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Medical Coverage Policy

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Lumbar Fusion for Spinal Instability and Degenerative Disc Conditions, Including Sacroiliac Fusion

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Overview

This Coverage Policy addresses lumbar spinal fusion, also referred to as lumbar arthrodesis and sacroiliac fusion. In general, spinal fusion is a method of surgery often employed to control low back pain attributed to various back conditions. During spinal fusion two or more vertebrae are fused together creating a single, solid bone with the intent of eliminating motion and to restore stability of the spine.

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

Use of tobacco products have been shown to adversely affect bone healing. Smoking is associated with an increased risk of pseudoarthrosis. As a result, for lumbar or

sacroiliac fusion surgical procedures other than those performed for emergent medical conditions, Cigna requires a statement that the individual is a non-smoker or will refrain from use of tobacco products for at least six (6) weeks prior to the planned surgery.

LUMBAR FUSION FOR INSTABILITY:
Single or multilevel lumbar fusion is considered medically necessary for ANY of the following indications when there is an associated spinal instability:

- acute spinal fracture
- neural compression after spinal fracture
- epidural compression or vertebral destruction from tumor
- spinal tuberculosis
- spinal debridement for infection
- spinal deformity which may be defined as ANY of the following:
  - idiopathic adolescent scoliosis over 40°
  - progressive degenerative lumbar scoliosis and/or lateral listhesis resulting in neuroforaminal stenosis and/or neurological symptoms
  - sagittal or coronal imbalance of at least 5 cm is present, as measured on long-plate, standing radiographs of the entire spine documented progression of deformity by at least 10° as measured on consecutive radiographs over a one year period
  - a degenerative adult or post-procedural scoliosis measuring at least 30° in the coronal plane or lateral listhesis measuring at least 10%
  - proximal junctional kyphosis defined as a segmental Cobb angle of at least 10° or 10° of progression from the immediate postoperative images

LUMBAR FUSION FOR IATROGENIC INSTABILITY
Lumbar fusion is considered medically necessary for intraoperative iatrogenic spinal instability of the level or levels involved resulting from ANY of the following surgical procedures:

- removal of 50% or more of the facets bilaterally
- removal of 75% or more of a single facet
- resection of the pars interarticularis or pars fracture

LUMBAR FUSION FOR INSTABILITY: SPINAL STENOSIS
Single level lumbar fusion (e.g., L4–L5) is considered medically necessary for the treatment of spinal stenosis when there is an associated anterolisthesis, and ALL of the following criteria are met:

- back pain with neurogenic claudication symptoms or radicular pain
- failure of at least three (3) consecutive months of physician-supervised conservative medical management including exercise, nonsteroidal and/or steroidal medication (unless contraindicated), physical therapy and activity lifestyle modification
- clinically significant functional impairment (e.g., inability to perform household chores or prolonged standing, interference with essential job functions)
- central, lateral recess, foraminal stenosis or synovial cyst is demonstrated on imaging studies (e.g., radiographs, magnetic resonance imaging [MRI], computerized tomography [CT], myelography)
- radiographic evidence of **EITHER** of the following:
  - evidence of dynamic instability (i.e., flexion-extension radiographs, comparison of a supine and upright image with a difference in translational alignment between vertebrae greater than 3 mm between views)

  - spondylolisthesis (i.e., at least 3 mm of anterolisthesis of the upper vertebra in relation to the lower vertebra) is present, either isthmic, secondary to a posterior arch fracture, or degenerative type
- the individual is a nonsmoker, or in the absence of progressive neurological compromise has refrained from use of tobacco products for at least 6 weeks prior to the planned surgery

LUMBAR FUSION FOR INSTABILITY: SPONDYLOLYSIS/ ISTHMIC SPONDYLOLISTHESIS
Lumbar fusion* is considered medically necessary for spondylolysis (i.e., pars interarticular fracture) or isthmic spondylolisthesis when BOTH of the following criteria is met:

- the individual is a nonsmoker, or in the absence of progressive neurological compromise has refrained from use of tobacco products for at least 6 weeks prior to the planned surgery
- **ANY** of the following:
  - multilevel spondylolysis
  - rapidly progressive neurologic compromise (i.e., cauda equina syndrome [loss of bowel/bladder control]) symptomatic Grade 1 or 2 spondylolisthesis (anterolisthesis) and **EITHER** of the following:
    - radiograph documentation supporting progression of anterolisthesis
    - **BOTH** of the following:
      - failure of at least six (6) consecutive months of physician-supervised conservative treatment including exercise, nonsteroidal and/or steroidal medication (unless contraindicated), physical therapy and activity lifestyle modifications
      - clinically significant functional impairment (e.g., inability to perform household chores or prolonged standing, interference with essential job functions)
  - symptomatic Grade 3 or higher spondylolisthesis (anterolisthesis) demonstrated on plain x-rays with 50% or more anterior slippage and **EITHER** of the following:
    - radiograph documentation supporting progression of anterolisthesis
    - **BOTH** of the following:
      - clinically significant functional impairment (e.g., inability to perform household chores or prolonged standing, interference with essential job functions)
      - failure of at least three (3) consecutive months of physician-supervised conservative management including exercise, nonsteroidal and/or steroidal medications (unless contraindicated), physical therapy and activity lifestyle modification

***Note:** Typically, single level fusion is generally considered appropriate for treatment of single level spondylolysis or Grade 1 or 2 spondylolisthesis. Two levels of fusion may be appropriate for multilevel spondylolysis or Grade 3 and higher spondylolisthesis.

LUMBAR FUSION FOR FLATBACK SYNDROME:
Single or multilevel lumbar fusion is considered medically necessary for unremitting pain associated with flatback syndrome when imaging studies demonstrate sagittal imbalance (e.g., loss of lumbar lordosis, forward flexed posture, lumbar kyphosis) and ALL of the following criteria are met:

- sagittal imbalance in the sagittal vertical axis of at least +5 cm is present, as measured on long-plate, standing radiographs of the entire spine or a pelvic incidence-lumbar lordosis mismatch of at least 10 degrees
- the individual is a nonsmoker, or in the absence of progressive neurological compromise

has refrained from use of tobacco products for at least 6 weeks prior to the planned surgery

- **EITHER** of the following:
  - imbalance is progressive resulting in either neurologic compromise (e.g., compression of neural structures) or neurologic symptoms with objective neurologic findings
  - the individual is experiencing clinically significant functional impairment (e.g., inability to perform household chores or prolonged standing, interference with essential job functions) and failure of at least three months of conservative medical management to relieve symptoms including exercise, nonsteroidal and/or steroidal medication (unless contraindicated), physical therapy, and activity lifestyle modification

LUMBAR FUSION WITHOUT INSTABILITY: DEGENERATIVE DISC DISEASE

Single level lumbar fusion for degenerative disc disease without lumbar instability is considered medically necessary when there is unremitting back pain and significant functional impairment for at least 12 months duration, and during which time ALL of the following criteria have been met: unremitting back pain and significant functional impairment continues despite at least six

(6) consecutive months of structured*, physician supervised conservative medical management, including **ALL** of the following components

- exercise, including core stabilization exercises
- nonsteroidal and/or steroidal medication (unless contraindicated)
- physical therapy, including passive and active treatment modalities
- activity/lifestyle modification
- participation in 3 or more individual or group cognitive behavioral therapy (CBT) sessions provided by a licensed healthcare professional, with competence in principles and practice of CBT, (e.g., PT, OT, psychiatrist, psychologist, social worker, psychiatric nurse, other licensed professional) providing individualized treatment that includes **ALL** of the following elements:
  - disease education
  - activity and lifestyle modification
  - stress management (stress management typically also includes strategies to deal with emotions such as fear, anxiety, sadness that can interfere with pain management)

- single level degenerative disc disease, demonstrated on appropriate imaging studies (i.e., computerized tomography [CT] scan, magnetic resonance imaging [MRI], or discography) as the likely cause of back pain
- statement from a primary care physician, neurologist, physiatrist, psychiatrist, psychologist, or other licensed behavioral and/or medical health care provider provider not involved with the recommended plan of treatment, attesting to the absence of untreated, underlying mental health conditions/issues (e.g., depression, drug, alcohol abuse) as a major contributor to chronic back pain
- the individual is a nonsmoker, or in the absence of progressive neurological compromise has refrained from use of tobacco products for at least 6 weeks prior to the planned surgery

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

LUMBAR FUSION FOLLOWING PRIOR SPINAL SURGERY: WITH SPONDYLOLISTHESIS

Single level lumbar fusion is considered medically necessary for EITHER of the following post-surgical conditions when there is an associated spondylolisthesis (i.e.,

anterolisthesis):

- recurrent disc herniation, when it has been at least 3 months from the previous surgery
- adjacent segment degeneration, when it has been at least 6 months from the previous surgery

and ALL of the following criteria are met:

- recurrent symptoms consistent with neurological compromise
- clinically significant functional impairment (e.g., inability to perform household chores or prolonged standing, interference with essential job functions)
- neural compression is documented by recent appropriate post-operative imaging
- failure of three (3) consecutive months of physician-supervised conservative management including exercise, nonsteroidal and/or steroidal medications (unless contraindicated), physical therapy and activity lifestyle modification anterolisthesis (anterior translation of the vertebra on the adjacent vertebra below) resulting in a Grade 1 spondylolisthesis or anterior segmental instability (e.g., 4mm displacement of the involved vertebra on the adjacent vertebra below)
- individual experienced some relief of pain symptoms following the prior spinal surgery
- the individual is a nonsmoker, or in the absence of progressive neurological compromise has refrained from use of tobacco products for at least 6 weeks prior to the planned surgery

LUMBAR FUSION FOLLOWING PRIOR SPINAL SURGERY: WITHOUT SPONDYLOLISTHESIS
Single level lumbar fusion is considered medically necessary for treatment of symptomatic adjacent or same segment disc degeneration following prior spinal surgery (e.g., discectomy, laminectomy), in the absence of spondylolisthesis, when ALL of the following criteria have been met:

- unremitting pain and significant functional impairment for at least 12 months that persists despite at least six (6) consecutive months of structured*, physician-supervised conservative medical management, which includes **ALL** of the following components
  - exercise, including core stabilization exercises
  - analgesics, nonsteroidal anti-inflammatory medication, unless contraindicated
  - physical therapy, including passive and active treatment modalities
  - activity/lifestyle modification
- single level degenerative disc disease, demonstrated on appropriate imaging studies (i.e., computerized tomography [CT] scan, magnetic resonance imaging [MRI], or discography) as the likely cause of pain
- the individual is a nonsmoker, or in the absence of progressive neurological compromise has refrained from use of tobacco products for at least 6 weeks prior to the planned surgery

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

LUMBAR / SACROILIAC JOINT FUSION FOLLOWING PRIOR SPINAL SURGERY: PSEUDOARTHROSIS
Single level lumbar fusion OR sacroiliac joint fusion is considered medically necessary for the treatment of pseudoarthrosis (i.e., nonunion of prior fusion) at the same level when it has been at least 12 months from the prior surgery and ALL of the following criteria are met:

- imaging studies confirm evidence of a pseudoarthrosis (e.g., radiographs, CT)
- failure of three (3) consecutive months of physician-supervised conservative management which includes exercise, nonsteroidal and/or steroidal medications (unless contraindicated), physical therapy and activity lifestyle modification
- the individual is a nonsmoker, or in the absence of progressive neurological compromise has refrained from use of tobacco products for at least 6 weeks prior to the planned surgery

LUMBAR FUSION NOT MEDICALLY NECESSARY
Lumbar fusion is considered not medically necessary for ANY of the following indication:

