a randomized controlled trial, while the others were observational studies. From the data extracted, visual analog scale (VAS) and Oswestry Disability Index (ODI) were considered the primary outcomes. The author's analysis concluded that PTED resulted in a shorter hospital length of stay, but MED was superior for intraoperative fluoroscopy and total cost. Significant lower back pain was found in the PTED group short term and at one year postoperatively. No differences were found regarding the pain score or ODI. The authors' meta-analysis concluded that both the PTED and MED are safe and effective in treating lumbar disc herniation. Limitations included small number of studies included for review and findings based mainly on observational studies. Furthermore, different methodologies contributed to heterogeneity in the analyses and the surgeon skill level may have introduced bias.

Chen et al (2018) conducted a systematic review and meta-analysis to compare efficacy and safety between PETD and PEID for L5-S1 LDH. Nine studies involving 621 patients met inclusion criteria. Only three of these studies were reported to be randomized controlled trials. The results indicated that PETD was significantly associated with greater fluoroscopy times (mean difference 9.28 times); and longer operative time (mean difference 16.51 minutes) compared with PEID. However, there were no distinct differences between PETD and PEID in estimated blood loss (P = 0.24), bedtime after surgery (P = 0.32), hospitalization time (P = 0.27), or MacNab evaluation (P = 0.78). Similarly, no obvious differences were detected between PETD and PEID regarding VAS, JOA score, or ODI when measured preoperatively, 1 day postoperatively, 3 months postoperatively, or at the last follow up. In addition, no significant difference was found regarding overall incidence of complications between PETD and PEID (P = 0.14). Nevertheless, a significantly lower incidence rate of dural tear was observed in PETD compared with PEID (P = 0.04). The authors concluded that PETD had comparable clinical efficacy and safety compared with PEID; however, PEID was superior to PETD regarding fluoroscopy times and operative time. Therefore, PEID might be a better surgical procedure for L5-S1 LDH. The findings are limited by lack of separation in the analysis between randomized controlled trials and observational studies.

Liu et al. (2018, included in the Yu systematic review cited above) evaluated the clinical outcomes of PETD, micro endoscopic discectomy (MED), and microdiscectomy (MD) for treatment of symptomatic LDH. One hundred ninety-two patients with symptomatic LDH at L3-4 and L4-5 were included in this retrospective cohort study. The patients were divided into groups as follows: group A was treated with PETD and included 60 patients (31 men and 29 women) with a mean age of 36.2 years; group B was treated with MED and included 63 patients (32 men and 31 women) with a mean age of 33.1 years; and group C was treated with MD and included 69 patients (36 men and 33 women) with a mean age of 34.0 years. There were no significant differences in mean preoperative ODI score, and VAS scores for LBP and leg pain among groups A, B, and C. Incision length, duration of the operation, blood loss, creatine phosphokinase, length of hospital stay, and postoperative incision pain according to the VAS were best in the PETD group ($p < 0.05$). Fifty-five (91.6%), 59 (93.7%), and 62 patients (89.9%) had at least 2 years of follow-up in groups A, B, and C,

respectively. At the last follow-up, VAS scores of LBP and leg pain, and ODI scores were significantly better than preoperative correlates in all groups. The authors concluded that PETD, MED, and MD were all reliable techniques for the treatment of symptomatic LDH. With a restricted indication, PETD can result in rapid recovery and better clinical results after at least 2 years of follow-up. Findings are limited by the observational and retrospective design of the study. Additional studies with randomization, longer outcomes, and larger patient populations are needed to further evaluate PETD.

Transforaminal (TESSYS®) and Interlaminar Endoscopic Surgical Systems

A 2019 ECRI clinical evidence assessment on Transforaminal Endoscopic Spine System (TESSYS) (Joimax, Inc.) for Treating Lumbar Disc Herniation concluded that low-quality studies at high risk of bias and RCTs provide mixed evidence on efficacy and compared different procedures at different time points, which prevents drawing efficacy conclusions for percutaneous transforaminal endoscopic discectomy (PTED) with TESSYS or determining how it compares with other minimally invasive surgeries for lumbar hernia repair. TESSYS appears to be safe, with no AE differences between groups for most comparisons and a lower TESSYS event rate in one RCT.

In a prospective cohort study of 80 patients who underwent TESSYS for LDH, Wu et al. (2018, included in 2019 ECRI assessment above) evaluated outcome predictors in 36 men and 44 women with a mean age of 48.76±15.60 years (range: 24-78 years). The mean follow-up time was 25.15±9.76 months (range: 12-48 months). LDH with older age (odds ratio [OR]: 6.621; 95% confidence interval [CI], 0.632-20.846; $p=0.019$), high-intensity zone (HIZ) (OR: 8.152; 95% CI, 0.827-4.380; $p=0.003$), and larger disk herniation (OR: 6.819; 95% CI, 0.113-4.825; $p=0.017$) were the most significant negative outcome predictors. The study is limited by its lack of randomization and small patient population.

In a retrospective case series, Kosztowski et al. (2018) evaluated the risk for reherniation in the first year after transforaminal endoscopic decompression in 46 consecutive male and 38 female patients. Four patients required microdiscectomy due to reherniation at 5 months, 8 months, 9 months, and 10 months postoperatively. All the patients in the series reportedly improved immediately following their endoscopic procedures, and no patients presented with symptoms suggestive of reherniation until 5 months after their initial endoscopic surgery. Patients with reherniation tended to be young: 31, 45, 48, and 49 years of age: all less than the average patient age who underwent endoscopic surgery. The 1-year reherniation rate in this study is 4.7%. According to the authors, this suggests that the benefit of this technique may be that it is ultra-minimally invasive, but it may only be equal, not superior to microdiscectomy in its rate of reherniation. The study was limited by lack of comparison group and loss to follow up. RCTs with larger patient populations and longer follow-up periods are needed to further evaluate this technique in the treatment of LDH.

Pan et al. (2016, included in 2019 ECRI assessment above) performed a prospective case series to investigate the clinical outcomes of transforaminal endoscopic system (TESSYS) for discogenic lLBP (DLBP). Consecutive patients (N=62) with one-level DLBP underwent TESSYS from January 2010 to December 2013 with a mean follow-up of 26.8 ± 4.2 months. The VAS was used for back pain, the ODI for lumbar function, and the modified MacNab criteria for clinical global outcomes. Twenty-four patients showed only inflammatory granuloma on annulus tear tissues (Group A), 16 patients showed no annulus tear but adhesion and inflammatory granuloma among the intracanal annulus fibrous posterior longitudinal ligament and the abdomen side of the dura sac (Group B) and 22 patients showed both (Group C). The success rate of group C was much higher than A and B. The whole success

rate was 75.8%. Of the 4 patients with poor result, 2 refused further surgical treatment and showed either no improvement or worsening. The remaining 2 patients had spinal fusion surgery and achieved better results. VAS and ODI had significantly improved after surgery ($P < 0.01$). No unexpected complications were seen. The authors concluded that TESSYS is an effective method in treating DLBP. The findings of this study need to be validated by well-designed studies and are limited by lack of comparison group.

Sanusi et al. (2015) conducted a two-year retrospective case series of patients (N=201) who underwent transforaminal endoscopic discectomy at a tertiary neurosurgical center in the United Kingdom by a single surgeon. Mean time of onset of symptoms was 5.5 months and the most common level was L4/5 (53%). All endoscopic discectomies were performed under local anesthesia. The VAS of the pain dropped from an average of 7/10 pre-operatively to 0-1/10 in 95% of patients two weeks post operatively. Eighty-seven percent of the patients went back to their normal daily activities within two weeks. There were no cases of cerebrospinal fluid leak, hematoma formation or wound infection. One percent of patients developed a nerve root injury. 6% of patients had recurrent herniation and required microdiscectomy. The authors concluded that endoscopic discectomy can be an alternative approach to microdiscectomy, and the data shows that the far lateral endoscopic discectomy using the TESSYS technique has comparable outcomes to microdiscectomy. The study is limited by its retrospective observations and lack of comparison group.

Transforaminal Lumbar Interbody Fusion (TLIF)

Evidence in the peer-reviewed scientific literature evaluating percutaneous endoscopic fusion is limited to case series involving small sample populations. Published trials comparing this approach to open conventional approaches are lacking and strong conclusions regarding safety and efficacy cannot be made. Further studies are needed to establish safety and efficacy of this approach to lumbar fusion.

