

MEDICAL POLICY

Medical Policy Title	Spine Procedures for Managed Medicaid (MMC), Health and Recovery Plan (HARP), Child Health Plus (CHP), and Essential Plan (EP) Members
Policy Number	7.01.126
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Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to [Product Disclaimer](#))

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- Fusion (Arthrodesis)
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POLICY STATEMENT(S)

[Cervical Spine Procedures](#)

[Cervical Spine Arthrodesis](#)

- I. Cervical spine arthrodesis is considered **medically appropriate** when documentation meets **ALL** the following:

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- A. The individual has **ANY** of the following clinical conditions:
 - 1. Cervical disc herniation;
 - 2. Cervical instability;
 - 3. Cervical spondylosis; **or**
 - 4. Cervical stenosis;
- B. Clinical presentation includes **ANY** of the following:
 - 1. Myelopathy (e.g., bowel or bladder dysfunction, gait disturbance, hyperreflexia, upper extremity weakness);
 - 2. Objective neurologic deficit (e.g., motor weakness, sensory loss, abnormal reflexes); **or**
 - 3. Radiculopathy (e.g., numbness, paresthesias, or radiating upper extremity pain);
- C. Conservative management meets **EITHER** of the following:
 - 1. No conservative management is required for **ANY** of the following:
 - a. Cervical myelopathy;
 - b. Progressive neurologic deterioration;
 - c. Severe spinal cord compression with significant neurologic findings;
 - d. Spinal instability requiring surgical stabilization;
 - e. Tumor, infection or instability resulting from trauma; **or**
 - 2. For all other indications, conservative management must include **BOTH** the following:
 - a. Physical therapy (PT) meets **All** the following:
 - i. Participation for a minimum of 6 weeks during the previous 6 months;
 - ii. Failure to improve symptoms or functional impairments;
 - iii. Supervised by a licensed PT, chiropractor, or through tele-rehab PT; **and**
 - b. Pain management includes **ALL** the following:
 - i. Interventional pain management strategies (e.g., epidural steroid injections, facet injections, or selective nerve root blocks) have been considered, when clinically indicated;
 - ii. Non-steroidal anti-inflammatory drugs (NSAIDs) for a minimum of 4 weeks, unless contraindicated;
 - iii. Non-pharmacologic pain management such as activity modification, rest periods, splinting, or therapeutic exercises;
- D. Preoperative cervical spine imaging obtained within 6 months prior to surgery includes **ANY**

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of the following:

1. Computed tomography (CT);
 2. CT Myelogram;
 3. Magnetic resonance imaging (MRI); **or**
 4. Radiographs (x-rays) as supplemental (e.g., flexion/extension);
 - E. If surgery is deemed medically appropriate, refer to the Policy Guidelines for Site of Care criteria.
- II. Cervical spine arthrodesis is considered **not medically necessary** for **ANY** of the following contraindications:
- A. Uncontrolled diabetes with hemoglobin A1C (HbA1C) greater than 8%;
 - B. Medical comorbidity with increased surgical risk (e.g., anemia, malnutrition, severe cardiovascular or pulmonary disease);
 - C. Active infection, systemic or localized to the operative field;
 - D. Allergy or hypersensitivity to implant materials; **or**
 - E. Compromised bone integrity due to severe osteoporosis or metabolic bone disease that has not been adequately treated.

Cervical Spine Corpectomy

- III. Anterior cervical spine corpectomy is considered **medically necessary** when **ALL** the following are met:
- A. A complete or partial cervical corpectomy is planned with removal of at least one-half of a vertebral body; and
 - B. Treatment is for **one** (1) or more of the following:
 1. Infection;
 2. Malignancy;
 3. Compression located at or posterior to the vertebral body level; **or**
 4. Trauma;
 - C. Cervical fusion is performed as part of the procedure, given fusion criteria are met.

Cervical Spine Disc Arthroplasty

- IV. Cervical disc arthroplasty (artificial disc replacement) is considered **medically appropriate** when the documentation meets **ALL** the following:
- A. Clinically significant cervical disc disease, including **ALL** the following:
 1. Objective findings correlate with compression of the spinal cord or nerve root (e.g.,

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- dermatomal sensory deficit, motor weakness, altered reflexes); and
 - 2. Radiculopathy and/or myelopathy attributable to degenerative disc disease at one (1) or two (2) levels between C3 and C7, with central, lateral recess, or foraminal compression (e.g., herniated disc or spondylotic osteophyte);
- B. Conservative management meets **EITHER** of the following:
- 1. Conservative management is **not** required when **ANY** of the following is documented:
 - a. Objective neurological deterioration (e.g., increasing motor loss) across serial examinations;
 - b. Myelopathy attributable to spinal cord compression (e.g., cord signal change on MRI);
 - c. New-onset bowel or bladder dysfunction due to cervical spinal cord compression;
 - d. Symptoms of nerve root or spinal cord compression are severe or rapidly progressive, requiring hospitalization or immediate surgery;
 - e. Motor weakness is significant or rapidly progressing (e.g., motor grade $\leq 3/5$, or interference with activities of daily living); **or**
 - 2. For all other indications, conservative management must include **BOTH** of the following:
 - a. Physical therapy (PT) meets **all** the following:
 - i. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
 - ii. Participation for a minimum of 6 weeks during the previous 6 months; **and**
 - iii. Failure to improve symptoms or functional impairments;
 - b. Pain management includes **ALL** the following:
 - i. Interventional pain management strategies (e.g., epidural steroid injections, facet injections, or selective nerve root blocks) have been considered, when clinically indicated;
 - ii. Non-steroidal anti-inflammatory drugs (NSAIDs) for a minimum of 4 weeks, unless contraindicated; **and**
 - iii. Non-pharmacologic pain management such as activity modification, rest periods, splinting, or therapeutic exercises;
- C. Advanced imaging (MRI or CT) demonstrates nerve root and/or spinal cord compression at the level(s) concordant with the clinical presentation;
- D. Documentation confirms skeletal maturity;
- E. The cervical disc replacement device is used in accordance with U.S. Food and Drug Administating (FDA)-approved labeling;

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- F. If surgery is deemed medically appropriate, refer to the Policy Guidelines for Site of Care criteria.
- V. Cervical disc arthroplasty (artificial disc replacement) is considered **not medically necessary** for **ANY** of the following contraindications:
 - A. Uncontrolled diabetes with hemoglobin A1C (HbA1C) greater than 8%;
 - B. Medical comorbidity with increased surgical risk (e.g., anemia, malnutrition, severe cardiovascular or pulmonary disease);
 - C. Active malignancy involving the cervical spine or metastatic disease;
 - D. Allergy or sensitivity to materials used in the implant (e.g., titanium, polyethylene, cobalt, chromium, molybdenum);
 - E. Inflammatory or autoimmune arthropathy, including spondyloarthropathies (e.g., rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis);
 - F. Metabolic bone disease (e.g., Paget disease, osteomalacia);
 - G. Marked cervical instability (e.g., greater than 3.5 millimeters translation and/or angular difference greater than 11 degrees);
 - H. Clinically significant cervical anatomical deformity (e.g., fixed kyphosis);
 - I. Facet arthropathy graded as moderate or worse at the involved level;
 - J. Active infection, local or systemic;
 - K. Ossification of the posterior longitudinal ligament (OPLL) at the level to be treated;
 - L. Osteoporosis or osteopenia;
 - M. Severe spondylosis (e.g., bridging osteophytes, greater than 50% loss of disc height, or segmental motion less than 2 degrees) and past surgical history at the requested level; **or**
 - N. Structural vertebral body deficiency or deformity resulting from prior trauma (e.g., malunion, nonunion, or fracture callus).

Cervical Spine Decompression or Fusion Procedures

Anterior With Fusion (ACDF) or without Fusion & Posterior With or Without Fusion

- VI. Anterior cervical decompression with fusion (ACDF) or posterior cervical decompression with or without fusion (laminectomy, laminoforaminotomy, laminoplasty) is considered **medically appropriate** when the documentation meets **ALL** the following:
 - A. Nicotine-free status is documented by **EITHER** of the following:
 - 1. No history of smoking; or
 - 2. Cotinine testing (serum, urine, or saliva) results less than or equal to 10 ng/mL, confirming the individual has refrained from nicotine use (e.g., smoking, use of

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smokeless tobacco products, or nicotine replacement therapy) for a minimum of six (6) weeks prior to the planned surgery;

Exception: Urgent or emergent cervical fusion is not subject to nicotine abstinence requirements when surgical delay may compromise the individual's clinical status.

B. When documentation meets **ONE (1) of the following:**

1. Cervical myelopathy or radiculopathy when symptoms are attributed to cervical deformity, herniated disc; segmental instability; or spondylosis when **both** of the following are met:
 - a. Conservative management meets **BOTH** of the following:
 - i. Physical therapy (PT) meets **all** the following:
 - a) Participation for a minimum of 6 weeks during the previous 6 months;
 - b) Failure to improve symptoms or functional impairments; **and**
 - c) Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
 - ii. Pain management includes **all** the following:
 - d) Interventional pain management strategies (e.g., epidural steroid injections, facet injections, or selective nerve root blocks) have been considered, when clinically indicated;
 - e) Non-steroidal anti-inflammatory drugs (NSAIDs) for a minimum of 4 weeks, unless contraindicated; **and**
 - f) Non-pharmacologic pain management such as activity modification, rest periods, splinting, or therapeutic exercises;
 - b. CT or MRI obtained within 6 months prior to surgery identifies compression of the spinal cord or nerve roots at levels concordant with the clinical presentation;
2. Decompression with fusion may be performed as an initial treatment without a trial of conservative management when documentation meets **ALL** the following:
 - a. When **any** of the following upper motor signs are present:
 - i. Clonus;
 - ii. Hyperreflexia (exaggerated deep tendon reflexes);
 - iii. Impaired walking or loss of coordination;
 - iv. Motor weakness; **or**
 - v. Positive Babinski or Hoffmann sign;
 - b. Significant neural compression (cord or nerve root) from infection, trauma, or tumor, defined by **either** of the following;

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- i. Spinal canal diameter less than 10 mm; **or**
 - ii. Neurologic findings (e.g., loss of hand dexterity or gait/balance impairment);
 - c. X-rays identify fracture or segmental instability, defined by **either** of the following:
 - i. C1-level subluxation with an atlantodental interval greater than 3 mm in an adult or 5 mm in a child; **or**
 - ii. Sagittal plane instability, defined by **either** of the following:
 - a) Rotation greater than 11 degrees at a single motion segment; **or**
 - b) Anterior subluxation greater than 3.5 mm associated with spinal cord dysfunction or radiculopathy;
3. Decompression without fusion may be performed as an initial treatment without a trial of conservative management when documentation meets **ALL** the following:
- a. Imaging (X-ray) confirms no segmental instability;
 - b. When **any** of the following upper motor neuron signs are present:
 - i. Clonus;
 - ii. Impaired walking or loss of coordination;
 - iii. Hyperreflexia (exaggerated deep tendon reflexes);
 - iv. Motor weakness; **or**
 - v. Positive Babinski or Hoffmann sign;
 - c. Significant neural compression (cord or nerve root) from infection, trauma, or tumor, defined by **either** of the following:
 - i. Spinal canal diameter less than 10 mm; **or**
 - ii. Neurologic findings (e.g., loss of hand dexterity or gait/balance impairment).

VII. Cervical decompression or fusion is considered **not medically necessary** for **either** of the following:

- A. Stand-alone decompression (without fusion) for spinal deformity (e.g. cervical kyphosis) requiring stabilization (fusion);
- B. The presence of **ANY** of the following contraindications:
 - 1. Uncontrolled diabetes with hemoglobin A1C (HbA1C) is greater than 8%;
 - 2. Medical comorbidity with increased surgical risk (e.g., anemia, malnutrition, severe cardiovascular or pulmonary disease);
 - 3. Absent or limited symptom burden without significant functional limitation (e.g., minor radicular complaints without instability or motor weakness);

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4. Neck pain in the absence of neurologic impairment, with no radiographic evidence of spinal cord or nerve root compression; **or**
5. Imaging findings are not consistent with the individual's reported symptoms or objective clinical examination findings.

Anterior & Posterior Decompression, With or Without Fusion

VIII. Anterior and posterior cervical spine decompression, with or without fusion, is considered **medically appropriate** when the documentation meets **ALL** the following:

- A. Comorbid conditions have been identified and addressed;
- B. Conservative management meets **BOTH** of the following:
 1. Physical therapy (PT) meets **all** the following:
 - a. Participation for a minimum of 6 weeks during the previous 6 months;
 - b. Failure to improve symptoms or functional impairments; **and**
 - c. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
 2. Pain management includes **ALL** the following:
 - a. Interventional pain management strategies (e.g., epidural steroid injections, facet injections, or selective nerve root blocks) have been considered, when clinically indicated;
 - b. Non-steroidal anti-inflammatory drugs (NSAIDs) for a minimum of 4 weeks, unless contraindicated; **and**
 - c. Non-pharmacologic pain management such as activity modification, rest periods, splinting, or therapeutic exercises;
- C. Imaging (CT, MRI, X-ray) reveals segmental instability or disc pathology;
- D. Axial and non-radicular neck pain;
- E. Anatomic source of pain (e.g., cervical facet [zygapophyseal] joint) has been identified and treated;
- F. No more than two (2) levels are affected;
- G. Nicotine-free status is documented by **EITHER** of the following:
 1. No history of smoking; **or**
 2. Cotinine testing (serum, urine, or saliva) results less than or equal to 10 ng/mL, confirming the individual has refrained from nicotine use (e.g., smoking, use of smokeless tobacco products, or nicotine replacement therapy) for a minimum of six (6) weeks prior to the planned surgery;

Exception: Urgent or emergent cervical fusion is not subject to nicotine abstinence

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requirements when surgical delay may compromise the individual's clinical status.

