MEDICAL POLICY

Medical Policy Title	**Lumbar Fusion**
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POLICY STATEMENT(S)

Lumbar Fusion with Decompression

I. Lumbar fusion (arthrodesis) with decompression (indirect or direct) in **adult patients** is considered **medically necessary** for the following indications:

A. Actual Instability

1. When **ALL** the following criteria are met:

a. The individual is a candidate for lumbar decompression (refer to Corporate Medical Policy #7.01.113 Lumbar Decompression);

AND

b. Imaging shows **ANY** of the following:

i. Degenerative spondylolisthesis without spondylolysis with **EITHER** of the following:

a) Dynamic segmental instability documented by flexion-extension plain x-rays or comparison of a supine and upright image, with a difference in translational alignment between vertebrae greater than 3 mm between views; **or**

b) Meyerding Grade II or higher spondylolisthesis;

ii. Spondylolisthesis with spondylolysis (e.g., Isthmic Spondylolisthesis) with **ANY** of the following:

a) Multi-level spondylolysis on plain X-rays;

b) Meyerding Grade I or II spondylolisthesis (anterolisthesis) and plain X-rays supporting progression of anterolisthesis;

c) Meyerding Grade III or higher spondylolisthesis (anterolisthesis) with 50% or more anterior slippage or plain X-rays supporting progression of anterolisthesis; **or**

d) Progressive spinal pain without confirmatory imaging of progression of spondylolisthesis;

OR

iii. Postoperative instability created by disruption of the posterior elements due to facet joint excision that exceeds 50% bilaterally or 75% or more of a single facet during spinal decompression;

OR

iv. Pars fracture;

OR

v. Previous lumbar spinal decompression that resulted in iatrogenic spondylolisthesis; (Please note criteria exception: When instability is created or identified intra-operatively, the above imaging criteria are **NOT** required.)

AND

c. Documentation of nicotine-free status including **EITHER** of the following:

i. Individual is a never smoker; **or**

ii. Individual has refrained from smoking, use of smokeless tobacco products, or nicotine replacement therapy for at least six (6) weeks prior to planned surgery as evidenced by blood cotinine lab results of < 10ng/mL.

B. Anticipated Iatrogenic Instability

1. When **ALL** the following criteria are met:

a. The individual is a candidate for lumbar decompression (refer to Corporate Medical Policy #7.01.113 Lumbar Decompression);

AND

b. Anticipated iatrogenic instability with **ANY** of the following:

i. Created by disruption of the posterior elements due to facet joint excision that exceeds 50% bilaterally or 75% or more of a single facet during decompression;

ii. Created by removal of the pars interarticularis performed that requires fusion to stabilize;

iii. Created by decompression for Meyerding Grade I or higher spondylolisthesis with foraminal stenosis; or

iv. Created by complete or partial corpectomy (i.e., removal of at least one-third of the vertebral body [not for resection of osteophytes alone]);

AND

c. Documentation of nicotine-free status including **EITHER** of the following:

i. Individual is a never smoker; **or**

ii. Individual has refrained from smoking, use of smokeless tobacco products, or nicotine replacement therapy for at least six (6) weeks prior to planned surgery as evidenced by blood cotinine lab results of < 10ng/mL.

C. Adult Degenerative Spinal Deformity

1. When **ALL** the following criteria are met:

a. The individual is a candidate for lumbar decompression or corpectomy (refer to Corporate Medical Policy #7.01.113 Lumbar Decompression);

AND

b. Imaging findings show **EITHER** of the following:

i. Coronal plane deformity which includes **ANY** of the following:

a) Cobb angle greater than 30 degrees;

b) Asymmetric disc collapse causing symptomatic foraminal narrowing; **or**

c) Coronal imbalance causing head and trunk shift off the midline;

OR

ii. Sagittal imbalance which includes **ANY** of the following:

a) Sagittal vertebral axis measurement greater than 8 cm; **or**

b) Pelvic incidence-lumbar lordosis greater than 15 degrees;

AND

c. Documentation of nicotine-free status including **EITHER** of the following:

i. Individual is a never smoker; **or**

ii. Individual has refrained from smoking, use of smokeless tobacco products, or nicotine replacement therapy for at least six (6) weeks prior to planned surgery as evidenced by blood cotinine lab results of < 10ng/mL.

D. Initial Disc Herniation

1. When **ALL** the following criteria are met:

a. The individual is a candidate for an initial primary discectomy (refer to Corporate Medical Policy #7.01.98 Lumbar Microdiscectomy);

AND

b. Advanced imaging shows **ANY** of the following:

i. Primary extraforaminal disc herniation at L5-S1, in which far lateral approach is not feasible because of the presence of the iliac wings;

ii. Primary foraminal disc herniation for which facet restriction is necessary to retrieve the disc, which will result in iatrogenic instability; **or**

iii. Primary disc herniation in the lumbar spine that is at the level of the spinal cord (i.e., low lying conus medullaris);

AND

c. Documentation of nicotine-free status including **EITHER** of the following:

i. Individual is a never smoker; **or**

ii. Individual has refrained from smoking, use of smokeless tobacco products, or nicotine replacement therapy for at least six (6) weeks prior to planned surgery as evidenced by blood cotinine lab results of < 10ng/mL.

E. Recurrent Disc Herniation

1. When **ALL** the following criteria are met:

a. The individual is a candidate for repeat lumbar discectomy (refer to Corporate Medical Policy #7.01.98 Lumbar Microdiscectomy);

AND

b. Imaging shows evidence of anterolisthesis at the requested level(s) that results in **EITHER** of the following:

i. Dynamic segmental instability on flexion-extension plain x-rays or comparison of a supine and upright image, with a difference in translational alignment between vertebrae greater than 3 mm between views; or

ii. Meyerding Grade II or higher spondylolisthesis;

AND

c. Documentation of nicotine-free status including **EITHER** of the following:

i. Individual is a never smoker; **or**

ii. Individual has refrained from smoking, use of smokeless tobacco products, or nicotine replacement therapy for at least six (6) weeks prior to planned surgery as evidenced by blood cotinine lab results of < 10ng/mL.

F. Second or Greater Recurrent Disc Herniation

1. When **ALL** the following criteria are met:

a. The individual is a candidate for repeat lumbar discectomy (refer to Corporate Medical Policy #7.01.98 Lumbar Microdiscectomy);

AND

b. Documentation of nicotine-free status including **EITHER** of the following:

i. Individual is a never smoker; **or**

ii. Individual has refrained from smoking, use of smokeless tobacco products, or nicotine replacement therapy for at least six (6) weeks prior to planned surgery as evidenced by blood cotinine lab results of < 10ng/mL.

Lumbar Fusion without Decompression

II. Lumbar fusion (arthrodesis) without decompression in **adult patients** is considered **medically appropriate** for the following indications:

A. Degenerative Spondylolisthesis without Spondylolysis

1. When **ALL** the following criteria are met:

a. Imaging at the requested level(s) shows **EITHER** of the following:

i. Dynamic segmental instability on flexion-extension plain x-rays or comparison of a supine and upright image, with a difference in translational alignment between vertebrae greater than 3 mm between views; **or**

ii. Meyerding Grade II or higher spondylolisthesis;

AND

b. Subjective symptoms include significant level of pain on a daily basis defined as clinically significant functional impairment (e.g., inability to perform household chores, prolonged standing, etc.);

AND

c. Less than clinically meaningful improvement with **BOTH** of the following for at least three (3) consecutive months (unless contraindicated):

i. Prescription strength analgesics, steroids, gabapentinoids or NSAIDs; **and**

ii. Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician;

AND

d. Absence of untreated, underlying mental or behavioral health disorders (e.g., depression, chronic pain syndrome, secondary gain, opioid and alcohol use disorders);

AND

e. Documentation of nicotine-free status including **EITHER** of the following:

i. Individual is a never smoker; **or**

ii. Individual has refrained from smoking, use of smokeless tobacco products, or nicotine replacement therapy for at least six (6) weeks prior to planned surgery as evidenced by blood cotinine lab results of < 10ng/mL.