Giordan et al. (2021) performed a systematic review and meta-analysis to assess transforaminal endoscopic lumbar foraminotomy (TELF) outcomes in the treatment of lumbar foraminal stenosis consequent to bony stenosis or lateral disc herniation. Multiple databases were searched for studies published in the English language, involving patients older than 18 years old who underwent endoscopic foraminotomy. Outcomes included the rate of patients who showed "excellent" and "good" postoperative improvement, decreased leg pain, and improved Oswestry Disability Index (ODI) scores. A total of 14 studies that included 600 patients, were included in the analysis. Approximately 85% of patients improved significantly after TELF, without significant differences among different groups and with almost negligible adverse events rates. Mean leg pain decreased an average of 5.2 points, and ODI scores improved by 41.2%. Patients with previous spine surgery or failed back surgery syndrome had higher postoperative leg dysesthesia rates after TELF (14% vs. 1%, respectively). The investigators concluded that TELF is a useful and safe method to achieve decompression in foraminal stenosis. According to the investigators, the main limitation in this analysis is the lack of individual patient data, making predictive analysis subject to confounding bias. Also, six studies were estimated to have an elevated risk of bias. The investigators indicated that this systematic review and meta-analysis lacks randomized studies and that the level of evidence is relatively low (mostly level III), but that this is the best that is currently available from the literature.

In a systematic review and meta-analysis, Kou et al. (2021) compared clinical efficacy and safety of endoscopic lumbar interbody fusion (Endo-LIF) and minimally invasive

transforaminal lumbar interbody fusion (MIS-TLIF) in treatment of lumbar degenerative diseases. A literature search was performed using multiple databases. Studies published up to November 15, 2020, that compared Endo-LIF with MIS-TLIF for treating lumbar degenerative diseases were retrieved. Data were extracted according to predefined clinical outcome measures. Primary outcomes were preoperative and postoperative visual analog scale for leg and back pain and Oswestry Disability Index scores. Secondary outcomes were operative time and intraoperative blood loss; length of hospitalization; and complication, reoperation, and fusion rates. Data analysis was conducted with statistical software. The meta-analysis included 6 studies comprising 480 patients. Results of the merged analysis revealed similar complication, reoperation, and fusion rates and preoperative and postoperative visual analog scale for leg and back pain and Oswestry Disability Index scores for Endo-LIF and MIS-TLIF. Nevertheless, with the exception of longer operative time, Endo-LIF compared favorably with MIS-TLIF, with less intraoperative blood loss, shorter hospital stay, and better long-term functional outcome. Based on the evidence provided by this study, the investigators concluded that there is no significant difference in clinical efficacy and safety between Endo-LIF and MIS-TLIF in the treatment of lumbar degenerative diseases. Although Endo-LIF has a longer operative time, it has the advantages of less tissue trauma and rapid recovery after operation. This systematic review and meta-analysis has some limitations. First, it included 6 articles, and several of these articles had methodological defects. Therefore, the validity of the available data may lead to unsatisfactory results. Second, the total number of patients included is relatively small, which may have an impact on the study results owing to the limited statistical capacity of the data. Third, because of the small number of current relevant studies, with most of the follow-up periods lasting about 12 months, a comparison of the long-term clinical outcomes of the 2 surgical techniques could not be obtained. Therefore, more studies with longer follow-ups are needed to compare the long-term clinical outcomes of Endo-LIF with MIS-TLIF.

Zhu et al. (2021) conducted a systematic review and meta-analysis to compare clinical outcomes and complications of percutaneous endoscopic transforaminal lumbar interbody fusion (PE-TLIF) and minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) in treating degenerative lumbar disease. A comprehensive search of multiple databases was performed to identify related studies reporting the outcomes and complications of PE-TLIF and MIS-TLIF for degenerative lumbar disease. The clinical outcomes were assessed by the Visual Analog Scale and Oswestry Disability Index. In addition, the operative time, intraoperative blood loss, time to ambulation, length of hospital stay, fusion rate, and surgery-related complications were summarized. Forest plots were constructed to investigate the results. A total of 28 studies involving 1,475 patients were included in this meta-analysis. PE-TLIF significantly reduced operative time, intraoperative blood loss, time to ambulation, and length of hospital stay compared to MIS-TLIF. Moreover, PE-TLIF was superior to MIS-TLIF in the early postoperative relief of back pain. However, there were no significant differences in medium to long-term clinical outcomes, fusion rate, and incidence of complications between PE-TLIF and MIS-TLIF. The investigators concluded that medium to long-term clinical outcomes and complication rates of PE-TLIF were similar to MIS-TLIF for the treatment of degenerative lumbar disease. However, PE-TLIF shows advantages in less surgical trauma, faster recovery, and early postoperative relief of back pain. This systematic review and meta-analysis has some limitations. First, there is a high degree of statistical heterogeneity among the included studies. Another limitation is that most of the included studies are nonrandomized controlled trials. Randomized controlled trials are needed to confirm the results of this analysis.

Zhao et al. (2021) compared the clinical efficacy of percutaneous full-endoscopic transforaminal lumbar interbody fusion (Endo-TLIF) with percutaneous pedicle screws

(PPSs) performed by using a visualization system with that of minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) for the treatment of degenerative lumbar spinal stenosis (LSS). From June 2017 to May 2018, the data of 78 patients who met the selection criteria were retrospectively reviewed and were divided into the Endo-TLIF group (40 cases) and the MIS-TLIF group (38 cases) according to the surgical method used. The visual analog scale (VAS) and the Japanese Orthopaedic Association (JOA) scale were administered preoperatively and at the 1-week, 3-month, and 1-2-year follow-ups. The fusion rate and major complications, including revision, were also recorded. All the patients were followed up for 24 to 34 months, with an average follow-up of 30.7 months. The intraoperative blood loss and length of hospital stay for the Endo-TLIF group were statistically significantly lower than those for the MIS-TLIF group. The VAS and JOA scores of the patients in the two groups at postoperative 1 week, 3 months, 1 year, 2 years were statistically significantly improved from the preoperative scores. The VAS and JOA scores of the Endo-TLIF group were statistically significantly better than those of the MIS-TLIF group at 3 months and 1 year after surgery. There were no statistically significant differences in the scores between the two groups at any of the other time points. There was no significant difference in the intervertebral altitude between the two groups at the 3-month or final follow-up. Dural tears, cerebrospinal fluid leakage, infection, and neurologic injury did not occur. Both groups showed good intervertebral fusion at the last follow-up. The intervertebral fusion rate was 97.5% in the Endo-TLIF group and 94.7% in the MIS-TLIF group, with no statistically significant difference between the two groups. The authors concluded that endo-TLIF with percutaneous pedicle screws performed by using a visualization system for lumbar degenerative disease may be regarded as an efficient alternative surgery for degenerative lumbar spinal stenosis. It is a safe and minimally invasive way to perform this surgery and has shown satisfactory clinical outcomes. This is a retrospective study with a small sample size. Long-term follow-up and multicenter, randomized controlled clinical trials are needed to verify the results of this study.

ECRI (2019) conducted a clinical evidence review of the Transforaminal Endoscopic Spine System. They concluded that low-quality studies at high risk of bias and RCTs provide mixed evidence on efficacy and compared different procedures at different time points, which prevents drawing efficacy conclusions for percutaneous transforaminal endoscopic discectomy (PTED) with TESSYS or determining how it compares with other minimally invasive surgeries for lumbar repair. The nonrandomized comparisons are at high risk of bias due to lack of randomization, retrospective design, and/or single-center focus; the case series and cohort study are at high bias due to lack of randomization, small size, and single-center focus. Studies primarily measured efficacy using subjective measures of pain relief and disability.

Lan et al. (2018) compared the efficacy and safety in the management of lumbar diseases performed by either posterior lumbar interbody fusion (PLIF) or transforaminal lumbar interbody fusion (TLIF). Sixteen studies involving 1502 patients were included in the metanalysis. The authors found that while TLIF was superior to PLIF, both achieved similar outcomes. While interbody fusion is considered the gold standard, both PLIF and TLIF have been promoted as promising techniques however the authors indicate these techniques remain controversial. Limitations of the study identified additional well-designed RCTs with long-term outcomes and larger sample sizes are warranted.
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~~A Hayes technology report (2018) stated that low-quality evidence from direct comparisons for MITLIF may offer benefit over OTLIF on some clinical and safety outcomes, as well as certain perioperative measures. However, due to the lack of good-quality randomized controlled trials with sufficient duration of follow-up, the balance of benefits and harms between MITLIF and OTLIF remains unclear, and the superiority or equivalence of MITLIF has not yet been definitively established.~~

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A retrospective study by Price et al. (2017) compared clinical results and radiographic outcomes of minimally invasive surgery (MIS) versus open techniques for transforaminal lumbar interbody fusion (TLIF). A consecutive series of 452 1 or 2-level TLIF patients at a single institution between 2002 and 2008 were analyzed. A total of 148 were MIS patients and 304 were open. Oswestry disability index (ODI) and visual analog (VAS) pain scores were documented preoperatively and postoperatively. Fusion was at a minimum of 1-year follow-up. The author's concluded MIS TLIF produces comparable clinical and radiologic outcomes to open TLIF with the benefits of decreased intraoperative blood losses, shorter operative times, shorter hospital stays and fewer deep wound infections. Results are limited by study design, and lack of a control. Further prospective studies investigating long-term functional results are required to assess the definitive merits of percutaneous instrumentation of the lumbar spine.

