MEDICAL POLICY

MEDICAL POLICY DETAILS	
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Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), 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 STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, Lumbar Fusion (Arthrodesis) with Decompression (Indirect or Direct) in adult patients has been medically proven to be effective and, therefore, is considered **medically necessary** for the following indications:

A. Actual Instability

1. When **ALL** of 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;

OR

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** of 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** of 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** of 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** of 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** of 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.

II. Based upon our criteria and assessment of the peer-reviewed literature, Lumbar Fusion (Arthrodesis) without Decompression in adult patients has been medically proven to be effective and, therefore, is considered **medically appropriate** for the following indications:

A. Degenerative Spondylolisthesis without Spondylolysis
i. When **ALL** of 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
c. Subjective symptoms include **BOTH**:
i. 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**
ii. Significant functional limitations have resulted in diminished quality of life and impaired, age-appropriate activities of daily living;
AND
d. 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
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.

B. Spondylolisthesis with Spondylolysis (e.g., Isthmic Spondylolisthesis)
1. When **ALL** of 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:
i. 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**

ii. Significant functional limitations have resulted in diminished quality of life and impaired, age-appropriate activities of daily living;

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. Discogenic Lower Back Pain/Degenerative Disc Disease

1. When **ALL** of 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:
      i. Significant level of pain on a daily basis defined as clinically significant functional impairment (e.g., inability to perform household chores, prolonged standing; **and**
      ii. Significant functional limitations have resulted in diminished quality of life and impaired, age-appropriate activities of daily living;

   AND

   d. Structured physician-supervised, multi-modal, non-operative management of medical care with licensed healthcare professionals which includes **ALL** of 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. Adult Degenerative Spinal Deformity
1. When **ALL** of 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.

III. Based upon our criteria and assessment of the peer-reviewed literature, Repeat Lumbar Fusion (arthrodesis) (with or without decompression) at the Same Level in adult patients has been medically proven to be effective and, therefore, is considered **medically necessary** for **EITHER** of the following indications:

A. Malposition or Failure of Implant/Instrumentation or Structural Bone Graft
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** of 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.

IV. Based upon our criteria and assessment of the peer-reviewed literature, Lumbar Fusion (Arthrodesis) for Adjacent Segment Disease in adult patients has been medically proven to be effective and, therefore, is considered **medically necessary** when **ALL** of 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;
AND
C. Imaging at the requested level(s) shows evidence of anterolisthesis on plain x-rays resulting in **EITHER** of the following:
1. 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 three (3) mm between views; **or**
2. Meyerding Grade II or higher spondylolisthesis;
AND
D. Significant initial relief of symptoms following prior lumbar spinal fusion(s).

V. Based upon our criteria and assessment of the peer-reviewed literature, Lumbar Fusion (with or without Decompression) Following Failed Lumbar Disc Arthroplasty Surgery in adult patients has been medically proven to be effective and, therefore, is 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** of 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).

VI. Based upon our criteria and assessment of the peer-reviewed literature, Lumbar Posterior Column Osteotomy (PCO) (i.e., Smith-Peterson osteotomy [SPO] or Ponte osteotomy) has been medically proven to be effective

and, therefore, is considered **medically necessary** (in addition to a lumbar fusion) when **ALL** of 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 saggital 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** of the criteria for lumbar fusion have been met per applicable procedure policy criteria listed above to include:
   1. Lumbar Fusion (Arthrodesis) with Decompression (Indirect or Direct);
   2. Adjacent Segment Disease;
   3. Lumbar Fusion (Arthrodesis) without Decompression;
   4. Lumbar Fusion (with or without Decompression) Following Failed Disc Arthroplasty Surgery;
   5. Repeat Lumbar Fusion (Arthrodesis) at the Same Level.

VII. Based upon our criteria and assessment of the peer-reviewed literature, Lumbar Three-Column Osteotomy (i.e., pedicle subtraction osteotomy (PSO) or Vertebral Column Resection (VCR) has been medically proven to be effective and, therefore, is considered **medically necessary** (in addition to a fusion) when **ALL** of the following criteria are met:

A. Performed for **EITHER** of the following indications:
   a. Correction of fixed saggital plane deformity requiring more than 30 degree of correction (PSO); **or**
   b. Large fixed coronal deformities greater than 60 degrees that are amenable to asymmetric osteotomy;

AND

B. **ALL** of the criteria for lumbar fusion have been met per applicable procedure policy criteria listed above to include:
   a. Lumbar Fusion (Arthrodesis) with Decompression (Indirect or Direct);
   b. Adjacent Segment Disease;
   c. Lumbar Fusion (Arthrodesis) without Decompression;
   d. Lumbar Fusion (with or without Decompression) Following Failed Disc Arthroplasty Surgery;
   e. Repeat Lumbar Fusion (Arthrodesis) at the Same Level.