B. Spondylolisthesis with Spondylolysis (e.g., Isthmic Spondylolisthesis)

1. When **ALL** the following criteria are met:
    a. Imaging at the requested level(s) shows **ANY** of the following:
        i. Meyerding Grade I or II spondylolisthesis (anterolisthesis) with plain x-rays supporting progression of anterolisthesis;
        ii. Meyerding Grade III or higher spondylolisthesis (anterolisthesis) identified on plain x-rays with 50% or more anterior slippage or plain x-rays supporting progression of anterolisthesis;
        iii. Progressive spinal pain without confirmatory imaging of progression of spondylolisthesis; **or**
        iv. Multi-level spondylolysis on plain x-rays;

        AND

    b. Subjective symptoms include significant level of pain on a daily basis defined as clinically significant functional impairment (e.g., inability to perform household chores, prolonged standing, etc.);

        AND

    c. Less than clinically meaningful improvement with **BOTH** of the following for at least three (3) consecutive months (unless contraindicated):
        i. Prescription strength analgesics, steroids, gabapentinoids or NSAIDs; **and**
        ii. Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician;

        AND

    d. Absence of untreated, underlying mental or behavioral health disorders (e.g., depression, chronic pain syndrome, secondary gain, opioid and alcohol use disorders);

        AND

    e. Documentation of nicotine-free status including **EITHER** of the following:
        i. Individual is a never smoker; or
        ii. Individual has refrained from smoking, use of smokeless tobacco products, or nicotine replacement therapy for at least six (6) weeks prior to planned surgery as evidenced by blood cotinine lab results of < 10ng/mL.

C. <u>Discogenic Lower Back Pain/Degenerative Disc Disease</u>

1. When **ALL** the following criteria are met:
    a. Plain x-rays and advanced diagnostic imaging studies (i.e., CT, MRI) at the requested level(s) show moderate to severe single-level disc degeneration;

AND

b. Presence of chronic, unremitting, discogenic axial lower back pain and associated disability secondary to single-level degenerative lumbar disc disease (DDD) for at least one (1) year;

AND

c. Subjective symptoms include significant level of pain on a daily basis defined as clinically significant functional impairment (e.g., inability to perform household chores, prolonged standing, etc);

AND

d. Structured physician-supervised, multi-modal, non-operative management of medical care with licensed healthcare professionals which includes **ALL** the following:

   i. Regularly scheduled appointments;

   ii. Follow-up evaluation; and

   iii. Less than clinically meaningful improvement with the following (unless contraindicated):

      a) Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for at least twelve (12) months; **and**

      b) Prescription strength analgesics, steroids, gabapentinoids or NSAIDs for at least twelve (12) consecutive months; **or**

      c) Epidural steroid injection(s)/or selective nerve root block(s); **or**

      d) Facet joint injection(s)/medial branch block(s)/radiofrequency ablation(s);

   AND

e. Absence of untreated, underlying mental or behavioral health disorders (e.g., depression, chronic pain syndrome, secondary gain, opioid and alcohol use disorders);

AND

f. Documentation of nicotine-free status including **EITHER** of the following:

   i. Individual is a never smoker; **or**

   ii. Individual has refrained from smoking, use of smokeless tobacco products, or nicotine replacement therapy for at least six (6) weeks prior to planned surgery as evidenced by blood cotinine lab results of < 10ng/mL.

D. <u>Adult Degenerative Spinal Deformity</u>

1. When **ALL** the following criteria are met:
    a. Imaging findings show **EITHER** of the following:
        i. Coronal plane deformity which includes **ANY** of the following:
            a) Cobb angle greater than 30 degrees;
            b) Asymmetric disc collapse causing symptomatic foraminal narrowing;
            c) Coronal imbalance causing head and trunk shift off the midline; **or**
        ii. Sagittal imbalance which includes **ANY** of the following:
            a) Sagittal vertebral axis measurement greater than 8 cm; **or**
            b) Pelvic incidence-lumbar lordosis greater than 15 degrees

        AND
    b. Less than clinically meaningful improvement with **BOTH** of the following for at least three (3) consecutive months (unless contraindicated):
        i. Prescription strength analgesics, steroids, gabapentinoids or NSAIDs; **and**
        ii. Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician;

        AND
    c. Absence of untreated, underlying mental or behavioral health disorders (e.g., depression, chronic pain syndrome, secondary gain, opioid and alcohol use disorders);

        AND
    d. Documentation of nicotine-free status including **EITHER** of the following:
        i. Individual is a never smoker; **or**
        ii. Individual has refrained from smoking, use of smokeless tobacco products, or nicotine replacement therapy for at least six (6) weeks prior to planned surgery as evidenced by blood cotinine lab results of < 10ng/mL.

<u>Repeat Lumbar Fusion at the Same Level</u>

III. Repeat lumbar fusion (arthrodesis) (with or without decompression) at the same level in **adult patients** is considered **medically necessary** for **EITHER** of the following indications:
    A. <u>Malposition or Failure of Implant/Instrumentation or Structural Bone Graft</u>
        1. When the following criteria is met:
            a. Post-operative imaging shows evidence of malposition or failure of the implant/instrumentation or structural bone graft (e.g., migration, pedicle screw

breakage, pedicle screw loosening, dislodged hooks, rod breakage, rod bending, rod loosening, loss of curve correction, decompensation, etc.);

OR

B. Symptomatic Pseudoarthrosis

1. When **ALL** the following criteria are met:

a. Greater than six (6) months since the prior lumbar fusion ~~surgery~~;

AND

b. Subjective symptoms include significant level of pain on a daily basis defined as clinically significant functional impairment (e.g., inability to perform household chores, prolonged standing, etc.)

AND

c. Post-operative physical exam findings are concordant with the individual's symptoms;

AND

d. Less than clinically meaningful improvement with six (6) weeks of non-surgical treatment with **BOTH** of the following (unless contraindicated):

i. Prescription strength analgesics, steroids, gabapentinoids or NSAIDs; and

ii. Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician;

AND

e. Post-operative imaging (performed at no less than six (6) months after the lumbar fusion) shows pseudoarthrosis at the requested level(s);

AND

f. Post-operative MRI/CT findings are concordant with the individual's symptoms;

AND

g. Absence of unmanaged significant mental or behavioral health (e.g., major depressive disorder, chronic pain syndrome, secondary gain, opioid or alcohol use disorders);

AND

h. Documentation of nicotine-free status including **EITHER** of the following:

i. Individual is a never smoker; **or**

ii. Individual has refrained from smoking, use of smokeless tobacco products, or nicotine replacement therapy for at least six (6) weeks prior to planned surgery as evidenced by blood cotinine lab results of < 10ng/mL.

Adjacent Segment Disease

IV. Lumbar fusion (arthrodesis) for adjacent segment disease in **adult patients** is considered **medically necessary** when **ALL** the following criteria are met:

A. The individual meets criteria for lumbar fusion (see Policy Statement I or II);

AND

B. The prior adjacent-level lumbar fusion was performed at least six (6) months prior.

Lumbar Fusion Following Failed Disc Arthroplasty Surgery

V. Lumbar fusion (with or without decompression) following failed lumbar disc arthroplasty surgery in **adult patients** considered **medically necessary** when performed for **EITHER** of the following indications:

A. Failed Lumbar Disc Arthroplasty Implant

1. When the following criteria is met:

a. Post-operative imaging shows evidence of lumbar disc arthroplasty implant malposition or failure (e.g., subsidence, loosening, infection, dislocation/subluxation, vertebral body fracture, dislodgement).

OR

B. Evidence of Neural Structure Compression

1. When **ALL** the following criteria are met:

a. Greater than six (6) months since the prior lumbar disc arthroplasty surgery;

AND

b. The individual meets criteria for lumbar fusion (arthrodesis) with decompression or lumbar fusion (arthrodesis) without decompression (see Policy Statement I or II);

AND

c. Post-operative MRI/CT shows evidence of neural structure compression (e.g., either retained disc material or a recurrent disc herniation).