- with initial primary laminectomy/discectomy for nerve root decompression or spinal stenosis in the absence of instability or spondylolisthesis treatment of spinal stenosis in the absence of spondylolisthesis, foraminal stenosis, or spinal instability
- chronic low back pain without a clear cause demonstrated on imaging studies

LUMBAR FUSION EXPERIMENTAL, INVESTIGATIONAL, UNPROVEN
The following are each considered experimental, investigational or unproven:

- lumbar fusion for treatment of multiple-level (i.e., >1 level) degenerative disc disease
- ANY of the following surgical techniques/devices used for lumbosacral surgery:
  - minimally invasive approaches using only indirect visualization (e.g., endoscopic fusion, percutaneous fusion [video imaging])
  - pre-sacral interbody approach, including axial interbody approach [AxiaLif®] (CPT codes 22586, 22899)
  - interlaminar/ interspinous lumbar instrumented fusion (e.g., ILIF™)
  - dynamic spine stabilization device systems, including hybrid dynamic stabilization systems (e.g., Dynesys®, Stabilimax™ NZ)
  - total facet arthroplasty, including Total Facet Arthroplasty System™ (CPT code 0202T)
  - posterior spinal fusion involving only fusion of the facet joint (i.e., isolated facet fusion) with or without allograft bone graft substitutes and/or the use of implants, and when used exclusively as stand-alone stabilization devices (e.g., TruFuse® [any level], NuFix™ [any level]), threaded dowels, cages) (CPT codes 0221T, 0222T)
  - interspinous fixation/posterior non-pedicle supplemental fixation devices (e.g., Affix® Next Gen Spinous Process Plate System, Aspen™ Spinous Process Fixation System, coflex-F® (CPT codes 22899, HCPCS code L8699)
  - personalized (i.e., customized, patient-specific 3D printed) anterior, posterior, or lateral interbody cage (implantable) (CPT code C1831)
  - expandable mesh intervertebral body containment device/intervertebral system (e.g., OptiMesh [Spineology Inc.]; OptiLiF procedure [Spineology Inc.])

OPEN SACROILIAC (SI) JOINT FUSION
Open sacroiliac joint fusion is considered medically necessary when ALL of the following criteria are met:

- appropriate imaging studies demonstrate localized sacroiliac joint pathology
- the individual is a nonsmoker, or in the absence of progressive neurological compromise will refrain from use of tobacco products for at least 6 weeks prior to the planned surgery
- **ANY** of the following:
  - post-traumatic injury of the SI joint (e.g., following pelvic ring fracture)
  - as an adjunctive treatment for sacroiliac joint infection or sepsis
  - management of sacral tumor (e.g., partial sacrectomy)
  - when performed as part of multisegmental long fusions for the correction of spinal

deformity (e.g., idiopathic scoliosis, neuromuscular scoliosis)

Open sacroiliac joint fusion is considered experimental, investigational or unproven for ANY other indication, including the following:

- mechanical low back pain
- sacroiliac joint syndrome
- degenerative sacroiliac joint
- presence of neural compression as seen on an MRI or CT that correlates with the patient's symptoms or other more likely source for their pain (e.g., radicular pain)

PERCUTANEOUS SACROILIAC (SI) JOINT FUSION

Percutaneous sacroiliac joint fusion, using an FDA-approved implant*, placed across the SI joint (i.e., transfixing device), using a lateral transarticular or a posterior-oblique approach, and intended to promote bone fusion, is considered medically necessary for the treatment of low back/buttock pain resulting from degenerative sacroiliitis or sacroiliac joint disruption when ALL of the following criteria are met:

- presence of non-radiating, unilateral pain that is caudal to the lumbar spine (L5 vertebra), localized over the posterior sacroiliac joint, and consistent with sacroiliac joint pain and that impairs physical activities
- statement from a primary care physician, neurologist, physiatrist, psychiatrist, psychologist, or other licensed behavioral and/or medical health care provider attesting to the absence of **EACH** of the following:
  - untreated, underlying mental health conditions/issues (e.g., depression, drug, alcohol abuse) as a major contributor to chronic back pain
  - generalized pain behavior (e.g., somatoform disorder)
  - generalized pain disorder (e.g., fibromyalgia)
- the individual is a nonsmoker, or in the absence of progressive neurological compromise will refrain from use of tobacco products for at least 6 weeks prior to the planned surgery
- presence of localized tenderness with palpation of the posterior sacroiliac joint in the absence of tenderness of similar severity elsewhere (e.g. greater trochanter, lumbar spine, coccyx) and no other obvious sources for their pain exists
- positive response to the thigh thrust test OR compression test
- positive response to at least two of the following additional provocative tests:
  - Gaenslen's test
  - distraction test
  - Patrick's sign
- failure of six (6) consecutive months of physician-supervised conservative management which includes exercise, medications (unless contraindicated), active physical therapy and activity lifestyle modification
- diagnostic imaging studies confirm **ALL** of the following:
  - imaging (plain radiographs and a CT or MRI) of the SI joint excludes the presence of destructive lesions (e.g., tumor, infection) or inflammatory arthropathy
  - imaging of the ipsilateral hip (plain radiographs) that excludes the presence of osteoarthritis
  - imaging of the lumbar spine (CT or MRI) that excludes neural compression or other degenerative conditions that can be causing low back or buttock pain
- at least 75% reduction of pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced sacroiliac joint injection on two separate occasions, at least two months apart.
- a trial with at least one therapeutic intra-articular SI joint injection (i.e., corticosteroid injection)

***Note:** The name and manufacturer of the SI joint device must be included in the request.

Percutaneous SI joint fusion for SI joint pain is considered experimental, investigational or unproven for ANY other indication, including the following:

- Presence of systemic inflammatory arthropathy (e.g., ankylosing spondylitis, rheumatoid arthritis)
- The individual has osteopenia or osteoporosis (e.g., T-score < -1.0)
- Presence of generalized pain behavior (e.g., somatoform disorder), generalized pain disorder (e.g., fibromyalgia) or untreated, underlying mental health conditions/issues (e.g., depression, drug, alcohol abuse) as a major contributor to chronic back pain Presence of infection, tumor, or fracture
- Presence of acute, traumatic instability of the SIJ
- Presence of neural compression as seen on an MRI or CT that correlates with the patient's symptoms or other more likely source for their pain (e.g., radicular pain)
- Mechanical low back pain
- Minimally invasive approaches, including posterior or posterior dorsal approach to access the SI joint (CPT codes 22899, 27299, 0775T), including use of only bone grafts and no internal fixation
- Use of implants other than those which are placed across the joint (transfixing) to promote fusion (e.g., allograft, synthetic, nonmetallic implants [e.g., CornerLoc, LinQ])
- Insertion of both a lateral transfixing and intra-articular (non-transfixing) device during the same operative session (e.g., Hybrid SI joint fusion)
- Use of percutaneous intra-articular implant
- 3D printed SI joint fusion devices

General Background

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

Lumbar fusion, also referred to as lumbar arthrodesis, is a well-established method of treatment for infectious conditions of the spine (e.g., spinal tuberculosis) and for progressive spinal deformities (e.g., scoliosis) and traumatic injuries. Lumbar fusion is currently a proposed method of surgery to control low back pain attributed to abnormal or unstable vertebrae and pain due to mechanical degeneration of the intervertebral disc. Additionally, lumbar fusion is performed for clearly defined spinal instability. Although somewhat controversial, these indications have been expanded to include pain from degenerative disorders without deformity or neurological deficit. Surgery for degenerative disc disease typically leads to improvement in only 65% of cases, 35% are generally no better with respect to axial pain following surgery, and some patients continue to have activity limitations caused by pain or stiffness (Gardocki, Park, 2021). A less stringent approach to patient selection is warranted for conditions where the literature clearly supports improvement in pain and disability, for controversial conditions patients should be more carefully selected.

Arthrodesis is usually performed for conditions that involve only one vertebral segment; however it is necessary to fuse two segments in order to stop movement, which is referred to as a single level fusion. The general consensus in the medical literature is that the addition of multiple levels increases the complexity of the surgery and risks compared to single-level fusion. It has been reported in the literature that rate of nonunion (pseudoarthrosis) increases with multilevel fusions. Lumbar fusion of more than two segments (single level), is not typically recommended, particularly for degenerative disease, and is unlikely to reduce pain, as it removes normal motion in the lower back and may cause strain on other remaining joints. Added stress on nearby vertebrae can accelerate the degenerative process. When compared with one level ALIF two level anterior lumbar interbody procedures for DDD have been shown to significantly increase the odds of adjacent segment reoperation rates, greater intraoperative blood loss, extended hospitalization and non-home discharge (Martini, et al., 2020). Within this study, comparing single level and two level ALIF, the two level cohort had significantly more subjects overall who underwent subsequent reoperation at an adjacent segment (14.7% versus 7.5%, respectively). None of the subjects had DDD on preoperative imaging.

Specific patient selection guidelines for lumbar fusion have not been well-defined in the medical literature. Factors to be considered are the patient's history, physical exam, and response to conservative measures, psychosocial profile, diagnostic test results, and the physician's expertise. Patients should be educated regarding alternative treatments, benefits and associated risks in order to allow for realistic expectations after surgery.

Tobacco use is considered a risk factor for poor healing and is associated with nonunion. It is well-established that smoking is a preventable cause of morbidity and mortality. Deyo and colleagues evaluated trends and complications in adults who underwent lumbar fusion for spinal stenosis and noted that not only did major complications increase with increased comorbidity, but that there was a substantially greater risk among those with chronic lung disease compared to those without (Deyo, et al., 2010). Particularly with spinal fusion, tobacco use has been associated with increased risk of pseudoarthrosis (Brown, et al., 1986). Anderson et al. (2010) reported that smoking negatively affects fusion mass and furthermore; smoking results in lower bone mineral density, particularly in the spine. In addition, tobacco use has been associated with poorer clinical outcomes such as less pain relief, poorer functional rehabilitation and less overall patient satisfaction (Vogt, et al., 2002). The American Academy of Orthopedic Surgeons (AAOS) strongly recommends avoiding use and exposure to tobacco products due to the severe and negative impact on the musculoskeletal system including the bones, muscle, tendons and ligaments (AAOS, 2010). Lumbar fusion is in most situations an elective surgery; it is strongly recommended that individuals be in the best physical condition prior to undergoing surgery. A policy statement published by the International Society of Advancement for Spine Surgery (ISASS, 2011) indicates that while undergoing conservative care prior to surgery smokers should be encouraged to stop smoking as smoking aggravates low back pain, is a risk factor for multiple systemic health problems, and increases the risk from poor outcomes of spine surgery (ISASS, 2011). Cessation of smoking has been shown to increase fusion rates to near those of nonsmokers (Anderson et al., 2001). Various tests are available for evaluation of tobacco use status or exposure.

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

There is no consensus in the published scientific literature regarding the optimal duration for conservative treatment prior to surgical intervention for low back pain; recommendations range from at least three months to greater than 12 months (Herkowitz, Sidhu, 1995; Hanley and David,

1999; Kwon, et al., 2003). Nevertheless, despite varying recommendations, fusion for chronic degenerative discogenic related back pain, without instability and neural compression, is considered an option when all other established treatments have failed to improve symptoms.

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

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

Facet syndrome as a cause of low back pain is less common than degenerative disc disease and is not a clearly identified source of back pain. Facet joints are the articulations or connections between the vertebrae. Nociceptive nerve fibers have been identified in the facet joint capsules, in synovial tissue and in pericapsular tissue. It is hypothesized that increased motion and instability of the motion segments can lead to stress on the facet joint capsule, ultimately leading to the production of pain. Pain is characterized as worsening in extension and easing with flexion; it may radiate to the lateral buttock and thigh. Facet blocks have been the suggested treatment of choice and in some cases have been used as diagnostic criteria for patient selection. However, inconsistent outcomes have been reported (Esses, Moro, 1993; Lovely, Rastogi, 1997). Fusing the joints has been suggested as a treatment modality; however lumbar fusion for facet syndrome is no longer generally accepted (International Society for the Advancement of Spine Surgery, [ISASS], 2011). According to ISASS (2011) the surgery should only be performed in the context of a clinical trial.