- H. If surgery is deemed medically appropriate, refer to the Policy Guidelines for Site of Care criteria.
- IX. Cervical spine decompression or fusion is considered **not medically necessary** when:
 - A. Stand-alone decompression (without fusion) for spinal deformity (e.g. cervical kyphosis) requiring stabilization (fusion);
 - B. The presence of **ANY** of the following contraindications:
 - 1. Uncontrolled diabetes with hemoglobin A1C (HbA1C) is greater than 8%;
 - 2. Medical comorbidity with increased surgical risk (e.g., anemia, malnutrition, severe cardiovascular or pulmonary disease);
 - 3. Absent or limited symptom burden without significant functional limitation (e.g., minor radicular complaints without instability or motor weakness);
 - 4. Neck pain in the absence of neurologic impairment, with no radiographic evidence of spinal cord or nerve root compression; **or**
 - 5. Imaging findings are not consistent with the individual's reported symptoms or objective clinical examination findings.

Lumbar-Sacral Spine Procedures

Lumbar Fusion (Arthrodesis)

- X. Lumbar spine fusion (arthrodesis) is considered **medically appropriate** when documentation meets **ALL** the following:
 - A. The individual has **ANY** of the following:
 - 1. Neurogenic claudication or radiculopathy attributable to degenerative disease;
 - 2. Recurrent lumbar disc herniation necessitating segmental stabilization;
 - 3. Persistent, clinically significant axial low back pain accompanied by **any** of the following:
 - a. Degenerative spondylolisthesis; **or**
 - b. Neurogenic claudication
 - 4. Segmental instability demonstrated on imaging (e.g., abnormal motion on flexion-extension views);
 - 5. Symptomatic degenerative spondylolisthesis; **or**
 - 6. Symptomatic spinal deformity (e.g., scoliosis);
 - B. Symptom burden includes **EITHER** of the following:
 - 1. Clinically significant pain; **or**

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2. Functional impairment that interferes with activities of daily living;
 - C. Conservative management meets **EITHER** of the following:
 1. No requirement for conservative management for **any** of the following:
 - a. Cauda equina syndrome;
 - b. Deteriorating or marked motor/sensory deficit (e.g., weakness, foot drop);
 - c. Instability or neurologic impairment secondary to spinal infection or tumor for which surgical intervention is indicated; **or**
 - d. Traumatic spinal instability;
 2. For all other indications, conservative management includes **BOTH** of the following:
 - a. Physical therapy (PT) meets **all** the following:
 - i. Participation for a minimum of 6 weeks during the previous 6 months;
 - ii. Failure to improve symptoms or functional impairments; **and**
 - iii. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
 - b. Pain management includes **ALL** the following:
 - i. Interventional pain management strategies (e.g., epidural steroid injections, facet injections, or selective nerve root blocks) have been considered, when clinically indicated;
 - ii. Non-steroidal anti-inflammatory drugs (NSAIDs) for a minimum of 4 weeks, unless contraindicated; **and**
 - iii. Non-pharmacologic pain management such as activity modification, rest periods, splinting, or therapeutic exercises;
 - D. Preoperative lumbar spine imaging includes **BOTH** of the following:
 1. Findings consistent with clinical presentation; **and**
 2. Obtained within 6 months prior to surgery using **any** of the following:
 - a. CT;
 - b. CT myelogram;
 - c. MRI; **or**
 - d. X-ray;
 - E. If surgery is deemed medically appropriate, refer to the Policy Guidelines for Site of Care criteria.
- XI. Lumbar spine fusion (arthrodesis) is considered **not medically necessary** for **ANY** of the following contraindications:

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- A. Insufficient symptom burden or functional impairment to warrant a surgical procedure (e.g., asymptomatic, incidental imaging findings);
- B. Active infection, systemic or localized to the operative field, except when the fusion is intended to treat the infection;
- C. Compromised bone integrity due to severe osteoporosis or metabolic bone disease that has not been adequately treated.

Lumbar Spine Decompression

XII. Lumbar decompression (facetectomy, foraminotomy, laminectomy, laminotomy) is considered **medically appropriate** when the documentation meets **ALL** the following:

- A. Subjective symptoms include **EITHER** of the following:
 - 1. Significant level of pain daily; **or**
 - 2. Significant functional impairment affecting activities of daily living (e.g., household tasks, prolonged standing, walking);
- B. Documentation confirms **EITHER** of the following clinical presentations:
 - 1. Neurogenic claudication includes **ALL** the following symptoms:
 - a. Symptoms involving the low back, buttocks, or legs;
 - b. Functional impairment related to diminished capacity to ambulate or stand;
 - c. At least **ONE (1)** of the following symptoms are present:
 - i. cramping;
 - ii. decreased strength,
 - iii. heaviness;
 - i. numbness
 - ii. pain; **or**
 - iii. paresthesias;
 - d. Relief from sitting or lumbar flexion;
 - e. Exacerbated with standing or walking; **or**
 - 2. Radiculopathy secondary to lumbar stenosis includes **ALL** the following symptoms:
 - a. Pain radiating into the buttock or legs is ongoing;
 - b. A symptom pattern that follows the distribution of the involved nerve root; **and**
 - c. **One (1) or more** of the following:
 - i. Sensory loss in a dermatomal pattern;

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- ii. Nerve root–specific muscle weakness;
 - iii. Reproduction of symptoms with the contralateral (crossed) straight leg raise;
 - iv. Positive femoral nerve stretch maneuver;
 - v. Positive straight leg raise (SLR) or comparable nerve tension sign; **or**
 - vi. Reflex abnormality (e.g., absent or diminished);
- C. Conservative management meets **EITHER** of the following:
- 1. No requirement for conservative management for **any** of the following:
 - a. Cauda equina syndrome;
 - b. Neurologic deterioration over time (e.g., declining functional capacity, new/worsening foot drop or motor strength);
 - c. Motor deterioration progressed over a short period of time;
 - d. Significant motor weakness of 3/5 or less on manual muscle testing; **or**
 - e. Significant neurologic compromise resulting from lumbar neural compression, supported by imaging findings consistent with the clinical presentation;
 - 2. For all other indications, conservative management includes **BOTH** of the following:
 - a. Physical therapy (PT) meets **all** the following:
 - i. Participation for a minimum of 6 weeks during the previous 6 months;
 - ii. Failure to improve symptoms or functional impairments; **and**
 - iii. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
 - b. Pain management includes **ALL** the following:
 - i. Interventional pain management strategies (e.g., epidural steroid injections, facet injections, or selective nerve root blocks) have been considered, when clinically indicated;
 - ii. Non-steroidal anti-inflammatory drugs (NSAIDs) for a minimum of 4 weeks, unless contraindicated; **and**
 - iii. Non-pharmacologic pain management such as activity modification, rest periods, splinting, or therapeutic exercises;
- D. Preoperative lumbar spine imaging (e.g., CT, MRI) includes **BOTH** of the following:
- 1. Obtained within 6 months prior to surgery; **and**
 - 2. Stenosis (central canal, lateral recess, or foraminal) at the identified level(s) is consistent with clinical presentation;
- E. Nicotine-free status is documented by **EITHER** of the following:

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1. No history of smoking; **or**
2. Cotinine testing (serum, urine, or saliva) results less than or equal to 10 ng/mL, confirming the individual has refrained from nicotine use (e.g., smoking, use of smokeless tobacco products, or nicotine replacement therapy) for a minimum of six (6) weeks prior to the planned surgery;

Exception: Urgent or emergent lumbar fusion is not subject to nicotine abstinence requirements when surgical delay may compromise the individual's clinical status.

- F. If surgery is deemed medically appropriate, refer to the Policy Guidelines for Site of Care criteria.

Lumbar Fusion: Single Level With or without Decompression

XIII. Single level lumbar fusion, with or without decompression (laminectomy, laminotomy, facetectomy, foraminotomy) is considered **medically appropriate** when **EITHER** of the following are met:

- A. Chronic axial low back pain associated with degenerative disc disease and a condition requiring spinal stabilization and **ALL** the following:
 1. Axial low back pain without associated radiculopathy that has persisted for a minimum of 6 months,
 2. Conservative management requirements are documented as **either**:

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- a. No conservative management required, as lumbar fusion is first line treatment for **any** of the following conditions:
 - i. Cauda equina syndrome with bowel or bladder dysfunction accompanied by neurologic deficits;
 - ii. Acute, progressive and significant motor weakness consistent with severe neurologic compromise; or
 - iii. Spinal infection, tumor or malignancy;

OR

- b. Conservative management failed to improve symptoms or functional abilities and includes **BOTH** the following:
 - i. Physical therapy (PT) meets **all** the following:
 - a) Participation for a minimum of 6 weeks during the previous 6 months;
 - b) Supervised by a licensed physical therapist, chiropractor, or through tele-rehab PT;
 - ii. Pain management includes **all** the following:
 - c) Interventional pain management trial (e.g., epidural steroid injections, facet injections, or selective nerve root blocks), unless documentation supports rationale for why trial is not appropriate;
 - d) Non-steroidal anti-inflammatory drugs (NSAIDs) for a minimum of 4 weeks, unless contraindicated; **and**
 - e) Non-pharmacologic pain management such as activity modification, rest periods, splinting, or therapeutic exercises;
- B. Preoperative imaging (e.g., CT, MRI, X-rays) obtained within 6 months prior to the procedure confirms deformity-related findings that correspond with the individual's examination findings and presentation;
- C. Documented objective findings confirming a structural abnormality for which fusion is needed to restore segmental stability, evidenced by **ANY** of the following:
 - 1. Spondylolisthesis accompanied by instability on dynamic or side-by-side comparative imaging;
 - 2. Abnormal segmental motion, defined as more than 3 mm of translational displacement between flexion and extension views on dynamic X-rays; **and**
 - 3. Symptomatic, localized spinal deformity that requires operative stabilization;
- D. Nicotine-free status is documented by **EITHER** of the following:
 - 1. No history of smoking; **or**

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2. Cotinine testing (serum, urine, or saliva) results less than or equal to 10 ng/mL, confirming the individual has refrained from nicotine use (e.g., smoking, use of smokeless tobacco products, or nicotine replacement therapy) for a minimum of six (6) weeks prior to the planned surgery.

Exception: Urgent or emergent lumbar fusion is not subject to nicotine abstinence requirements when surgical delay may compromise the individual's clinical status.

- E. If surgery is deemed medically appropriate, refer to the Policy Guidelines for Site of Care criteria.

Repeat Lumbar Fusion at the Same Level

XIV. 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. 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** the following criteria are met:
 - a. Greater than six (6) months since the prior lumbar fusion;
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;

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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 validated by objective cotinine testing methods (serum, urinary, or saliva) verified as within the normal range for the testing method and lab at which the test was performed.

Pediatric Scoliosis

XV. Surgical management of scoliosis in the pediatric population is considered **medically appropriate** when documentation meets **ALL** of the following:

A. The clinical presentation meets **ALL** the following:

1. Physical examination findings include **ANY** of the following:
 - a. Unequal shoulder or pelvic (iliac crest) heights;
 - b. Trunk shift or lateral lean in posture;
 - c. Paraspinal/rib prominence elicited on the Adams forward-bend maneuver;
 - d. Asymmetric waist contour or hip alignment; **or**
 - e. Clinically apparent curvature of the spine;
2. Diagnostic imaging obtained within the preceding 12 months confirms **ANY** of the following:
 - a. Cobb measurement of 50 degrees or more in a child at or approaching the end of skeletal growth (maturity);
 - b. Early-onset scoliosis exhibiting a curve exceeding 40 degrees with substantial remaining growth potential;

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- c. Documented curve advancement to a Cobb measurement of 45 degrees or more despite a trial of non-operative conservative management;
 - d. Worsening deformity producing truncal imbalance, loss of function, or a demonstrable likelihood of continued progression;
 - 3. Preoperative imaging includes **ALL** the following:
 - a. Obtained within the last 12 months of the planned procedure;
 - b. Documentation of the measured Cobb angle;
 - c. Imaging findings are concordant with the diagnosed deformity and planned surgical correction;
 - d. X-rays including standing PA and lateral spine; **and**
 - e. MRI has been obtained when **ANY** of the following are identified:
 - i. Abnormal findings on neurologic examination;
 - ii. Atypical curve features; **or**
 - iii. Rapid curve progression;
- B. Treatment includes **BOTH** of the following:
 - 1. Non-surgical management includes **BOTH** the following:
 - a. Use of a brace or spinal orthosis maintained until the individual reaches skeletal maturity (end of growth) prior to surgical consideration, or until the curve advances beyond 45 degrees; and
 - b. Physical therapy (PT) meets **all** the following:
 - i. Participation for a minimum of 6 weeks during the previous 6 months;
 - ii. Failure to improve symptoms or functional impairments; **and**
 - iii. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
 - 2. Surgical management includes **ANY** of the following:
 - a. Posterior instrumented spinal arthrodesis (fusion) indicated for curves in the range of approximately 45 to 50 degrees or above;
 - b. Vertebral body tethering (VBT) when **all** the following are present:
 - i. Cobb measurement between 35 and 65 degrees;
 - ii. Bracing has failed, is not tolerated, or is otherwise unsuitable;
 - iii. Skeletal immaturity with meaningful growth remaining;
 - c. In early-onset disease with a curve exceeding 40 degrees and substantial residual growth, a growth-preserving construct (traditional growing rods or magnetically

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controlled growing rods);

- C. If surgery is deemed medically appropriate, refer to the Policy Guidelines for Site of Care criteria.