Pediatric Spinal Deformity

VI. Lumbar Fusion (arthrodesis) in pediatric patients is considered **medically necessary** when the following criteria is met:

A. Imaging studies (advanced imaging or plain X-rays) show the presence of **ANY** of the following pediatric spinal deformities that warrant definitive surgical treatment:

1. Adolescent idiopathic scoliosis with over 50° curve
2. Congenital scoliosis
3. Neuromuscular scoliosis

4. Infantile/juvenile scoliosis

VII. Lumbar Osteomy is considered **medically necessary** (in addition to lumbar fusion) for pediatric patients when **ALL** the criteria in policy statement VIII (Posterior Column Osteotomy [PCO]) and policy statement IX (Three-Column Osteotomy) are met.

Posterior Column Osteotomy (PCO)

VIII. Lumbar posterior column osteotomy (i.e., Smith-Peterson osteotomy [SPO] or ponte osteotomy) is considered **medically necessary** (in addition to a lumbar fusion) when **ALL** the following criteria are met:

A. Correction of non-fixed deformity requiring 5 degree to 10 degree of correction (SPO) per spinal segment for **EITHER** of the following:

1. Lumbar saggital plane deformities where sagittal vertical axis (SVA) is greater than 8cm or pelvic incidence-lumbar lordosis (PI-LL) is less than 15 degrees; **or**
2. Larger coronal deformities where there is limited flexibility, and the Cobb angle is greater than 30 degrees;

AND

B. Posterior column osteotomy is limited to a maximum of four (4) posterior column osteotomies performed in the apex of the deformity per correction surgery (criteria exception: There is no limit to posterior column osteotomies for the correction of Scheuermann's Kyphosis as this deformity is long, gradual, rounded, and amendable to more than four (4) posterior column osteotomies);

AND

C. **ALL** the criteria for lumbar fusion have been met per applicable procedure policy criteria listed above to include:

1. Pediatric spinal deformity
2. Lumbar fusion with decompression;
3. Adjacent segment disease;
4. Lumbar fusion without decompression;
5. Lumbar fusion following failed disc arthroplasty surgery;
6. Repeat lumbar fusion at the same level.

Three-Column Osteotomy

IX. Lumbar three-column osteotomy (i.e., pedicle subtraction osteotomy (PSO) or vertebral column resection (VCR) is considered **medically necessary** (in addition to a fusion) when **ALL** the following criteria are met:

A. Performed for **EITHER** of the following indications:

1. Correction of fixed saggital plane deformity requiring more than 30 degrees of correction (PSO); **or**
2. Large, fixed coronal deformities greater than 60 degrees that are amenable to asymmetric osteotomy;

AND

B. **ALL** the criteria for lumbar fusion have been met per applicable procedure policy criteria listed above to include:

1. Pediatric spinal deformity
2. Lumbar fusion with decompression;
3. Adjacent segment disease;
4. Lumbar fusion without decompression;
5. Lumbar fusion following failed disc arthroplasty surgery;
6. Repeat lumbar fusion at the same level.

X. Lumbar spinal fusion is considered **not medically necessary** for **ANY** of the following sole indications:

A. Disc herniation in the absence of **ANY** of the following:

1. Primary extraforaminal disc herniation at L5-S1, in which a far lateral approach is not feasible because of the presence of the iliac wings;
2. Primary foraminal disc herniation for which facet resection is necessary to retrieve the disc, which will result in iatrogenic instability; **or**
3. Primary disc herniation in the lumbar spine that is at the level of the spinal cord (i.e., low-lying conus medullaris);

B. Multi-level degenerative disc disease without instability;

C. Neuro-compressive pathology;

D. Facet joint disorders without instability;

E. Initial discectomy/laminectomy without instability;

F. Spondylolysis without spondylolisthesis;

G. As an adjunct to primary decompression of central or lateral recess stenosis, in the absence of instability, spondylolisthesis, or an actual or anticipated bony resection that will result in iatrogenic instability.

XI. The following devices/procedures are considered **investigational** under circumstances that include, but are not limited to, the following:

A. The device/implant has not been approved by the U.S. Food and Drug Administration (FDA);

B. Dynamic (intervertebral) stabilization device (e.g., Dynesys, Stabilimax NZ);

C. Personalized (implantable) anterior or lateral body interbody cage (e.g., Apprevo personalized 3-D printed spinal cage);

D. Interspinous and interlaminar distraction devices;

E. Isolated facet fusion, with or without instrumentation, including allograft bone graft substitutes used exclusively as stand-alone stabilization devices (e.g., Trufuse [any level], Nufix [any level]);

F. Total facet arthroplasty.

G. Pre-sacral interbody fusion, including axial lumbar interbody fusion (AxiaLIF);

H. Minimally invasive lumbar spinal fusions using direct visualization via endoscopy (endoscopic fusion) or indirect visualization (e.g., percutaneous fusion);

I. Anterior interbody fusion or implantation of intervertebral body fusion devices using laparoscopic approach, or laparoscopic anterior lumbar interbody fusion (LALIF);

J. Interlaminar lumbar instrumented fusion (e.g., ILIF);

K. Interspinous fixation/posterior non-pedicle supplemental fixation devices for spinal fusion (e.g., Affix, Aspen Spinous Process Fixation System); or

L. Least invasive lumbar decompression interbody fusion (e.g., LINDIF).

RELATED POLICIES

Corporate Medical Policy

7.01.113 Lumbar Decompression

7.01.98 Lumbar Microdiscectomy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Minimum documentation requirements needed to complete a spinal surgery prior authorization request include **ALL** the following:

A. CPT codes, ICD-10 codes, and disc levels or motion segments involved for planned surgery must be provided;

B. Detailed documentation of the type, duration and frequency of provider-directed non-surgical treatment (e.g., interventional pain management, medication management, chiropractic care, physical therapy or provider-directed active exercise program, etc.) that includes response to each treatment:

1. Detailed documentation explaining why a sufficient trial of non-surgical treatment was contraindicated (if applicable);

2. Detailed documentation of less than clinically meaningful improvement for each treatment;

C. Written reports/interpretations of the most recent advanced diagnostic imaging reports (e.g., computed tomography [CT] scan, magnetic resonance imaging [MRI], or Myelography) performed, read, and interpreted by an independent radiologist. Clinically significant discrepancies in interpretation between the surgeon and the radiologist need to be reconciled prior to the documentation submission;

D. The documentation for spinal fusion surgery requests must include flexion-extension plain x-rays based upon indications for instability or other plain x-rays that document failure of instrumentation, fusion, etc.;

E. Documentation of nicotine-free status including **EITHER** of the following (unless this is an urgent/emergent request for fusion/ disc arthroplasty or when myelopathy is present):

1. Individual is a never smoker; **or**

2. Individual has refrained from smoking, use of smokeless tobacco products, and/or nicotine replacement therapy for at least six (6) weeks prior to planned surgery as evidenced by blood cotinine lab results of < 10ng/mL.

II. Urgent/Emergent Conditions: All individuals being evaluated for spine surgery should be screened for indications of a medical condition that requires urgent/emergent treatment. The presence of urgent/emergent indications/condition warrants definitive surgical treatment. Imaging findings noted in the applicable procedure policy statement are required. Provider-directed, non-surgical management, proof of smoking cessation, absence of unmanaged significant mental or behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary gain, opioid and alcohol use disorders) and time frame for repeat procedure are **NOT** required.

Urgent/emergent conditions for lumbar fusion include **ANY** of the following:

A. Traumatic spinal fractures or dislocations (with or without neural compression) when instability is present, or decompression of the spinal canal is anticipated to result in iatrogenic instability;

B. Infection (e.g., discitis, epidural abscess, osteomyelitis) when instability is present, or debridement and/or decompression is anticipated to result in iatrogenic instability;

C. Primary or metastatic neoplastic disease-causing pathologic fracture, cord compression when instability is present or resection and/or decompression is anticipated to result in iatrogenic instability;

D. A condition otherwise meeting criteria listed in the applicable procedure section of the policy statements with documentation of severe debilitating pain or dysfunction to the point of being incapacitated.

