Surgical Treatment for Spine Pain (for New Jersey Only)

Policy Number: CS115NJ.Z
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Instructions for Use

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Related Policies

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- Vertebral Body Tethering for Scoliosis (for New Jersey Only)

Application

This Medical Policy only applies to the state of New Jersey.

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 following 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 indications for a surgical spine procedure that is performed to alleviate symptoms or prevent clinical deterioration are considered proven and medically necessary if not addressed in the above criteria:

- Congenital or idiopathic deformity or bone disease other than scoliosis
- Muscular dystrophy
- Laminectomy procedure to provide surgical exposure to treat lesions within the spinal canal

Interspinous process fusion devices is proven and medically necessary when used in conjunction with any of the following procedures:
- Open laminar and/or facet decortication and fusion
- Autograft inter-and extra-spinous process decortication and fusion
- Interbody fusion of the same motion segment

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):
- 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®)
- 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®)
- Dividing treatment of symptomatic, multi-site spinal pathology via anterior or posterior approach into serial, multiple, or staged sessions when one session can address all sites
- 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 procedures; 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

For information on vertebral body tethering, refer to the Medical policy titled Vertebral Body Tethering for Scoliosis (for New Jersey Only).

Documentation Requirements

Medical notes documenting the following, when applicable:
- Condition requiring procedure
- History and co-morbid medical condition(s)
  - Smoking history/ status, including date of last smoking cessation
- 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
- Upon request, we may request the 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: When requested, 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)
  - Upon request, diagnostic imaging must be submitted via the external portal at www.uhcprovider.com/paan; faxes will not be accepted
- Diagnostic image(s) report(s), including presence or absence of:
  - Segment (s) instability
  - Spinal cord compression
  - Disc herniation
  - Nerve root compression
  - Quantification of subluxation, translation by flexion, angulation when appropriate
  - Discitis

    - Epidural abscess
- Physical exam, including neurologic exam, including degree and progression of curvature (for scoliosis), if applicable
    - Degree and progression of curvature (for scoliosis)
    - Quantification of relevant muscle strength
- Whether the surgery will be performed with direct visualization or only with endoscopic visualization
- Complete report(s) of diagnostic tests
    - Results of biopsy(ies)
    - Results of bone aspirate
- 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

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) Spinal Fusions. The technique provides access to the spine along the long axis of the spine, as opposed to anterior, posterior, or lateral approaches. The surgeon enters the back through a very small incision next to the tailbone and the abnormal disc is taken out. Then a bone graft is placed where the abnormal disc was and is supplemented with a large metal screw. Sometimes, additional, smaller screws are placed through another small incision higher on the back for extra stability (Cragg, et al., 2004).

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; Qassem 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.

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 (Mild®): A percutaneous procedure for decompression of the central spinal canal in individuals with Lumbar Spinal Stenosis. 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).

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.

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 2 pair of serrated wings extending from the upper and lower long arms of the U. The U portion is inserted horizontally between 2 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 Spinal 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.

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.

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.

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]).

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, 2 thin, hollow tubes are placed in the lower back, over the left half and right half of the sacrum, guided by images from x-rays or computed tomography scans. The surgeon then advances a needle through each tube to the site of the sacral fracture and injects 2 to 5 mL of bone cement (Hayes, 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:

- 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. (Ghogawala 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).

Staged Multi-Session: Includes procedures performed on different days or requiring an additional anesthesia session.

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 (see 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 Coverage Determination 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

CPT Code	Description
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
0719T	Posterior vertebral joint replacement, including bilateral facetectomy, laminectomy, and radical discectomy, including imaging guidance, lumbar spine, single segment
20930	Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)
20931	Allograft, structural, for spine surgery only (List separately in addition to code for primary procedure)
20939	Bone marrow aspiration for bone grafting, spine surgery only, through separate skin or fascial incision (List separately in addition to code for primary procedure)
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)
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)

CPT Code	Description
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)
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

CPT Code	Description
22802	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments
22804	Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments
22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments
22810	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments
22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments
22818	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); single or 2 segments
22819	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); 3 or more segments
22830	Exploration of spinal fusion
22840	Posterior non-segmental instrumentation (e.g., Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)
22841	Internal spinal fixation by wiring of spinous processes (List separately in addition to code for primary procedure)
22842	Posterior segmental instrumentation (e.g., pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments (List separately in addition to code for primary procedure)
22843	Posterior segmental instrumentation (e.g., pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments (List separately in addition to code for primary procedure)
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

CPT Code	Description
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)
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
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
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)

CPT Code	Description
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], [eg, 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] [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; single vertebral segment (List separately in addition to code for primary procedure)
63053	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, 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)