Lumbar Spine Discectomy/Microdiscectomy

XVI. A lumbar discectomy/microdiscectomy is considered **medically appropriate** when the documentation meets **ANY** of the following:

- A. MRI confirms an intervertebral disc herniation concordant with the clinical presentation, and **ALL** the following
 - 1. Functional impairment attributable to radiculopathy;
 - 2. Conservative management includes **either** of the following:
 - a. No conservative management is required for microdiscectomy for **either** of the following:
 - i. Cauda equina syndrome; **or**
 - ii. Motor weakness is severe (e.g., $\leq 3/5$) or worsening over a short period of time;
 - b. All other indications, **both** of the following conservative management are met:
 - i. Physical therapy (PT) meets **all** the following:
 - a) Participation for a minimum of 6 weeks during the previous 6 months;
 - b) Failure to improve symptoms or functional ability; **and**
 - c) Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
 - ii. Pain management includes **all** the following:
 - a) Interventional pain management strategies (e.g., epidural steroid injections, facet injections, or selective nerve root blocks) have been considered, when clinically indicated;
 - b) Non-steroidal anti-inflammatory drugs (NSAIDs) for a minimum of 4 weeks, unless contraindicated; **and**
 - c) Non-pharmacologic pain management such as activity modification, rest periods, splinting, or therapeutic exercises.

Lumbar Osteotomy

XVII. Lumbar osteotomy of the spine is considered **medically appropriate** when documentation meets **ALL** the following:

- A. A spinal alignment abnormality includes **both** of the following:
 - 1. Documented for a minimum of 6 months; **and**

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2. Standing X-rays confirm the presence **of any** of the following:
 - a. Flatback deformity;
 - b. Fixed kyphotic deformity;
 - c. Fixed sagittal-plan deformity;
 - d. Moderate-to-severe sagittal malalignment;
 - e. Sagittal malalignment following prior fusion that causes functional impairment; **or**
 - f. Symptomatic spinal deformity for which surgical correction is indicated;
- B. Associated symptoms include **any** of the following:
 1. Neurologic impairment confirmed by objective findings on physical examination;
 2. Radicular symptoms that correspond with findings on diagnostic imaging;
 3. Neurogenic claudication;
 4. Chronic midline (axial) low back pain caused by the deformity;
 5. Difficulty walking, including decreased tolerance;
 6. Impaired ability to remain upright;
 7. Impaired ability to maintain a horizontal gaze due to deformity; **or**
 8. Meaningful loss of function affecting the performance of activities of daily living;
- C. Preoperative imaging includes **ALL** the following:
 1. Obtained within 3 to 6 months prior to surgery;
 2. Advanced imaging of the lumbar spine (CT or MRI);
 3. Standing X-rays document the presence of a spinal alignment abnormality; and
 4. Correlation between imaging findings, clinical findings, and the planned corrective procedure;
- D. Conservative management meets **EITHER** of the following:
 1. No conservative management is required for **any** of the following:
 - a. Cauda equina syndrome;
 - b. Bowel or bladder dysfunction caused by compression of neural structures;
 - c. Neurologic deficit continues to worsen over time; or
 - d. Neurologic decline occurring over a short interval;
 2. For all other indications, conservative pain management includes **all** the following:
 - a. Pharmacological treatment with **either** of the following, as clinically indicated:

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- i. Analgesics or anti-inflammatory medication (e.g., NSAIDs); **or**
 - ii. Corticosteroid injection(s);
 - b. Participation in **at least one (1)** of the following treatments:
 - i. Activity modification and/or avoidance of aggravating activities;
 - ii. Acupuncture;
 - iii. Biofeedback techniques;
 - iv. Cognitive behavioral therapy (CBT);
 - v. Transcutaneous electrical nerve stimulation (TENS);
 - c. Physical therapy (PT) meets **all** the following:
 - i. Participation for a minimum of 6 weeks during the previous 6 months;
 - ii. Failure to improve symptoms or functional limitations; **and**
 - iii. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
- E. If surgery is deemed medically appropriate, refer to the Policy Guidelines for Site of Care criteria.

Percutaneous Lumbar Discectomy / Disc Decompression

XVIII. Percutaneous lumbar discectomy and disc decompression procedures are considered **investigational**.

RELATED POLICIES

Corporate Medical Policy

7.01.122 Interventional Pain Management for Safety Net Members

POLICY GUIDELINE(S)

- I. Relative contraindications and preoperative risk factors include psychological and behavioral health conditions that may affect the clinical presentation of pain (e.g., depression, hypochondriasis), or resemble radiculopathy or instability (e.g., peripheral neuropathy, piriformis syndrome, myofascial pain, sacroiliac dysfunction).

Setting (inpatient, outpatient, ambulatory):

- II. Inpatient services are **medically appropriate** when documentation meets **ANY** of the following:
- A. Clinical condition for **either** cervical or lumbar spine are met:
 - 1. Cervical spine surgery for **any** of the following:
 - a. Anterior cervical procedure with increased concern for **any** of the following:

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- iv. Early post-operative airway compromise; **or**
 - v. Neck hematoma requiring admission-level monitoring;
 - b. Cervical myelopathy with **any** of the following:
 - i. Balance impairment;
 - ii. Functional decline requiring close neurological monitoring; **or**
 - iii. Gait impairment;
 - c. Complex cervical spine pathology with **any** of the following:
 - i. Infection/abscess;
 - ii. Posterior longitudinal ligament; **or**
 - iii. Tumor;
 - d. Complex deformity surgery with **any** of the following examples:
 - i. Circumferential (anterior/posterior) cervical reconstruction;
 - ii. Fixed cervical kyphosis requiring osteotomy-based correction;
 - iii. Long-segment cervical or cervicothoracic fusion for deformity correction;
 - iv. Multilevel corpectomy performed for deformity correction; **or**
 - v. Staged cervical deformity correction;
 - e. Multi-level cervical fusion or reconstruction involving 3 or more spinal levels; **or**
- 2. Lumbar spine surgery for **any** of the following:
 - a. Bowel/bladder dysfunction caused by lumbar compression;
 - b. Cauda equina syndrome;
 - c. Complex deformity surgery with **ANY** of the following examples:
 - i. Deformity reconstruction extending to the sacrum/pelvis;
 - ii. Long-segment fusion for fixed sagittal and/or coronal deformity;
 - iii. Pedicle subtraction osteotomy (PSO);
 - iv. Revision deformity reconstruction (e.g., flatback correction) requiring major realignment;
 - v. Vertebral column resection (VCR) or other three-column osteotomy;
 - d. Complex lumbar pathology which will increase perioperative risk and monitoring needs, e.g., tumor, infection, abscess;
 - e. Multi-level lumbar fusion or reconstruction involving 3 or more spinal levels;

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- f. Pre-operative immobility;
 - g. Pre-operative inability to ambulate safely, which is a barrier to safe discharge planning; **or**
 - h. Rapidly progressive motor deficit caused by lumbar nerve root compression requiring close neurological monitoring; **or**
- B. General indications for either cervical or lumbar spine surgery with **ANY** of the following:
 - 1. Anesthesia risk and age for **any** of the following:
 - a. Age is 85 years old or older; **or**
 - b. American Society of Anesthesiologists (ASA) score is 3 or greater;
 - 2. Alcohol use with history of withdrawal seizures or delirium tremens;
 - 3. Bleeding and anticoagulation risk with **any** of the following:
 - a. Abnormal coagulation labs within past 30 days;
 - b. Active anticoagulants NOT reversed;
 - c. Inherited/acquired coagulopathy;
 - d. Platelets less than 100,000 within past 30 days; **or**
 - e. Significant bleeding history;
 - 4. Cardiac disease, significant, with **any** of the following:
 - a. Congestive heart failure (ejection fraction less than 35%);
 - b. Uncontrolled arrhythmia while on antiarrhythmics; **or**
 - c. Coronary artery disease (CAD), unstable;
 - 5. Chronic kidney disease stage 4 to 5, end-stage renal disease (ESRD) or significant renal impairment with **any** of the following:
 - a. Dialysis dependent (hemodialysis or peritoneal dialysis);
 - b. eGFR is less than 30 mL/min/1.73m² within the last 30 days; **or**
 - c. Serum creatinine is more than 3 mg/dL within the last 30 days;
 - 6. Cognitive impairment, dementia, schizophrenia, bipolar disorder or recurrent major depression that increases post-operative risk;
 - 7. Functional status and anticipated post-acute needs with **ANY** of the following:
 - a. Dependent functional status (documented dependence in 2 or more basic activities of daily living (bathing, dressing, toileting, transferring, feeding)); **or**
 - b. Pre-operative evaluation indicates anticipated discharge to rehabilitation unit or

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short-term nursing facility. If no inpatient criterion is met, proceed to outpatient criteria;

8. Pulmonary disease is significant (e.g., chronic obstructive pulmonary disease, emphysema, home oxygen use);
9. Transient ischemic attack or stroke occurred within the last 3 months;

III. Outpatient services for cervical or lumbar spinal surgery when documentation meets **ALL** of the following:

- A. Inpatient criteria are not met;
- B. **ANY** of the following:
 1. American Society of Anesthesiologists (ASA) score is I or II.
 2. Discharge safety barrier documented for first 24-48 hours, eg, caregiver absent, unsafe home environment, long travel distance with limited access to urgent care.
 3. Extended outpatient recovery or monitoring anticipated with **ANY** of the following:
 - a. Pain control needed beyond routine recovery
 - b. Nausea/vomiting control
 - c. Mild respiratory monitoring
 - d. Short term neurological checks
 - e. Need for outpatient department capabilities beyond an ambulatory surgery center, (e.g., anticipated difficult airway, prolonged procedure time, prior unanticipated anesthetic or surgical complication requiring additional care)

IV. Ambulatory Surgical Center (ASC) services for cervical or lumbar spinal surgery when the documentation meets **ALL** the following

- A. American Society of Anesthesiologists (ASA) score is I or II.
- B. Outpatient services criteria are not met;
- C. Inpatient services criteria are not met;
- D. Post-discharge supervision plan is addressed with ANY of the following:
 1. A responsible adult caregiver is available for the first 24 to 48 hours;
 2. A safe post-discharge supervision plan is described for the first 24 to 48 hours;
 3. There is NO documented barrier to safe discharge planning for the first 24 to 48 hours;
- E. Procedure medical necessity criteria are met; **and**
- F. Same-day discharge is clinically appropriate based on the planned procedure and available clinical information.

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DESCRIPTION

Radiculopathy

Radiculopathy, for the purpose of this policy, is defined as the presence of pain, dysesthesia(s), or paresthesia(s) reported by the individual in a level-specific referral pattern of an involved named spinal root(s) causing significant functional limitations, (i.e., diminished quality of life and impaired age-appropriate activities of daily living).

Spinal Stenosis

Spinal stenosis refers to the narrowing of the spinal canal usually due to spinal degeneration that occurs with aging. It may also be the result of spinal disc herniation, osteoarthritis, or a tumor.

Clinically Meaningful Improvement

Clinically meaningful improvement is defined as a global assessment showing at least 50% improvement.

Cervical Degenerative Disc Disease (DDD)

Cervical DDD is a manifestation of spinal spondylosis that causes deterioration of the intervertebral discs of the cervical spine. Symptoms of cervical DDD include arm pain, weakness, and paresthesia associated with cervical radiculopathy. Disc herniation, osteophytes, kyphosis, or instability that compress the spinal cord can result in myelopathy, which is manifested by subtle changes in gait or balance, and, in severe cases, leads to weakness in the arms or legs and numbness of the arms or hands.

Anterior Cervical Discectomy and Fusion (ACDF)

ACDF is currently considered the definitive surgical treatment for symptomatic DDD of the cervical spine. The goals of ACDF are to relieve pressure on the spinal nerves (decompression) and to restore spinal column alignment and stability.

Artificial Intervertebral Disc Arthroplasty (AIDA)

AIDA, the replacement of the intervertebral disc with an artificial device is proposed as an alternative ACDF to treat symptomatic DDD. It is thought that an artificial disc would restore, not only the anatomy, but also normal mechanical function. Many designs have been proposed over the past 40 years, both total disc and disc nucleus (partial disc replacement or PDA) devices.

Total Artificial Disc

A total artificial disc replaces the entire disc, including nucleus, annulus, and end plate, and consists of a polyurethane nucleus designed to fit between two titanium alloy surfaces. An artificial disc nucleus is designed to replace only the degenerative nucleus; most of the annulus is left intact. Partial disc replacement is also referred to as a nucleus arthroplasty. Hybrid constructs or procedures that combine ACDF with cervical artificial disc replacement (C-ADR) in a single procedure are also being investigated. The intent of the hybrid construct is to avoid multilevel fusion and maintain

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cervical motion when the individual has more than one level of symptomatic cervical disc disease.

Discectomy is a surgical procedure in which one (1) or more intervertebral discs are removed. Extrusion of an intervertebral disc beyond the intervertebral space can compress the spinal nerves and result in pain, numbness, and weakness. Discectomy is intended to treat symptoms by relieving pressure on the affected nerve root(s). Discectomy can be performed by a variety of surgical approaches, with either open surgery or minimally invasive techniques.

The main alternative to open discectomy is microdiscectomy, which is a minimally invasive procedure that involves a smaller incision, visualization of the disc through a special camera, and removal of disc fragments using special instruments. Because less resection can be performed in a microdiscectomy, it is usually reserved for smaller herniations, in which a smaller amount of tissue needs to be removed. Removal of the disc itself must be done under direct visualization to be considered microdiscectomy.

The Barricaid ACD (Intrinsic Therapeutics, Woburn, MA) is implanted during a lumbar discectomy procedure, to act as a barrier to block the annular defect and reduce reherniation and reoperation. The device is a permanent implant, consisting of titanium and a flexible woven polymer fabric component intended to close an annular defect with a bone anchor to affix the device in place.