Lumbar Fusion for Instability
Lumbar fusion has been proposed and resulted in improved clinical outcomes for treatment of iatrogenic instability, lumbar stenosis, degenerative spondylolisthesis, progressive degenerative scoliosis, and pseudoarthrosis.

Spinal Deformity: Spinal deformity typically refers to any malalignment of the spine regardless of the etiology. Treatment for deformity is based on the individual's symptoms and extent of deformity; criteria such as progression of curve, presence of symptoms and functional impairment, disability, response to conservative care and patient counseling as indicated are factors to be considered. In skeletally mature adults, surgical treatment of asymptomatic deformity is not medically necessary.

Iatrogenic Spinal Instability/Spinal Stenosis: Spinal instability may result from spinal stenosis that involves a narrowing of the spinal canal, nerve root canals, or intervertebral foramina due to spondylosis and degenerative disc disease, along with facet degeneration. It is a part of the aging process and is frequently seen in patients age 50 and older. Symptoms typically include low back pain, radiating leg pain and possible bladder and bowel difficulties. Central stenosis involves the area between the facet joints, the lateral recess involves the area at the lateral border of the dura and extends to the medial border of the pedicle, and the foraminal region is ventral to the pars. A synovial cyst, which is a fluid filled sac that results from degeneration in the facet joint, may also lead to spinal stenosis. Generally synovial cysts occur in

the L4-L5 region, are often accompanied by instability, and cause pressure on the spinal canal resulting in symptoms similar to stenosis. Diagnostic imaging includes computed tomography (CT) scans, magnetic resonance imaging (MRI) and/or myelography. In the absence of a neurologic deficit, and when conservative measures fail to relieve symptoms (back pain, sciatica), surgical treatment involves decompression (laminectomy) of the stenotic segments and correction of any associated deformity such as disc herniation, spondylolisthesis, scoliosis, or multidirectional malalignment. Neurological symptoms improve significantly following surgery however back pain may still be present, primarily due to pre-existing degenerative changes. Fusion is indicated only if there is radiographic evidence of instability (e.g., spondylolisthesis). Spinal instability associated with stenosis may arise intraoperatively; cases of severe stenosis require more extensive decompression (i.e., complete facetectomy or resection of pars interarticularis creating a pars defect), which may destabilize the spine. According to a policy statement published by ISASS (2011) on lumbar fusion surgery is indicated when an adequate decompression for the treatment of spinal stenosis requires creation of a pars defect or removal of either 75% of one facet joint or 50+% of both facet joints. Nonetheless, while lumbar fusion may be indicated to avoid postoperative instability in some situations (e.g., revision decompression surgery) iatrogenic instability generally does not result from primary routine decompression or laminectomy for treatment of spinal stenosis or disc herniation.

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

- Of patients with mild to moderate lumbar spinal stenosis initially receiving medical/interventional treatment and followed for two to 10 years, approximately 20-40% will ultimately require surgical intervention. Of the patients who do not require surgical intervention, 50-70% will have improvement in their pain.
- In patients with severe symptoms of lumbar spinal stenosis, decompressive surgery alone is effective approximately 80% of the time.
- In patients with lumbar spinal stenosis and spondylolisthesis, decompression with fusion results in better outcomes than decompression alone.
- Of patients with lumbar spinal stenosis without spondylolisthesis or instability, there is no evidence to support the addition of a fusion.

Spondylolisthesis: Spondylolisthesis is an acquired condition that involves the anterior displacement of one vertebral segment over subjacent vertebrae (NASS, 2014a). More specifically, anterolisthesis is an anterior translation of the vertebrae and occurs most commonly, however it may also occur in a posterior direction (retrolisthesis) or lateral direction (laterolisthesis). It most commonly occurs at the lumbosacral junction with L5 slipping over S1 (Vokshoor and Keenan, 2021). Based on etiology it is classified into 5 types: congenital or dysplastic, isthmic, degenerative, traumatic, and pathologic. It may be caused by chronic disc degeneration and/or facet degenerative changes (i.e., degenerative spondylolisthesis, most commonly L4-L5), segmental-rotational instability, or trauma (i.e., acute fracture). Isthmic spondylolisthesis typically occurs as a result of an anatomic defect in the pars, usually at level L5-S1. As the vertebra slips forward, the spinal nerves may be pinched, resulting in symptoms. Diagnosis is confirmed by radiography (e.g., standing, flexion-extension lateral views) which reveals instability when there is 4-5 mm of translation; CT and MRI (Canale, Beaty, 2007). Stabilization of the spinal segment and decompression of the neural elements if needed are the primary goals of surgery.

The grade of spondylolisthesis is determined by the degree of slippage of the vertebral body. A commonly adopted method of grading spondylolisthesis is the Meyerding classification as follows (Williams, 2021):

- Grade I: slippage 0% to 25%
- Grade II: slippage 26% to 50%

- Grade III: slippage 51% to 75%
- Grade IV: slippage 75% to 100%

- spondyloptosis > 100 % For some individuals, the condition may remain stable and in the absence of neurological compromise patients often do well with conservative care. Conservative measures should be tried and exhausted first. Surgical treatment may be indicated for progressive neurological deficit, cauda equina compression with leg weakness, sensory loss, or bowel and bladder incontinence; and persistent and severe back and leg pain despite aggressive conservative treatment (Rainville, Mahmood, 2019).

  Recommendations for the performance of lumbar fusion in addition to decompression for spinal stenosis, with or without spondylolisthesis are mixed. NASS published evidence based clinical guidelines for spondylolisthesis supporting surgical decompression and lumbar fusion for the treatment of individuals with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis to improve clinical outcomes compared with decompression alone. For symptomatic single level degenerative spondylolisthesis that is low grade (<20%) and without lateral foraminal stenosis, decompression alone with preservation of midline structures provides outcomes that are equivalent to decompression with fusion (NASS, 2014a). Ghogawala, et al., (2016) compared clinical outcomes of subjects who underwent decompression laminectomy alone to decompression laminectomy with fusion. Although the rate of follow-up was not high (68% at four years), the results of this randomized trial suggest that adding fusion to decompression resulted in outcomes using SF-36 that were slightly better than when decompression was performed alone. Forsth and colleagues (2016) reported results of a randomized controlled trial evaluating the efficacy of fusion in addition to decompression for treatment of lumbar stenosis, with or without degenerative spondylolisthesis. The results of this trial lend support that adding fusion to the decompression procedure did not result in better clinical outcomes at two and five year follow-up. According to the authors, enrolled subjects were randomized to undergo either decompression plus fusion (n=113) or decompression alone (n=120). Using ODI (primary outcome) and six-minute walk test (secondary outcome) the authors reported at two years post-procedure there was no significant difference in outcomes between groups. Results were consistent when evaluated again at five year follow-up with 96% of subjects reporting information. There was no significant difference between the fusion group and the decompression alone group in any of the seven patient reported outcome measures (ASA score, ODI, VAS back and leg pain, EQ-5D score ZCQ score, six minute walk test).

  Spondylolysis: Spondylolysis is a bone defect in the pars interarticularis; the isthmus or bone bridge between the inferior and superior articular surfaces of the neural arch of a single vertebrae, most often the result of a stress fracture nonunion. The condition is an acquired condition, occurs commonly at a young age and may occur with or without spondylolisthesis. The main presenting symptom is back pain which is often nonspecific. In children conservative treatment involves orthotic bracing, activity modification and physical therapy. In adults treatment involves education, analgesics and NSAIDS, 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 (Rainville, Mahmood, 2019).

  Degenerative Scoliosis: Degenerative scoliosis is characterized by degeneration of the facets and discs, which leads to spinal curvature. Curve progression or lateral listhesis may imply instability and result in back and leg pain (e.g., claudication and radiculopathy). Although most patients can be treated conservatively, researchers agree that surgery is indicated when conservative measures fail and when there is progression of the deformity, neurogenic claudication, and/or neurological deficits. In degenerative scoliosis, the curvature in the lumbar or thoracolumbar spine is often less than 40°. In cases of minimal stenosis (<25–30°), a simple

laminectomy decompression yields favorable results. In cases of excessive resection of bone, fusion is recommended at the level of destabilization. If patients have more pronounced deformities with any degree of lateral listhesis, a fusion may be performed at the time of decompression (Gelalis, Kang, 1998).

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

Flat-back Syndrome: Flat-back syndrome is a spinal condition that is associated with loss of normal lumbar lordosis and is often the result of prior spinal surgery involving distraction instrumentation. The condition may also occur as a result of aging (e.g., degenerative). Sagittal imbalance results in back pain; a forward tilting of the trunk and inability to stand erect are characteristic of the condition as well as muscle fatigue from trying to compensate for loss of the sagittal balance. The goal of treatment is to restore balance and relieve pain. Short term relief may be obtained with NSAIDS, exercise, physical therapy and activity modification. If the patient remains symptomatic or if the imbalance is progressive resulting in neurological compromise, surgical intervention is indicated. When surgical intervention is indicated osteotomy in addition to spinal fusion may be required to restabilize the spine.

Lumbar Fusion in the Absence of Instability
Degenerative Disc Disease: Degenerative disc disease (DDD) is considered a normal part of the aging process. Clinical symptoms are typically consistent with mechanical back pain, which is aggravated by activity and relieved by rest. Determining if a disc is the primary source of pain is challenging and treatment, particularly surgical, is considered controversial for this indication (Deyo, et al., 2004). Discography can be useful in determining the location of pain but does not determine instability, and some authors have questioned the diagnostic utility of this procedure. In contrast to conditions resulting in instability, DDD is described as axial spine pain with no or minimal abnormalities of spinal alignment or disc contour. Primary treatment is nonsurgical and involves education regarding the disease process, activity modification, muscle strengthening and analgesics (e.g., NSAIDS, local injection) as needed. Surgery may be indicated if conservative measures fail and disc disease is limited to a few lumbar segments. Evidence supporting lumbar fusion however, as a method of treatment for DDD is limited, and few well-designed clinical studies have supported arthrodesis as superior to nonoperative therapy for improving clinical outcomes. Surgery leads to improvement in only 65% of cases, 35% are no better or worse with respect to axial spine pain (Gardocki, Park, 2021). Moreover, despite improvement after surgical treatment patients continue to have activity limitations caused by pain and stiffness. Lumbar fusion is associated with more risks than conservative treatment, and when compared to structured rehabilitation and behavioral therapy programs there is no meaningful difference in clinical outcomes (e.g., pain relief, functional improvement). Authors stress the importance of accurate patient selection and identification of the source of pain.

Literature Review: Few randomized controlled clinical trials have compared lumbar fusion to nonoperative care in the published medical literature. There is limited evidence demonstrating patients with chronic low back pain treated with surgery have better clinical outcomes when compared to standard conservative management (Fritzell, et al., 2001). When comparing intense rehabilitation and cognitive therapy to lumbar fusion, the reported clinical outcomes demonstrate lumbar fusion is no more effective than intense rehabilitation combined with cognitive therapy

(Brox, et al., 2010; Mirza, et al., 2007; Brox, et al., 2006; Fairbank, et al., 2005; Brox, et al., 2003; Ibrahim, et al., 2001). Follow-up within these randomized controlled clinical trials and systematic reviews ranged from one to four years following surgery, with patient populations that range from 60 to 394 participants. One study was a merged RCT and reported on combined data from the Brox studies (2003, 2006) at four year follow-up (Brox, et al., 2010). The main outcome measured was the ODI score in most of the studies; some used VAS and SF-36 as a supplemental measure. The intensive rehabilitation program varied in length and type of treatment among studies; however it generally included regularly scheduled physical therapy, cognitive behavioral therapy, spine stabilization exercise, coping strategies, education regarding activity modification, and daily hydrotherapy (in some centers).