~~A retrospective study by~~ **Villavicencio et al. (2010) conducted a retrospective study comparing** ~~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.

~~Professional Societies~~ Clinical Practice Guidelines

American Association of Neurological Surgeons/Congress of Neurological Surgeons (AANS/CNS)

The AANS/CNS published a guideline update in 2014 on the performance of fusion procedures for degenerative disease of the lumbar spine, with part of the guideline update focused on interbody techniques for lumbar fusion. This guideline did not offer any specific recommendations pertaining to TLIF in general, or MITLIF specifically. The authors indicated that there was no conclusive evidence of superior clinical or radiographic outcomes based on technique when performing interbody fusion. Therefore, no general recommendations were offered regarding the technique that should be used to achieve interbody fusion. The authors also noted that they did not analyze any comparisons of minimally invasive surgery (MIS) versus traditional open surgery in this report (Mummaneni et al., 2014).

North American Spine Society (NASS)

NASS published clinical guidelines for treatment of adult isthmic spondylolisthesis (Kreiner et al., 2014) and degenerative spondylolisthesis (Matz et al., 2014). These guidelines did not offer any specific recommendations pertaining to the use of MITLIF versus OTLIF procedures. However, both guidelines recommend the development of randomized controlled trials or prospective comparative studies comparing MIS versus traditional open surgical techniques in adult patients with these conditions ~~(Kreiner et al., 2014; Matz et al., 2014). In addition, NASS recommends that future studies provide clear and consistent definitions of what MIS techniques entail (Matz et al., 2014.).~~

~~**Spinal Fusion**~~

~~Lumbar spinal fusion has been shown to result in reduced pain and improved function in select patients. Minimally invasive techniques have been developed for intertransverse process, posterior lumbar interbody, and transforaminal lumbar interbody fusions.~~

~~***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. The average sample size of these studies varies but range on average from 40 to more than 200 patients. Many studies are outdated with average being over twenty years ago. 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.~~

~~***Transforaminal Lumbar Interbody Fusion (TLIF)***~~

~~Evidence in the peer-reviewed scientific literature evaluating percutaneous endoscopic fusion is limited to case series involving small sample populations. Published trials comparing this approach to open conventional approaches are lacking and strong conclusions regarding safety and efficacy cannot be made. Further studies are needed to establish safety and efficacy of this approach to lumbar fusion.~~

~~ECRI (2019) conducted a clinical evidence review of the Transofaminal Endoscopic Spine System. They concluded that low quality studies at high risk of bias and RCTs provide mixed evidence on efficacy and compared different procedures at different time points, which prevents drawing efficacy conclusions for percutaneous transforaminal endoscopic discectomy (PTED) with TESSYS or determining how it compares with other minimally invasive surgeries for lumbar repair. The nonrandomized comparisons are at high risk of bias due to lack of randomization, retrospective design, and/or single center focus; the case series and cohort study are at high bias due to lack of randomization, small size, and single center focus. Studies primarily measured efficacy using subjective measures of pain relief and disability.~~

~~A Hayes technology report (2018) stated that low quality evidence from direct comparisons for MITLIF may offer benefit over OTLIF on some clinical and safety outcomes, as well as certain perioperative measures. However, due to the lack of good quality randomized controlled trials with sufficient duration of follow up, the balance of benefits and harms between MITLIF and OTLIF remains unclear, and the superiority or equivalence of MITLIF has not yet been definitively established.~~

~~Lan et al. (2018) compared the efficacy and safety in the management of lumbar diseases performed by either posterior lumbar interbody fusion (PLIF) or transforaminal lumbar interbody fusion (TLIF). Sixteen studies involving 1502 patients were included in the metanalysis. The authors found that while TLIF was superior to PLIF, both achieved similar outcomes. While interbody fusion is considered the gold standard, both PLIF and TLIF have been promoted as promising techniques however the authors indicate these techniques remain controversial. Limitations of the study identified additional well-designed RCTs with long term outcomes and larger sample sizes are warranted.~~

~~A retrospective study by Price et al. (2017) compared clinical results and radiographic outcomes of minimally invasive surgery (MIS) versus open techniques for transforaminal lumbar interbody fusion (TLIF). A consecutive series of 452 1 or 2 level TLIF patients at a single institution between 2002 and 2008 were analyzed. A total of 148 were MIS patients and 304 were open. Oswestry disability index (ODI) and visual analog (VAS) pain scores were documented preoperatively and postoperatively. Fusion was at a minimum of 1 year follow up. The author's concluded MIS TLIF produces comparable clinical and radiologic outcomes to open TLIF with the benefits of decreased intraoperative blood losses, shorter operative times, shorter hospital stays and fewer deep wound infections. Results are limited by study design, and lack of a control. Further prospective studies investigating long term functional results are required to assess the definitive merits of percutaneous instrumentation of the lumbar spine.~~

~~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.~~

~~Professional Societies~~

~~*American Association of Neurological Surgeons/Congress of Neurological Surgeons (AANS/CNS)*~~

~~The AANS/CNS published a guideline update in 2014 on the performance of fusion procedures for degenerative disease of the lumbar spine, with part of the guideline update focused on interbody techniques for lumbar fusion. This guideline did not offer any specific recommendations pertaining to TLIF in general, or MITLIF specifically. The authors indicated that there was no conclusive evidence of superior clinical or radiographic outcomes based on technique when performing interbody fusion. Therefore, no general recommendations were offered regarding the technique that should be used to achieve interbody fusion. The authors also noted that they did not analyze any comparisons of minimally invasive surgery (MIS) versus traditional open surgery in this report (Mummaneni et al., 2014).~~

~~*North American Spine Society (NASS)*~~

~~NASS published clinical guidelines for treatment of adult isthmic spondylolisthesis (Kreiner et al., 2014) and degenerative spondylolisthesis (Matz et al., 2014). These guidelines did not offer any specific recommendations pertaining to the use of MITLIF versus OTLIF procedures. However, both guidelines recommend the development of randomized controlled trials or prospective comparative studies comparing MIS versus traditional open surgical techniques in adult patients with these conditions (Kreiner et al., 2014; Matz et al., 2014). In addition, NASS recommends that future studies provide clear and consistent definitions of what MIS techniques entail (Matz et al., 2014).~~

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

~~Evidence in the published scientific literature and from professional organizations supports lumbar fusion as an established standard of treatment for a selected group of patients with low back pain. Data comparing DLIF/XLIF to other traditional or minimally invasive approaches to interbody fusion is limited therefore no conclusions can be drawn regarding efficacy compared to other standard surgical approaches. While additional clinical trials are necessary to demonstrate impact on meaningful long-term clinical outcomes, the published evidence suggests in the short- to intermediate-term lateral interbody fusion is safe and effective as an alternative to anterior or posterior fusion approaches. Although there are no formal professional society statements supporting lateral interbody fusion in the form of XLIF or DLIF, the North American Spine Society (NASS, 2014) indicates these methods are a modified standard approach for lateral interbody fusion (archived 2020).~~

~~A 2018 Hayes literature search identified five studies that evaluated the efficacy and safety of XLIF for the treatment of chronic LBP in adults with degenerative spinal disorders. Overall, a low-quality body of evidence suggests that XLIF may be efficacious in improving pain, disability, and quality of life (QOL). Comparative evidence does not demonstrate a clear clinical benefit of XLIF over other interbody fusion techniques, and procedural benefits vary between comparisons. Study limitations include observational and retrospective study design. The evidence lacked an overall consistency across outcomes. Furthermore, the lack of studies sufficiently powered to determine differences between groups confounds determinations that can be made regarding the comparative effectiveness of XLIF with other interbody fusion techniques.~~

~~A poor-quality registry analysis compared XLIF with ALIF in patients with DDD or grade 1 to 2 spondylolisthesis with follow-up of > 24 months (Malham et al., 2016). The results suggest that VAS back and leg pain, ODI, and SF-36 scores for both groups were statistically significantly improved from baseline without between-group statistically significant differences in the number of patients who met predefined MCID criteria. Improvements in patient-reported clinical outcomes were clinically significant for both the XLIF and ALIF groups; respective scores for XLIF and ALIF groups were: VAS back pain improvement, 56% and 64%; VAS leg pain improvement, 57% and 65%; ODI score improvement, 52% and 60%; SF-36 physical component score improvement, 48% and 44%. The number of major or minor complications was not significantly different between groups. Study limitations include the observational and retrospective study design, between-group baseline differences, potential for selection bias demonstrated by implementing different inclusion criteria for intervention groups, and small sample size.~~