III. Congenital, Neuromuscular, or Infantile/Juvenile/Adolescent Idiopathic Scoliosis: The presence of adolescent idiopathic scoliosis with over 50-degree curves or congenital, neuromuscular, or

infantile/juvenile scoliosis warrants definitive surgical treatment. Confirmatory imaging studies (advanced or plain x-rays) are required. The following criteria are **NOT** required for the above confirmed conditions:

A. Provider-directed non-surgical management;

B. Proof of smoking cessation;

C. Absence of unmanaged significant mental or behavioral health disorders.

DESCRIPTION

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. Conservative management typically consists of rest, exercise, analgesics, local injections, lumbar bracing, physical therapy, and chiropractic care. 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.

Spinal fusion/arthrodesis, also known as spondylodesis or spondylosyndesis, is a well-established surgical technique for infectious conditions of the spine (e.g., spinal tuberculosis). It has also been considered the standard treatment for progressive spinal deformities (e.g., scoliosis) and traumatic injuries. Additionally, lumbar fusion is performed for clearly defined spinal instability. Fusing of the spine is used primarily to eliminate the pain caused by abnormal motion of the vertebrae by immobilizing the faulty vertebrae themselves. Supplementary bone tissue, either from the patient (autograft) or a donor (allograft), is used in conjunction with the body's natural bone growth (osteoblastic) processes, to fuse the vertebrae. There are two main types of lumbar spinal fusion, which may be used in conjunction with each other. Posterolateral fusion places the bone graft between the transverse processes in the back of the spine. These vertebrae are then fixed in place with screws and/or wire through the pedicles of each vertebra, attaching to a metal rod on each side of the vertebrae. Interbody fusion places the bone graft between the vertebrae in the area usually occupied by the intervertebral disc. The fusion then occurs between the endplates of the vertebrae. Using both types of fusion is known as 360-degree fusion. There are three types of interbody fusion: anterior lumbar interbody fusion (ALIF); posterior lumbar interbody fusion (PLIF); and transforaminal lumbar interbody fusion (TLIF). Interbody cages, instrumentation such as plates, pedicle screws, or rods, and osteo-inductive agents such as recombinant human bone morphogenetic protein (rhBMP) may be used to stabilize the spine during the months following surgery, to improve fusion success rates. External factors such as smoking, osteoporosis, certain medications, and heavy activity can prolong or even prevent the fusion process.

The Meyerding Classification Grade of Spondylolisthesis is determined by measuring the degree of slip using standing, neutral lateral radiographs of the lumbar spine. The classification system divides slip into five grades: 0% to 25% is Grade I, 25% to 50% is Grade II, 50% to 75% is Grade III, 75% to 100% is Grade IV, and greater than 100% is Grade V.

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

Scoliosis

Scoliosis, lateral curvature of the spine with associated rotation of the spinal column, is a structural alteration that occurs in a variety of conditions. Progression of the curvature during periods of rapid growth can result in significant deformity, which may be accompanied by cardiopulmonary compromise. Adolescent idiopathic scoliosis (AIS) is the most common type of scoliosis. Other types include congenital scoliosis, neuromuscular scoliosis, and syndromic scoliosis.

Spinal Osteotomy

Spinal osteotomy is an umbrella term for surgical techniques used by spinal surgeons to correct spinal deformity. Spinal osteotomies can be performed on pediatric or adult patients. The purpose of a spinal osteotomy is to establish normal range spinal curvature, relieve pain, and improve quality of life. These can be broken down into posterior column osteotomy (PCO), including Ponte osteotomy and Smith-Petersen osteotomy (SPO), pedicle subtraction osteotomy (PSO), or vertebral column resection (VCR).

Minimally Invasive / Minimal Access Techniques for Lumbar Interbody Fusion

Interbody fusion of the lumbar spine can be approached from an anterior, posterior, or lateral direction. These procedures are traditionally performed with an open approach (long incision with wide retraction of the musculature). One of the drawbacks of conventional lumbar fusion is the extensive soft tissue dissection that is necessary, to expose the anatomic landmarks for screw insertion, to achieve a proper lateral-to-medial screw trajectory, and to develop an acceptable fusion bed. The tissue injury that occurs during the surgical approach can result in increased post-operative pain, lengthened recovery time, and impaired spinal function. Blood loss during open lumbar fusion surgery can also be quite significant. These conventional approaches can now be performed through minimally invasive/minimal access procedures. A variety of minimally invasive/minimal access procedures are being investigated, with the intent of limiting iatrogenic damage to muscular, ligamentous, neural, and vascular structures. Among the techniques investigated are laparoscopic anterior lumbar interbody fusion (LALIF), posterior lumbar interbody fusion (PLIF), transforaminal lumbar interbody fusion (TLIF), lateral interbody fusion (e.g., Extreme Lateral Interbody Fusion [XLIF] or Direct Lateral Interbody Fusion [DLIF]), and para-axial interbody fusion (AxiaLIF).

The following minimally invasive/minimal access techniques for lumbar interbody fusion (LIF) are appropriate treatment alternatives to standard open lumbar fusion: Anterior lumbar interbody fusion (ALIF), Direct lateral interbody fusion (DLIF), Extreme lateral interbody fusion (XLIF), Posterior lumbar interbody fusion (PLIF), and Transforaminal lumbar interbody fusion (TLIF).

Anterior access provides direct visualization of the disc space through an abdominal incision, potentially allowing a more complete discectomy and better fusion than lateral or posterior approaches. An anterior approach avoids trauma to the paraspinal musculature, epidural scarring, traction on nerve roots, and ductal tears. However, the retraction of the great vessels, peritoneal contents, and superior hypogastric sympathetic plexus with a peritoneal or retroperitoneal approach place these structures at risk of iatrogenic injury. Access to the posterior space for the treatment of nerve compression is also limited. Laparoscopic Anterior Lumbar Interbody Fusion (LALIF) is a minimally invasive technique that has been proposed as an alternative to the open surgical approach to spinal fusion. This method employs a laparoscope to remove the diseased disc and insert an implant into the disc space, which is intended to stabilize and promote fusion. This technique is evolving as a method of minimizing soft-tissue injury and is associated with a learning curve.

Posterior LIF can be performed through either a traditional open procedure with a midline incision or with a minimally invasive approach using bilateral paramedian incisions. In the open procedure, the midline muscle attachments are divided along the central incision, to facilitate wide muscle retraction and laminectomy. Minimally invasive/minimal access PLIF uses tubular retractors (e.g., METRx, Luxor), to allow access and open visualization of the surgical area. These tubular retractors may be used to open smaller, central, bilateral working channels to access the pedicles and foramen. Minimally invasive PLIF typically involves partial laminotomies and facetectomies. The decompression allows treatment of spinal canal pathology (e.g., spinal stenosis, lateral recess and foraminal stenosis, synovial cysts, and hypertrophic ligamentum flavum), as well as stabilization of the spine through interbody fusion.

Transforaminal LIF, performed through an open technique, is also performed through a posterior approach. Access to the spine is through the foramen, which is enlarged by removal of surrounding bone. In minimally invasive TLIF, a single incision about 2 to 3 cm in length is made approximately 3 cm lateral to the midline. A tubular retractor is docked on the facet joint complex, and a facetectomy with partial laminectomy is performed. Less dural retraction is needed, with access through the foramen via unilateral facetectomy, and contralateral scar formation is eliminated. TLIF provides access to the posterior elements, along with the intervertebral disc space.

Axial lumbar interbody fusion (AxiaLIF), also called anterior para-axial, trans-sacral or paracoccygeal interbody fusion, is a minimally invasive technique designed to provide anterior access to the L4-S1 disc spaces for interbody fusion. It is performed percutaneously, under fluoroscopic guidance via the pre-sacral space. 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.

Lateral interbody fusion (e.g., Extreme Lateral Interbody Fusion [XLIF] or Direct Lateral Interbody Fusion [DLIF]) uses specialized retractors in a minimally invasive, lateral approach to the anterior spine through the psoas. In comparison with ALIF, the lateral approach does not risk injury to the peritoneum or great vessels. However, exposure to the spine may be more limited, and dissection of the psoas major places the nerves of the lumbar plexus at risk. Electromyographic monitoring and dissection, predominantly within the anterior psoas major, may be utilized to reduce the risk of nerve root injury. These various factors decrease the ability to perform a complete discectomy and address

pathology of the posterior elements. The XLIF surgical technique incorporates two systems developed by NuVasive: the MaXcess System and the NeuroVision JJB System.