Cognitive behavioral therapy (CBT) in the context of management of chronic back pain focuses on identifying and correcting negative thoughts and behaviors to reduce the occurrence of pain. In a more general sense, cognitive therapy typically includes instruction about the disease process, instruction regarding how choices related to stress, actual physical activity, and adherence impacts the disease process, as well as impacting pain and disability. There is also emphasis on developing specific strategies to successfully manage fear, anxiety and sadness related to the condition. Provided by an experienced licensed healthcare professional, cognitive behavioral therapy assists an individual in developing positive thoughts and behaviors that improve coping strategies. In general, duration of therapy is short term, consisting of weekly sessions for eight to 10 weeks; involves an initial session to gather information and establish a relationship, and subsequent sessions focused on behavior modification, problem-solving, and cognitive restructuring. CBT also includes between session activities where the individual can practice and apply new skills with an evaluation that is conducted during a follow-up session (e.g., third session). In relation to the published clinical trials evaluating fusion for treatment of DDD, treatment sessions included instructional sessions regarding the disease process, which included but was not limited to pain receptors, facet joints, and muscle involvement. Additionally, subjects were encouraged to use their backs, to bend and to not be too cautious. The information was reinforced through various types of sessions which included individual, group discussions and lectures at various points in time.

In 2001 Fritzell (n=294) reported that in a well-informed and carefully selected group of patients with chronic low back pain, at two year follow-up, lumbar fusion was significantly superior compared to nonsurgical treatments, which included physical therapy, education, treatment aimed at pain relief, cognitive and functional training, and coping strategies. The authors acknowledged there was still considerable pain at two years in the surgical group, although the pain was reduced. It is uncertain if the results at two years were maintained over time. The results of a meta-analysis (Ibrahim et al., 2001) indicate spinal fusion for chronic low back pain did show a marginal improvement in the ODI scores compared to nonsurgical intervention, however surgery was found to be associated with a significant risk of complications; the evidence did not support routine fusion for the treatment of chronic pain. When comparing lumbar fusion with cognitive intervention and exercise, Brox et al. (2003) reported at one year follow-up the ODI was significantly reduced from 41 to 26 after surgery, compared with 42 to 30 after cognitive intervention and exercise. The overall surgical success rate was 70% with the cognitive intervention with exercise success rate of 76%. The main outcome measure indicated equal improvement in both groups. In 2005 Fairbanks and colleagues compared lumbar fusion to intense rehabilitation. Both groups reported reduction in disability at two year follow-up. The surgery groups ODI score improved significantly more than in those allocated to rehabilitation, although clinically the difference was small when considering risks and additional costs of surgery. Brox et al. (2006) reported that ODI was significantly improved from 47 to 38 after fusion and from 45 to 32 after cognitive rehabilitation. The reported success rate in the fusion group was 50% versus 48% in the cognitive intervention group. In the authors' opinion, lumbar fusion failed to show any benefit over cognitive intervention. When reporting four year follow-up from two merged RCTs, Brox and associates (2010) noted long-term improvement was not better after instrumented

fusion; lumbar fusion was not superior when compared to cognitive intervention and exercise for relieving symptoms, improving function or return to work.

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

In 2015 Noshchenko et al. published the results of a systematic review with meta-analysis evaluating long-term patient-centered clinical outcomes following lumbar fusion for spondylosis, performed with or without decompression, and compared fusion outcomes with the results of alternative surgical or nonsurgical treatments that are claimed to maintain mobility of the spine. Included in the analysis were RCTS reporting patient-centered clinical outcomes before treatment and at 12, 24, or > 24 months follow-up, rate of complications, and additional surgical treatments. In total 38 studies involving 5738 participants were reviewed. Primary outcomes included disability status, physical status, and pain status. Secondary outcomes included rate of additional surgical treatment for a related complication or condition. The authors concluded there was a strong or at least moderate treatment effect demonstrated in all studies at 12, 24, and 48-72 months of follow-up, despite use of varied scales. The level of evidence was graded as moderate at 12 and 24 months and low at 48-72 months. The pooled long term treatment effect of fusion exceeded that of nonsurgical treatment with a moderate level of evidence ($P < 0.0001$), and decompression without fusion at a low level of evidence ($P < 0.005$). At 12 and 24 months fusion showed a small inferiority versus disc replacement ($P < 0.001$) but not after 24 months following surgery. In the authors opinion surgical stabilization of the lumbar spine is an effective treatment for spondylosis due to disc degeneration and herniation, stenosis, in particular complicated by radiculopathy, grade I and II spondylolisthesis, degenerative spine deformity and instability, particularly in subjects with severe chronic low back pain resistant to three or more months of conservative therapy (Noshchenko, et al., 2015).

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

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

Fusion may be performed alone or in combination with other procedures such as decompression (e.g., discectomy, corpectomy) or laminectomy. Discectomy involves removal of the intervertebral

disc, either partial or complete. Corpectomy involves resection of the vertebral body, either partial or complete. According to NASS, a corpectomy of the lumbar spine, when performed with anterior spinal decompression, involves removal of at least one-third of the vertebral body (NASS, 2007). Laminectomy involves removal of the posterior arch of the vertebra.

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

Open lateral approaches have historically been considered a well-established method of performing spinal surgery for indications such as treatment of spinal tumors or fractures. Lateral interbody fusion differs from standard approaches in that the spine is approached from the side (lateral), rather than through the abdominal cavity (anterior) or the back (posterior). During a direct lateral or extreme lateral approach, a narrow passageway is created through the underlying tissues and the psoas muscle using tubular dilators, without cutting the muscle; which is the major difference between the open approach and lateral approach. The interbody device and bone graft are inserted via the tubular dilator. 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) and transforaminal lumbar interbody fusion (TLIF). Only those vertebrae of the spine that have clear access from the side of the body can be approached using this technique; the procedure is contraindicated for L5-S1 levels.

Other terms seen in the medical literature in reference to this approach involve two retractor systems (which are not implantable devices), DLIF (Sofamor Danek, Medtronic, Memphis, TN) and XLIF® (Nuvasive, San Diego, CA). Lateral interbody fusion may also be referred to as the trans-psoas approach or lateral extracavitary lumbar interbody fusion. In theory, a lateral interbody fusion is considered minimally invasive/disruptive, reduces complications, avoids the major blood vessels, and only requires small 3–4 cm incisions. Limitations of the approach include potential injury to the lumbar plexus.

Literature Review: Evidence in the published literature addressing the safety and efficacy of lateral interbody fusion for degenerative lumbar conditions is limited to feasibility studies (Bergey, et al, 2004; Ozgur, et al., 2006), a prospective chart review compared to a historical cohort (Knight, et al., 2009), prospective case series (Rodgers, et al., 2010b), retrospective case series (Lee, et al., 2014), retrospective reviews (Ozgur, et al., 2010; Rodgers, et al., 2010a) and few early case reports. Although limited, the published evidence lends some support to improved technical outcomes, such as shorter length of hospital stay, operative time and less blood loss. Some improvements in pain using VAS scores with XLIF procedures have been reported. The

approach for lateral interbody fusion may be considered a modification to an accepted lateral approach for spinal surgery in general, however there are few published studies examining clinical outcomes, such as functional ability and successful fusion rates, following DLIF/XLIF procedures. Berjano et al. (2015) reported the results of a case series (n=77) conducted to evaluate the fusion rate of individuals who underwent XLIF using CT. According to the authors 87.1% of subjects who underwent XLIF were completely fused at a mean follow-up of 34.5 months. Rodgers et al. (2010b) reported the results of a prospective case series (n=66) evaluating radiographic and computed tomography (CT) assessment of interbody fusion 12 months following XLIF. A total of 97% of patients were judged fused by CT; by radiograph criteria 98.4% of patients were judged as fused. On average, there was an 80% reduction in pain, listhesis improved by 75%, and patient satisfaction was high at 89.4%. There were no reoperations due to pseudoarthrosis. This group of authors noted that with a traditional open approach fusion rates are 95% or better. In a retrospective review of prospectively collected outcomes, Ozgur et al. (2010) reported two year clinical and radiograph success of lateral interbody fusion (n=66) as a treatment for degenerative conditions. Clinical outcomes included VAS and ODI scores, radiographs were used to verify solid fusion. Pain scores decreased significantly by 37% at two years; functional ODI scores decreased significantly by 39% from preoperative, clinical success by ODI changes was achieved in 71% of patients. Radiograph success was achieved in 91% of patients; one patient developed pseudoarthrosis. In the authors opinion the lateral interbody fusion is a safe and effective treatment option. Rodgers et al. (2010a) compared the incidence of early complications and predictive factors affecting complication rates in obese (n=156) and non-obese (n=157) patients who underwent XLIF. The authors reported there was no greater risk in obese patients when compared to non- obese, complications were minimal and comparable in each group.

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

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

Spine Society (NASS) indicates these methods are a modified standard approach for lateral interbody fusion.

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

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

Overall, a variety of implants have been investigated as alternatives to rigid interbody or posterolateral intertransverse process spinal fusion. One device currently undergoing a clinical trial is the ACADIA™ Facet Replacement System (Facet Solutions, Hopkinton, MA). Although devices are undergoing clinical trials sponsored primarily by the manufacturers, at this time there are no FDA approved posterior facet joint implants.

Literature Review: Evidence in the published peer-reviewed scientific literature evaluating facet arthroplasty and associated devices consists of preliminary biomechanical studies, pilot studies, and some cadaveric studies (Zhu, et al., 2007; Phillips, et al., 2009). Further well-designed studies supporting long term outcomes are needed to support safety and efficacy of this technology.

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

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

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

Literature Review: Evidence in the medical literature evaluating the effectiveness of axial lumbar interbody fusion is limited to published reviews, technical reports, case reports, and prospective and retrospective case series (Marotta, et al., 2006; Yuan, et al., 2006, Aryan, et al., 2008; Botolin, et al., 2010, Patil, et al., 2010; Tobler and Ferrara, 2011; Durrani, et al, 2011; Gundanna, et al., 2011; Lindley, et al., 2011; Gerszten, et al., 2012; Marchi, et al., 2012; Tobler, et al., 2013; Zeilstra, et al., 2013; Boachie-Adjei, et al., 2013, Whang, et al., 2013, Schroeder, et al, 2015; Balsano, et al., 2020)Much of the published evidence involves small sample populations, lack control groups, and report short-term clinical outcomes. Balsano et al. (2020) reported the outcomes of 43 subjects who underwent AxiaLif using a minimally invasive approach as treatment of L5 isthmic spondylolisthesis low grade dysplasia, primary, and secondary degenerative disc disease secondary to previous discectomy. Outcomes were measured using VAS and ODI scores at one, six, 12 and 24 months follow-up in addition to post-operative radiographs and in some subjects, CT scans. The authors reported that VAS back scores were reduced on average over baseline by 50%, 57%, 71%, 77% at 3, 6, 12 and 24 months, respectively ($p<0.001$) and ODI scores demonstrated an average reduction over baseline of 38%, 51%, 67%, and 72% at the same time points ($p<0.001$). A total of 63% of cases demonstrated complete fusion, 30% of cases had partial fusion, and 5% had absence of bony bridging confirmed radiographically. Two major complications were reported and included a retroperitoneal hematoma and spondylodiscitis. In the authors opinion results demonstrated good radiographic and clinical outcomes with an acceptable rate of complications and noted further the technique may be considered an alternative to access L5-S1 interbody space in patients with favorable anatomy or have a contraindication to the open anterior approach.