CPT Code	Description
63085	Vertebral corpectomy (vertebral body resection), partial or complete, transthoracic approach with decompression of spinal cord and/or nerve root(s); thoracic, single segment
63086	Vertebral corpectomy (vertebral body resection), partial or complete, transthoracic approach with decompression of spinal cord and/or nerve root(s); thoracic, each additional segment (List separately in addition to code for primary procedure)
63087	Vertebral corpectomy (vertebral body resection), partial or complete, combined thoracolumbar approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic or lumbar; single segment
63088	Vertebral corpectomy (vertebral body resection), partial or complete, combined thoracolumbar approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic or lumbar; each additional segment (List separately in addition to code for primary procedure)
63090	Vertebral corpectomy (vertebral body resection), partial or complete, transperitoneal or retroperitoneal approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic, lumbar, or sacral; single segment
63091	Vertebral corpectomy (vertebral body resection), partial or complete, transperitoneal or retroperitoneal approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic, lumbar, or sacral; each additional segment (List separately in addition to code for primary procedure)
63101	Vertebral corpectomy (vertebral body resection), partial or complete, lateral extracavitary approach with decompression of spinal cord and/or nerve root(s) (e.g., for tumor or retropulsed bone fragments); thoracic, single segment
63102	Vertebral corpectomy (vertebral body resection), partial or complete, lateral extracavitary approach with decompression of spinal cord and/or nerve root(s) (e.g., for tumor or retropulsed bone fragments); lumbar, single segment
63103	Vertebral corpectomy (vertebral body resection), partial or complete, lateral extracavitary approach with decompression of spinal cord and/or nerve root(s) (e.g., for tumor or retropulsed bone fragments); thoracic or lumbar, each additional segment (List separately in addition to code for primary procedure)
63170	Laminectomy with myelotomy (e.g., Bischof or DREZ type), cervical, thoracic, or thoracolumbar
63172	Laminectomy with drainage of intramedullary cyst/syrinx; to subarachnoid space
63173	Laminectomy with drainage of intramedullary cyst/syrinx; to peritoneal or pleural space
63180	Laminectomy and section of dentate ligaments, with or without dural graft, cervical; 1 or 2 segments
63182	Laminectomy and section of dentate ligaments, with or without dural graft, cervical; more than 2 segments
63185	Laminectomy with rhizotomy; 1 or 2 segments
63190	Laminectomy with rhizotomy; more than 2 segments
63191	Laminectomy with section of spinal accessory nerve
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
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

CPT Code	Description
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
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)

Description of Services

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

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.

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.

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.

Villavicencio et al. (2010) conducted a retrospective study comparing minimally invasive and open 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.

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. 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 .

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 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.

Clinical Practice Guidelines

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 2 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.

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).

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 2 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 9152 patients. A single-level L5-S1 fusion was performed in 8034 patients (88%), and a two-level L4-S1 fusion was performed in 1118 patients (12%). Complications were reported in 1.3% of patients with the most commonly reported complications being bowel injury (0.6%) and transient intraoperative hypotension (0.2%). Other complications noted include superficial wound and systemic infections, migration, subsidence, presacral hematoma, sacral fracture, vascular injury, nerve injury and ureter injury. The overall complication rate was similar between single-level (1.3%) and two-level (1.6%) fusion procedures, with no significant differences noted for any single complication. The authors concluded that the overall complication rates compare favorably with those reported in trials of open and minimally invasive lumbar fusion surgery.

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).

Spinal Decompression and Interspinous Process Decompression Systems

Interspinous Process Decompression (IPD) Systems

There has been an increasing body of published literature on outcomes related to Interspinous Devices which affix to the spinous processes for the purposes of augmenting fusion. There is still limited evidence published about outcomes of such devices that are used for stabilization of a motion segment, but the evidence has improved with regards to the quality of studies that support this technique. There are limited prospective randomized trials with sufficient follow-up which evaluate the efficacy or safety of this class of devices in comparison to pedicle screw fixation. However, there are published prospective studies that support the use of this technology for stabilization of single level degenerative spondylolisthesis when combined with a direct decompression and fusion.

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 2 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 2 RCTs and 3 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. 542 patients affected by symptomatic lumbar spine degenerative disease were enrolled in a controlled trial. 422 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 2 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 2 randomized controlled trials, the other studies with the X-STOP device were not of high methodologic quality. Nevertheless, analysis of these studies showed that X-STOP may improve outcome when compared to nonoperative treatment in a select group of patients, aged 50 or over, with radiologically confirmed lumbar canal stenosis and neurogenic claudication. Studies on the other devices show satisfactory outcome to varying degrees. However, due to small number and poor design of the studies, it is difficult to clearly define indications for their use in lumbar degenerative disease. The authors concluded that lumbar ISPs may have a potential beneficial effect in a select group of patients with degenerative disease of the lumbar spine. However, further well-designed prospective trials are needed to clearly outline the indications for their use.