Lumbar Decompression

Narrowing/stenosis or spondylolisthesis that creates a narrowing of the spinal canal can cause chronic pain, numbness, and muscle weakness in an individual's arms or legs. Spinal decompression can be performed anywhere along the spine from the neck (cervical) to the lower back (lumbar). The procedure is performed through a surgical incision in the back (posterior). The lamina is the bone that forms the backside of the spinal canal and makes a roof over the spinal cord. Removing the lamina and other soft tissues gives more room for the nerves, relieves pressure, and allows for removal of bone spurs. Depending on the extent of stenosis, one vertebra (single-level) or more (multi-level) may be involved. There are several types of decompression surgery:

- Laminectomy is the removal of the entire bony lamina, a portion of the enlarged facet joints, and the thickened ligaments overlying the spinal cord and nerves.
- Laminotomy is the removal of a small portion of the lamina and ligaments, usually on one side. Laminotomy leaves the natural support of the lamina in place, decreasing the chance of post-operative spinal instability. In some cases, an endoscope may be used, allowing for a smaller, less-invasive incision.
- Foraminotomy is the removal of bone around the neural foramen, the space between vertebrae where the nerve root exits the spinal canal. This method is used when disc degeneration has caused the height of the foramen to collapse, resulting in a pinched nerve. It can be performed with a laminectomy or laminotomy.
- Corpectomy is the removal of one or more vertebral bodies from the spine, as well as the intervertebral discs above and below the surgical level. Lumbar corpectomy is an effective surgical option for various pathologies of the lumbar spine including trauma, infection and tumor.

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Percutaneous Image-Guided Spinal Decompression

Posterior decompression for spinal stenosis has been evolving toward increasingly minimally invasive procedures in an attempt to reduce postoperative morbidity and spinal instability.

Percutaneous image-guided minimally invasive spinal decompression using a specially designed tool kit (mild) has been proposed as an ultra-minimally invasive treatment of central lumbar spinal stenosis. Using a 6-gauge cannula clamped in place with a back plate, single-use tools (portal cannula, surgical guide, bone rongeur, tissue sculptor, trocar) are used to resect thickened ligamentum flavum and small pieces of lamina. The tissue and bone sculpting are conducted entirely under fluoroscopic guidance, with contrast media added throughout the procedure to aid visualization of the decompression. The process is repeated on the opposite side for bilateral decompression of the central canal. The devices are not intended for use near the lateral neural elements and are contraindicated for disc procedures.

Stabilization/Distracton Implants

Implanted interspinous/interlaminar blocking or spacer devices are intended to relieve symptoms of neurogenic intermittent claudication secondary to lumbar spinal stenosis, theoretically, by enlarging the neural foramen and decompressing the cauda equina. They also limit extension of the spine in the affected area when the patient stands and walks. The interspinous implant is placed between the spinous processes of the symptomatic levels of the lumbar spine, through a small incision under local or general anesthetic.

Interspinous spacers can also be classified by design as static or dynamic. Static devices, such as the X-STOP (Medtronic Spine), ExtenSure (NuVasive), and Wallis implants (Abbott Spine), are noncompressible spacers. Despite being made of different materials; the intention of the device is to maintain a constant degree of distraction between the spinous processes. As the lumbar spine is mobile, the degree of distraction varies with flexion and extension with a static device.

Other interspinous devices, such as the DIAM (Medtronic Spine) are dynamic in that they are made of elastomeric materials that function as a rubbery bumper between the bones. The DIAM system requires removal of the interspinous ligament, which is secured with laces around the upper and lower spinous processes.

Another dynamic interlaminar device option has also been developed. The Coflex device (Paradigm Spine), previously called the Interspinous U, is an axially compressible, U-shaped piece of metal that is interposed between adjacent lamina. It has two sets of wings, which are placed around the inferior and superior spinous processes. By inserting the device in a somewhat compressed or preloaded condition, the device can expand/distract further with flexion. Interlaminar stabilization with this device is performed after decompression of stenosis at the affected level(s).

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

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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.

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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

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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).

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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

Evidence for the Prestige Disc is available from the non-inferiority randomized, controlled trial (RCT) presented to the FDA, comparing the Prestige disc with fusion, and from a published report on 421 cases from the trial. Statistical non-inferiority was demonstrated on all outcome measures. Outcomes at two years were similar in both groups. Disc recipients improved more than the fusion group only on neurological status; however, the information provided about how this was evaluated is insufficient to understand its significance. Sixty-month follow-up of participants in this clinical trial was reported by J.K. Burkus et al. All participants were followed up in this FDA-regulated, post-approval study, and outcomes at 60 months were reported on approximately half of the original RCT participants. The majority of the remaining patients had not yet reached that point in their follow-up, rather than being lost to follow-up. About 18% of all participants were actually lost to follow-up at 60 months. The Neck Disability Index (NDI) improved by 38.4 points for the Prestige disc, compared to 34.1 for ACDF ($p=0.022$). For most other clinical outcomes, the Prestige disc was similar to ACDF, with no significant difference between groups in improvement in neck pain score (56.0 vs. 52.4) or arm pain score (52.5 vs. 47.7 – both, respectively). There was a trend for greater neurologic success in the Prestige disc group (95% vs. 89%, $p=0.051$). Need for additional surgery was similar between the two procedures, and there was no significant difference in the percentage of patients requiring adjacent-level surgery (2.9% vs. 4.9% for ACDF). No implant migration was observed up to 60 months. Bridging bone was observed in three of 94 patients (3.2%) with the Prestige disc. The Prestige LP artificial disc was approved by the FDA in 2014. It differs from the original Prestige cervical disc in terms of material and fixation.

J.K. Burkus and colleagues (2014) assessed the long-term safety and efficacy of cervical disc replacement with the Prestige Cervical Disc in a prospective, randomized, multi-center trial at seven years of follow-up. The study included 541 patients with single-level cervical disc disease with radiculopathy who were randomized to one of two treatment groups: 276 investigational group patients underwent anterior cervical discectomy and arthroplasty with the Prestige disc, and 265 control group patients underwent ACDF. Clinical outcomes included NDI, the 36-item short-form health survey, and neck and arm pain scores. Radiographs were assessed for angle of motion and fusion. Clinical and radiographic outcomes were evaluated pre-operatively, intra-operatively, and at 1.5, 3, 6, 12, 24, 36, 60, and 84 months post-operatively. Of the 541 patients treated, 395 patients (73%; 212 investigational and 183 control patients) completed seven years of clinical follow-up. Significant improvements achieved by 1.5 months in both groups were sustained at the seven-year mark. In the investigation group, mean NDI improvements from pre-operative scores were 38.2 and 37.5 at 60 and 84 months, respectively. In the control group, the corresponding means were 33.8 and 31.9. The differences between the investigation and control groups at the 60-month and 84-

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month periods were significant ($p = 0.014$ and 0.002 , respectively). The overall rates of maintenance or improvement in neurological status in the investigation group were significantly higher: 92.2% and 88.2% at 60 months and 84 months, respectively, compared with 85.7% and 79.7% in the control group ($p = 0.017$ and 0.011 , respectively). At 84 months, the percentage of working patients in the investigational group was 73.9%, and in the control group, 73.1%. Post-operatively, the implant effectively maintained average angular motion of 6.67° at 60 months and 6.75° at 84 months. Cumulative rates for surgery at the index level were lower ($p < 0.001$) in the investigational group (11 [4.8%] of 276) when compared with the control group (29 [13.7%] of 265) (based on life-table method), and there were statistical differences between the investigational and control groups with specific regard to the rate of subsequent revision and supplemental fixation surgical procedures. Rates for additional surgical procedures that involved adjacent levels were lower in the investigational group than in the control group (11 [4.6%] of 276 vs 24 [11.9%] of 265, respectively). The authors concluded the following: Cervical disc arthroplasty has the potential for preserving motion at the operated level, while providing biomechanical stability and global neck mobility, and may result in a reduction in adjacent-segment degeneration. The Prestige Cervical Disc maintains improved clinical outcomes and segmental motion achieved after implantation at seven-year follow-up.

Murrey et al (2008) reported the two-year follow-up of the pivotal FDA randomized non-inferiority trial to determine the safety and efficacy of ProDisc-C in comparison with ACDF. Clinical outcomes at 24-month follow-up were reported to be similar in the ProDisc-C and fusion groups for the following components: neurological success (91% vs. 88%, respectively), NDI (21.4 vs. 20.5 points), reduction in pain scores (e.g., 46 mm vs. 43 mm reduction in neck pain on a visual analog scale), and patient satisfaction (83 mm vs. 80 mm). Four-year interim follow-up of participants in this clinical trial was reported by Delamarter et al. All participants in the clinical trial were followed up in this FDA-regulated, post-approval study. At 48 months, follow-up rates for ProDisc-C and ACDF were 63% and 46.2%, respectively. It was not reported what proportion of these patients had not yet reached 48 months post-surgery or were lost to follow-up at that time point. Also included in this report was 24-month follow-up on 77% of 136 continued access patients who received the ProDisc-C after the clinical trial. Clinical outcomes were similar between the three groups, with point estimates in favor of ProDisc-C. The NDI at 48 months was 20.3 for ProDisc-C versus 21.2 for ACDF. Neurologic success was achieved in 88.9% of ProDisc-C patients, compared to 74.4% of ACDF patients ($p=0.067$). There was a cumulative incidence of additional surgeries of 2.9% (three patients) in the ProDisc-C group and 11.3% (12 patients) in the ACDF group. Two patients were converted to fusion with removal of the device; one patient had decompression with supplemental fixation without removal of the device. At 48 months, five ProDisc-C patients (7.7%) were found to have bridging bone. Five-year results of this trial were published by Zigler et al. in 2013, with follow-up rates of 72.7% for ProDisc-C and 63.5% for ACDF. Outcomes on the NDI were found to be similar (50-60% improved), along with VAS for arm pain (18 for both groups) and scores on the SF-36. VAS for neck pain was modestly improved with ProDisc-C compared to ACDF (21 vs. 30), although the proportion of patients who achieved a clinically significant improvement in neck pain was not reported. There was a lower percentage of patients with ProDisc-C who had secondary surgery at either the index or adjacent level (2.9% vs. 14.5%).

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G.M. Malham et al (2014) evaluated the clinical and radiographic outcomes in C-ADR patients using the ProDisc-C device, with a five- to nine-year follow-up. Data were collected through a prospective registry, with retrospective analysis performed on 24 consecutive patients treated with C-ADR by a single surgeon. All patients underwent single- or two-level C-ADR with the ProDisc-C device. Outcome measures included neck and arm pain (visual analogue scale), disability (NDI), complications, and secondary surgery rates. Flexion-extension cervical radiographs were performed to assess range of motion (ROM) of the device and adjacent segment disease (ASD). Average follow-up was 7.7 years. Neck and arm pain improved 60% and 79%, respectively, and NDI had an improvement of 58%. There were no episodes of device migration or subsidence. Mean ROM of the device was 6.4°. Heterotopic ossification was present in seven patients (37%). Radiographic ASD below the device developed in four patients (21%) (one single-level and three two-level C-ADR). No patient required secondary surgery (repeat operations at the index level or adjacent levels). Fourteen out of 19 patients (74%) were able to return to employment, with a median return to work time of 1.3 months. The authors concluded that the ProDisc-C device for C-ADR is a safe option for patients, providing excellent clinical outcomes, satisfactory return-to-work rates, and maintenance of segmental motion, despite radiographic evidence of heterotopic ossification and ASD on long-term follow-up. This study is limited due to being a small, single-center study that was not randomized. Also, the follow-up rate was only 79%.

Patients receiving the FDA approved BRYAN Cervical Disc system should have failed at least six weeks of non-operative treatment prior to implantation of the device. Heller and colleagues published the results of a non-inferiority trial in 2009. This multi-center RCT investigated the safety and efficacy of the device in 242 patients, compared to 221 patients undergoing an anterior cervical discectomy. At 24-month follow-up, both groups had similar improvements in clinical outcomes. Four-year follow-up was reported for 181 patients (75% of 242) who received the Bryan disc and 138 patients (62% of 223) who underwent ACDF (Sasso et al.). It was reported that 25% of AIDA and 38% of the ACDF patients failed to return for follow-up at 48 months, due, in part, to FDA and institutional review board approvals and the need for additional patient consent for the continuation study. Overall success was defined as an improvement of equal to or greater than 15 points in the NDI, neurologic improvement, no serious adverse events related to the implant or surgical implantation procedure, and no subsequent surgery or intervention that would be classified as a treatment failure. The four-year overall success rates were significantly greater in the Bryan (85.1%) than the ACDF (72.5%) group. This finding was driven largely by differences in the NDI success (90.6% of arthroplasty and 79.0% of ACDF). Neurologic success rates were not different between the groups. Arm pain improved from a baseline of 71.2 in both groups to 16.6 for the Bryan disc and 22.4 for ACDF, which was a statistically significant difference between groups. The improvement in neck pain scores was also significantly better in the Bryan disc group (from 75.4 to 20.7), compared to patients with fusion (from 74.8 to 30.6). Improvement in the SF-36 physical component score was also significantly greater in the arthroplasty group (15.8 vs. 13.1). There was no significant difference in additional surgical procedures at either the index (3.7% Bryan, 4.5% ACDF) or adjacent (4.1% Bryan, 4.1% ACDF) levels. FDA-required follow-up will continue for 10 years after the index surgery.

Phillips and colleagues reported the results of the two-year, FDA-regulated, multi-center, randomized

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non-inferiority trial of the PCM Cervical Disc in 2013. The investigator and surgical staff were not blinded to treatment assignment, and patients were informed of the treatment assignment after surgery. Out of the 416 patients who were randomized (224 PCM, 192 ACDF), 340 (82%, 189 PCM and 151 ACDF) were per protocol for the 24-month primary endpoint of overall success. Overall success was defined as at least 20% improvement in NDI; absence of reoperation, revision, or removal; maintenance or improvement in neurological status; and absence of radiographic or major complications during the 24-month follow-up period. At 24 months, overall success was 75.1% in the PCM group and 64.9% in the ACDF group, which was statistically non-inferior and superior for AIDA. There was a trend toward a greater neurological success rate in the PCM group (94.7%), compared with ACDF (89.5%, $p = 0.10$). There was no significant difference between the groups for VAS pain scores, SF-36 component scores, or implant- or surgery-related adverse events (5.2% PCM vs. 5.4% ACDF). Patients with prior fusion were included in this study. Overall success for the two sub-groups in this analysis was similar (65.4% PCM and 64.3% ACDF).