A retrospective case series (Aryan, et al., 2008) involved 35 patients who underwent percutaneous paracoccygeal axial fluoroscopically-guided interbody fusion (axiaLif) and demonstrated that at an average of 17.5 months post-procedure, 32 subjects had radiographic evidence of stable cage placement and fusion. However, the authors acknowledged further investigation is warranted before recommending the routine use of this surgical technique. In a more recent study AxiaLif was extended to a two-level fusion at both L4-L5 and L5-S1; however this was a biomechanical study on cadaveric spine segments. Patil et al. (2010) reported the

results of a case series involving 50 individuals who underwent ALIF and evaluated outcomes such as ODI scores, VAS scores, and postoperative radiographs. At an average follow-up of 12 months 96% of patients went on to have a solid fusion, and both VAS scores and ODI scores improved. The most common complications reported were superficial infection and pseudoarthrosis. Schroeder et al. (2015) published a systematic review of peer-reviewed articles related to fusion rate of L5-S1 and the safety of axial interbody fusion published between 1/1/2000 and 8/17/2014. A total of 15 articles met inclusion criteria; 13 case series and 2 retrospective cohort studies. The authors reported that axial interbody fusion was associated with a high fusion rate (93.15%), and a complication rate of 12.9%, based on mainly retrospective case series. The limited prospective data reviewed suggests the actual fusion rate may be lower and the complication rate may be higher than currently reported.

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.

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

Percutaneous/endoscopic lumbar fusion: Percutaneous endoscopic lumbar fusion is an emerging minimally invasive approach being investigated as an alternative to other well-established approaches to 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.

Literature review: 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.

Spinal Instrumentation
Several types of instrumentation/stabilization devices have been developed as a method of improving the success of spinal fusion. Spinal instrumentation helps the fusion success by limiting motion at the fused segment to correct a deformity or to be used as a splint or load sharing while the bone grafts heal. Three types of spine instrumentation, often used in combination with bone grafting, include pedicle screws with rods, anterior interbody cages, and posterior lumbar cages. Bone grafts are commonly used to promote the union of adjacent vertebrae and may be used alone or together with devices such as spinal fusion cages. Authors have suggested that interbody

fusion is less successful if structural support is not provided for the intervertebral space (Molinari, Lebwhol, 2018).

Personalized 3D Printed Spine Cage: 3D printing, also referred to as "additive manufacturing" or "rapid prototyping", is a process that creates a three dimensional object using successive layers of raw material (FDA, 2020). 3D printing has been utilized for a variety of medical applications, including the production of orthopaedic implants. These devices can be 3D printed in standard sizes, 3D printed in non-standard sizes and patient matched, or 3D printed as personalized/customized devices. 3D printed devices that are personalized and customized to the individual cannot be marketed to the general public (FDA, 2020). The FDA further notes that "modifications to a 510(k)-cleared device that maintain its original intended use and that could be clinically studied do not appropriately qualify as a custom device." Personalized or customized devices are unique to each individual. One device that has received 510(k) approval is the UNiD IB3D (Medicrea International S.A., France). According to the approval the device is manufactured using titanium alloy and is designed individually for each patient, it is indicated for spinal fusion procedures as treatment of degenerative disc disease at one or two contiguous levels (FDA, K200316).

The technology of 3D printing involves pre-surgical medical imaging and digital data which is utilized to develop a computer-assisted design (CAD), which is then translated into a virtual 3D model. The virtual 3D model can then can be digitally manipulated to account for patient-specific anatomy and implant surface refinement. The final step in the manufacturing process is to convert the data from the virtual model into a stereolithographic (SLA) format for 3D printing. Stereolithography systems use a vat of liquid material to create a device using a photochemical process to form polymers which are then used to develop a 3D solid device.

One application currently under investigation is personalized spine implants. These devices (e.g., interbody cages, vertebral body cages) are primarily purported for use during anatomically challenging, and complex spinal surgeries to restore patient specific anatomy and spinal stability (e.g., oncological tumor resection, congenital anomaly) and less so for degenerative disorders (Fiani, et al, 2021). Proposed advantages of 3D spine implants include decreased time in the operating room, decreased radiation exposure to patients, and improved fit which may lead to increased ossification and less subsidence, improving surgical outcomes. Proponents claim additive manufacturing also allows for development of rough or porous surface textures that theoretically increase osteoblastic activity and promote bone ingrowth. Some of the barriers to 3D printing include accessibility, time to plan and print which varies but may take anywhere from days to months, an unknown long-term response to some of the biomaterials being used and unknown fusion rates in comparison to off-the-shelf spine implants, which have been used for many years and are made in a variety of sizes and shapes.

Evidence in the published, peer-reviewed scientific literature evaluating personalized 3D spine implants consist mainly of case series and case reports, with small sample populations and lack of controls. Long term data regarding fusion success, durability, and overall performance in comparison to standard spine implants is also lacking. In addition, 3D printed spinal implants are typically manufactured from titanium alloy or poly-ether-ether-ketone (PEEK) or polycarbonate due to biocompatibility and ability to enhance bone healing (Fiani, et al., 2021), similar to conventional implants, however manufacturing processes have not been standardized, other materials are being investigated which have not been fully evaluated, and FDA regulations/approval processes are not firmly established. At present, whether personalized 3D printed spine implants provide comparable or improved benefits in terms of clinical outcomes is unknown, additional evidence is required to firmly establish safety and efficacy.

Interspinous Fixation/Posterior Non-Pedicle Supplemental Fixation Device: There has been recent interest in the use of posterior non-pedicle supplemental fixation devices as a method of temporary fixation of the thoracic, lumbar and sacral spine while waiting for bony fusion to take place, as an alternative to pedicle screws. Posterior non-pedicle supplemental fixation devices (e.g., Aspen MIS Fusion System, Zimmer Biomet) have been explored as a method of temporary spinal fixation while waiting for bony fusion to occur. These devices differ from interspinous process spacer devices (e.g., X-STOP) in that they are used for fixation rather than for motion preservation. Several devices, including but not limited to the following, have been cleared by the U.S. Food and Drug Administration and are intended to be used as an adjunct to interbody fusion, not as stand-alone fixation devices:

- Aspen MIS Fusion System, Zimmer Biomet, Broomfield, CO)
- Affix® Next Gen Spinous Process Plate System (NuVasive, Inc., San Diego, CA)
- The Coflex-F® Interlaminar Stabilization System (Paradigm Spine, LLC, NY, NY)

Literature Review: Evidence in the published peer-reviewed scientific literature is lacking; long-term safety and efficacy has not been established despite FDA approvals for most of these devices. Interspinous fixation, including posterior non-pedicle supplemental fixation devices, has not been proven to result in net health outcomes that are as good as or superior to those obtained with standard surgical approaches. According to recent NASS coverage policy recommendations (NASS, 2014b), interspinous fixation with fusion for stabilization is currently not indicated as an alternative to pedicle screw fixation with lumbar fusion procedures.

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

U. S. Food and Drug Administration (FDA): Pedicle screw spinal systems are prosthetic devices regulated by the FDA, some as Class II devices and some as Class III devices depending on the condition being treated and the particular device. In 2003, the FDA granted 510(k) approval for Dynesys® Dynamic Stabilization System (Zimmer, Biomet Spine, Inc. Westminister, CO). Since the approval of the Dynesys device, other dynamic stabilization systems have received FDA approval for spinal immobilization and stabilization during fusion and include the CD Horizon® Spinal System (Medtronic Sofamor Danek, Inc., USA; the N Fix II Dynamic Stabilization System (N Spine, Inc., San Diego, CA) and the Dynesys-Transition-Optima (DTO) (Zimmer Spine) hybrid stabilization and fusion system, to name a few device systems.

Literature Review: The clinical utility of dynamic stabilization devices has not been proven in the peer-reviewed, scientific literature. Many of the studies evaluate the Dynesys Spinal System; few studies can be found evaluating other devices. The published evidence is not robust; a majority of the studies are retrospective or prospective case series and lack a control group (Grob, et al., 2005; Schnake, et al., 2006; Welch, et al., 2007; Beastall, et al., 2007; Bothman, et al., 2007; Schaeren, et al., 2008; Hu, et al., 2011; Pham, et al., 2016; Zhang, et al., 2018; Akyoldas, et al., 2020). Length of follow-up extends to four years in a few studies but on average the follow-up period is two years. In general sample populations are small ranging on average from 25 to 100 subjects. While some authors reported improvement in pain and function (Korovessis, et al., 2004; Schnake, et al., 2006; Welch, et al., 2007; Bothman, et al., 2007; Hu, et al., 2011) adjacent segment degeneration has also been documented following insertion (Schnake, et al., 2006; Schaeren, et al., 2008). Adjacent segment motion following Dynesys was evaluated by Cakir et al. (2009) who reported that Dynesys had no beneficial effect on adjacent segment

mobility compared with monosegmental instrumented fusion. Kumar et al. (2008) reported that disc degeneration at the bridged and adjacent segment continued despite Dynesys stabilization. Furthermore, some study participants have required reintervention—revision surgery and/or a need for removal of the device has been reported (Grob, et al., 2005; Welch, et al., 2007). Fei et al. (2015) compared radiographic and clinical outcomes between posterior dynamic stabilization (n=95) and posterior lumbar fusion (81). The authors noted that at three years follow-up there was no superior improvement in clinical outcomes, there were no advantages on leg and back VAS or ODI scores and randomized controlled trials are still needed. Overall, the body of evidence does not permit strong scientific conclusions regarding safety and efficacy for these devices. In addition, there are some clinical trials that have been published reporting on the use of dynamic stabilization devices in the absence of fusion, however, none of these devices have received FDA approval for this indication.

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

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

Expandable Intervertebral Body Mesh Fusion Device: The Spineology Interbody Fusion System (Spineology, St. Paul, MN), also referred to as OptiMesh®, is described as a biocompatible, porous polyester mesh pouch knitted from polyethylene terephthalate thread. The device is indicated for use as an adjunct to fusion during an intervertebral body fusion procedure performed at a single level in the lumbar spine from L2 to S1. It is intended to be used with compatible allograft and autograft along with supplemental posterior fixation systems used in the lumbar spine. Once the fusion cavity has been prepared the mesh device is introduced into the cavity using a working cannula. Following placement the mesh is filled with graft material and secured in place. In contrast to use of an interbody cage, the mesh device is intended to reduce the impact on surrounding anatomical structures and tissue and allow for preservation of the facet joint.

U. S. Food and Drug Administration (FDA): Spineology Interbody Fusion System received 510(k) approval from the FDA in 2003 as a Class II device. At that time there was a black box warning indicating that the safety and effectiveness of this device used for fusion of the interbody space was not established. Subsequently in 2020 the device was reclassified by the FDA, at which time the FDA granted a DeNovo approval for use indicating the device is intended for use as an adjunct to an intervertebral body fusion at one level in the lumbar spine from L2 to S1 in skeletally mature patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history, physical examination, and radiographic studies. Eligible patients shall have undergone six (6) months of conservative (non-operative) care.

Literature Review: Evidence is in the peer-reviewed scientific literature evaluating OptiMesh consists of case reports, retrospective case series, and the industry sponsored FDA IDE trials (Driver, et al., 2021; Chi, et al., 2022). These studies consist of small sample populations, some with high dropout rates, and short term outcomes therefore no strong conclusions can be made regarding safety and efficacy. At present there is insufficient evidence in the form of high-quality peer-reviewed medical literature to establish the efficacy of the Spineology Interbody Fusion System (OptiMesh®) on spine fusion outcomes.