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

A Hayes report assessed the use of the coflex Interlaminar Stabilization device for the treatment of lumbar spinal stenosis in adults. An overall low-quality body of evidence suggests that the coflex device plus decompression may result in similar outcomes compared with decompression with fusion for up to 8 years, and compared with decompression alone for up to 2 years. Adverse events were similar between the coflex device and comparator groups, and the coflex device may have an advantage in operative time and hospital length of stay. According to Hayes, the uncertainty associated with this body of evidence is due to the limited number of good to fair quality studies showing a distinct benefit of the coflex device over traditional surgical interventions over the long term and a lack of definitive patient selection criteria (Hayes, 2021).

Fan and Zhu (2020) conducted a systematic review and network meta-analysis investigating whether the coflex device, decompression, or fusion resulted in better outcomes for LSS when compared with each other. Ten RCTs were eligible for inclusion in this analysis, but only 6 included the coflex device as an intervention. Included studies were required to be RCTs, to be published in the English or Chinese language, and to report clinical outcomes for patients with lumbar degenerative disease (LDD) on Visual Analogue Scale (VAS) scores, Oswestry Disability Index (ODI) scores, or complications. Exclusion criteria included lower-quality study designs or studies that had incomplete data. All studies were assessed using the Cochrane risk of bias tool. Nine studies reported ODI outcomes, and, after pooling results, no significant difference in postoperative mean differences were observed between the coflex device and fusion groups. However, for VAS pain outcomes, a significant postoperative difference was observed, with a mean difference of −0.42 in the coflex device group and −0.37 in the fusion group compared with decompression alone. According to the authors, subgroup analyses to determine consistency of the effect showed good convergence efficiency. The authors summed the number of adverse events (AEs) reported across the trials and found that in the decompression alone group, 13 patients had AEs (8 relapse and 3 dural sac rupture), the coflex device group had 4 AEs (2 dural sac rupture, 1 coflex device loosening, and 1 vertebral fracture), and the PLIF group had 14 AEs (3 relapse, 2 infection, 2 dural sac rupture, 1 venous thromboembolism, 2 intervention loosening, and 1 vertebral fracture). No statistical comparison between groups was reported for complications, and the authors did not provide an overall grade of the evidence.

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.

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. NASS (2018) reviewed this study and noted: Overall, the results of this study on a strict evidence-based medicine level can be summarized as not finding a significant difference in the primary outcome measure(s). However, when considering the significant difference in subsequent epidural injections, which is a secondary outcome measure, the composite clinical success score becomes different.

A systematic review by Machado et al. (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, included in the Hayes report above) 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. 211 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. 80 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 the Hayes and ECRI reports 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, included in the Hayes report above).

Bae and colleagues (2016, included in the Hayes report above) 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.

ECRI (2021) performed clinical evidence review of Superion Indirect Decompression System. The case series, historical control studies, and before-and-after studies are at high risk of bias due to 3 or more of the following: single-center focus, small sample size, retrospective design, and lack of randomization and independent controls. Two historical control and 2 before-and-after studies assessed the same group of Superion-treated patients; thus, independent RCTs comparing Superion with other devices and laminectomy are needed to validate findings. Independent RCTs comparing Superion with other devices are required to validate long-term health outcomes.

Hayes (2020; Updated September 2021) performed a full-text review of clinical studies using superion interspinous spacers (ISS) for the treatment of lumbar spinal stenosis and neurogenic claudication. Studies were of very poor or poor quality and no comparative studies were identified. According to Hayes, clinical studies do not demonstrate equal or superior benefits or advantages over commercially available alternatives or fusion surgery. Based on a review of 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. Recommendations from guidelines are mixed for the use of interspinous spacers, with some determining evidence to be sufficient to support use, while others determined evidence is insufficient to support use. Therefore, the impact of the Superion ISS on long-term net health outcomes is not currently known and requires further investigation.

Patel et al. (2015, included in the ECRI and Hayes reports above) 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, included in the ECRI and Hayes reports above) 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.