~~A 2012 study examining the clinical outcome and fusion rates of 30 XLIF procedures (Malham et al., 2012) evaluated pain, disability, and quality of life. CT assessment of fusion was also performed. Average follow up time was 11.5 months. Complications were observed: clinical subsidence, cage breakage upon insertion, new postoperative motor deficit and bowel injury. Approach side-effects were radiographic subsidence and anterior thigh sensory changes. Two patients required reoperation; microforaminotomy and pedicle screw fixation respectively. VAS back and leg pain decreased 63% and 56%, respectively. ODI improved 41.2% with 51.3% and 8.1% improvements in PCS and MCS. Complete fusion (last follow-up) was observed in 85%. The authors felt XLIF does provide superior treatment, clinical outcomes, and fusion rates compared to conventional surgical approaches. However, they caution surgical mentor supervision for early cases.~~

~~Professional Societies/Position Statements~~

~~*American Association of Neurological Surgeons/Congress of Neurological Surgeons (AANS/CNS)*~~

~~In an evidence-based guideline on interbody fusion procedures for degenerative disease of the lumbar spine, AANS/CNS states that there is insufficient evidence to recommend a treatment standard (Resnick et al., 2014). Lateral interbody fusion (including its synonyms) is not mentioned.~~

~~*National Institute for Health and Care Excellence (NICE)*~~

~~NICE defines lateral interbody spinal fusion as a procedure that removes all or part of the damaged disk and inserts a supporting structure, with the objective of fusing two vertebrae to prevent painful joint motion through an incision in the patient's side. In its evidence based draft recommendations, NICE states that current evidence on the safety of lateral (extreme, extra, and direct lateral) interbody fusion in the lumbar spine for LBP shows that there are serious recognized complications, although evidence on efficacy is adequate in quality and quantity. The procedure may be used if arrangements are provided for clinical governance, audit, and consent (NICE, 2017).~~

~~Axial Lumbar Interbody Fusion (AxiaLIF)~~

~~Although this method may be considered an emerging minimally invasive surgical approach, no randomized controlled trials were found in the peer reviewed, published, scientific literature supporting safety and efficacy. Improvement in net health outcomes has not been 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.~~

~~Evidence from case series in one systematic review and one additional case series (not in the systematic review) is at too high a risk of bias to support conclusions on safety and effectiveness of one-level lumbar interbody fusion or L5-S1 spondylolisthesis or spondylosis with AxiaLIF. Multicenter randomized controlled trials (RCTs) comparing AxiaLIF to traditional interbody approaches are needed to assess AxiaLIF for one- and two-level interbody fusions and to compare axial lumbar interbody fusion with other surgical approaches. 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. (ECRI, 2018; updated 2020)~~

~~Hayes performed a literature review of the AxiaLIF system. The overall quality of the evidence was low. The published studies included small study populations, lacked control groups, and reported on relatively short-term outcomes. Due to the lack of comparative studies, there is no evidence to determine if AxiaLIF confers any health benefits compared with standard open and other minimally invasive fusion procedures. In addition, questions regarding long-term improvement in functional status and quality of life have not been adequately addressed. Randomized controlled trials are needed to better define patient selection criteria and the optimal clinical role of AxiaLIF compared with other fusion techniques. The evidence is currently insufficient to allow conclusions regarding the long-term health benefits, relief of symptoms, improvement in functional levels, complication and failure rates, and the need for additional surgery. (Hayes, 2015, archived 2020)~~

~~Schroeder et al. (2015) performed a systematic review of seventy-four articles discussing safety profile of axial interbody arthrodesis, but only 15 (13 case series and two retrospective cohort studies) met the study inclusion criteria. The authors concluded that review of the literature indicates that an axial interbody fusion performed at the lumbosacral junction is associated with a high fusion rate (93.15%) and an acceptable complication rate (12.90%). However, these results are based mainly on retrospective case series by authors with a conflict of interest. The limited prospective data available indicate that the actual fusion rate may be lower, and the complication rate may be higher than currently reported.~~

~~Zeilstra et al (2013) reported their 6-year single-center experience with L5-S1 axial lumbar interbody fusion (AxiaLIF). A total of 131 patients with symptomatic degenerative disc disease refractory to non-surgical treatment were treated with AxiaLIF at L5-S1 and were followed for a minimum of 1 year. Main outcomes included back and leg pain severity, Oswestry Disability Index score, working status, analgesic medication use, patient satisfaction, and complications. Back and leg pain severity decreased by 51% and 42%, respectively, during the follow-up period. Back function scores improved 50% compared to baseline. The authors concluded that single-level AxiaLIF is a safe and effective means to achieve lumbosacral fusion in patients with symptomatic degenerative disc disease. Moreover, they noted that "Our study is limited by the retrospective nature of the analysis. Additionally, all patients underwent fusion at L5 to S1 and, therefore, no conclusions can be drawn regarding the effectiveness or safety of 2-level AxiaLIF from~~

~~this report. Lastly, mean patient follow-up was 21 months. Although this represents one of the longest follow-up reports following AxiaLIF surgery, long-term clinical and radiographic outcomes are unknown."~~

~~In a 5-year post-marketing surveillance study, Cundanna et al. (2011) reported complications associated with axial presacral lumbar interbody fusion in 9,152 patients. A single-level L5-S1 fusion was performed in 8,034 patients (88%), and a two-level L4-S1 fusion was performed in 1,118 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.~~

~~Professional Societies/Position Statements~~

~~*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 (2014). Surgical decompression is recommended for patients with symptomatic neurogenic claudication due to lumbar stenosis without spondylolisthesis who elect to undergo surgical intervention. In the absence of deformity or instability, lumbar fusion has not been shown to improve outcomes in patients with isolated stenosis, and therefore it is not recommended.~~

~~*National Institute for Health and Clinical Excellence (NICE)*~~

~~The NICE guidance stated that the evidence on the safety of transaxial interbody lumbosacral fusion for severe chronic low back pain shows that there are serious but well recognized complications. 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, 2018).~~

~~*North American Spine Society (NASS)*~~

~~NASS published guidelines on the treatment of degenerative spondylolisthesis in 2014. NASS has stated that there is insufficient evidence to make a recommendation for or against the cost-effectiveness of minimal access based surgical treatments compared to traditional open surgical treatments for degenerative lumbar spondylolisthesis. This guideline did not specifically address axial lumbosacral interbody fusion (AxiaLIF).~~

~~Spinal Decompression and Interspinous Process Decompression Systems~~

~~Interspinous Process Decompression (IPD) Systems~~

~~Evidence in the published peer-reviewed scientific literature is lacking; long-term safety and efficacy has not been established despite FDA approvals for most of these devices. Overall, use of interspinous or interlaminar distraction devices (spacers) used as an alternative to spinal decompression show high failure and complication rates. Greater certainty about the net health benefit of these devices may be obtained when recently completed and moderately sized RCT on decompression with and without the~~

~~implants are published. The evidence at this time is insufficient to determine the effects of the technology on health outcome.~~

~~A 2015 meta-analysis by Hong et al. included 20 studies with 3,155 patients in the interspinous spacers group and 50,983 patients treated with open decompression. Results of this meta-analysis were similar to those obtained in the more selective analysis by Wu et al. There was no significant difference between the two procedures for improvement rate, Oswestry Disability Index (ODI), or visual analog scale (VAS) for back or leg pain. Although secondary outcomes such as operative and hospitalization time, perioperative blood loss, and postoperative complication rate were superior in the spacer group, reoperation rate was higher in that group (16.5% vs. 8.7%). Because of the higher reoperation rate the authors concluded that, while the use of spacers may be a viable technique, they could not conclude that it had replaced open decompression surgery as the gold standard for treatment of lumbar spinal stenosis.~~

~~In 2014, Wu et al., conducted a meta-analysis of two RCTs and three non-randomized prospective comparative studies. There were 204 patients in the interspinous spacer group and 217 patients in the decompressive surgery group. Pooled analysis showed no significant difference at 12 and 24 months between the spacer and decompression groups for low back pain, leg pain, ODI, Roland Disability Questionnaire (RDQ) or complications. However, the traditional decompressive surgery group had a significantly lower incidence of reoperation, with 11 of 160 cases requiring reoperation compared to 31 of 161 cases in the interspinous spacer group. Several limitations to this meta-analysis were listed, with the primary concern being the small number of studies in the published literature comparing spacers and traditional decompression surgery. Although risk of bias was analyzed, no narrative critical appraisal of the included articles was provided. The authors noted the high reoperation rate associated with spacer use and stated that the indications, risks, and benefits of these devices required careful consideration before surgery.~~

~~X-STOP~~

~~Studies with long-term follow-up are needed to ascertain the clinical longevity and durability of any beneficial effects of the X-STOP device, and to evaluate safety. Definitive patient selection criteria for X-STOP therapy have not been established, and it remains unclear whether the efficacy and safety of the X-STOP device are sufficient to allow patients to undergo this treatment instead of decompression laminectomy.~~