Professional Societies/Organizations
In 2021 NASS updated their recommendations for lumbar fusion (NASS, 2021). They noted the available evidence reviewed was published up to 6/6/2019, data subsequent to that date was not considered. In the absence of evidence based criteria recommendations reflect multidisciplinary expertise of the authors. Within this document, NASS notes that lumbar fusion is indicated when specific criteria are met for infection, tumor, traumatic injuries, deformity, stenosis, disc herniation, synovial cysts, single level discogenic low back pain, and pseudoarthrosis. Health disparities are not mentioned within the document.

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

Washington State Department of Labor and Industries (WSDLI): The WSDLI published guidelines in 2009 based on a health technology assessment report regarding lumbar fusion and discography in patients with chronic low back pain and uncomplicated degenerative disc disease. Uncomplicated disc disease excluded the following conditions: radiculopathy, functional neurologic deficits, spondylolisthesis, isthmic spondylosis, primary neurogenic claudication with stenosis, fracture, tumor, infection or inflammatory disease, and degenerative disease associated with significant deformity. Individuals with any of these listed conditions and no prior lumbar surgery may be considered a candidate for single level lumbar fusion surgery after failure of three months of conservative therapy and when other medical necessity criteria are met, including instability defined as anterior/posterior translation of 4mm at L3-4, 5mm translation at L5-S1, or 11 degrees greater end plate angular change at a single level. If the patient has had prior surgery, criteria vary depending on the location and type of prior surgery. Because of potential risk for poor outcomes the following are considered relative contraindications and require additional consideration prior to surgery:

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

disorder and high degrees of somatization on clinical or psychological evaluation.

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

American Pain Society: Guidelines for interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain, published by the American Pain Society (Chou, et al., 2009), state that based on moderate quality evidence, for patients with nonradicular low back pain, common degenerative spinal changes, and persistent and disabling symptoms, it is recommended that clinicians discuss risks and benefits of surgery as an option. They further recommend that shared decision-making regarding surgery for nonspecific low back pain include a specific discussion about intensive interdisciplinary rehabilitation with a cognitive/behavioral emphasis, as a similarly effective option; the small to moderate average benefit from surgery versus noninterdisciplinary nonsurgical therapy; and the fact that the majority of such patients who undergo surgery do not experience an optimal outcome (defined as minimum or no pain, discontinuation of or occasional pain medication use, and return of high level function).

The American Association of Neurological Surgeons (AANS)/Congress of Neurological Surgeons (CNS) Joint Section on Disorders of the Spine and Peripheral Nerves: The AANS/CNS published various guidelines regarding the performance of fusion procedures for degenerative disease of the lumbar spine in 2005 (Resnick, et al., 2005). Within these guidelines, specific surgical treatments were analyzed and recommendations provided. In 2014 several of these guidelines were updated (Eck, et al., 2014; Resnick et al., 2014a; Resnick et al., 2014b; Munnameni, et al., 2014; Groff, et al., 2014). Overall, recommendations pertinent to patient selection and type of intervention vary, however the 2014 guidelines support the following:

- Lumbar fusion for patients with disabling low back pain due to one- or two-level degenerative disease without stenosis or spondylolisthesis, whose pain is refractory to conservative care.
- Surgical decompression for patients with symptomatic neurogenic claudication due to lumbar stenosis without spondylolisthesis; in the absence of deformity or instability, the inclusion of lumbar fusion is not recommended in this subgroup.
- Lumbar fusion for patients presenting with stenosis and spondylolisthesis.
- Interbody techniques are associated with higher fusion rates compared with posterolateral lumbar fusion in patients with degenerative spondylolisthesis who have preoperative instability; improved fusion rates however do not translate into improved clinical outcomes and adding POF to interbody techniques is not recommend due to lack of evidence supporting a substantial clinical benefit.
- Pedicle screw fixation as a supplement to posterolateral fusion be reserved for individuals who are at increased risk of nonunion/pseudoarthrosis.

Sacroiliac Joint Fusion
The sacroiliac (SI) joint is located in the pelvis and links the iliac bones (pelvis) to the spine. Similar to other joints, the sacroiliac joint can become damaged by injury or by usual wear and tear on the joint surfaces. Sacroiliac joint fusion is an established treatment for sacroiliac joint

conditions such as joint damage resulting from trauma, infection, cancer, and joint instability (e.g., pelvic fracture).

Whether or not sacroiliac joint disease can be a source of mechanical back pain is debatable. Physical examination is often inaccurate in confirming a diagnosis and the sensitivity and specificity of radiographs is low. It is generally agreed that fluoroscopically guided intra-articular injection of a local anesthetic helps to confirm or exclude the diagnosis. Symptoms associated with sacroiliac joint disease include pain in the upper legs, buttocks, and spine which is often aggravated by sitting, lifting, running or walking.

Sacroiliac joint fusion may be performed as a minimally invasive procedure or as an open surgical procedure requiring a larger incision and subsequent increased recovery time. Percutaneous sacroiliac joint fusion is a minimally invasive approach in which instrumentation involving cages or screws, with or without bone graft, are placed percutaneously in order to achieve a fusion. Fusion of the sacroiliac joint, combined with bone grafts and other metal implant devices, is an extensive procedure; it is generally considered a salvage procedure when all other measures have failed to provide relief of pain.

Various implant systems have been developed and received FDA clearance through the 510(k) process or approval under Title 21 CFR Part 1271 (i.e., structural allografts, demineralized bone allografts) used with SI joint devices, and are intended for fixation of the pelvis and other large bones, for conditions including degenerative sacroiliitis and sacroiliac joint dysfunction. The iFuse Implant System™ (SI Bone, Cupertino, CA) is a device that received FDA (510k) clearance in 2008 and consists of porous plasma spray coated rigid titanium implants which are inserted across the SI joint to create fixation. According to the FDA the implant system is intended for fracture fixation of large bones and large bone fragments of the pelvis, for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. This device is recommended by the manufacturer for use as a fixation device for minimally invasive sacroiliac fusion with the proposed advantages of potential for earlier weight bearing, less invasive surgery and shorter length of hospital stay. Evidence in the medical literature suggests the device is primarily used for minimally invasive sacroiliac fusion for the treatment of sacroiliac pain resulting from degenerative sacroiliitis or sacroiliac joint disruption (Cummings, Capobianco, 2013; Rudolf, 2012; Sachs, Capobianco, 2012; Miller, et al., 2013). One other device, the SImmetry® SI Joint Fusion System (Zyga Technology Inc, Minnetonka MN), received 510(k) clearance in 2011. This system is also intended for fixation of large bones, including the pelvis, for treatment of sacroiliac joint disruptions and sacroiliitis. An initial approval on this device was granted in 2010 based on predicate devices such as SI Joint Fusion System (SI Bone, Inc.). These devices may be used with or without bone graft materials. Other similar devices include, but are not limited to:

- Catamaran SIJ™ Fixation Device (Tenon Medical Inc, Los Gatos, CA) (K180818, FDA) is described as a titanium implant inserted using an inferior-posterior approach to the SI joint, passing longitudinally through both the axial and sagittal planes of the ilium and sacrum, in contrast to other devices which are implanted and aligned across the joint (i.e., perpendicular)
- Genesys Spine Sacroiliac Joint Fusion System (Genesis Spine, Austin TX; [K191748, FDA]) is described as a threaded implant designed to secure the sacroiliac joint and minimize micromotion in order to enable bony fusion. Fusion across the graft space can be aided by the addition of bone graft material to the lumen of each screw; fenestration in each screw allow for direct allograft apposition across the sacroiliac joint, all implants are fabricated from medical grade titanium alloy.
- MSB Sacroiliac Joint Fusion Device (Medtronic Sofamor Danek, Memphis, TN; [K110472, FDA]) described as a titanium alloy, one design consists of a solid outer form, and a second which contains holes along the sides for packing graft material, both designs are cannulated and can be implanted using a minimally invasive approach.

- RIALTO™ SI Fusion System (Medtronic Sofamor Danek, Inc., Memphis, TN; [K161210, FDA]). The RIALTO™ SI Fusion System is a cylindrical threaded implant in contrast to devices such as iFuse which is triangular. The RIALTO™ implant is made using Titanium Alloy and are 40mm to 60mm in length with a diameter of 12mm.
- SiFix® Sacroiliac Intra-articular Fusion Allograft (NuTech Spine, Inc., Birmingham, Alabama; 510(k) not required) described as a cancellous allograft material indicated for SI joint fusion which contains no metal, this allograft is used as part of dorsal approach to SI Joint fusion.
- SILok® (Sacroiliac Joint Fusion System (Globus Medical Inc., Audubon, Pa; [K183119, FDA]) which is described as a hydroxyapatite coated screw intended for use during lateral and posterior approaches to the SI joint to optimize fusion across the joint.
- SiJoin Direct Posterior Fusion (VGI Medical LLC, FL; 510(k) not required), a structural allograft). The SiJoin fusion implant is a cortical allograft designed to be posteriorly implanted within the plane of the SI joint stabilizing the joint, and uses bone graft material to enhance the potential for fusion.
- SambaScrew® SI Fixation System (OrthoFix Medical Inc, TX; [K121148, FDA]) described as a cannulated metallic bone screw designed to stabilize the sacroiliac (SI) joint.
- Firebird SI Fusion system (Orthoifix, Inc. [K211710, FDA]) is a 3D printed titanium implant designed to compress and stabilize the SI joint. It is FDA approved for immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion as a pedicle screw fixation system (T1-S2/Ilium) and has a 50% porous mid shaft region that allows for bone to grow into its surface. It is intended to be used with autograft or allograft.

Literature Review: A majority of the evidence evaluating sacroiliac fusion for treatment of chronic back pain is limited to small case series and retrospective studies involving small sample populations and few published reviews (Al-khayer, et al., 2008; Wise and Dall, 2008; Buchowski, et al., 2005; Zelle, et al., 2005; Cohen, et al., 2005; Shutz and Grob, 2006). Reported clinical outcomes are mixed, sample populations are small, and various techniques are used, therefore no strong conclusions can be made regarding safety and efficacy when performed for the treatment of mechanical back pain.

Much of the evidence evaluating the use of the iFuse Implant System™ for sacroiliac fusion as a treatment of sacroiliac pain resulting from degenerative sacroiliitis or sacroiliac joint disruption consists largely of retrospective case series involving small sample groups evaluating short-term to mid-term outcomes, systematic reviews, and few randomized controlled trials (Chang, et al., 2022; Schmidt, et al., 2021; Darr and Cher, 2018; Vanaclocha, et al., 2017; Bornemann R, et al., 2017; Polly, et. al, 2016; Duhon, et al., 2016; Sturesson, et al., 2016; Heiney, et al, 2015; Zaidi, et al; 2015; Rudolf, Capobianco, 2014; Sachs, et al., 2014**;** Duhon, et al., 2013; Cummings, Capobianco, 2013; Rudolf, 2012; Sachs, Capobianco, 2012). The authors of a systematic review and meta-analysis of two RCTS and one retrospective cohort comparing minimally invasive SI joint fusion with conservative management (n=388 subjects, conservative care: 207, surgical: 181) concluded that using a pooled mean difference analysis, minimally invasive SI joint fusion demonstrated greater reduction in visual analog scale-pain score compared to conservative management: −37.03 points ($P < 0.001$) and that surgery was also associated with a greater reduction in ODI outcome: −21.14 points ($P < 0.001$). Among the study groups occurrence of adverse events were low and comparable. The review also included one cost-effectiveness analysis that reported surgery is more cost-effective than conservative management (Herman, et al., 2022).