VIII. Based upon our criteria and assessment of the peer-reviewed literature, Lumbar Spinal Fusion has not been medically proven to be effective and is, therefore, 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.

IX. Based upon our criteria and assessment of the peer-reviewed literature, the following devices/procedures have not been medically proven to be effective and, therefore, 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.

Please refer to Corporate Medical Policy #7.01.83 Minimally Invasive/Minimal Access Techniques for Lumbar Interbody Fusion which includes an investigational statement for the following devices/procedures:

- *Minimally invasive lumbar spinal fusions using direct visualization via endoscopy (endoscopic fusion) or indirect visualization (e.g., percutaneous fusion)*
- *Pre-sacral interbody fusion including AxialLIF*
- *Anterior interbody fusion or implantation of intervertebral body fusion devices using laparoscopic approach*
- *Interlaminar lumbar instrumented fusion (e.g., ILIF)*
- *Interspinous fixation/posterior non-pedicle supplemental fixation devices for spinal fusion (e.g., Affix, Aspen Spinous Process Fixation System, Coflex-F)*
- *Least invasive lumbar decompression interbody fusion (e.g., LINDIF)*

Refer to Corporate Medical Policy #7.01.113 Lumbar Decompression

Refer to Corporate Medical Policy #7.01.98 Lumbar Microdiscectomy

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

POLICY GUIDELINES

I. Minimum documentation requirements needed to complete a spinal surgery prior authorization request include **ALL** of 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, manual 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.

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).

RATIONALE

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).

Disc Herniation/Degenerative Disc Disease (DDD)

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.

T. Ibrahim and colleagues performed a meta-analysis of RCTs to investigate the effectiveness of surgical fusion for the treatment of chronic low back pain compared to non-surgical intervention. The meta-analysis comparison was based on the mean difference in Oswestry Disability Index (ODI) change from baseline to the specified follow-up of patients undergoing surgical versus non-surgical treatment. Of the 58 articles identified, three studies were eligible for primary analysis and one study for sensitivity analysis, with a total of 634 patients. The authors found that surgical fusion for chronic low back pain favored a marginal improvement in the ODI, compared to non-surgical intervention. This difference in ODI was not statistically significant and was of minimal clinical

importance. Surgery was found to be associated with a significant risk of complications. Therefore, the cumulative evidence at the present time does not support routine surgical fusion for the treatment of chronic low back pain.

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

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). Long-term follow-up of a large case series by Danielson and Nachemson supports guidelines from the Scoliosis Research Society that fusion can reduce curve progression in patients with curves greater than 40°. This is likely to result in reduced morbidity for treated patients.

Adult Symptomatic Lumbar Scoliosis

A cohort study in 2009 by Bridwell et al. reported a prospective, multi-center cohort 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.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
22207	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (e.g., pedicle/vertebral body subtraction); lumbar (Effective 01/01/08)
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) (Effective 01/01/08)

Code	Description
22214	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; lumbar (Effective 01/01/00)
22216	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; each additional vertebral segment (List separately in addition to primary procedure) (Effective 01/01/00)
22224	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; lumbar (Effective 01/01/22)
22226	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; each additional vertebral segment (List separately in addition to code for primary procedure) (Effective 01/01/22)
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 (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], [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; single vertebral segment (List separately in addition to code for primary procedure)
63053	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; each additional segment (List separately in addition to code for primary procedure)

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
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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*Key Article

KEY WORDS

Degenerative disc disease, disc herniation, lumbar arthrodesis, lumbar fusion, spinal stenosis, spondylodesis, spondylosyndesis, spondylolisthesis, lumbar posterior column osteotomy (PCO), lumbar three-column osteotomy, pedicle subtraction osteotomy (PSO) or vertebral column resection (VCR)

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

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.