Clinical Practice Guidelines

North American Spine Society (NASS)

Interspinous Fusion Devices

In 2019, the North American Spine Society issued a coverage position on the use of interspinous devices with lumbar fusion. The North American Spine Society noted that although there is still limited evidence, interspinous fixation with fusion for stabilization may be considered when utilized in the context of lumber fusion procedures for patients with diagnoses including stenosis, disc herniations, or synovial facet cysts in the lumbar spine, as an adjunct to cyst excision which involves removal of greater than 50 percent of the facet joint. They also noted that this is when utilized in conjunction with a robust open laminar and/or facet decortication and fusion, and/or a robust autograft inter-and extra-spinous process decortication and fusion, and/or an interbody fusion of the same motion segment. The North American Spine Society also noted that “No literature supports the use of interspinous fixation without performing an open decortication and fusion of the posterior bony elements or interbody fusion.”

Interspinous Decompression Devices (Without Fusion)

The North American Spine Society (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.

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.

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.

A Hayes report for the Vertos mild procedure included 6 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, updated May 2021).

Staats 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) 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 2 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 M mild LD 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 onne-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

American Academy of Orthopaedic Surgeons (AAOS)

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

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 interspinious 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 1166 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.

Clinical Practice Guidelines

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

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 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. 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).

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 6 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 2 cortical screws and local cancellous bone grafts. Visual analog scale and Oswestry disability assessment were used to measure outcomes which showed significant improvement at 1-year follow-up. The authors found that patients with degenerative spondylolisthesis with lower grade slips and normal anterior structures represent an ideal indication for facet fusion. The study is limited by short term follow-up, subjective outcomes and lack of comparison to other treatment modalities.

Clinical Practice Guidelines

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.

Spinal Procedures to Alleviate Symptoms or Prevent Clinical Deterioration

Sun et al. (2019) evaluated the safety and efficacy of laminoplasty versus laminectomy in the treatment of spinal cord tumors (SCTs). 16 studies addressing SCTs with at least 6 months follow-up were found and analyzed. The authors concluded that laminoplasty might be a better and safer procedure for treatment of SCTs, however more well-designed studies with larger samples sizes are needed to further evaluate this conclusion.

Chen (2019) identified six patients diagnosed with congenital sacral myelomeningocele. The case series presented 4 patients with repaired myelomeningocele who experienced retethered spinal cord and progressive dural ectasia; 1 patient with lipomyelomeningocele who had previously undergone detethering surgery and duraplasty; and 1 patient with a newly diagnosed symptomatic Tarlov cyst. Although these cases have different underlying diseases, they all share a similar feature of expansile CSF accumulation in the sacral area. All 6 patients subsequently underwent sacral laminoplasty with titanium mesh. Limitations included low number of participants, lack of control group and short follow-up.

Mendenhall et al. (2019) performed a retrospective review of 361 patients with complex spine surgery. The authors examined the literature for spinal instrumentation techniques that have been utilized on the pediatric population; the indications for these procedures were divided into four categories: degenerative, congenital, trauma and tumor. Ages of the patients consisted of those 3 months old to 21 years. The surgical procedures performed included those at the craniocervical junction, subaxial cervical spine, thoracic spine, thoracolumbar junction, lumbar spine, sacrum and pelvis. The types of spinal instrumentation included (but not limited to) occipital screws, translaminar screws, cervical lateral mass screws, and pedicle screws. The authors noted that a major difference between adolescent and adult spine surgery is the potential continued growth and this growth factor must be factored into the decision making for fusion. The author’s review of these procedures and instrumentation provides benchmarks and outcomes for comparison on the techniques performed.

Clinical Practice Guidelines

American Association of Neurological Surgeons (AANS)

The AANS states the following:

- For surgery of a spinal cord injury, immediate surgery may be performed to stabilize the spine thus preventing future pain or deformity.
- For spinal tumors, surgical indications are done for intractable pain, spinal cord decompression, and stabilization of pathological fractures
- For spinal infections, surgery may be indicated for spinal instability, neurological defects, sepsis, failure of IV antibiotics
- For lumbar spinal stenosis, surgery is only recommended after failure of non-surgical management

Staged, Multi-Session

Staged, multi-sessions generally involves a circumferential (anterior and posterior) procedure performed at two separate operative sessions several days apart. Assessment of the safety and effectiveness of staged procedures requires data from well-designed clinical trials that compare the peri- and post-operative health outcomes when compared to single session surgery. Current literature review did not provide any beneficial effect in any of the studies regarding staged multi section procedures. (Rao, 2011).

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.

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.

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.

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.

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.
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Policy History/Revision Information

Date	Summary of Changes
07/01/2022	**Applicable Codes** • Updated list of applicable CPT codes to reflect quarterly edits; added 0719T **Supporting Information** • Archived previous policy version CS115NJ.Y

Instructions for Use

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