Both open and minimally invasive/minimal access interbody fusion surgeries may also include decompression of the spinal canal, use of interbody cages, bone grafts, osteoinductive agents (e.g., recombinant human bone morphogenetic protein), and insertion of pedicle screws and rods to increase stability of the spine.

Interlaminar lumbar instrumented fusion (ILIF) combines direct neural decompression with an allograft interspinous spacer to maintain the segmental distraction, and a spinous process fixation plate, or other fixation options such as cortical pedicle screws to maintain stability for eventual segmental fusion (e.g., Coflex-F).

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

SUPPORTIVE LITERATURE

Lumbar spinal fusion is a surgical procedure and does not require approval by the U.S. Food and Drug Administration (FDA). A variety of instrumentation used in lumbar spinal fusion is cleared for marketing by the FDA.

Smoking

Tobacco use is considered a risk factor for poor healing and is associated with non-union. It is well-established that smoking is a preventable cause of morbidity and mortality. 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 2011 policy statement published by the International Society of Advancement for Spine Surgery (ISASS) indicated 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. The North American Spine Society (NASS) lists the absence of smoking for at least three months prior to the surgery date in its coverage policy recommendations for lumbar fusion to relieve discogenic low back pain. Anderson et al. (2010) reported that smoking negatively affects fusion mass and results in lower bone mineral density, particularly in the spine. Deyo et al. (2010) 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 there was a substantially greater risk among those with chronic lung disease compared to those without. Particularly with spinal fusion, tobacco use has been associated with increased risk of pseudarthrosis. 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).

Cotinine, the primary metabolite of nicotine, is currently regarded as the best biomarker of tobacco smoke exposure. Measuring cotinine is preferable to measuring nicotine because cotinine persists longer in the body, with a plasma half-life of about 16 hours. Non-smokers exposed to typical levels of second-hand smoke have serum cotinine levels lower than one ng/ml, with heavy exposure to second-hand smoke producing levels in the 1-10 ng/ml range. Active smokers almost always have levels higher than 10 ng/ml and sometimes higher than 500 ng/ml. Therefore, non-smoking is defined as a serum cotinine level of less than or equal to 10 ng/ml (National Biomonitoring Program, Centers for Disease Control and Prevention, Dec 2013).

Khalid et al (2022) examined the outcomes of single-level lumbar fusion surgery in active smokers and in smokers undergoing recent cessation therapy. MARINER30, an all-payer claims database, was used to identify patients undergoing single-level lumbar fusions between 2010 and 2019. The primary outcomes were the rates of any complication, symptomatic pseudarthrosis, need for revision surgery, and all-cause re-admission within 30 and 90 days. The exact matched population analyzed in this study contained 31,935 patients undergoing single-level lumbar fusion with 10,645 (33 %) in each of the following groups: (i) active smokers; (ii) patients on smoking cessation therapy; and (iii) those without any smoking history. Patients undergoing smoking cessation therapy have reduced odds of developing any complication following surgery (OR 0.86, 95 % CI: 0.80 to 0.93) when compared with actively smoking patients. Non-smokers and patients on cessation therapy had a significantly lower rate of any complication compared with the smoking group (9.5 % versus 17 % versus 19 %, respectively). The authors concluded that when compared with active smoking, pre-operative smoking cessation therapy within 90 days of surgery decreased the likelihood of all-cause post-operative complications. However, there were no between-group differences in the likelihood of pseudarthrosis, revision surgery, or re-admission within 90 days.

In a retrospective, database study, Connor et al (2022) used the Nationwide Readmissions Database (NRD) to determine if tobacco use is associated with increased 30- and 90-day re-admission among patients undergoing surgery for degenerative spine disorders. Patients who underwent elective spine surgery were identified in the NRD from 2010 to 2014. The study population included patients with degenerative spine disorders treated with discectomy, fusion, or decompression. Descriptive and multi-variate logistic regression analyses were carried out to identify patient and hospital factors associated with 30- and 90-day re-admission, with significance set at p value of < 0.001. Within 30 days, 4.8 % of patients were re-admitted at a median time of 9 days. The most common reasons for 30-day re-admission were post-operative infection (12.5 %), septicemia (3.5 %), and post-operative pain (3.0 %). Within 90 days, 7.3 % were re-admitted at a median time of 18 days. The most common reasons for 90-day re-admission were post-operative infection (9.6 %), septicemia (3.5 %), and pneumonia (2.3 %). After adjustment for patient and hospital characteristics, tobacco use was independently associated with re-admission at 90 days (OR 1.05, 95 % CI: 1.03 to 1.07, $p < 0.0001$; but not 30 days (OR 1.02, 95 % CI: 1.00 to 1.05, $p = 0.045$). The authors concluded that tobacco use was associated with re-admission within 90 days after cervical and thoracolumbar spine surgery for degenerative disease. Tobacco use is a known risk factor for adverse health events and therefore should be considered when selecting patients for spine surgery.

<u>Disc Herniation/Degenerative Disc Disease (DDD)</u>

Current evidence, which includes a large, multi-center, randomized, controlled trial (RCT) by Weinstein and colleagues known as Spine Patient Outcomes Research Trial (SPORT), supports that surgical treatment with discectomy improves outcomes for lumbar disc herniation with radiculopathy. However, there is no evidence to support that the addition of spinal fusion to discectomy improves outcomes in patients with the sole indication of lumbar disc herniation without instability (e.g., Takeshima et al., 2000, Otani et al., 2014).

W.C. Jacobs and colleagues (2011) conducted a systematic review to assess the effects of surgery versus conservative therapy (including epidural injections) for patients with sciatica due to lumbar disc herniation. RCTs of adults with lumbar radicular pain that evaluated at least one clinically relevant outcome measure (pain, functional status, perceived recovery, lost days of work) were included. In total, five studies were identified, two of which had a low risk of bias. One study compared early surgery with prolonged conservative care followed by surgery, if needed; three studies compared surgery with usual conservative care; and one study compared surgery with epidural injections. Data were not pooled because of clinical heterogeneity and poor reporting of data. One large low-risk-of-bias trial demonstrated that early surgery in patients with six to 12 weeks of radicular pain leads to faster pain relief when compared with prolonged conservative treatment, but there were no differences after one and two years. Another large, low-risk-of-bias trial comparing surgery and usual conservative care found no statistically significant differences on any of the primary outcome measures after one and two years. Future studies should evaluate which patients benefit more from surgery and which from conservative care.

Evidence supporting lumbar fusion as a method of treatment for DDD is limited, and few well-designed clinical studies have supported arthrodesis as superior to non-operative therapy for improving clinical outcomes (e.g., Resnick et al., 2005). When comparing intense rehabilitation and cognitive therapy to lumbar fusion, the reported clinical outcomes demonstrate that lumbar fusion is no more effective than intense rehabilitation combined with cognitive therapy (e.g., Brox et al., 2010; Mirza et al., 2007; Brox et al., 2006; Fairbank et al., 2005). The North American Spine Society (NASS) states that lumbar fusion is not indicated for disc herniation as an adjunct to primary excision of a central or posterolateral disc herniation at any level, in the absence of instability or spondylolisthesis.

Chronic Low Back Pain (CLBP)

A systematic review from 2013 by Saltychev et al. compared lumbar fusion versus conservative treatment in patients with CLBP. The meta-analysis of four trials with a total of 666 patients reported a reduction in the ODI that was -2.91 in favor of lumbar fusion. However, this did not attain statistical significance or the minimal clinically significant difference in ODI of 10 points. The review concluded that there is strong evidence that lumbar fusion does not lead to a clinically significant reduction in perceived disability compared with conservative treatment in patients with CLBP and degenerative spinal disease. The review also concluded that it is unlikely that further research on the subject would alter this conclusion.