FDA approval was based on a prospective, multi-center, two-arm, randomized (1:1), unmasked, concurrently controlled, non-inferiority clinical study that compared the safety and effectiveness of the SECURE-C Cervical Artificial Disc to the standard of care (ACDF) using a plate (ASSURE Anterior Cervical Plate System) and structural allograft in treating patients with intractable symptomatic cervical disc disease (SCDD) at one level between C3 and C7. Based on the FDA conclusion, the study data indicated that, at 24 months post-operatively, the SECURE-C device is at least as effective as ACDF in terms of clinically significant improvement on the NDI and maintenance or improvement in neurological status and is statistically superior to ACDF in terms of subsequent surgeries at the index level, device-related adverse event rates, and overall success according to both composite definitions analyzed.

The Mobi-C Cervical Disc Prosthesis received FDA approval, in August 2013. Data from a single-level clinical study was the basis for the PMA approval decision. The study was a prospective, multi-center, two-arm, randomized (2:1), unmasked, concurrently controlled, non-inferiority clinical study to compare the safety and effectiveness of the Mobi-C Cervical Disc Prosthesis to the standard of care ACDF. The study data indicated that, at 24 months post-operatively, the Mobi-C device is at least as effective as the control treatment ACDF for the patient population and indications studied in this investigation, in terms of the overall success according to the protocol-specified composite primary endpoint and alternative primary endpoint definitions analyzed.

Two- and four-year results from the two-level Mobi-C IDE trial were reported by Davis et al in 2013 and 2015, respectively. In this non-inferiority trial, 225 patients received the Mobi-C device at two contiguous levels, and 105 patients received two-level ACDF. At 24 months, the follow-up rate was 98.2% for the AIDA group and 94.3% for the ACDF group. At 48 months, the follow-up rate was 89.0% for AIDA and 81.2% for the ACDF group. Both groups showed significant improvement in NDI score, VAS neck pain, and VAS arm pain from baseline to each follow-up point, with Mobi-C meeting the non-inferiority margin. Subsequent testing for superiority showed that AIDA patients had significantly greater improvement than ACDF patients in NDI and had higher NDI success rates (79.3% vs 53.4% at 48 months, $p < 0.000$) and overall success rates (66.0% vs 36.0% at 48 months) at all time points. AIDA resulted in significantly greater improvement in VAS neck pain at three and

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six months post-operatively, but not at 12, 24, 36, or 48 months. Arm pain scores did not differ between the groups. The Mobi-C group had a lower reoperation rate (4.0% vs 15.2% $p<0.000$). At 48 months, adjacent-level degeneration was observed in 41.5% of AIDA patients and 85.9% of ACDF patients with available radiographs, while 25.6% of AIDA patients showed clinically relevant heterotopic ossification.

Post hoc analysis of data from the pivotal one- and two-level Mobi-C trials was reported by Bae and colleagues in 2015. Comparison showed no significant difference between one- and two-level AIDA on clinical outcomes (NDI, VAS, SF-12), major complication rates (4.3% for one-level AIDA, 4.0% for two-level AIDA), or subsequent surgery rates (3.0% of one-level, 4.0% of two-level). Clinically relevant heterotopic ossification was observed in 23.8% of one-level patients and 25.7% of two-level patients. Huppert et al. compared outcomes between single- (n=175) and multi-level (2-4 levels, n=56) AIDA with the Mobi-C device in a prospective, multi-center study from Europe. The age of the patients was significantly higher, and the time since symptom onset was significantly longer in the multi-level group. At two years, there was no significant difference between groups for the radicular VAS, cervical VAS, or NDI. Range of motion was similar in the two groups. The overall success rate was 69% for both the single-level group and multilevel group. There was a trend for more patients in the single-level group to return to work (70% versus 46%), and for the return to work to occur sooner (4.8 months versus 7.5 months). A similar percentage of patients underwent adjacent-level surgery (2.3% for single-level and 3.6% for multi-level).

After several years of follow-up, randomized trials of all of the artificial cervical discs met non-inferiority criteria, as measured by the NDI and overall success composite outcome. Mid-term outcomes have been reported on four of the devices (Prestige ST, ProDisc-C, Mobi-C, Bryan discs). The trial results are consistent with continued non-inferiority of AIDA for all devices and lower cumulative reoperation rates at four to five years. Several recent meta-analyses and systematic reviews (Badhiwala et al 2020; Deng et al 2020; Gendreau et al 2020; Goedmakers et al 2020; Zhang et al 2020) have concluded that, while longer-term follow-up is required, mid- to long-term results identify artificial cervical disc arthroplasty as a viable treatment option for patients suffering symptomatic disc degeneration, with similar outcome results to ACDF.

Ten-year outcomes of one- and two- level Mobi-C trials were reported by Kim and colleagues in 2021. At ten years, patients continued to have significant improvement over baseline Neck Disability Index (NDI), neck and arm pain, neurologic function, and segmental range of motion (ROM). NDI and pain outcomes at the 10-year mark were significantly improved from seven-year outcomes. Segmental and global range of motion (ROM) and sagittal alignment also were maintained from seven to ten years. Clinically relevant adjacent segment pathology was not significantly different between seven and ten years. The incidence of motion restricting heterotopic ossification at the ten-year mark was not significantly different between seven years for one-level (30.7% vs. 29.6%) or two-level (41.7% vs. 39.2%) patients. Additionally, only two subsequent surgeries were reported after 7 years.

Currently, there is insufficient literature investigating the safety and efficacy of hybrid procedures. Larger sample populations and longer-term outcomes are necessary to determine the effect of this procedure on health outcomes (Grasso et al 2020; Scott-Young et al 2020; Yang et al 2020).

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Partial disc replacement systems are in the earliest stages of investigation. Partial disc replacement systems are considered investigational due to the lack of FDA approval and lack of long-term studies of these devices that demonstrate their safety and improvement on patient health outcomes over standard fusion procedures.

Tobacco Use

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. In most situations, this is considered an elective surgery; it is strongly recommended that individuals be in their best physical condition prior to undergoing surgery.

Overall, the literature suggests that lumbar discectomy provides effective clinical benefit in carefully selected patients with sciatica. There is strong evidence in favor of microdiscectomy surgery over conservative treatment at short-term follow-up. The comparative evidence on lumbar discectomy versus conservative care consists of a small number of randomized, controlled trials (RCTs) and non-randomized comparative studies. The RCT evidence is limited by a lack of high-quality trials. In most, a high percentage of patients in the conservative care group crossed over to receive surgery. This high degree of contamination reduced the ability to detect a difference when assessed by intention-to-treat (ITT) analysis. Analysis by treatment received was also flawed because of the potential noncomparability of groups, resulting from the high volume of crossover. Despite the methodologic limitations of the evidence, the RCTs are consistent in demonstrating a probable short-term benefit for surgery and a more rapid resolution of pain and disability. For the ITT analyses, there were small differences in favor of surgery, which sometimes were statistically significant and at other times, were not. In contrast, on analysis by treatment received and in the non-randomized comparative studies, there were larger differences in favor of surgery that exceeded the threshold for clinical significance. At one year or longer, outcomes from surgery and conservative care appear to be equivalent.

In 2015, Lewis and colleagues published a network meta-analysis comparing 21 different strategies for treatment of sciatica. Reviewers included a total of 122 comparative studies, 90 of which were RCTs. For disc surgery, eight studies compared surgery with conservative care (three RCTs, one quasi-RCT, four cohort studies), and 34 studies compared discectomy with alternative treatments, including other surgical variations. For the main outcome (overall recovery), surgery was better than exercise therapy, traction, and percutaneous discectomy. However, for the outcome of pain, disc surgery was not found to be better than alternative treatments.

A systematic review based on a Cochrane review was published by Jacobs et al in 2011. Reviewers evaluated surgery and conservative management of sciatica due to lumbar herniated disc. They included five (5) RCTs, four (4) of which are discussed below, with the additional trial being a 1983 trial which was excluded from this review. Reviewers assigned a low risk of bias to two of the four trials: the randomized Spine Patient Outcomes Research Trial (SPORT) and the Leiden-The Hague Spine Intervention Prognostic Study. They determined that pooling of the results was not appropriate, due to differences in study methodologies, so a qualitative synthesis of the data was performed. Reviewers concluded that surgery was likely to lead to better short-term control of leg

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pain, but that the overall quality of the body of evidence for this outcome was low. No differences were demonstrated between surgical and conservative care outcomes at one year and beyond.

Chou et al (2009) published a systematic review of the evidence for efficacy of different surgical procedures for back pain, in conjunction with development of clinical guidelines for the American Pain Society. For the comparison of discectomy with nonsurgical care, four (4) studies were included, three (3) of which are reviewed below. Studies were not pooled. Reviewers found that discectomy, performed either by open surgery or microdiscectomy, had superior outcomes for pain and disability at up to three months, but no definite benefits at longer time points.

Weinstein et al (2006) reported on SPORT, a moderately-large trial that compared discectomy to non-operative care in patients with lumbar disc herniation and included both a randomized and a non-randomized component. The RCT included 501 patients randomized to discectomy or to usual care. Discectomy was performed by the open technique, and, in some cases, the medial border of the superior facet joint was removed. Crossover was allowed during the trial; 107 of the 245 patients assigned to usual care underwent surgery, and 140 of the 245 patients assigned to surgery underwent surgery. The main outcomes were changes from baseline in the bodily pain and physical function subscales of the SF-36, and the modified Oswestry Disability Index (ODI) measured at time points up to two years. Secondary outcomes included self-reported improvement, work status, satisfaction with care, and a symptom severity measure (Sciatica Bothersomeness Index). For the primary outcomes evaluated using ITT analysis, improvements in ODI scores were superior for the surgery group at three months, but, at the one- and two-year follow-ups, there were no significant group differences on either primary outcome. For secondary outcomes, there were significant improvements for the surgery group on the Sciatica Bothersomeness Index at all time points, and satisfaction with care was superior for the surgery group at three (3) months, but not at longer time points. A secondary analysis was performed on a treatment-received basis, and this analysis showed significantly greater improvements for the surgery group at all time points. The estimated treatment effects for the SF-36 bodily pain and physical function subscales were 15.0 and 17.5, respectively, on a 0-to-100 scale. The estimated change in the ODI score was -15.0 on a 0 to 100 scale.

Devices for Annular Repair Following Spinal Surgery

For individuals who have a lumbar herniated disc and undergo discectomy, use of a bone-anchored annular closure device has been evaluated as a means to reduce reherniation and reoperation in a systematic review and RCTs. Although a key RCT found beneficial effects in terms of reoperation and reherniation, the evidence is limited by a lack of blinding. In patients with lumbar radiculopathy with disc herniation who receive discectomy and an annular closure device, the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Thome and colleagues (2018) conducted a randomized, controlled trial at 21 European centers, to determine whether use of a bone-anchored ACD, in addition to lumbar microdiscectomy, resulted in lower reherniation and reoperation rates and increased overall success, compared to lumbar microdiscectomy alone. A total of 554 patients were randomized to the ACD group (n=267) and the control (N=283). Enrolled patients were 21 to 75 years of age, with imaging confirmation of single-level disc herniation between L1 and S1, disc height 5mm or greater, who had attempted nonsurgical

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treatment for six (6) weeks or more. Results at 2 years showed symptomatic reherniation was lower in the ACD group (12% versus 25%, ($p < .001$). Reoperation was also lower in the ACD group (5% versus 13%; $p = .0001$). There were no differences in all-cause serious adverse events when ACD was compared to controls.

Three-year findings were published by Kienzler et al (2019). Results demonstrated that lumbar discectomies using ACD resulted in fewer symptomatic reherniations than discectomies without ACD implantation (15% vs. 30%), as well as fewer reoperations (11% versus 19%). Disability and quality of life scores demonstrated modest improvement in the ACD group over the control group at the three-year mark. Four-year reoperation rates were 14.4% with ACD and 21.1% with controls (Nanda et al. 2019). The study was funded by Intrinsic Therapeutics.

Five-year follow-up outcomes remained lower in patients receiving an annular closure device, with the risk of symptomatic reherniation (18.8% vs. 31.6%; $p < .001$) and reoperation (16.0% vs. 22.6%; $p = .03$) (Thome et al., 2021). None of the investigators were blind to treatment assignment, and only patients at specific sites were blind.

Cho et al (2019) published a smaller ($n = 60$) RCT conducted solely in Korea. Patients were randomized ($n = 30$ ACD and $n = 30$ conventional lumbar discectomy) and were followed for 24 months. The primary endpoint of the trial was disc height. Patients treated with an annular closure device had maintained disc height at 24-months to a greater extent than those with discectomy alone (86.3% vs. 79.2%; $p = .04$). Back pain and leg pain were similarly improved in both treatment groups, without a statistical difference between the two groups. Recurrent herniation was more common with discectomy alone. The study is limited by a small sample size, large loss to follow-up ($\leq 70\%$ at 2-year follow-up), and unclear blinding limit the validity of this trial.

Miller et al. (2020) published a systematic review and meta-analysis of the Barricaid annular device in patients at high risk for lumbar disc reherniation. Four trials (2 RCTs) were included in the meta-analysis (Cho et al 2019; Thome et al 2018; Barth et al 2016; Vukas et al 2013). The 2018 trial by Thome, summarized above, was the only trial to find a significant decrease in symptomatic reherniation or reoperation at 2 years. The other 3 trials all indicated nonsignificant reduction for both outcomes. The authors reported that overall results of the meta-analysis favored the use of an annular device for post-discectomy patients with large annular defects.