~~In 2015, Lønne et al. reported a trial of X-STOP versus minimally invasive decompression in 96 patients with symptoms of neurogenic intermittent claudication relieved on flexion. Intention-to-treat analysis showed no significant differences between the groups in primary and secondary outcome measures at up to 2-year follow-up. However, the number of patients having secondary surgery due to persistent or recurrent symptoms was significantly higher in the X-STOP group. The study was terminated after planned mid-term analysis due to the higher reoperation rate with X-STOP.~~

~~In 2015, 2- and 3-year results were published from an FDA-regulated, multicenter randomized, investigational device exemption (IDE), non-inferiority trial comparing the Superion interspinous spacer with the X-STOP. A total of 391 patients with intermittent neurogenic claudication despite 6 months of nonsurgical management were enrolled, randomized, and implanted with either Superion or X-STOP spacers, and followed for 2 years. The primary end point was a composite of clinically significant improvement in at least 2 of 3 ZCQ domain scores compared with baseline, freedom from reoperation,~~

~~revision, removal, or supplemental fixation at the index level, freedom from epidural steroid injection or nerve block within 12 weeks of the 2-year visit, freedom from rhizotomy or spinal cord stimulator at any level, and freedom from major implant or procedure-related complications. The primary noninferiority end point was met, with a Bayesian posterior probability of 0.993. However, 111 patients (28%; 54 Superion, 57 XSTOP) were withdrawn from the study during follow-up due to a protocol-defined secondary intervention (Patel).~~

~~At 3-year follow-up, there were 120 patients in the Superion ISS group and 129 in the X-STOP group remaining (64% of 391). Of these, composite clinical success was obtained in 52.5% of patients in the Superion ISS group and 38.0% of the X-STOP group (p = 0.023). The 36-month clinical outcomes were reported for 82 patients in the Superior ISS group and 76 patients in the X-STOP group (40% of 391). It is not clear from the report whether the remaining patients were lost to follow-up or were considered treatment failures and censured from the results. In addition, interpretation of this study is limited by questions about the efficacy of the comparator and lack of a control group treated by surgical decompression.~~

~~Puzzilli et al (2014) prospectively evaluated patients treated for symptomatic lumbar spinal stenosis with interspinous process decompression (IPD) implants compared with a population of patients managed with conservative treatment in a multicenter study. Five hundred forty-two patients affected by symptomatic lumbar spine degenerative disease were enrolled in a controlled trial. Four hundred twenty-two patients underwent surgical treatment consisting of X-STOP device implantation, whereas 120 control cases were managed conservatively. Both patient groups underwent follow-up evaluations at 6, 12, 24, and 36 months using the Zurich Claudication Questionnaire, the Visual Analog Scale score and spinal lumbar X-rays, CT scans and MR imaging. One-year follow-up evaluation revealed positive good results in the 83.5% of patients treated with IPD with respect to 50% of the nonoperative group cases. In 24 of 422 patients, the IPD device had to be removed, and a decompression and/or pedicle screw fixation was performed because of the worsening of neurological symptoms. The authors concluded results support the effectiveness of surgery in patients with stenosis. IPD may offer an effective and less invasive alternative to classical microsurgical posterior decompression in selected patients with spinal stenosis and lumbar degenerative disk diseases.~~

~~Hartjen et al. (2016) conducted a multicenter, prospective comparative study to assess the efficacy and safety of X-STOP in 55 patients with LSS. There were two groups: patients who were new study participants and patients from a prior RCT (Zucherman et al., 2005) who did not respond to nonsurgical management and crossed over to treatment with the X-STOP. Outcomes were pain and disability assessed by the ZCQ and SF-36. Patients were evaluated at 6 weeks, 6 months, 12 months, and 2 years.~~

- ~~At 2 years, 61% of the patients had a significant improvement in the symptom severity domain and 60% had a significant improvement in the physical function domain of the ZCQ. At 2 years, there was a 24.5% improvement in the mean symptom severity domain and a 27.8% improvement in the mean physical function domain. According to the ZCQ patient satisfaction domain, 71% of the patients were at least somewhat satisfied with their surgical results.~~
- ~~At 2 years, there was statistically significant improvement in the SF-36 Physical Component Summary score and the individual domains of physical function, role physical, bodily pain, vitality, and social function (p < 0.001 for all outcomes). There was no significant improvement in the general health domain.~~

- ~~The mean improvements in ZCQ and SF-36 scores were not as pronounced in the crossover group compared with the new participants.~~

~~Strömqvist et al. (2013) reported the 2-year outcomes of a noninferiority randomized trial of 100 patients with symptomatic one- or two-level lumbar spinal stenosis with neurogenic claudication relieved on flexion. Patients were randomized in a 1:1 ratio to undergo either X-STOP implantation or conventional surgical decompression. At 6, 12, and 24 months follow-up, there was no significant difference in scores for symptoms and function, or for complication rates. Reoperation rates were significantly higher in the X-STOP group than in the decompression group. Long-term data is needed to determine the durability of treatment effects and to compare the long-term reoperation rates.~~

~~Nandakumar et al. (2013) reported 2-year follow-up results of patients treated with the X-STOP for symptomatic spinal stenosis. 46 of 57 patients completed the ZCQ questionnaire at 2 years. Results found 70% were satisfied at 2-years with the surgery. Single level and double level insertions did not have significant difference in clinical outcome.~~

~~Miller and Block (2012) published the preliminary results of a multicenter randomized investigational device exemption (IDE) non-inferiority trial which was regulated by the FDA. A total of 166 individuals with moderate lumbar spinal stenosis (LSS) unresponsive to conservative care were treated randomly with the Superion (n = 80) or X-STOP (n = 86) interspinous spacer. Study participants were followed through 6 months post-treatment. At 6 month follow-up, the preliminary results suggest that the Superion interspinous spacer and the X-STOP each effectively alleviate pain and improve back function in individuals with moderate LSS who are unresponsive to conservative care. The complication rate was similar for both groups; 20 % for the Superion group and 20% for the X-STOP group. The FDA-mandated primary endpoint of this IDE clinical trial is 2 years, with post-market surveillance scheduled for 10 years.~~

~~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 two 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.~~

~~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.~~

~~CoFlex~~

~~ECRI (2019) conducted an evidence review of the CoFlex interlaminar stabilization device for treating lumbar spinal stenosis. The health technology assessment literature search identified two systematic reviews, two randomized controlled trials, four non-randomized controlled trials and three cost analysis studies. The two systematic reviews addressed the safety and efficacy of the CoFlex device as compared to decompression and/or fusion. The evidence from the literature review suggests the CoFlex device may be effective at reducing pain and improving patient functionality along with quality of life than decompression alone. Limitations of the evidence included risk of bias in four of the studies due to lack of randomization, small sample sizes and lack of long-term outcomes.~~

~~The literature search of the CoFlex interlaminar stabilization device that evaluated the efficacy and safety of the CoFlex Interlaminar Stabilization device for treating symptomatic LSS. An overall low-quality body of evidence suggests that the CoFlex device is associated with similar improvements in pain, function, and disability compared with fusion or decompression alone with up to 5-years follow-up and without substantial unique safety concerns. Study limitations such as an inadequate follow-up time, small sample size, retrospective design, or lack of a control group. Interstudy comparisons are hampered by heterogeneous patient populations, and differences in study design, treatment protocols, and comparators. Additional, high-quality studies are needed before definitive conclusions can be reached. (Hayes 2018, updated 2020).~~

~~In a prospective, randomized multicenter study, Schmidt et al. (2018, included in ECRI report above) reported on the 2-year results of a study comparing treatment with decompression with interlaminar stabilization with the CoFlex device to decompression alone in individuals with moderate to severe lumbar spinal stenosis at one or two adjacent levels. A total of 115 individuals were randomized to each arm. A composite clinical success (CCS) measure consisting of four components: ODI improvement > 15 points, survivorship with no secondary surgeries or lumbar injections, maintenance or improvement of neurological symptoms, and no device- or procedure-related severe AEs. At 24 months, there were no significant differences between the groups in the patient reported outcomes: the ODI scores, VAS back and neck pain scores and the Zürich Claudication Questionnaire. There were no significant differences in patient-reported outcomes between the groups. There were no significant differences in the primary outcome measures between the groups. However, when the secondary measure outcome of subsequent epidural injections (4.5% in the D+ILS group versus 14.8% in the DA group) was included in the CCS, the result became significant.~~

~~A systematic review by Machado and colleagues (2016) included three studies which compared interspinous process spacer devices to conventional decompression. The authors noted no studies directly compared spacers with decompression surgery but were based on indirect comparisons. A total of 355 individuals were included in studies for the CoFlex and X-stop devices. The authors concluded that while surgery using the interspinous spacer devices resulted in less blood loss and shorter hospital stays when compared to fusion, use of the devices did not lead to improved outcomes when compared to~~

~~decompression. In addition, interspinous spacer devices were associated with higher reoperation rates.~~