Another systematic review published in 2022 involving 40 studies (two RCTs, three controlled cohort studies, and 35 uncontrolled studies) concluded minimally invasive SI joint fusion is likely more effective than conservative management for reducing pain and opioid use and improving

physical function and quality of life for individuals meeting criteria for SI joint fusion who have not responded to conservative care (Chang, et al., 2022).

A majority of the published studies have evaluated SI joint fusion outcomes using a lateral transiliac approach with device placement through the ileum and across the SI joint. Few authors have reported outcomes using a direct dorsal approach, which involves the placement of bone allograft products or devices into the ligamentuous portion of the joint, involving dissection of the muscle and the removal of a portion of the ligaments covering the outer posterior surface of the joint (Lorio, et al., 2020). The dorsal approach uses allograft bone products, these products are not specifically indicated/approved for SI joint fusion. According to a policy update published by ISASS regarding minimally invasive surgical SI joint fusion (Lorio, et al, 2020) the posterior dorsal approach has "fallen out of favor secondary to problems with both allografts (pseudarthrosis secondary to graft fracture or resorption) and cages (migration and subsidence, loss of lumbar lordosis, high pseudarthrosis rates, and the established need for supplemental spinal fixation)". Within the policy update the authors note that "only 3 low-quality studies address the safety and effectiveness of MIS posterior SIJF with this technique" , furthermore there is no evidence to support safety or effectiveness in the medical literature to support the use of the latest generation of bone allograft products for posterior MIS SIJF, noting furthermore that most products are not cleared through the FDA 510(k) process but rather are cleared as human cell and tissue products without equivalence testing. According to the policy update minimally invasive posterior dorsal SI joint fusion is not recommended. Within another publication Martin et al. (2020) reviewed evidence evaluating minimally invasive SI joint fusion, outcomes reported in the studies reviewed by this group of authors using a dorsal approach were not found to be equivalent or superior to those using a lateral approach, further illustrating inferiority of this approach.

Authors are investigating combining SI Joint fusion with decertification and grafting, which in theory may result in more enhanced growth of bridging and more rapid arthrodesis. Using this technique with the SImmetry device, Kucharzyk and colleagues (2022) (EVoluSIon study) reported 12 month results demonstrating a statistically significant mean VAS pain score reduction of 56.8% and improvement in ODI scores by 43.9% following surgery (n=250). Study participants also had a significant decline in opioid, narcotic and nonopioid pain medication use. At 1 year, 68.7% of patients showed fusion of the SI joint. Limitations of the trial include only 80% of subjects available for follow-up, interim short term outcomes as the study is designed for 24 months follow-up, and lack of a control group for comparison.

Whang and colleagues (2019) published five year clinical and radiographic outcomes following minimally invasive SI joint fusion using triangular titanium implants. The study groups were two multicenter clinical trials (INSITE, (NCT01681004 [a prospective, RCT of SIJ fusion vs non-surgical management] and SIFI, NCT01640353 [prospective multicenter single-arm study). Inclusion criteria for both studies were chronic SI joint pain resulting from sacroiliitis or SI joint disruption diagnosed by history, physical examination which included a positive Fortin Finger test, and at least 3 positive physical examination signs as well as confirmatory diagnostic SI joint block with anesthetic. Exclusion criteria included severe low back or hip pain due to other reasons, SI joint dysfunction due to autoimmune or inflammatory conditions and osteoporosis. Clinical outcomes were measured using VAS, ODI, and EuroQOL-5D scores; radiological outcomes were assessed using CT scans. The primary five year endpoint was defined as at least 30% apposition of bone to both sacral and iliac sides of at least 2 of 3 iFuse implants, other endpoints included degree of bridging, evidence of device loosening, signs of bone remodeling , device failure or migration and heterotopic ossification. A total of 103/127 subjects were enrolled in the trial with five year follow-up available for 93 subjects (six subjects were lost to follow-up, two died, two withdrew consent). At five years the mean SI joint pain score decreased from 81.5 to 27.1 ($p<0.0001$), with 77 subjects having at least a 20 point improvement in pain scores. Study success was observed in 76 subjects (defined as at least 20 point improvement in VAS in the absence of severe device

related adverse events). ODI scores decreased from 56.3 to 29.9 with 64 subjects having at least a 15 improvement from baseline. EuroQOL score was also improved at five year follow-up. Satisfaction rates were high at 6 months and at all subsequent time periods. The most common adverse events reported included SI joint pain and contralateral SI joint pain. A total of 43 serious adverse events occurred but none were related to the device. The authors reported that independent radiographic analysis showed a high rate (98%) of bone apposition to implants on both the sacral and iliac sides of the SI joint, with a high rate of bony bridging (87%) (i.e., bony fusion) and a low rate of radiolucencies suggestive of loosening (5%). Limitations of the study as noted by the authors included lack of long term outcomes for the concurrent control groups.

Darr and Cher (2018) reported four year outcomes on subjects who underwent SI joint fusion for treatment SI joint dysfunction (n=103). The authors combined subjects from two prior clinical trials; subjects from one RCT comparing SI joint fusion with non-surgical management (INSITE) and subjects from a single arm clinical trial (SIFI), the study was designed to conduct follow-up extending out to five years. At four years there were 91 subjects available for evaluation. The authors reported there were improvements in pain, disability, and quality of life scores as well as a decrease of the proportion of subject's opioid use compared with baseline, from 77% to 43% respectively. Follow-up for the control group from the INSITE trial however was not reported as part of the study.

Dengler et al. (2017) published one-year results of a prospective randomized controlled trial comparing conservative management (n=51) versus minimally invasive surgical treatment (n=52) for SI joint pain using the iFuse implant. At 12 month follow-up mean low back pain improved by 41.6 VAS points in the SI joint surgery group versus 14 points in the conservative management group ($P<0.0001$), mean ODI scores improved by 25 point versus 8.7 points in the group treated conservatively ($P<0.0001$); and mean improvement in leg pain scores were better and superior in the SI joint surgery group compared to those who received conservative management. The authors noted the study is limited by lack blinding and subjective nature of the assessment tools.

Polly and colleagues (2015) published the results of a RCT comparing minimally invasive sacroiliac joint fusion using titanium implants (iFuse (n=102) with nonsurgical management (n=46) for treatment of sacroiliitis or SI joint dysfunction. Success rates and ODI scores were higher in the experimental group at both six and twelve month follow-up. The authors noted that pain, disability and quality of life scores also improved after crossover of subjects from the nonsurgical to surgical group, which was allowed after the six month study visit was completed and involved 35/44 subjects. The authors recently published the two year results of the same study group (Polly, et al., 2016). Eighty-nine of the 102 SI fusion subjects were available for 24 month follow-up. Improved quality of life scores, pain scores and ODI continued in favor of SI joint fusion compared to non-surgical management. In addition, in the SI fusion group opioid use decreased by 9% at six months and by 29.6% at 24 months while opioid use in the non-surgical management group increased by 7.5% at six months (24 month results were not reported). Four subjects in the SI fusion group required revision surgery related to impingement syndrome (n=1), suboptimal implant position (n=2), and a hairline fracture of the ipsilateral ilium (n=1). Subjects in the crossover group obtained similar benefits to those initially assigned to SI joint fusion. Limitations of the study include short-term follow-up, high crossover at six months, use of a non-surgical comparison group, lack of radiograph confirmation of fusion, and lack of blinding.

Duhon et al. (2015) reported the early results of a prospective multicenter single-arm interventional clinical trial evaluating titanium implants for MIS SI joint fusion (n=172) for treatment of degenerative sacroiliitis and SI joint dysfunction. Follow-up was conducted at various time points up to and including 12 months post-procedure and involved SI joint and back pain VAS scores, ODI scores, SF-36 scores, and quality of life scores. Improvement was reported for all measures at both six and 12 months. Twenty four month outcomes of this study were published in

2016 (Duhon, et al., 2016). Of the 149 subjects (86.6%) available for follow-up, outcomes demonstrate continuation of decreased SI joint pain (30.4 at 12 months; 26.0 at 24), improved ODI scores (31.5 at 12 months, 30.9 at 24), and improvement in quality of life scores. In addition, the authors reported a decrease in the proportion of subjects taking opioids for SI joint or low back pain from baseline to 24 months, 76.2% and 55.0% respectively. The authors reported seven device-related adverse events within the 24 month follow-up which included neuropathic pain due to implant impingement on the sacral nerve (n=3) and SI joint or hip pain (n=4) due to the presence of the implant. Additionally, there were 26 procedure-related events (infection, irritation and drainage, SI joint pain from malposition) and eight subjects who required one or more revision surgeries on the index side. Imaging outcomes for 97% of subjects showed adherence of bone to at least two implants on both sacral and ilial sides. Bridging across the SI joint was seen in only approximately 22% of cases. Limitations of this study include lack of control group, incomplete 24 month follow-up, and short-term outcomes.

Limited evidence is available comparing different minimally invasive devices. Tran and colleagues (2019) published the results of a systematic review/meta-analysis comparing pain, disability and quality of life outcomes for subjects who underwent SI fusion using multiple techniques. Twenty studies met inclusion criteria, had adequate data for analysis, and were included in the review. A total of 14 trials evaluated the iFuse device, six evaluated screw-type devices. Median sample size for the iFuse trials was 60 subjects and for the screw-type trials it was 20 subjects. Four of the iFuse trials were RCTs, none included a placebo or sham treatment group. There were no RCTS investigating the screw-type devices. Average follow-up ranged from two weeks to three years across all trials. The results of the meta-analysis demonstrated iFuse had significantly better outcomes when compared to screw-type techniques in all three categories: pain, disability and quality of life. Limitations noted by the authors include potential treatment bias resulting from an imbalance of the available studies, and lack of comparative data including well-powered RCTs evaluating long-term outcomes.

Evidence in the peer-reviewed published scientific literature tends to support the clinical utility of percutaneous /minimally invasive SI fusion using iFuse and other similar FDA approved stabilization system for sacroiliitis and sacroiliac joint dysfunction when used to transfix the joint. However evidence was not found in the medical literature supporting indications other than these, therefore no conclusions can be made regarding clinical utility and overall improvement in health outcomes.

Professional Societies/Organizations
In 2021 the Washington State Health Care Authority published an evidence report evaluating the safety and efficacy of SI joint fusion. Inclusion criteria consisted of randomized controlled trials (RCTs) or controlled cohort studies (CCSs) that reported efficacy outcomes (e.g., pain, physical function), safety outcomes (e.g., adverse events, revision surgery), or cost analyses in addition to select uncontrolled studies that reported safety outcomes. A total of 57 studies were included, 9 were controlled studies (2 RCTs and 7 CCSs), 43 were uncontrolled studies, and 5 were cost studies. The authors concluded for reduction of pain, improving function and improving quality of life, minimally invasive SI joint fusion surgery is likely more effective than conservative management at 6 months follow-up and at 1 to 2 years of follow-up.