Spinal Stenosis with Spondylolisthesis

The SPORT RCT, reported by Weinstein and Colleagues, compared surgical and nonsurgical treatment for lumbar degenerative spondylolisthesis in two articles dated 2007 and 2009. All patients had neurogenic claudication or radicular leg pain associated with neurologic signs, spinal stenosis shown on cross-sectional imaging, and degenerative spondylolisthesis shown on lateral radiographs, with symptoms persisting for at least 12 weeks. There were 304 patients in a randomized cohort and 303 patients in an observational cohort. About 40% of the randomized cohort crossed over in each direction by two years of follow-up. At the four-year follow-up timepoint, 54% of patients randomized to non-operative care had undergone surgery. Five percent of the surgically-treated patients received decompression only, and 95% underwent decompression with fusion. Analysis was by the treatment that was received, due to the high percentage of crossovers. This analysis, controlled for baseline factors, showed a significant advantage for surgery at up to four years of follow-up for all primary and secondary outcome measures.

Adolescent Idiopathic Scoliosis (AIS)

Treatment of scoliosis currently depends on three factors: the cause of the condition (idiopathic, congenital, secondary), the severity of the condition (degrees of curve), and the remaining growth expected for the patient at the time of presentation. Children who have vertebral curves measuring between 25° and 40° with at least two years of growth remaining are considered to be at high risk of curve progression. Because severe deformity may lead to compromised respiratory function and is associated with back pain in adulthood, in the U.S., surgical intervention with spinal fusion is typically recommended for curves that progress to 45° or more. (Richards et al., 2005).

Kolenko et al (2020) states that children who have curves approaching 50° should be referred to an orthopedic surgeon for consultation. The goals of surgical treatment include preventing curve progression while obtaining spinal correction, realignment, and multilevel fusion. Corrective surgeries most frequently follow a posterior approach, but anterior and a combination of anterior and posterior surgery are dependent on surgeon preference and curve type. Current techniques aim to either fuse the spine or modulate growth. Both posterior and anterior spinal fusions use a combination of implants to provide surgical correction and result in 15% to 48% Cobb angle improvement on the coronal plane

In a systematic review and meta-analysis, Faldini et al (2024) examined if Ponte osteotomies (POs) allow for a better correction in AIS surgery and examined their safety profile. Meta-analyses were carried out to estimate the differences between patients treated with and without POs; $p < 0.05$ was considered significant. A total of 9 studies were included. No significant difference in thoracic kyphosis (TK) change between patients treated with and without POs was found (+3.8°; $p = 0.06$). Considering only hypo-kyphotic patients, a significant difference in TK change resulted in POs patients (+6.6°; $p < 0.01$), while a non-significant TK change resulted in normo-kyphotic patients (+0.2°; $p = 0.96$). No significant difference in coronal correction (2.5°; $p = 0.10$) was recorded. Significant estimated blood loss (EBL) (142.5 ml; $p = 0.04$) and surgical time (21.5 mins; $p = 0.04$) differences were found with POs. Regarding complications rate, the meta-analysis showed a non-significant log OR of 1.1 ($p = 0.08$) with POs. The authors concluded that POs allowed for the restoration of TK in hypokyphotic AIS, without a significantly greater TK change in normo-kyphotic patients, nor a significantly better coronal correction. Moreover, these researchers stated that

considering the significantly greater EBL and the trend toward a higher complications rate, the correct indication for POs is crucial. They noted that particularly in hypokyphotic patients, the benefits of TK restoration may overcome the risks. Conversely, the routine use of POs in non-severe, non-stiff, and normo-kyphotic curves should be discouraged. The researchers stated that further comparative studies, with better stratified patients according to pre-operative TK and more precise measurement methods, will further shed a light on this topic.

In a retrospective review, Kelly et al (2010) examined the long-term clinical and radiographic outcomes of anterior spinal fusion with instrumentation for thoracolumbar and lumbar curves in AIS. The study aimed to evaluate a group of patients based on Scoliosis Research Society (SRS)-30 and Oswestry data as well as radiographic and magnetic resonance imaging (MRI) and report the results of long-term follow-up of this surgical treatment for this curve pattern in AIS. During 1984 to 1995, 31 patients with the diagnosis of AIS underwent anterior spinal instrumentation and fusion for thoracolumbar or lumbar scoliosis at our institution. A retrospective review of this patient group was performed to evaluate patient satisfaction, functional outcome, curve progression, implant failure, and disc degeneration. Radiographs and lumbar MRIs were obtained along with SRS-30 Questionnaire and Oswestry Disability Index data. Eighteen patients were available for review. Average follow-up for this study was 16.97 years. Based on SRS-30 and the Oswestry Disability Index data, most patients had good function scores and acceptable pain levels. Radiographs demonstrated no progression of the thoracolumbar or thoracic curves. Implant failure was identified in 2 patients. Radiographic changes of early degenerative disc disease were identified in most patients but had no correlation with SRS or Oswestry data. These degenerative changes were evident on both radiographs and MRI. Authors concluded, the anterior approach in the treatment of thoracolumbar and lumbar curves in AIS offers good long-term functional outcomes for patients. Despite expected degenerative changes, patients scored well on the SRS and Oswestry tests and were able to pursue careers and family activities.

Adult Symptomatic Lumbar Scoliosis

A cohort study in 2009 by Bridwell et al. reported a prospective, multi-center study that compared operative versus non-operative treatment of adult symptomatic lumbar scoliosis (defined as a minimum Cobb angle of 30°) in 160 consecutively enrolled patients. Operative versus non-operative treatment was decided by the patient and medical team. Non-operative treatment included observation (21%), medications (26%), medications plus physical therapy and/or injections (40%), and other treatment without medications (13%). For analysis, the patients were matched using propensity scores that included baseline Cobb angle, Oswestry Disability Index (ODI), Scoliosis Research Society subscore, and a numerical rating scale for back and leg pain. The percentage of patients who returned for follow-up at two years was higher for operative than non-operative patients (95% vs 45%), though the baseline measures for patients who were lost to follow-up was similar to those who were followed for two years. At the two-year follow-up, non-operative treatment had not improved quality of life or any other outcome measures, while the operative group showed significant improvement in all outcomes.

Cummings and colleagues (2024) performed a systematic review/meta-analysis of seven original articles discussing fractional curve correction of lumbosacral spinal deformity (LsFC) in adults who

underwent anterior lumbar interbody fusion (ALIF) or transforaminal lumbar interbody fusion (TLIF) correction techniques with a comparison of radiographic results. Limited level III and IV evidence suggested ALIF as advantageous for reducing the coronal Cobb angle of the LsFC in de novo adult (thoraco) lumbar scoliosis. Relative efficacy of ALIF and TLIF in the LsFC for restoration of global coronal alignment may be dictated by several factors, including directionality and magnitude of preoperative coronal deformity. Given the limited and low-quality evidence, additional research is warranted to determine the ideal interbody support strategies to address the LsFC in adult (thoraco) lumbar scoliosis.

Isthmic Spondylolisthesis

An RCT compared fusion versus an exercise program for patients with symptomatic isthmic spondylolisthesis. Results of this trial support that the use of fusion for this condition improves functional status, compared with conservative treatment. Moller and Hedlund reported a study of 111 patients with adult isthmic spondylolisthesis who were randomly assigned to posterolateral fusion (with or without instrumentation, n=77) or to an exercise program (n=34). Inclusion criteria for the study were lumbar isthmic spondylolisthesis of any grade, at least one year of low back pain or sciatica, and a severely restricted functional ability. The mean age of patients was 39 years, with a mean age at onset of symptoms of 26 years. At one- and two-year follow-up, functional outcome (assessed by the Disability Rating Index) had improved in the surgery group, but not in the exercise group. Pain scores improved in both groups but were significantly better in the surgically treated group compared with the exercise group.

Adult Degenerative Spinal Deformity

Degenerative spinal deformity results from cumulative degenerative changes focused in the intervertebral discs and facet joints that occur asymmetrically to produce deformity. Adult spinal deformity (ASD) is characterized by malalignment in the sagittal and/or coronal plane and, in adults, presents with pain and disability. Nonoperative management is recommended for patients with mild, nonprogressive symptoms; however, evidence of its efficacy is limited. Surgery aims to restore global spinal alignment, decompress neural elements, and achieve fusion with minimal complications. The surgical approach should balance the desired correction with the increased risk of more aggressive maneuvers. In well-selected patients, surgery yields excellent outcomes.