~~Musacchio et al. (2016) completed a prospective, randomized, controlled trial that was conducted at 21 centers. The purpose of this study was to investigate 5-year outcomes associated with an interlaminar device. Results of this 5-year follow-up study demonstrate that decompression and interlaminar stabilization with CoFlex is a viable alternative to traditional decompression and fusion in the treatment of patients with moderate to severe stenosis at one or two lumbar levels. Additional randomized, controlled studies are needed to clearly outline the indications for their use.~~

~~Moojen et al. (2015) completed a randomized double-blind study in which interspinous process devices (IPDs) are implanted to treat patients with intermittent neurogenic claudication (INC) based on lumbar spinal stenosis. It is hypothesized that patients with lumbar spinal stenosis treated with IPD have a faster short-term recovery, an equal outcome after 2 years and less back pain compared with bony decompression. Five neurosurgical centers included participants. Two hundred eleven participants were referred to the Leiden-The Hague Spine Prognostic Study Group. 159 participants with INC based on lumbar spinal stenosis at one or two levels with an indication for surgery were randomized into two groups. Patients and research nurses were blinded for the allocated treatment throughout the study period. Eighty participants received an IPD, and 79 participants underwent spinal bony decompression. The primary outcome at long-term (2-year) follow-up was the score for the Zurich Claudication Questionnaire. Repeated measurement analyses were applied to compare outcomes over time. This double-blinded study could not confirm the advantage of IPD without bony decompression over conventional 'simple' decompression, two years after surgery. Moreover, in the IPD treatment arm, the reoperation rate was higher and back pain was even slightly more intense compared to the decompression treatment arm. The use of interspinous implants did not result in a better outcome than conventional decompression, and the reoperation rate was significantly higher.~~

~~Richter et al. (2014, included in ECRI report above) also published 2-year follow-up results for 60 patients who underwent decompressive surgery with or without implantation of the CoFlex device. Though comparative, this study was not a randomized trial; treatment was allocated at the discretion of the surgeon. The authors reported no significant between-group differences in any outcome measures and concluded that "additional placement of a CoFlex™ interspinous device does not improve the already good clinical outcomes after decompression surgery for LSS in this 24-month follow up interval."~~

~~In a multicenter, randomized controlled manufacturer-funded Food and Drug Administration (FDA) Investigational Device Exemption (IDE) trial conducted in the United States, compared outcomes between decompression followed by CoFlex implantation and decompression followed by instrumented posterolateral spinal fusion in 322 patients (215 CoFlex and 107 fusions). Patients were stratified by site and number of vertebral levels to be treated and were randomized to treatment with the CoFlex, or spinal fusion group. The primary objective was to evaluate the safety and efficacy of CoFlex interlaminar stabilization compared with posterior spinal fusion in the treatment of 1- and 2-level spinal stenosis and degenerative spondylolisthesis. Patient follow-up at minimum 2 years was 95.3% and 97.2% in the CoFlex and fusion control groups, respectively. Patients taking CoFlex experienced significantly shorter operative times, blood loss, and length of stay. There was a trend toward greater improvement in mean Oswestry Disability Index scores in the CoFlex cohort. Both groups demonstrated significant improvement from baseline in all~~

~~visual analogue scale back and leg parameters. The overall adverse event rate was similar between the groups, but CoFlex had a higher reoperation rate. At 2 years, fusions exhibited increased angulation and a trend toward increased translation at the superior adjacent level, whereas CoFlex maintained normal operative and adjacent level motion. While the changes with fusion were expected, longer follow-up is needed to determine whether motion preservation with CoFlex leads to lower reoperation rates, compared with fusion, for adjacent level disease (Davis et al. 2013).~~

~~Bae and colleagues (2017) performed a 3-year follow-up analysis of the Davis (2013a) RCT. At 36 months, 91% (195/215) of the CoFlex group and 88% (94/107) of the fusion group were included in the analysis. The initial efficacy endpoints (composite scores) were modified for use at 36 months. At 36 months, 62.2% of the individuals in the CoFlex group compared to 48.9% of the individuals in the 94 group reported composite clinical success scores. There are several limitations in this study including the limited follow-up period and the heterogeneous mix of individuals. The authors noted that an RCT comparing decompression and stabilization with CoFlex device to decompression alone will be underway in the near future. Four-year follow-up was reported in 2015 and 5-year follow-up was reported in 2016. The reported rate of follow-up at 5 years ranged from 40% to 100%, depending on the outcome measured. For example, the ODI at 6 months was reported for 56% of patients, while major device-related complications and composite clinical success were reported for 100% of patients. Interpretation of the 5-year results is limited by the variable loss to follow-up in outcomes.~~

~~Superion~~

~~Evidence is lacking, large well-designed studies in the peer review scientific literature comparing stand-alone use of Superion device to established surgical decompression are needed. Published studies do not demonstrate any long-term health outcome advantage with the use of Superion as an alternative to standard surgical treatment. Large population sufficiently powered randomized controlled trials that demonstrate long-term health outcome advantages are needed.~~

~~Hayes (2020) performed full-text review of systematic studies using Superion interspinous spacers for the treatment of lumbar spinal stenosis and neurogenic claudication. Based on a review of these guidelines and position statements, guidance appears to confer no support or unclear support for the Superion Interspinous Spacer, specifically, for the treatment of lumbar spinal stenosis with neurogenic claudication. Studies were of very poor or poor quality and no comparative studies were identified. Studies do not demonstrate equal or superior benefits or advantages over commercially available alternatives or fusion surgery.~~
~~Therefore, the impact of the Superion ISS on long-term net health outcomes is not currently know and requires further investigation.~~

~~ECRI (2019) performed clinical evidence review of Superion decompression system. Study limitations include single-center focus, small sample size, retrospective design, and lack of controls, randomization, and blinding. Independent RCTs comparing Superion with other devices are required to validate long-term health outcomes.~~

~~Patel et al. (2015) reported 3-year clinical outcomes from the randomized, controlled US Food and Drug Administration Investigational Device Exemption trial of the Superion® for the treatment of moderate degenerative lumbar spinal stenosis. The 3-year outcomes from this randomized controlled trial demonstrate durable clinical improvement consistently across all clinical outcomes for the Superion® in the treatment of patients with moderate~~

~~degenerative lumbar spinal stenosis. Longer-term studies are in progress as part of FDA post-approval requirements.~~

~~Nunley et al. (2017) reported 5-year clinical outcomes of a randomized controlled U.S. FDA noninferiority trial in individuals with moderate lumbar spinal stenosis. While the original trial compared the Superion to the X STOP device, the analysis was restricted to the Superion trial arm. A total of 73% of the living individuals who received the spacer device participated in the 5-year clinical outcomes assessment. Outcomes were assessed using the ZCQ, leg and back pain severity by VAS, and the ODI. The authors reported success rates in all areas of assessment, 84% reported clinical success in at least two of the three ZCQ domains, 80% leg pain VAS scores, 65% back pain VAS scores and 65% for ODI scores. There remains a lack of studies which compare interspinous spacers to standard treatments, such as decompression surgery. Overall, there is a lack of evidence to support that interspinous spacer devices are as safe and effective as the gold standard of decompression. In addition, there appears to be some concerns that the devices are not as effective as surgical decompression and lead to higher rates of reoperation.~~

~~*Professional Societies*~~

~~The North American Spine Society (NASS) issued a coverage position on the use of interspinous devices with lumbar fusion. NASS recommends that interspinous fixation with fusion for stabilization is currently not indicated as an alternative to pedicle screw fixation with lumbar fusion procedures.~~

~~NASS (2018) published specific coverage policy recommendations on the lumbar interspinous device without fusion and with decompression. NASS recommended that: "Stabilization with an interspinous device without fusion in conjunction with laminectomy may be indicated as an alternative to lumbar fusion for degenerative lumbar stenosis with or without low-grade spondylolisthesis (less than or equal to 3 mm of anterolisthesis on a lateral radiograph) with qualifying criteria when appropriate:~~

- ~~Significant mechanical back pain is present (in addition to those symptoms associated with neural compression) that is felt unlikely to improve with decompression alone. Documentation should indicate that this type of back pain is present at rest and/or with movement while standing and does not have characteristics consistent with neurogenic claudication.~~
- ~~A lumbar fusion is indicated post-decompression for a diagnosis of lumbar stenosis with a Grade 1 degenerative spondylolisthesis as recommended in the NASS Coverage Recommendations for Lumbar Fusion.~~
- ~~A lumbar laminectomy is indicated as recommended in the NASS Coverage Recommendations for Lumbar Laminectomy.~~
- ~~Previous lumbar fusion has not been performed at an adjacent segment.~~

~~Minimally Invasive Lumbar Decompression (MILD®)~~

~~Available studies have limitations that include non-controlled trials, case series, non-blinded studies, and small number of participants. Well-designed studies that include a larger number of participants at multi-centers, use of clear patient selection criteria, measures of outcome using standardized tools, comparison to conservative management, comparison with and without an anesthetic agent and longer-term outcomes are needed to validate the use/safety/effectiveness of this technology.~~