Trials investigate patient reported outcome measures for back and leg pain and often include the following measures:

Measure	Outcome Evaluated	Description	Minimal Detectable Difference (MDD) and Minimal Clinically Important Difference (MCID)

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Oswestry Disability Index (ODI)	Functional Disability and pain related to back conditions	Ten 5-point items; scores 0 (no disability) to 50 (totally disabled) or 0 to 100% of the maximum score	MDD: 8 to 10 points MCID varies; often 15 points (30 percentage points)
Zurich Claudication Questionnaire (ZCQ)	Pain, numbness, weakness, walking tolerance, and (if applicable, satisfaction with treatment results.	18 items; 3 subscales. The total score is expressed in points or as a percentage of maximum score (higher scores are worse)	MDD: 5 points MCID: Varies, sometimes defined as a detectable improvement on 2 of 3 subscales
Roland and Morris Disability Questionnaire (RMDQ)	Disability from back problems	24 items; scored 0-24 (higher scores are worse)	MCID: 30% reduction
Visual Analog Scale (VAS) for leg pain	Degree of leg pain	Patients indicate the degree of pain on a 0 to 100 scale	MDD: 5 points
Visual Analog Scale (VAS) for back pain	Degree of back pain	Patients indicated the degree of pain on a 0 to 100 scale	MDD: 2 points

The National Institutes of Health (NIH) funded the Spine Patient Outcomes Research Trial (SPORT) to study the outcomes from surgical and non-surgical management of three conditions: intervertebral disc herniation, degenerative spondylolisthesis, and lumbar spinal stenosis. Both surgical and non-surgical care of intervertebral disc herniation resulted in significant improvement in symptoms of low back and leg pain. However, the treatment effect of surgery for intervertebral disc herniation was less than that seen in individuals with degenerative spondylolisthesis and lumbar spinal stenosis. The preliminary four-year outcomes data demonstrated more significant degrees of improvement in pain levels and function with surgical versus non-surgical treatment in the chronic conditions of lumbar spinal stenosis and lumbar spinal stenosis with spondylolisthesis (Asghar2012; Weinstein 2006a; Weinstein 2006b; Weinstein 2007; Weinstein 2009).

Stabilization/Distraction Implants

Randomized, controlled trials that have compared the X-STOP device with nonoperative therapy reported greater short-term improvements in symptoms and functional status for the device groups. While this establishes that the use of this interspinous spacer can lead to better short-term symptom relief than continued conservative therapy, trials comparing this device with standard decompressive

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surgery reported that there is a higher reoperation rate for the devices, compared with decompressive surgery. In addition, case series suggest a high complication rate, thereby creating uncertainty around the risk/benefit ratio. In 2015, Medtronic discontinued sales and distribution of the X-STOP implant.

Davis et al (2013) conducted a randomized, prospective, multicenter investigational device exemption trial that aimed to evaluate the safety and efficacy of Coflex Interlaminar Stabilization compared with Posterolateral Spinal Fusion (PSF) to treat low-grade spondylolisthesis with spinal stenosis. A total of 322 patients from 21 sites in the United States were randomized 2:1 to receive decompression and coflex interlaminar stabilization or decompression and posterolateral spinal fusion with spinal instrumentation. At a minimum of two years, patient follow-up was 94.9% and 94.1% in the coflex and fusion control groups, respectively. There were no group differences at baseline for any demographic, clinical, or radiographic parameter. Coflex subjects experienced significantly shorter operative times ($p < 0.0001$), less estimated blood loss ($p < 0.0001$), and shorter length of stay ($p < 0.0001$) than fusion controls. Both groups experienced significant improvements from baseline at two years in ODI, VAS back, VAS leg, and ZCQ, with no significant group differences, with the exception of significantly greater ZCQ satisfaction with coflex at two years. FDA overall success was achieved in 62.8% of coflex subjects (59 of 94) and 62.5% of fusion controls (30 of 48) ($p = 1.000$). The reoperation rate was higher in the coflex cohort (14 [14.1%] of 99) compared with fusion (3 [5.9%] of 51, $p = 0.18$), although this difference was not statistically significant. Fusion was associated with significantly greater angulation and translation at the superior and inferior adjacent levels compared with baseline, while coflex showed no significant radiographic changes at the operative or index levels. Authors concluded, Coflex Interlaminar Stabilization is a less invasive, safe, and equally efficacious clinical solution to PSF to treat low-grade spondylolisthesis, and it appears to reduce stresses at the adjacent levels.

Schmidt et al (2018) reported on results of an RCT in patients with moderate-to-severe lumbar spinal stenosis and back pain with or without spondylolisthesis randomized to open microsurgical decompression with interlaminar stabilization using the coflex device ($n=110$) or open microsurgical decompression alone ($n=115$). The proportion of patients who met the criteria for composite clinical success at 24 months was statistically significantly higher in the coflex arm (58.4%) than in the decompression alone arm (41.7%; $p=.017$), with a treatment difference of 16.7% (95% CI, 3.1% to 30.2%). This result was driven primarily by the lower proportion of patients who received an epidural steroid injection in the coflex arm (4.5%) versus the decompression alone arm (14.8%; $p=.010$) at 24 months. The proportion of patients with ODI success among those censored for subsequent secondary interventions was not statistically significant between the treatment (75.6%) and the control arms (70.4%; $p=.47$). The difference in the proportion of patients overall who had ODI success was also not statistically significant (55% vs. 44%; $p=.091$). None of the other outcomes (including ZCQ, and VAS) showed statistically significant differences between the treatment and control arms. The study held multiple limitations, including potential bias, inconsistent reporting of analysis as intention-to treat, and most importantly, the exclusion of data on 20% of patients. Of the 254 patients that were randomized, data for only 204 were analyzed for the primary outcome

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measure. The authors did not explain the reason or approach to the missing data, or the implications on study results.

Li et al (2023) conducted a systematic review and meta-analysis to investigate evidence for the comparison of lumbar dynamic stabilization device Coflex with posterior lumbar fusion for lumbar spinal stenosis. A total of 26 studies were included and relational databases were searched up to October 2022. Lumbar dynamic stabilization device Coflex had shorter operation time (mean difference [MD] -50.77 min, 95% CI -57.24 to -44.30, $P < 0.00001$), less intraoperative blood loss (MD -122.21 mL, 95% CI -129.68 to -94.74, $P < 0.00001$), and shorter hospital stays (MD -3.21 days, 95% CI -4.04 to -2.37, $P < 0.00001$). The Japanese Orthopedic Association (JOA) score and ODI score were higher in the Coflex group during early follow-up. There was no significant difference between the two groups with the extension of follow-up time. Moreover, the Coflex group had a lower VAS score than fusion treatment ($P < 0.00001$). Finally, the Coflex group had lower total complications rate ($P = 0.03$), lower ASD rate ($P = 0.001$), and higher range of motion ($P < 0.00001$), but there was no significant difference in reoperation rate and internal fixation problems rate.

A Hayes (Hayes 2022) report assessed the use of the Coflex Interlaminar Stabilization device for the treatment of lumbar spinal stenosis in adults. An overall low-quality body of evidence suggests that the Coflex device plus decompression may result in similar outcomes compared with decompression with fusion for up to eight years and compared with decompression alone for up to two years. Adverse events were similar between the Coflex device and comparator groups, and the Coflex device may have an advantage in operative time and hospital length of stay. According to Hayes, the uncertainty associated with this body of evidence is due to the limited number of good to fair quality studies showing a distinct benefit of the Coflex device over traditional surgical interventions over the long term and a lack of definitive patient selection criteria.

Superion showed greater than 80% clinical success in all major primary endpoint components at 24 months, maintaining durability of effect through 36 months. Patients were randomized 1:1 to either the Superion system or the commercially available X-STOP device and followed for two years. The primary end point was a composite of clinically significant improvement in at least two of three ZCQ domain scores compared with baseline, freedom from reoperation, revision, removal, or supplemental fixation at the index level, freedom from epidural steroid injection or nerve block within 12 weeks of the two-year visit, freedom from rhizotomy or spinal cord stimulator at any level, and freedom from major implant or procedure-related complications. The primary noninferiority end point was met, with a Bayesian posterior probability of 0.993. However, 111 patients (28%; 54 Superion, 57 X-STOP) were withdrawn from the study during follow-up due to a protocol-defined secondary intervention. Modified intention-to-treat analysis showed clinical success (improvement, ≥ 20 mm/100) for leg pain in 76% to 77% of patients and for back pain in 67% to 68% of patients, with no significant differences between groups. At two years, ODI success was achieved in 63% of Superion patients and 67% of X-STOP patients ($p = 0.061$). Rates of complications and reoperations (44 [23.2%] Superion, 38 [18.9%] X-STOP) were similar between groups. Spinous process fractures, reportedly asymptomatic, occurred in 16.4% of Superion patients and 8.5% of X-STOP patients. Interpretation of this study is limited by the lack of a control group treated by surgical decompression (Patel et al 2015).

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While other static and dynamic interspinous distraction and interlaminar stabilization implants are currently being studied in clinical trials, the long-term safety and efficacy of these devices are not yet known. The Wallis System (originally from Abbott Spine; currently from Zimmer Spine) was introduced in Europe in 1986. The first-generation Wallis implant was a titanium block; the second-generation device is composed of a plastic-like polymer that is inserted between adjacent processes and held in place with a flat cord that is wrapped around the upper and lower spinous processes. In 2014, Marsh and colleagues reported on a RCT that compared decompression alone (n=30) versus decompression with a Wallis implant (n=30). Follow-up at an average of 40 months showed no significant differences between the groups in VAS for back or leg pain or in the ODI. Improvement in back pain was 3.5 of 10 with the Wallis implant, compared with 2.7 without ($p<0.192$). Improvement in ODI was 19.3 with the Wallis implant, compared to 10.6 without ($p=0.079$). Additional study in a larger population is needed.

Xin and colleagues conducted a meta-analysis of randomized controlled trials (2023) to assess the safety and effectiveness of interspinous spacer (IS) use in patients with lumbar spinal stenosis compared to decompressive surgery. Eight studies representing 852 individuals were included in the meta-analysis which demonstrated that IS use was comparable to decompressive surgery in terms of hospital stay, blood loss, spinous process fracture, disc height decrease, VAS score, ODI score, ZCQ symptom severity, however, had a higher rate of reoperation than decompression surgery. The authors concluded that given IS is a novel technique, further well-designed studies with longer term follow up are needed to fully evaluate its efficacy and safety.

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 (2001) reported that smoking negatively affects fusion mass and results in lower bone mineral density, particularly in the spine.

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

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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.

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

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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 was 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

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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 ($+3.8^\circ$; $p = 0.06$). Considering only hypo-kyphotic patients, a significant difference in TK change resulted in POs patients ($+6.6^\circ$; $p < 0.01$), while a non-significant TK change resulted in normo-kyphotic patients ($+0.2^\circ$; $p = 0.96$). 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

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comparative studies, with better stratified patients according to pre-operative TK and more precise measurement methods, will further shed 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 patients 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 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.

Cummins 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

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(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

A 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 (2000) 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

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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.

Ozgun 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.

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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

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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

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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)

North American Spine Society (NASS) coverage policy for Cervical Artificial Disc Replacement from 2015 (revised Feb 2024) indicate that cervical artificial disc replacement may be indicated for the following diagnoses with qualifying criteria, when appropriate:

- Radiculopathy related to nerve root compression from one- or two- level degenerative disease (either herniated disc or spondylotic osteophyte) from C3-7 in the following scenarios:
 - o Persistent symptoms despite at least 6 weeks of nonoperative management.
 - o Progressive or functionally limiting weakness correlating with the compressed nerve root.
 - o Inability to perform normal work duties or necessary activities of daily living because of

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severity of symptoms, despite nonoperative management.

- Myelopathy or myeloradiculopathy related to central spinal stenosis from one- or two-level degenerative disc disease from (either herniated disc or spondylotic osteophyte) C3-4.
- There is no significant evidence at this time to support the following:
 - o Its use for 3 or more levels.
 - o Its use for isolated axial neck pain. Neck pain, in addition to radiculopathy/myeloradiculopathy, is not an exclusionary criterion. There is early evidence for use in treatment of adjacent segment disease following an index fusion.

The American Academy of Orthopedic Surgeons (AAOS) 2010 strongly recommends avoiding use of and exposure to tobacco products, due to the severe and negative impact on the musculoskeletal system, including the bones, muscles, tendons, and ligaments.

According to the American Pain Society (APS), decompressive laminectomy may be an acceptable option for individuals experiencing disabling and persistent leg pain due to spinal stenosis, either with or without degenerative spondylolisthesis. The APS reports that decompressive laminectomy is associated with moderate benefits, compared to non-surgical therapy, through one (1) to two (2) years, though the effects of the procedure appear to diminish with long-term follow-up. Although individuals, on average, do not worsen without surgery, improvements are less than those observed in individuals with radiculopathy due to herniated lumbar disc. The APS guidelines indicate that there is insufficient evidence to determine whether laminectomy with fusion is more effective than laminectomy without fusion. The authors recommended that shared decision-making regarding surgery include a specific discussion about moderate/average benefits, which appear to decrease over time, in affected individuals who undergo surgery (Chou 2009).

In 2011, the North American Spine Society (NASS) issued evidence-based guidelines on the diagnosis and treatment of degenerative lumbar spinal stenosis. The guidelines stated that patients with mild symptoms of lumbar spinal stenosis are not considered surgical candidates; however, decompressive surgery was suggested to improve outcomes in patients with moderate-to-severe symptoms of lumbar spinal stenosis (grade B recommendation). NASS also indicated that current evidence was insufficient to recommend for or against the placement of interspinous process spacing devices to treat spinal stenosis. A 2013 update of this guideline from the Degenerative Lumbar Spinal Stenosis Work Group of the NASS notes the same recommendations.