Dynamic Stabilization Systems/Devices

There is insufficient research to show that spinal dynamic stabilization devices improve health outcomes for people with disorders of the spine at any level. No clinical guidelines based on research recommend spinal dynamic stabilization devices.

Personalized Anterior or Lateral Body Interbody Cage (Implantable)

There is insufficient research to show that implantable anterior and lateral body interbody cage devices improve health outcomes for people with disorders of the spine at any level. No clinical guidelines based on research support the medical necessity of the Aprevo 3-D manufactured cage as equivalent or superior to conventional spinal cages used for anterior interbody fusion.

Minimal Access Open Anterior, Posterior, and Transforaminal LIF

The available evidence (reviews, non-randomized comparative studies) suggests that, after an initial training period, the mid-term health outcomes (including complication and fusion rates, pain and function) following minimally invasive anterior, posterior, transforaminal, and extreme lateral interbody fusion (XLIF) approaches are comparable to standard open approaches for single-level interbody fusion of the lumbar spine. Intra- and peri-operative health outcomes (blood loss and hospital stay) have been shown to be improved (e.g., Kim et al., 2010; Park et al., 2007; Ghahreman et al., 2010; Kasis et al., 2009; Wang et al., 2010; Wu et al., 2010; Shunwu et al., 2010; Rouben et al., 2011).

Direct Lateral Interbody Fusion (DLIF)

The DLIF procedure utilizes specialized, FDA-approved instrumentation from Medtronic. While well-designed, comparative clinical trials are needed to demonstrate whether these procedures provide improved health outcomes with long-term follow-up, the outcomes from studies thus far demonstrate that DLIF has comparable outcomes to XLIF. Berjano et al. (2012) conducted a retrospective cohort review of 97 consecutive patients from three centers, with minimum six-month follow-up (mean 12 months, 93 patients available for follow-up). The main diagnosis was degenerative disc disease (DDD), with or without stenosis, or spondylolisthesis, grade I. Functional status was evaluated by pre-operative and last follow-up Oswestry Disability Index score. Leg and back pain were evaluated by visual analog scales (VAS). Complications were recorded, and permanent complications and neurological impairment were actively investigated at last follow-up. Clinical success was considered to be achieved when the patient increased functional ODI score by more than 12% or decreased back pain VAS by more than three points. No permanent neurological impairment or vascular or visceral injuries were observed by the investigators. Transient neurological symptoms presented in 7% of cases; all resolved within one month from surgery. Transient thigh discomfort was observed in 9% of cases. Clinical success was recorded in 92% of cases.

Extreme Lateral Interbody Fusion (XLIF)

While XLIF as an endoscopic surgical procedure does not require FDA approval, the instrumentation associated with the XLIF procedure does. NuVasive has developed the XLIF instrumentation/products for this surgical approach. This minimally invasive surgical platform is known as Maximum Access Surgery (MAS). MAS combines three categories of product offerings: NeuroVision, MaXcess, and specialized implants such as SpheRx and CoRoent. All surgical instrumentation associated with this procedure has received FDA approval either through the pre-market approval or Section 510(k) process.

Ozgur et al. (2006) reported on the surgical technique for XLIF of the lower lumbar spine. Thirteen patients with axial low back pain who failed at least six months of conservative management underwent the XLIF technique. The authors concluded that, in comparison to anterior laparoscopic approaches, the XLIF approach had the advantages of not needing to retract the great vessels, not requiring a steep learning curve, and no impairment to depth perception during the procedure. The most important advantage was a reduction in operative time. In this preliminary report, no complications were associated with the surgery.

In a 2009 report, Knight and colleagues compared complications from a series of 58 patients who underwent XLIF or DLIF (1- to 3-level) with a historical cohort of patients who underwent open posterolateral lumbar fusion. Thirteen patients (22.4%) experienced a mild or major complication. Nine of the complications were approach-related (two L4 nerve root injuries, six cases of meralgia paresthetica, and one case of significant psoas muscle spasm). In four additional cases, the procedure was aborted because of concerns about nerve proximity. Compared with the historical cohort, there was less blood loss (136 versus 489 mL), a shorter operative time (161 versus 200 mins.), a similar hospital stays (five days), and a similar percentage of complications (22.4 versus 22.5%). Approach-related complications in the open cohort included wound infection and dural tears.

In 2010, Rodgers et al. published a retrospective review of a database for all patients treated with the XLIF procedure by a single surgeon between 2006 and 2008, focusing on early complications (at less than three months) in obese and non-obese patients. Out of a total of 432 patients treated with XLIF during this period, 313 (72%) met the inclusion criteria for the study and had complete data; 156 were obese (greater than 30 kg/m2) and 157 were not obese. Patients who were obese were slightly younger (58.9 versus 62.9 years of age) and had a higher incidence of diabetes mellitus (48 versus 17) than patients who were not obese but were otherwise comparable at baseline. There were 27 complications (8.6%) in the entire group, which included cardiac and wound complications, vertebral body fractures (one requiring reoperation), nerve injuries, gastrointestinal injuries (one requiring reoperation), and hardware failures (one requiring reoperation for recurrent stenosis after cage subsidence). The complication and reoperation rates were not significantly different between the obese and non-obese groups. There were no cerebrospinal fluid leaks, no infections, and no required transfusions. The average length of hospital stay was 1.2 days. The authors noted that reliable automated neurological monitoring and fluoroscopic guidance, as well as meticulous attention to operative technique, are required, but early outcomes compared well with traditional interventions.

In 2011, Rodgers and colleagues reported a retrospective analysis of intra-operative and peri-operative complications from all consecutive patients (600 procedures, 741 levels) treated by two surgeons since the XLIF procedure was introduced at their institution. Of those procedures, 485 were single-level, 90 were two-level, and 25 involved three or more levels. The hospital stays averaged 1.2 days. There were 37 complications (6%), classified as medical (60%) or surgical (40%). Surgical complications included four transient post-operative neurologic deficits and one subcutaneous hematoma. There were no wound infections, no vascular injuries, and no intra-operative visceral injuries in this series. At a minimum one-year follow-up, VAS pain scores had decreased from an average 8.8 to 3.1.

Laparoscopic Anterior Interbody Lumbar Fusion (ALIF)

Currently, the published, peer-reviewed scientific literature does not allow strong conclusions regarding the overall benefit and long-term efficacy of the laparoscopic anterior approach, compared to open spinal fusion. Studies also report a potentially higher rate of complications with laparoscopic ALIF.

In review of the literature on laparoscopic ALIF, Inamasu et al. (2005) identified 19 studies that described the outcome of a L5-S1 laparoscopic ALIF, nine studies that described the outcome of the L4-L5 laparoscopic ALIF, and eight studies that described the outcome of a two-level laparoscopic

ALIF. The review concluded that there was no marked difference between laparoscopic ALIF and the open or mini-open ALIF, in terms of short-term efficacy (operative time, blood loss, and length of hospital stay), but there was a higher incidence of complications. In addition, the conversion rate to open surgery was considered to be high. It was noted that, at the time of the review article, some spine surgeons were abandoning the laparoscopic approach and switching to mini-open ALIF.

The largest trial on laparoscopic ALIF was a prospective, multi-center (19 surgeons from 10 U.S. centers), investigational device exemption (FDA-regulated) trial, published in 1999 by Regan et al. The study compared short-term outcomes from laparoscopic fusion of the spine (240 consecutive patients) and open ALIF (earlier cohort of 591 similar patients). Inclusion criterion was painful degenerative disc disease consisting of disc space narrowing at one or two contiguous levels (L4-L5 and L5-S1). Single-level fusion was performed on 215 patients using laparoscopy and on 305 patients using the open procedure; two-level fusions were performed on 25 patients via laparoscopy, and 286 patients with the open procedure. In 25 (10%) of the laparoscopy patients, conversion to an open procedure was required due to bleeding (n=6), anatomic considerations (n=5), adhesions or scar tissue limiting access to the spine (n=8), and technical difficulties in placing the threaded cage (n=6). The hospital stay was modestly shorter for the single-level laparoscopy group (3.3 versus 4 days), but not for patients undergoing two-level laparoscopy. Operative time was increased (201 versus 142 minutes) for the single-level laparoscopic approach (243 minutes for the 25 cases converted to open). For two-level laparoscopy, the procedure time was 146 minutes longer than for the open approach. The reoperation rate for single-level procedures was 4.7% in the laparoscopy group, compared with 2.3% in the open group (not significantly different). Major complications (implant migration, great vessel damage, pulmonary embolism) were significantly lower in the laparoscopy group (0% versus 2%). Post-operative complications were similar in the two groups, with an occurrence of 14.1% in the open approach group and 19.1% in the laparoscopic approach group.