~~The literature search identified six studies published in 11 publications that met the inclusion and exclusion criteria and evaluated the Vertos mild device kit and associated procedure (referred to as the Vertos mild procedure) for the treatment of LSS and ligamentum flavum hypertrophy. The authors concluded that the low quality body of evidence suggested statistically significant reductions in pain intensity and function, but that long-term durability and safety of more than 2 years is needed for the Vertos mild procedure. In addition, studies addressing appropriate patient selection criteria are needed to discern for whom the Vertos mild procedure may be most effective. Trials comparing the Vertos mild procedure with other minimally invasive procedures or open lumbar decompression are also needed. In addition, manufacturer support occurred in half of the studies. Limitations of the individual studies included limited follow up, lack of blinding, high attrition, absence of power analyses, and missing data for some outcomes and endpoints. (Hayes, 2019)~~

~~ECRI (2018) performed a literature review of the Vertos mild device kit. Despite the large amount of available data, some evidence gaps remain. These nonrandomized comparative studies are at high risk of bias from lack of controls and randomization. Additional RCTs are needed to verify findings and assess mild's effectiveness compared with other decompression procedures.~~

~~Staats and colleagues (2018, included in ECRI above) reported results of a prospective, multicenter, randomized controlled clinical study. This study evaluated the long-term durability of the minimally invasive lumbar decompression (MILD) procedure in terms of functional improvement and pain reduction for patients with lumbar spinal stenosis and neurogenic claudication due to hypertrophic ligamentum flavum. Follow-up occurred at 6 months and at 1 year for the randomized phase and at 2 years for MILD subjects only. Oswestry Disability Index, Numeric Pain Rating Scale, and Zurich Claudication Questionnaire were used to evaluate function and pain. Safety was evaluated by assessing incidence of device-/procedure-related adverse events. The authors concluded that MILD showed excellent long-term durability, and there was no evidence of spinal instability through 2 year follow up. Given the minimally invasive nature of this procedure, its robust success rate, and durability of outcomes, MILD is an excellent choice for first-line therapy for select patients with central spinal stenosis suffering from neurogenic claudication symptoms with hypertrophic ligamentum flavum. Despite the above findings that study did have the following limitations, lack of a control group at 2 year follow-up. The randomized controlled portion of the study concluded at the primary end point of 1 year, and supplementary follow up through 2 years was conducted for the MILD patient group only. This study did not compare efficacy directly with open surgical approaches, including lumbar decompression, fusion, or spacers.~~

~~In another study, Chopko (2013) evaluated the long-term effectiveness and safety of mild as a treatment of neurogenic claudication associated with lumbar spinal stenosis. The 2-year data are reported for 45 participants that were treated with mild at 11 US facilities. Outcome measurements included the VAS, ODI, and ZCQ. Interim data on the participants are included for 1 week, 6 months, and 1 year follow up. The authors reported that at 2 years, the subjects demonstrated a statistically significant reduction of pain as measured by VAS, and significant improvement in physical function and mobility as measured by ZQC and ODI. The authors also reported major improvement occurred by 1 week follow up and showed no difference between each subsequent follow up, suggesting considerable stability and durability of the initial result over time. There were no major adverse events or complications related to the procedure. Limitations of this study include its uncontrolled design and small size.~~

~~Brown et al. (2012) reported the results of a double-blind, randomized, prospective study of epidural steroid injections (ESI) and the mild procedure at a single pain management center. A total of 38 individuals with symptomatic lumbar spinal stenosis (LSS) participated in the study and were randomized into two treatment groups: 21 participants in the mild arm and 17 individuals in the ESI arm. Outcome measures were reported using the visual analog scale (VAS), the Oswestry Disability Index (ODI) and Zurich Claudication Questionnaire (ZCQ) patient satisfaction score. The authors reported that at 6 weeks, the mild participants improved from an average VAS baseline of 6.3 to a mean of 3.8). The ESI group had a mean VAS score of 6. at baseline compared with 6.3 at 6 weeks follow-up. Using the ODI, at 6 weeks follow-up, participants in the mild group demonstrated a decrease from a baseline mean ODI from 38.8 to 27.4. In the ESI group, the initial ODI was 40.5 and at 6 weeks follow-up, the ODI was 34.8. In the mild group, there was no significant change in the VAS and ODI scores from weeks 6 to 12. Participants in the ESI group were not measured at week 12. Participants were allowed to cross over from the ESI group to the mild group before 12 weeks and eventually, all of the participants in the ESI group had the mild procedure. A total of 14 of the 17 participants in the cross-over ESI group experienced an improvement in their VAS scores after the mild procedure. Limitations of the study include its small size and short follow-up.~~

~~One-year follow-up from an industry-sponsored multicenter study by Chopko and Caraway, 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. 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.~~

~~*Professional Societies/Position Statements*~~

~~American Academy of Orthopaedic Surgeons (AASOS)~~

~~At this time, there are no AAOS Clinical Practice Guidelines or AAOS Appropriate Use Criteria addressing the use of interspinous/interlaminar spacer devices.~~

~~International Society for the Advancement of Spine Surgery (ISASS)~~

~~In 2016, the ISASS published recommendations for decompression with interlaminar stabilization. ISASS concluded, based in part on a conference presentation of a study, that an interlaminar spacer in combination with decompression can provide stabilization in patients who do not present with greater than grade 1 instability. Recommended indications and limitations were described in the article. The document did not address interspinous and interlaminar distraction devices without decompression. (Guyer et al., 2016)~~

~~National Institute for Health and Clinical Excellence~~

~~The National Institute for Health and Clinical Excellence, since renamed the National Institute for Health and Care 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).~~

~~North American Spine Society (NASS)~~

~~The 2014 revised NASS clinical guideline on interspinous process spacing devices concluded that there is insufficient evidence to make a recommendation for or against the placement of an interspinous process spacing device in patients with lumbar spinal stenosis (LSS).~~

~~Spinal Stabilization~~

~~Dynamic Stabilization System~~

~~Due to the lack of data from well-designed, long-term, randomized controlled clinical trials, current evidence is insufficient to permit conclusions about whether any beneficial effect from dynamic stabilization provides a significant advantage over conventional fusion techniques. The published evidence is not robust; a majority of the studies are retrospective or prospective case series and lack controls. In addition, the complication rates and reoperation rates for dynamic stabilization compared with conventional fusion are unknown.~~

~~Pham et al. (2016) conducted a review of the literature to explore complications associated with the Dynesys stabilization system. The researchers evaluated 21 studies which included a total of 1,166 subjects with a mean age of 55.5 years and a mean follow-up period of 33.7 months. The data demonstrated a surgical-site infection rate of 4.3%, a pedicle screw loosening rate of 11.7%, a pedicle screw fracture rate of 1.6%, and an adjacent-segment disease (ASD) rate of 7.0%. Of studies reporting surgical revision rates, 11.3% of subjects required reoperation. Of subjects who developed ASD, 40.6% required a reoperation for treatment. The authors concluded that the Dynesys stabilization system has a similar complication rate compared with lumbar fusion studies and has a slightly lower incidence of ASD.~~

~~Professional Societies/Position Statements~~

~~*North American Spine Society (NASS)*~~

~~NASS published updated clinical practice guidelines in 2014 which addressed "flexible fusion," defined as dynamic stabilization without arthrodesis, for the treatment of degenerative lumbar spondylolisthesis. Due to the paucity of literature addressing the outcomes of these procedures, the workgroup was unable to make a recommendation. For future research, the workgroup recommended development of a large multicenter registry database, as well as prospective studies, with long-term follow-up comparing flexible fusion to medical or interventional treatment of this condition.~~

~~Percutaneous Sacroplasty~~

~~The literature search identified a nonrandomized controlled study and a few 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 post-surgery, 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, 2019).~~

~~Frey et al. (2017) reported on patients treated with percutaneous sacroplasty, particularly the long-term efficacy of sacroplasty vs nonsurgical management. This prospective, observational cohort study spanned ten years and comprised 240 patients with sacral insufficiency fractures. Thirty-four patients were treated with nonsurgical methods, and 210 patients were treated with sacroplasty. Pain, as measured by VAS, was recorded before treatment and at several follow-ups. Mean pretreatment VAS for the sacroplasty group was 8.29; for the nonsurgical treatment group, it was 7.47. Both forms of treatment resulted in significant VAS improvement from pretreatment to the 2-year follow-up. However, the sacroplasty treatment group experienced significant VAS score improvement consistently at many of the follow-up points (pretreatment to post; posttreatment through 2 weeks; 12 weeks through 24 weeks; 24 weeks through 1 year. Meanwhile, the group with nonsurgical treatment only experienced one significant pain improvement score at the 2-week follow-up posttreatment. One major limitation of this study was that the nonsurgical treatment group was not followed up with at the 10-year mark whereas the sacroplasty group did receive follow-up.~~