The North American Spine Society (NASS, 2021) published updated recommendations for minimally invasive SI joint fusion. Health disparities are not addressed in the updated document. NASS described the procedure as the insertion of a metallic device across the SI Joint which is intended to fuse the bone or lead to fusion of the joint, in contrast to insertion of screws without bone graft across the SI joint which is intended to stabilize but not fuse the joint. According to these recommendations much of the available literature is subject to potential bias, however multiple SI joint fusion devices have shown results which are similar. NASS policy

recommendations are as follows for treatment of SI joint pain, for patients with low back/buttock pain, who meet ALL of the following criteria:

- Have undergone and failed a minimum 6 months of intensive nonoperative treatment that must include medication optimization, activity modification, bracing and active therapeutic exercise targeted at the lumbar spine, pelvis, SIJ and hip including a home exercise program.
- Patient's report of nonradicular, typically unilateral pain that is caudal to the lumbar spine (L5 vertebra), localized over the posterior SIJ, and consistent with SIJ pain.
- A thorough physical examination demonstrating localized tenderness with palpation over the sacral sulcus (Fortin's point, ie, at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine or PSIS) in the absence of tenderness of similar severity elsewhere (eg, greater trochanter, lumbar spine, coccyx) and that other obvious sources for their pain do not exist.
- Positive response to a cluster of at least 3 provocative tests (eg, thigh thrust test, sacral thrust, compression, Gaenslen's test, distraction, Patrick's or FABER. Note that the thrust test is not recommended in pregnant patients or those with connective tissue disorders.
- Absence of generalized pain behavior (eg, somatoform disorder) or generalized pain disorders (eg, fibromyalgia).
- Diagnostic imaging studies that include ALL of the following:
  - Imaging (plain radiographs and a CT or MRI) of the SI joint that excludes the presence of destructive lesions (eg, tumor, infection) or inflammatory arthropathy that would not be properly addressed by percutaneous SIJ fusion.
  - Imaging of the pelvis (AP plain radiograph) to rule out concomitant hip pathology.
  - Imaging of the lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that , in combination with the patients history, physical and other testing would more likely be the source of their low back or buttock pain
  - At least 75% reduction of pain, documented by pain diary, for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular SIJ injection on 2 separate occasions.
- A trial of at least one therapeutic intra-articular SIJ injection (ie, corticosteroid injection).

In 2020, the International Society for the Advancement of Spine Surgery ISASS published a policy update titled: Minimally Invasive Surgical Sacroiliac Joint Fusion (for Chronic Sacroiliac Joint Pain): Coverage Indications, Limitations, and Medical Necessity" (Lorio, et al, 2020). Within this document the society notes that the purpose of the update is to review and analyze the expanding evidence base and to provide guidance relating to differences between the lateral and dorsal surgical procedures for surgical treatment of SI joint pain. According to ISASS lateral procedures are the preferred method of approach for primary or secondary SI joint pain disorders based primarily on two RCTs and five multicenter prospective trials which demonstrate consistent improvement in pain, function and quality of life scores compared to nonsurgical treatment. The posterior approach is significantly different and as such data from lateral studies with transfixing devices are not generalizable to posterior dorsal procedures. The authors reported that evidence consists mainly of one prospective multicenter study, no comparative studies, and only a small number of case series evaluating the dorsal approach. Due to the lack of evidence posterior dorsal SI joint fusion remains unproven.

Previously, in 2016, ISASS published a position statement regarding minimally invasive sacroiliac fusion (ISASS, 2016). Within this document ISASS notes minimally invasive SI joint fusion may be performed using a number of implants, including triangular porous, titanium implants, hollow modular screws, titanium cages, and allograft dowels. Two common surgical approaches include a lateral transarticular approach or a posterior approach, published data outcomes for the posterior approach are scarce. According to the statement, individuals with all of the following criteria may

be considered candidates for minimally invasive SI joint fusion, instrumentation utilized is the purview of the surgeon preference:

- Significant SIJ pain that impacts quality of life or significantly limits activities of daily living;
- SIJ pain confirmed with at least 3 physical examination maneuvers that stress the SIJ and reproduce the patient's typical pain
- Confirmation of the SIJ as a pain generator with ≥ 50% acute decrease in pain upon fluoroscopically guided diagnostic intra-articular SIJ block using local anesthetic.
- Failure to respond to at least 6 months of non-surgical treatment consisting of non-steroidal anti-inflammatory drugs and/or opioids (if not contraindicated) and one or more of the following: rest, physical therapy, SIJ steroid injection. Failure to respond means continued pain that interferes with activities of daily living and/or results in functional disability;
- Additional or alternative diagnoses that could be responsible for the patient's ongoing pain or disability have been ruled out (e.g., L5/S1 compression, hip osteoarthritis).

The National Institute for Health and Care Excellence (NICE) supports minimally invasive SI joint fusion for chronic SI joint pain (NICE, 2017). NICE issued the following recommendations:

- Current evidence on the safety and efficacy of minimally invasive sacroiliac (SI) joint fusion surgery for chronic SI pain is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.
- Patients having this procedure should have a confirmed diagnosis of unilateral or bilateral SI joint dysfunction due to degenerative sacroiliitis or SI joint disruption.
- This technically challenging procedure should only be done by surgeons who regularly use image-guided surgery for implant placement. The surgeons should also have had specific training and expertise in minimally invasive SI joint fusion surgery for chronic SI pain.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	No Determination found	
LCD	Palmetto	Lumbar Spinal Fusion (L37848)	9/09/2021
LCD	First Coast Options, Inc.	Lumbar Spinal Fusion for Instability and Degenerative Disc Conditions (L33382)	1/8/2019
LCD	National Government Services, Inc.	Minimally-invasive Surgical (MIS) Fusion of the Sacroiliac (SI) Joint (L36406)	10/10/2019
LCD	CGS Administrators, LLC	Minimally-Invasive Surgical (MIS) Fusion of the Sacroiliac (SI) Joint (L36494)	1/5/2023
LCD	Wisconsin Physicians Service Insurance Corporation	Percutaneous minimally invasive fusion/stabilization of the sacroiliac joint for the treatment of back pain (L36000)	6/30/2022

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

LUMBAR FUSION OPEN APPROACH

Spinal Instability with Specified Conditions

Considered Medically Necessary when criteria in the applicable policy statements listed above are met for the treatment of spinal instability when performed as either single or multilevel lumbar fusion:

CPT®* Codes	Description
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22534	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic or lumbar, each additional vertebral segment (List separately in addition to code for primary procedure)
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22585	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure)
22612	Arthrodesis, posterior or posterolateral technique, single interspace; lumbar (with lateral transverse technique, when performed)
22614	Arthrodesis, posterior or posterolateral technique, single interspace; each additional interspace (List separately in addition to code for primary procedure)
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar;
22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, each additional interspace (List separately in addition to code for primary procedure)
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace; lumbar;
22634	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace, each additional interspace and segment (List separately in addition to code for primary procedure);
22800	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments
22802	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments
22804	Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments

CPT®* Codes	Description
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

Spinal Instability with Spinal Stenosis and Associated Spondylolisthesis

Considered Medically Necessary when criteria in the applicable policy statements listed above are met for the treatment of spinal stenosis when there is an associated spondylolisthesis (i.e., anterolisthesis):

CPT®* Codes	Description
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22612	Arthrodesis, posterior or posterolateral technique, single interspace; lumbar (with lateral transverse technique, when performed)
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar;
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;

Spinal Instability with Spondylolysis or Isthmic Spondylolisthesis

Considered Medically Necessary when criteria in the applicable policy statements listed above are met for spondylolysis (i.e., pars interarticular fracture), or isthmic spondylolisthesis:

CPT®* Codes	Description
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22612	Arthrodesis, posterior or posterolateral technique, single interspace; lumbar (with lateral transverse technique, when performed)
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar;
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

CPT®* Codes	Description
	prepare interspace (other than for decompression), single interspace, lumbar, each additional interspace and segment (List separately in addition to code for primary procedure);

Degenerative Disc Disease without Instability

Considered Medically Necessary ONLY when criteria in the applicable policy statements listed above are met for the treatment of degenerative disc disease in the absence of instability:

CPT®* Codes	Description
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22612	Arthrodesis, posterior or posterolateral technique, single interspace; lumbar (with lateral transverse technique, when performed)
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar;
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;

Following Prior Spinal Surgery

Considered Medically Necessary when criteria in the applicable policy statements listed above are met for recurrent disc herniation when it has been at least 3 months from the prior surgery or adjacent segment disease and it has been at least 6 months from the prior spinal surgery and there is an associated spondylolisthesis (i.e., anterolisthesis):

CPT®* Codes	Description
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22612	Arthrodesis, posterior or posterolateral technique, single interspace; lumbar (with lateral transverse technique, when performed)
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar;
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;

Pseudoarthrosis

Considered Medically Necessary when criteria in the applicable policy statements listed above are met for the treatment of pseudoarthrosis (i.e., nonunion of prior fusion) at the same level when it has been at least 12 months from the prior surgery:

CPT®* Codes	Description
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22612	Arthrodesis, posterior or posterolateral technique, single interspace; lumbar (with lateral transverse technique, when performed)
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar;
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;

Other Procedures

Considered Experimental/Investigational/Unproven when used to represent isolated Facet fusion, pre-sacral interbody approach (e.g., AxiaLif®), total facet arthroplasty, personalized (3D printed) anterior and lateral interbody implantable cage, or expandable mesh intervertebral body containment device/intervertebral system (e.g., OptiMesh; OptiLiF procedure) for ANY indication:

CPT®* Codes	Description
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
22899	Unlisted procedure, spine
0202T	Posterior vertebral joint(s) arthroplasty (eg, facet joint[s] replacement), including facetectomy, laminectomy, foraminotomy and vertebral column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine
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

HCPCS Codes	Description
C1831	Interbody cage, anterior, lateral, or posterior, personalized (implantable)
L8699	Prosthetic implant, not otherwise specified

Considered Experimental/Investigational/Unproven when used to represent posterior non-pedicle supplemental fixation devices (e.g., Affix™, Aspen™ Spinous Process Fixation System, facet fixation devices):

CPT®* Codes	Description
22840†	Posterior non-segmental instrumentation (eg, 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)
22899	Unlisted procedure, spine

†**Note: Experimental/Investigational/Unproven only when used to represent interspinous fixation/posterior non-pedicle supplementation devices.**

HCPCS Codes	Description
L8699	Prosthetic implant, not otherwise specified

OPEN SACROILIAC(SI) JOINT FUSION

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
27280	Arthrodesis, sacroiliac joint, open, includes obtaining bone graft, including instrumentation, when performed

PERCUTANEOUS SACROILIAC (SI) JOINT FUSION

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device

Considered Experimental, Investigational or Unproven for minimally invasive approaches, including posterior or posterior dorsal approach to access the SI joint, including use of only bone grafts and no internal fixation devices:

CPT®* Codes	Description
27278	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, including placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s]), without placement of transfixation device
27299	Unlisted procedure, pelvis or hip joint
22899	Unlisted procedure, spine

CPT®* Codes	Description
0775T	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, includes placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s])
0809T	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, placement of transfixing device(s) and intra-articular implant(s), including allograft or synthetic device(s)

Other Procedures That May Be Related to Lumbar Fusion

Requires Clinical Review to determine Medical Necessity:

CPT®* Codes	Description
22207	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (eg, pedicle/vertebral body subtraction); lumbar
22208	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (eg, pedicle/vertebral body subtraction); each additional vertebral segment (List separately in addition to code for primary procedure)
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)
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)
22325	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; lumbar
22328	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; each additional fractured vertebra or dislocated segment (List separately in addition to code for primary procedure)
22840	Posterior non-segmental instrumentation (eg, 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 (eg, 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 (eg, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments (List separately in addition to code for primary procedure)
22844	Posterior segmental instrumentation (eg, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 13 or more vertebral segments (List separately in addition to code for primary procedure)
22845	Anterior instrumentation; 2 to 3 vertebral segments (List separately in addition to code for primary procedure)

CPT®* Codes	Description
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 fixation device
22850	Removal of posterior nonsegmental instrumentation (eg Harrington rod)
22852	Removal of posterior segmental instrumentation
22853	Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, 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) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, 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) (eg, 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)
64714	Neuroplasty, major peripheral nerve, arm or leg, open; lumbar plexus

***Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.**

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Revision Details

Type of Revision	Summary of Changes	Date
Annual review	• Revised policy statements for degenerative disc disease and percutaneous sacroiliac fusion.	1/15/2024

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