A prospective comparison of 50 consecutive patients (25 in each group) with disabling discogenic pain, who underwent single-level or two-level ALIF at L4-L5 with either a laparoscopic or mini-open approach, was reported by Zdeblick and David in 2000. There was no difference between the laparoscopic and mini-open approaches in terms of operating time (125 versus 123 minutes), blood loss (50 cc versus 55 cc), or length of hospital stay (1.4 versus 1.3 days) for single-level fusion. For two-level fusion, the operating time was increased for the laparoscopic procedure (185 versus 160 minutes). There was a 20% rate of complication in the laparoscopic group (disc herniation, ureter injury, iliac vein laceration, transient retrograde ejaculation, deep vein thrombosis) compared with 4% in the mini-open group (ileus). Exposure was considered inadequate in the laparoscopic group, with only a single interbody cage placed in 16% of patients in the laparoscopic group. All patients in the mini-open group had two interbody cages placed.

AxiaLIF

The AxiaLIF and AxiaLIF 2 Level Systems were developed by TranS1 and consist of techniques and surgical instruments for creating a pre-sacral access route to perform percutaneous fusion of the L5-S1 or L4-S1 vertebral bodies. The AxiaLIF 2 Level Systems received pre-market notification in April 2008. FDA pre-market notification [Section 510(k)] summaries indicate that the procedures are intended to provide anterior stabilization of the spinal segments as an adjunct to spinal fusion and to

assist in the treatment of degeneration of the lumbar disc, performance of lumbar discectomy, and performance of interbody fusion.

There is insufficient evidence to determine whether axial lumbar interbody fusion is as effective or as safe as other established surgical techniques.

Aryan and colleagues (2008) reported on their series of 35 patients, with average follow-up of 17.5 months. These patients had pain secondary to lumbar DDD, degenerative scoliosis, or lytic spondylolisthesis. In 21 of the patients, the AxiaLIF procedure was followed by percutaneous pedicle screw-rod fixation; two patients had extreme lateral interbody fusion combined with posterior instrumentation, and 10 had a stand-alone procedure. Two patients had axial LIF as part of a larger construct, after unfavorable anatomy prevented access to the L5-S1 disc space during open lumbar fusion. Thirty-two patients had radiographic evidence of stable cage placement and fusion at last follow-up.

In 2010, Patil and colleagues reported a retrospective review of 50 patients treated with AxiaLIF. Four patients (8%) underwent two-level AxiaLIF, and 16 patients (32%) underwent a combination of AxiaLIF with another procedure for an additional level of fusion. There were three reoperations due to pseudoarthrosis (n=2) and rectal injury (n=1). Other complications included superficial infection (n=5), hematoma (n=2), and irritation of a nerve root by a screw (n=1). At 12- to 24-month follow-up, VAS scores had decreased from 8.1 to 3.6 (n = 48). At an average 12-month follow-up, 47 of 49 patients (96%) with post-operative radiographs achieved solid fusion. There were no significant differences between pre- and post-operative disk space height and lumbar lordosis angle.

Interspinous Fixation Devices (IFDs)

There is a lack of evidence on the efficacy of IFDs in combination with interbody fusion. One risk is spinous process fracture, while a potential benefit is a reduction in adjacent segment degeneration. Randomized trials with longer follow-up are needed to evaluate the risks and benefits following use of IFDs compared with the established standard (pedicle screw with rod fixation).

PROFESSIONAL GUIDELINE(S)

In 2014, the North American Spine Society (NASS) issued coverage policy recommendations for the clinical indications for interspinous process fixation devices marketed as an alternative to pedicle screw fixation for lumbar fusion, which was revised in 2019 as follows:

NASS noted that although there is still limited evidence, interspinous fixation with fusion for stabilization may be considered when utilized in the context of lumbar fusion procedures for patients with diagnoses including stenosis, disc herniations, or synovial facet cysts in the lumbar spine, as an adjunct to cyst excision which involves removal of greater than 50 percent of the facet joint and when utilized in conjunction with a robust open laminar and/or facet decortication and fusion, and/or a robust autograft inter- and extra-spinous process decortication and fusion, and/or an interbody fusion of the same motion segment. NASS also noted that no literature supports the use of interspinous fixation without performing an open decortication and fusion of the posterior bony elements or interbody fusion.

In July 2018, the National Institute for Health and Care Excellence (NICE) provided evidence-based recommendations on transaxial interbody lumbosacral fusion for low back pain in adults. The recommendation, based on a literature review conducted in December 2017, states, "Evidence on the safety of transaxial interbody lumbosacral fusion for severe chronic low back pain shows that there are serious but well-recognized complications. Evidence on efficacy is adequate in quality and quantity. Therefore, this procedure may be used provided that standard arrangements are in place for clinical governance, consent and audit. This procedure should only be done by a surgeon with specific training in the procedure, who should carry out their initial procedures with an experienced mentor."

REGULATORY STATUS

Various instruments used in lumbar spinal fusion have been cleared for marketing by the FDA for specified indications. FDA device approval status can be determined using the following link: https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
22207	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (e.g., pedicle/vertebral body subtraction); lumbar
22208	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (e.g., pedicle/vertebral body subtraction); each additional vertebral segment (List separately in addition to code for primary procedure)
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)

Code	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)
22586 (E/I)	Arthrodesis, pre-sacral interbody technique, including disc preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace
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 (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, lumbar; each additional interspace and segment (List separately in addition to code for primary procedure)
22800-22812	Arthrodesis for spinal deformity (code range)
22840-22848	Spinal instrumentation (Add-on code range)

Code	Description
22853	Insertion of interbody biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)
22854	Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
63052	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; single vertebral segment (List separately in addition to code for primary procedure)
63053	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; each additional segment (List separately in addition to code for primary procedure)

HCPCS Codes

Code	**Description**
No codes	

ICD10 Codes

Code	Description
M40.35-M40.37	Flatback syndrome: thoracolumbar, lumbar or lumbosacral region (code range)
M41.05-M41.9	Scoliosis (code range: codes ending in 5 are thoracolumbar, ending in 6 are lumbar and ending in 7 are lumbosacral)
M43.00-M43.07	Spondylolysis: thoracolumbar, lumbar or lumbosacral region (code range)
M43.15-M43.17	Spondylolisthesis: thoracolumbar, lumbar or lumbosacral region (code range)
M43.27	Fusion of spine, lumbosacral region

Code	Description
M48.05-M48.07	Spinal stenosis: thoracolumbar, lumbar or lumbosacral region (code range)
M51.06	Intervertebral disc disorders with myelopathy, lumbar region
M53.2X5-M53.2X7	Spinal instabilities: thoracolumbar, lumbar or lumbosacral region (code range)
M53.86-M53.87	Other specified dorsopathies, lumbar or lumbosacral region (code range)
M96.0	Pseudarthrosis after fusion or arthrodesis
M96.1	Postlaminectomy syndrome, not elsewhere classified
S32.000A-S32.059S	Fracture of lumbar spine (code range)

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Based on our review, Lumbar Fusion, Lumbar Posterior Column Osteotomy (PCO) or Lumbar Three-Column Osteotomy are not addressed in National or Regional Medicare coverage determinations or policies.

Based upon our review, Minimally Invasive/Minimal Access Lumbar Interbody Fusion is not specifically addressed in National or Regional Medicare coverage determinations/policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates	
06/26/25	
Date	**Summary of Changes**
10/15/25	• Policy merged (previously 7.01.90 & 7.01.83). New policy title: Lumbar Fusion. Redundant criteria removed. Headings added throughout policy statements section. New pediatric lumbar fusion criteria added.
01/01/25	• Summary of changes tracking implemented.
10/15/25	• Original effective date