~~Dougherty et al. (2014) retrospectively evaluated outcomes of consecutive patients with SIF treated by percutaneous sacroplasty in an electronic database. The study included 57 patients (75% women; age 61 to 85 years, median 74 for men or 75 for women; duration of pain 2 to 5 weeks. Pain was measured at rest and, sometimes, during activity on an 11-point NRS (higher values = greater pain) or described by patients, opioid use was also evaluated before and at 1 to 5 weeks (median, 2.5) after sacroplasty. The study is limited by retrospective design, small sample size, lack of a control group, subjective outcome measures, inconsistent evaluation of pain, and short follow-up.~~

~~Kortman et al. (2013, included in Hayes report above) retrospectively examined outcomes of patients with painful SIF or symptomatic sacral lesions treated by percutaneous sacroplasty at any of six participating U.S. centers. Patients were included in the study if they had severe sacral pain refractory to standard conservative management (defined as any combination of bed rest, analgesics, partial weight bearing, and orthosis), imaging evidence of bilateral or unilateral SIF or focal or infiltrating sacral lesions, and symptoms attributable to sacral pathology. The SIF group consisted of 204 patients. The group with sacral lesions (SL group) included 39 patients. Sacroplasty entailed the long- or short-axis approach and PMMA or bioceramic cement, but the rate of each approach and the trade names for cement and other devices were not reported. Pain was evaluated by self-report, a VAS, and analgesic use before and at 1 month after sacroplasty. All~~

~~patients with SIF were followed for ≥ 1 year. Compared with pretreatment values, mean VAS scores improved significantly after sacroplasty in patients with bilateral SIF, patients with unilateral SIF, and patients with sacral lesions. In the entire group with SIF and the group with sacral lesions, respectively, 31% and 18% experienced complete pain relief and 3.0% and 10% experienced no significant pain relief. Use of narcotic, non-narcotic, and over the counter analgesics decreased markedly after versus before sacroplasty in both groups but data for analgesic use were not reported. The study is limited by retrospective design, lack of a control group, and use of subjective outcome measures.~~

~~Facet Fusion~~

~~Evidence is limited to small, uncontrolled trials with lack of blinding or long-term follow-up. Randomized, controlled trials comparing these allograft materials to standardized autograft materials are needed to determine long-term efficacy and impact on health outcomes. No studies were found that discussed facet fusion when done alone without an accompanying decompressive procedure. The current published evidence is insufficient to determine whether facet arthroplasty is as effective or as safe as spinal fusion, the current standard for surgical treatment of degenerative disc disease.~~

~~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 two 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.~~

~~*Professional Societies*~~

~~American Association of Neurological Surgeons (AANS)~~

~~AANS published a technical assessment of TruFUSE and Nufix 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. The AANS has no additional information on TruFUSE since 2009. The manufacturer has been contacted by AANS requesting any possible scientific data not identified in a literature search.~~

~~Lumbar fusion for facet syndrome is no longer generally accepted (International Society for the Advancement of Spine Surgery, [ISASS], 2011). According to the ISASS (2011) the surgery should only be performed in the context of a clinical trial.~~

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

A variety of endoscopes and associated surgical instruments and devices have received marketing clearance through the FDA's 510(k) process. See the following website for more information and search by product name in device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.

~~Interspinous Fixation Devices~~

~~Products used for interspinous fixation devices are extensive. Refer to the following website for more information and search by product name in device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed January 31, 2020)~~

~~Spinal Fusion Devices~~

~~Products used for spinal fusion and decompression devices are extensive. Refer to the following website for more information and search by product name in device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed January 31, 2020)~~

~~Spinal Stabilization Devices~~

~~Products used for spinal stabilization devices are extensive. Refer to the following website for more information and search by product name in device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed January 31, 2020)~~

~~Facet Arthroplasty~~

~~No facet arthroplasty devices have been approved by the U.S. Food and Drug Administration (FDA) at this time.~~

~~Percutaneous Sacroplasty~~

~~Sacroplasty is a procedure and, as such, is not regulated by the FDA. However, devices used in medical procedures do require FDA approval. The FDA has cleared an extensive variety of devices for use in sacroplasty. Products used for sacroplasty are extensive. Refer to the following website for more information and search by product name in device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed January 31, 2020)~~

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Policy History/Revision Information

Date	Summary of Changes
TBD	**Title Change/Template Update** • Relocated and reformatted content previously included in the Medical Policy titled *Surgical Treatment for Spine Pain (for Louisiana Only)* **Coverage Rationale** • Revised language to indicate the following spinal procedures are unproven and not medically necessary due to insufficient evidence of efficacy: ○ Axial lumbar interbody fusion (AxiaLIF®), a percutaneous pre-sacral access route to the L5-S1 vertebral bodies ○ Percutaneous image-guided lumbar decompression (PILD) ○ Percutaneous sacral augmentation (sacroplasty) with or without a balloon or bone cement ○ Automated percutaneous and percutaneous endoscopic discectomy (APLD) for intervertebral disc decompression ○ Minimally invasive lumbar decompression (mild®) ○ Laparoscopic anterior lumbar interbody fusion (LALIF) ○ Transforaminal lumbar interbody fusion (TLIF) which utilizes only endoscopy visualization (such as a percutaneous incision with video visualization) **Definitions** • Added definition of: ○ Automated Percutaneous Lumbar Discectomy (APLD) ○ Endoscope ○ Endoscopic Discectomy ○ Fluoroscopy ○ Interbody Fusion ○ Nucleoplasty ○ Open Spine Surgery ○ Percutaneous Endoscopic Lumbar Diskectomy (PELD) ○ Percutaneous Image-Guided Lumbar Decompression (PILD) ○ Presacral ○ Spinal Decompression ○ Transforaminal (TESSYS®) and Interlaminar Endoscopic Surgical Systems ○ Tubular Retractor • Removed definition of: ○ Anterior Lumbar Spine Surgery ○ Arthrodesis ○ Conservative Therapy ○ Direct Lateral Interbody Fusion (DLIF) ○ Disabling Symptoms ○ Dynamic Stabilization ○ Facet Arthroplasty

- Facet Fusion
- Facet Syndrome
- Interlaminar Stabilization Device
- Interspinous Process Decompression (IPD)
- Lumbar Spinal Stenosis (LSS)
- Neurogenic Claudication (also known as pseudoclaudication)
- Progressive
- Radicular Pain
- Spinal Fusion
- Spinal Instability of the Lumbar Spine
- Spinal Stabilization
- Spondylolisthesis
- Spondylolysis
- Staged Multi Session
- Total Facet Joint Arthroplasty
- Transforaminal Lumbar Interbody Fusion (TLIF)
- Unremitting
- X-STOP Interspinous Process Decompression (IPD) System

Applicable Codes

- Added CPT/HCPCS codes 62287 and G0276
- Removed CPT codes 0202T, 0219T, 0220T, 0221T, 0222T, 0274T, 0719T, 22100, 22101, 22102, 22103, 22110, 22112, 22114, 22116, 22206, 22207, 22208, 22210, 22212, 22214, 22216, 22220, 22222, 22224, 22226, 22532, 22533, 22534, 22548, 22551, 22552, 22554, 22556, 22558, 22585, 22586, 22590, 22595, 22600, 22610, 22612, 22614, 22632, 22633, 22634, 22800, 22802, 22804, 22808, 22810, 22812, 22818, 22819, 22830, 22840, 22841, 22842, 22843, 22844, 22845, 22846, 22847, 22848, 22849, 22850, 22852, 22853, 22854, 22855, 22859, 22867, 22868, 22869, 22870, 63001, 63003, 63005, 63011, 63012, 63015, 63016, 63017, 63020, 63030, 63035, 63040, 63042, 63043, 63044, 63045, 63046, 63047, 63048, 63050, 63051, 63052, 63053, 63055, 63056, 63057, 63064, 63066, 63075, 63076, 63077, 63078, 63081, 63082, 63085, 63086, 63087, 63088, 63090, 63091, 63101, 63102, 63103, 63170, 63172, 63173, 63185, 63190, 63191, 63197, 63200, 63250, 63251, 63252, 63265, 63266, 63267, 63268, 63270, 63271, 63272, 63275, 63277, 63280, 63282, 63285, 63286, 63287, 63290, 63300, 63301, 63302, 63303, 63304, 63305, 63306, 63307, and 63308
- Added notation to indicate CPT/HCPCS codes 0200T, 0201T, 0275T, and G0276 are not on the State of Louisiana Fee Schedule and therefore are not covered by the State of Louisiana Medicaid Program
- Removed notation pertaining to:
  - CPT codes 22554 and 22585
  - Unlisted codes for laparoscopic approaches

Supporting Information

- Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
- Archived previous policy version CS115LA.X

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit

plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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