In 2018, NASS published specific coverage policy recommendations on the lumbar interspinous device without fusion and with decompression. NASS recommended that:

"Stabilization with an interspinous device without fusion in conjunction with laminectomy may be indicated as an alternative to lumbar fusion for degenerative lumbar stenosis with or without low-grade spondylolisthesis (less than or equal to 3 mm of anterolisthesis on a lateral radiograph) with qualifying criteria when appropriate:

1. Significant mechanical back pain is present (in addition to those symptoms associated with neural compression) that is felt unlikely to improve with decompression alone. Documentation

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should indicate that this type of back pain is present at rest and/or with movement while standing and does not have characteristics consistent with neurogenic claudication.

2. A lumbar fusion is indicated post-decompression for a diagnosis of lumbar stenosis with a Grade 1 degenerative spondylolisthesis as recommended in the NASS Coverage Recommendations for Lumbar Fusion.
3. A lumbar laminectomy is indicated as recommended in the NASS Coverage Recommendations for Lumbar Laminectomy.
4. Previous lumbar fusion has not been performed at an adjacent segment.
5. Previous decompression has been performed at the intended operative segment.

Interspinous devices are NOT indicated in cases that do not fall within the above parameters. In particular, they are not indicated in the following scenarios and conditions:

- Degenerative spondylolisthesis of Grade 2 or higher.
- Degenerative scoliosis or other signs of coronal instability.
- Dynamic instability as detected on flexion-extension views demonstrating at least 3 mm of change in translation.
- Iatrogenic instability or destabilization of the motion segment.
- A fusion is otherwise not indicated for a Grade 1 degenerative spondylolisthesis and stenosis as per the NASS Coverage Recommendations for Lumbar Fusion.
- A laminectomy for spinal stenosis is otherwise not indicated as per the NASS Coverage Recommendations for Lumbar Laminectomy."

In 2022, NASS issued coverage policy recommendations related to lumbar decompression and included the following diagnoses with qualifying criteria: Lumbar spinal stenosis (primary or recurrent); Synovial facet cyst associated with either radiculopathy or neurogenic claudication; cauda equina syndrome caused by prominent compression of the thecal sac in the lumbar spine, with resultant saddle anesthesia, new onset loss of bowel/bladder function, or new onset of lower extremity neurologic deficits not explained by a more proximal lesion; tumor; fracture; epidural/subdural hematoma, infection, degenerative/isthmic spondylolisthesis; or additional diagnoses requiring nondecompressive laminectomies/laminotomies or other dorsal approaches.

In 2022, the American Society of Pain and Neuroscience (ASPN) (Deer et al) published a consensus guideline outlining best practices for minimally invasive lumbar spinal stenosis treatment. The following recommendation was provided with regard to the use of percutaneous image-guided lumbar decompression: "Percutaneous image-guided decompression should be considered for the treatment of symptomatic lumbar spinal stenosis with the presence of neurogenic claudication, with less than or equal to a grade 2 spondylolisthesis, and with a ligamentum flavum hypertrophy greater than or equal to 2.5mm." Grade A; Level of certainty high; Level of evidence 1-A.

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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

The U.S. Food and Drug Administration (FDA) regulates cervical artificial discs as medical devices. All cervical artificial discs including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: <https://www.fda.gov/medical-devices> [accessed 2026 May 18]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: [Medical Device Recalls](#) [accessed 2026 May 18]

The Mobi-C Cervical Disc Prosthesis received FDA approval in August 2013. is indicated for use in skeletally mature patients for reconstruction of the disc at either one or two levels level from C3-C7 following discectomy for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to diseased discs at one level or two adjacent levels.

The PCM Cervical Disc (NuVasive), which received five-year FDA approval in October 2012. Continued FDA approval is contingent on the submission of annual reports, which should include the number of devices sold, analysis of all explanted discs, and seven-year follow-up of the pre-market cohort with an evaluation of overall success. In addition, NuVasive will conduct 10-year enhanced surveillance of device-related adverse events.

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The SECURE-C Artificial Cervical Disc received FDA approval 2013 is intended to be used in skeletally mature patients to replace a cervical disc (from C3 to C7) following removal of the disc for conditions that result from a diseased or bulging disc (intractable radiculopathy or myelopathy) at only one level.

The Bryan Cervical Disc System received FDA approval based on PMA clearance in May 2009. Based on the information provided from the manufacturer and the FDA premarket approval, the device is indicated in skeletally mature patients for reconstruction of the discs from C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy.

ProDisc-C received approval from the FDA in 2007 based on a pre-market approval application (PMA).

Medtronic received FDA approval to market its Prestige Cervical Disc System in July 2007 for use in skeletally mature patients, for reconstruction of the discs from C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy.

The U.S. Food and Drug Administration (FDA) regulates annular repair devices as medical devices. All annular repair devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: <https://www.fda.gov/medical-devices> [accessed 2026 May 19]

Barricaid received FDA pre-market approval in February 2019. FDA indicated use is for reducing the incidence of reherniation, and reoperation in skeletally mature patients with radiculopathy (with or without back pain) attributed to a posterior or posterolateral herniation, and confirmed by history, physical examination and imaging studies which demonstrate neural compression using MRI to treat a large annular defect (between 4-6 mm tall and between 6-10 mm wide) following a primary discectomy procedure (excision of herniated intervertebral disc) at a single level between L4 and S1.

Other FDA approved closure devices Xclose Tissue Repair System (Anulex Technologies, Inc. Minnetonka, MN) approved in August 2006, and the Inclose Surgical Mesh Ssystem, approved in August 2005.

Three interspinous and interlaminar stabilization and distraction devices have been approved by the FDA, the X-STOP (Medtronic), Coflex (paradigm Spine), and Superion Indirect Decompression System (Vertiflex- acquired by Boston Scientific).

St. Francis Medical Technologies/Medtronic Spine LLC received FDA premarket approval for the X-STOP Interspinous Process Decompression (IPD) System on November 21, 2005, for use in patients who are moderately impaired in physical function and have a confirmed diagnosis of spinal stenosis, are 50 years of age or older, and experience relief in flexion from their leg/groin/buttock pain. No patient in the FDA study had a spondylolisthesis score greater than one. The device is approved for implantation at one or two lumbar levels, in patients for whom operative treatment is indicated at no more than two levels.

The Coflex Interlaminar Technology implant (Paradigm Spine) was approved by the FDA in October 2012 (P110008). The Coflex is indicated for use in one- to two-level lumbar stenosis from L1 to L5 in skeletally mature patients with at least moderate impairment in function, who experience relief in

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flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least six months of non-operative treatment. The Coflex is intended to be implanted midline between adjacent lamina of one to two contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s).

The FDA lists the following contraindications to use of the device:

1. "Prior fusion or decompressive laminectomy at any index lumbar level
2. Radiographically compromised vertebral bodies at any lumbar level(s) caused by current or past trauma or tumor (e.g. compression fracture)
3. Sever facet hypertrophy that requires extensive bone removal which would cause instability
4. Grade II or greater spondylolisthesis
5. Isthmic spondylolisthesis or spondylolysis (pars fracture)
6. Degenerative lumbar scoliosis (Cobb angle greater than 25°)
7. Osteoporosis
8. Back or leg pain of unknown etiology
9. Axial back pain only, with no leg, buttock or groin pain
10. Morbid obesity defined as a body mass index >40
11. Active or chronic infection- systemic or local
12. Known allergy to titanium alloys or MR contrast agents
13. Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction."

The FDA labeling contains multiple precautions and the following warning: "Data has demonstrated that spinous process fractures can occur with coflex implantation."

Vertiflex's Superion interspinous spacer system received FDA premarket approval in May 2015 for the treatment of moderate stenosis. Per the manufacturer, FDA approval was based on a 470-patient, multi-center, investigational device clinical trial that demonstrated safety, effectiveness, and a favorable risk-benefit profile (Patel et al. 2015)

Other devices that are not FDA approved are being investigated in clinical trials in both the U.S. and Europe, including The DIAM Spinal Stabilization System (Medtronic Sofamor Danek), In-Space (Synthes), FLEXUS (Globus Medical), ExtendSure, CoRoent (both from NuVasive), The NL-Prow (Non-Linear Technologies), Aperius (Medtronic Spine), and Falena (Mikail).

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- 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
Cervical Spine Surgery	
22210	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; cervical
22220	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; cervical
22510	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic
22526	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level
22548	Arthrodesis, anterior transoral or extraoral technique, clivus-C1-C2 (atlas-axis), with or without excision of odontoid process
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2
22554	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2
22590	Arthrodesis, posterior technique, craniocervical (occiput-C2)
22595	Arthrodesis, posterior technique, atlas-axis (C1-C2)
22600	Arthrodesis, posterior or posterolateral technique, single interspace; cervical below C2 segment
22800	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments
22802	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments
22804	Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments

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Code	Description
22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments
22810	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments
22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments
22818	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); single or 2 segments
22819	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); 3 or more segments
22843	Posterior segmental instrumentation (eg, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments (List separately in addition to code for primary procedure)
22849	Reinsertion of spinal fixation device
22850	Removal of posterior nonsegmental instrumentation (e.g., Harrington rod)
22852	Removal of posterior segmental instrumentation
22855	Removal of anterior instrumentation
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyctomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
63001	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), 1 or 2 vertebral segments; cervical
63015	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), more than 2 vertebral segments; cervical
63020	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, cervical

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Code	Description
63032	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; with repair of annular defect by implantation of bone-anchored annular closure device, including all imaging guidance, 1 interspace, lumbar (List separately in addition to code for primary procedure)
63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar (List separately in addition to code for primary procedure)
63040	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; cervical
63045	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; cervical
63050	Laminoplasty, cervical, with decompression of the spinal cord, 2 or more vertebral segments;
63051	Laminoplasty, cervical, with decompression of the spinal cord, 2 or more vertebral segments; with reconstruction of the posterior bony elements (including the application of bridging bone graft and non-segmental fixation devices [e.g., wire, suture, mini-plates], when performed)
63075	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophylectomy; cervical, single interspace
63081	Vertebral corpectomy (vertebral body resection), partial or complete, anterior approach with decompression of spinal cord and/or nerve root(s); cervical, single segment
63185	Laminectomy with rhizotomy; 1 or 2 segments
63190	Laminectomy with section of spinal accessory nerve
63250	Laminectomy for excision or occlusion of arteriovenous malformation of spinal cord; cervical
63300	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; extradural, cervical
63304	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; intradural, cervical

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Code	Description
0219T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical
0274T	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect im-age guidance (e.g., fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; cervical or thoracic
Lumbar Spine	
22207	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (eg, pedicle/vertebral body subtraction); lumbar
22214	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; lumbar
22224	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; lumbar
22511	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral
22514	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (e.g., kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar
22526	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace
22612	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)

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Code	Description
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar
22800	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments
22802	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments
22804	Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments
22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments
22810	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments
22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments
22819	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); 3 or more segments
22849	Reinsertion of spinal fixation device
22850	Removal of posterior nonsegmental instrumentation (eg, Harrington rod)
22852	Removal of posterior segmental instrumentation
22855	Removal of anterior instrumentation
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level

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Code	Description
22869	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level
62287	Decompression, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle-based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar.
62330	Decompression, percutaneous, with partial removal of the ligamentum flavum, including laminotomy for access, epidurography, and imaging guidance (ie, CT or fluoroscopy), bilateral; one interspace, lumbar
62380	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar
63005	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), 1 or 2 vertebral segments; lumbar, except for spondylolisthesis
63011	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), 1 or 2 vertebral segments; sacral
63012	Laminectomy with removal of abnormal facets and/or pars interticularis with decompression of cauda equina and nerve roots for spondylolisthesis, lumbar (Gill type procedure)
63017	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), more than 2 vertebral segments; lumbar
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar
63042	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; lumbar
63047	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; lumbar

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Code	Description
63056	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (e.g., herniated intervertebral disc), single segment; lumbar (including transfacet, or lateral extraforaminal approach) (e.g., far lateral herniated intervertebral disc)
63087	Vertebral corpectomy (vertebral body resection), partial or complete, combined thoracolumbar approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic or lumbar; single segment
63090	Vertebral corpectomy (vertebral body resection), partial or complete, transperitoneal or retroperitoneal approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic, lumbar, or sacral; single segment
63102	Vertebral corpectomy (vertebral body resection), partial or complete, lateral extracavitary approach with decompression of spinal cord and/or nerve root(s) (e.g., for tumor or retropulsed bone fragments); lumbar, single segment
63185	Laminectomy with rhizotomy; 1 or 2 segments
63190	Laminectomy with rhizotomy; more than 2 segments
63191	Laminectomy with section of spinal accessory nerve
63200	Laminectomy, with release of tethered spinal cord, lumbar
63252	Laminectomy for excision or occlusion of arteriovenous malformation of spinal cord; thoracolumbar
63303	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; extradural, lumbar or sacral by transperitoneal or retroperitoneal approach
63307	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; intradural, lumbar or sacral by transperitoneal or retroperitoneal approach
0202T	Posterior vertebral joint(s) arthroplasty (eg, facet joint[s] replacement), including facetectomy, laminectomy, foraminotomy, and vertebral column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine
0221T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; lumbar

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Code	Description
C9757	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar
S2350	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; lumbar, single interspace

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
Multiple	

REFERENCES

Alves O. Cervical total disc replacement: expanded indications. Neurosurg Clin N Am. 2021;32(4):437-448.

American Academy of Orthopaedic Surgeons. Preoperative risk factors [Internet]. 2024 [cited 2026 May]. Available from: <https://www.aaos.org/quality/quality-programs/quality-toolkits/smoking/>

American Geriatrics Society Expert Panel et al. American Geriatrics Society abstracted clinical practice guideline for postoperative delirium in older adults. J Am Geriatr Soc. 2015;63(1):142-150.

American Society of Anesthesiologists. Statement on ASA physical status classification system. Anesthesiol Open. 2026. Available from:

Medical Policy: Spine Procedures for Managed Medicaid (MMC), Health and Recovery Plan (HARP), Child Health Plus (CHP), and Essential Plan (EP) Members

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https://journals.lww.com/anesthesiologyopen/fulltext/2026/04000/american_society_of_anesthesiologists_statement_on.2.aspx

Auerbach AD. Preoperative evaluation. In: Goldman L, Schafer AI, editors. Goldman-Cecil Medicine. 27th ed. Philadelphia (PA): Elsevier; 2024. p. 2659-2668.e1.

Austevoll IM, et al. Decompression with or without fusion in degenerative lumbar spondylolisthesis. *N Engl J Med*. 2021;385:526-538.

Badhiwala JHA, et al. Evaluation and treatment of degenerative cervical myelopathy. In: Winn HR, editor. Youmans and Winn Neurological Surgery. 8th ed. Philadelphia (PA): Elsevier; 2023. p. 2517-2525.e4.

Bartleson JD. Mechanical and other lesions of the spine, nerve roots, and spinal cord. In: Goldman L, Schafer AI, editors. Goldman-Cecil Medicine. 27th ed. Philadelphia (PA): Elsevier; 2024. p. 2392-2407.

Benesch C, et al. Perioperative neurological evaluation and management to lower the risk of acute stroke in patients undergoing noncardiac, nonneurological surgery: a scientific statement from the American Heart Association/American Stroke Association. *Circulation*. 2021;143(19):407-409.

Boddapati V, et al. Are outpatient three- and four-level anterior cervical discectomies and fusion safe? *Spine J*. 2021;21(9):231-238.

Boss S, et al. Vertebroplasty and kyphoplasty. *Phys Med Rehabil Clin N Am*. 2022;33(2):425-453.

Bullock L, et al. Cauda equina syndrome. *Orthop Clin North Am*. 2022;53(2):247-254.

Butler AJ, et al. Discectomy. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 [cited 2026 May]. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK544281/>

Callanan G, et al. Cervical total disc replacement: long-term outcomes. *Neurosurg Clin N Am*. 2021;32(4):461-472.

Chang L, et al. Posterior thoracic and lumbar instrumentation. In: Winn HR, editor. Youmans and Winn Neurological Surgery. 8th ed. Philadelphia (PA): Elsevier; 2023. p. 2830-2830.e14.

Chen KT, et al. Current indications for spinal endoscopic surgery and potential for future expansion. *Neurospine*. 2023;20(1):33-42.

Cheng J, et al. Neck pain. In: Firestein GS, Budd RC, editors. Firestein & Kelley's Textbook of Rheumatology. Philadelphia (PA): Elsevier; 2024. p. 697-713.

Chowdhury SR, et al. Chronic kidney disease and anaesthesia. *BJA Educ*. 2022;22(8):321-328.

Congress of Neurological Surgeons. Systematic review and evidence-based guidelines for perioperative spine: preoperative surgical risk assessment [Internet]. 2021 [cited 2026 May]. Available from: <https://www.cns.org/guidelines/browse-guidelines-detail/2-preoperative-surgical-risk-assessment>

Connor M, et al. Tobacco use is associated with increased 90-day readmission among patients

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undergoing surgery for degenerative spine disease. 2022;12(5):787-794.

DePaola K, et al. Pediatric spine disorder. *Pediatr Clin North Am*. 2020;67(1):185-204.

Diltz ZR, et al. Perioperative management of comorbidities in spine surgery. *Orthop Clin North Am*. 2023;54(3):349-358.

Ding L, et al. Safety of outpatient vs inpatient anterior cervical discectomy and fusion: a systematic review and meta-analysis. *PeerJ*. 2025;13:e20045.

Donnally CJ III, et al. Cervical myelopathy. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 [cited 2026 May]. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK482312/>

Foreman M, et al. Management considerations for cervical corpectomy: updated indications and future directions. *Life (Basel)*. 2024;14(6):651.

Franco D, et al. Lumbar total disc replacement. *Neurosurg Clin N Am*. 2021;32(4):511-519.

Gadjradj PS, et al. Decompression alone versus decompression with fusion in patients with lumbar spinal stenosis with degenerative spondylolisthesis: a systematic review and meta-analysis. *Eur Spine J*. 2023;32(3):1054-1067.

Gardocki RJ, et al. Degenerative disorders of the cervical spine. In: Azar FM, Beaty JH, editors. *Campbell's Operative Orthopaedics*. 14th ed. Philadelphia (PA): Elsevier; 2021. p. 1682-1718.e5.

Gardocki RJ, et al. Degenerative disorders of the thoracic and lumbar spine. In: Azar FM, Beaty JH, editors. *Campbell's Operative Orthopaedics*. 14th ed. Philadelphia (PA): Elsevier; 2021. p. 1719-1801.e9.

Goldberg JL, et al. Algorithmic patient selection for minimally invasive versus open lumbar interbody fusion surgery. *Neurosurg Clin N Am*. 2023;34(4):599-607.

Grant LA. Skeletal trauma. In: Grant LA, Griffin N, editors. *Grainger & Allison's Diagnostic Radiology Essentials*. 3rd ed. Philadelphia (PA): Elsevier; 2025. p. 500-543.

Groves ML, et al. Neurosurgical evaluation and management of adults with achondroplasia. *Neurosurg Clin N Am*. 2022;33(1):25-35.

Hagan MJ, et al. Spinal cord injury in adult and pediatric populations. *Interdiscip Neurosurg*. 2022;29:101594.

Hammad AM, et al. Vertebral body tethering: an alternative to posterior spinal fusion in idiopathic scoliosis? *Front Pediatr*. 2023;11:1133049.

Hill AD, et al. Spinal cord disorders. In: *Rosen's Emergency Medicine: Concepts and Clinical Practice*. 10th ed. Philadelphia (PA): Elsevier; 2023. p. 1290-1300.e2.

Howell HJ, et al. Evidence-based guidelines for the surgical management of degenerative lumbar spondylolisthesis. *Neurosurg Clin N Am*. 2026;37(1):1-25.

Huynh K, et al. Airway management in acute hematoma formation following anterior cervical spine surgery. *Orthop Rev (Pavia)*. 2024;16(3):1-4.

Medical Policy: Spine Procedures for Managed Medicaid (MMC), Health and Recovery Plan (HARP), Child Health Plus (CHP), and Essential Plan (EP) Members

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Hutchins TA, et al. ACR appropriateness criteria: low back pain. J Am Coll Radiol. 2021;18(11 Suppl):S361-S379.

Jabbour SM, et al. Surgery in the geriatric patient. In: Cameron JL, Cameron AM, editors. Current Surgical Therapy. 15th ed. Philadelphia (PA): Elsevier; 2026. p. 1367-1373.

Joiner EF, et al. Posterior-based osteotomies for deformity correction. Neurosurg Clin N Am. 2023;34(4):555-566.

Kerolus MG, et al. Posterior percutaneous and minimally invasive approaches to decompression and arthrodesis of the cervical spine. In: Benzel's Spine Surgery. 5th ed. Philadelphia (PA): Elsevier; 2022. p. 949-956.e3.

Khalid SI, et al. The impact of smoking cessation therapy on lumbar fusion outcomes. World Neurosurg. 2022;164:e119-e126.

Lee BS, et al. Management of cervical spondylotic myelopathy. In: Schmidek and Sweet: Operative Neurosurgical Techniques. 7th ed. Philadelphia (PA): Elsevier; 2022. p. 1650-1663.e3.

Lin BHH, et al. Cervical arthroplasty for myelopathy: a systematic review. Semin Spine Surg. 2023;35(1):101012.

Maiga A, et al. Emergency care of neurologic injuries. In: Sabiston Textbook of Surgery. 22nd ed. Philadelphia (PA): Elsevier; 2026. p. 436-461.e2.

Martirosyan NL, et al. Anterior and lateral lumbar instrumentation. In: Winn HR, editor. Youmans and Winn Neurological Surgery. 8th ed. Philadelphia (PA): Elsevier; 2023. p. 2822-2829.e2.

McGrath K, et al. Degenerative spine disorders and multiple sclerosis. Neurol Clin. 2022;40(2):249-259.

Metkar US, et al. Spinal alignment and surgical correction in the aging spine and osteoporotic patient. N Am Spine Soc J. 2024;19:100531.

Miller JK, et al. Cauda equina syndrome. Br J Hosp Med (Lond). 2023;84(11):1-7.

National Health Service England. National suspected cauda equina syndrome pathway [Internet]. 2023 [cited 2026 May]. Available from: https://gettingitrightfirsttime.co.uk/surgical_specialties/spinal-surgery/

Nunley P, et al. Cervical total disc replacement: indications and technique. Neurosurg Clin N Am. 2021;32(4):419-424.

Oshlag B, et al. Neck injuries. Prim Care. 2020;47(1):165-176.

Parikh S, et al. Perioperative blood management. J Clin Med. 2025;14(11):3847.

Payares-Lizano M, et al. Pediatric orthopedic examination. Pediatr Clin North Am. 2020;67(1):1-21.

Renehan J, et al. Cervical laminoplasty. Semin Spine Surg. 2020;32(1):100777.

Resnick DK, et al. Update on spinal fusion. Neurol Clin. 2022;40(2):261-268.

Medical Policy: Spine Procedures for Managed Medicaid (MMC), Health and Recovery Plan (HARP), Child Health Plus (CHP), and Essential Plan (EP) Members

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Richardson BM, et al. Common pediatric musculoskeletal issues. *Prim Care*. 2021;48(3):417-428.

Rossi V, et al. Cervical spine surgery: arthroplasty versus fusion versus posterior foraminotomy. *Neurosurg Clin N Am*. 2021;32(4):483-492.

Saadeh YS, et al. Evaluation and treatment of degenerative lumbar spondylolisthesis. In: Winn HR, editor. *Youmans and Winn Neurological Surgery*. 8th ed. Philadelphia (PA): Elsevier; 2023. p. 2510-2516.e2.

Seiber FE, et al. American Society of Anesthesiologists practice advisory for perioperative care of older adults scheduled for inpatient surgery. *Anesthesiology*. 2025;142(1):122-151.

Seshadri A, et al. Prevention of alcohol withdrawal syndrome in the surgical ICU: an American Association for the Surgery of Trauma Critical Care Committee clinical consensus document. *Trauma Surg Acute Care Open*. 2022;7:e001010.

Simplify Cervical Artificial Disc - P200022 [Internet]. U.S. Food and Drug Administration; 2020 [cited 2026 May]. Available from: <https://www.fda.gov/medical-devices/recently-approved-devices/simplify-cervical-artificial-disc-p200022>

Sorour O, et al. Enhanced recovery after surgery protocols and spinal deformity. *Neurosurg Clin N Am*. 2023;34(4):677-687.

Tavanaei R, et al. Postoperative complications of anterior cervical discectomy and fusion: a comprehensive systematic review and meta-analysis. *N Am Spine Soc J*. 2025;21:100596.

Thompson A, et al. 2024 AHA/ACC/ACS/ASNC/HRS/SCAI/SCCT/SCMR/SVM guideline for perioperative cardiovascular management for noncardiac surgery. *Circulation*. 2024;150(19):e351-e442.

Valero-Moreno F. Radiculopathy from foraminal stenosis. In: Chaichana KL, Quiñones-Hinojosa A, editors. *Comparative Management of Spine Pathology*. Philadelphia (PA): Elsevier; 2023. p. 88-93.

Wang TY, et al. Preoperative optimization for patients undergoing elective spine surgery. *Clin Neurol Neurosurg*. 2021;206:106445.

Warner WC, et al. Scoliosis and kyphosis. In: Azar FM, Beaty JH, editors. *Campbell's Operative Orthopaedics*. 14th ed. Philadelphia (PA): Elsevier; 2021. p. 1998-2196.e28.

Webb CW, et al. Lumbar spinal stenosis: diagnosis and management. *Am Fam Physician*. 2024;109(4):350-359.

Weinberg DS, et al. Cervical laminoplasty: indication, technique, complications. *J Spine Surg*. 2020;6(1):290-301.

Williams KD. Fractures, dislocations, and fracture-dislocations of the spine. In: Azar FM, Beaty JH, editors. *Campbell's Operative Orthopaedics*. 14th ed. Philadelphia (PA): Elsevier; 2021. p. 1832-1923.

William J, et al. Degenerative cervical myelopathy. *Orthop Clin North Am*. 2022;53(4):509-521.

Wolfa CE, et al. Posterior subaxial and cervicothoracic instrumentation. In: Winn HR, editor. *Youmans and Winn Neurological Surgery*. 8th ed. Philadelphia (PA): Elsevier; 2023. p. 2807-2814.e2.

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Yoon WW, et al. Herniated discs: when is surgery necessary? EFORT Open Rev. 2021;6(6):526-530.

Zhang AS, et al. Cervical myelopathy: diagnosis, contemporary treatment, and outcomes. Am J Med. 2022;135(4):435-443.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

[Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis \(NCD 150.13\)](#)
[accessed 2026 Sep 10]

[Thermal Intradiscal Procedures \(TIPs\) \(NCD 150.11\)](#) [accessed 2026 Sep 10]

[Laser Procedures \(NCD 140.5\)](#) [accessed 2026 Sep 10]

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- 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

09/17/26

Date	Summary of Changes
01/01/27	• Original effective date
09/17/26	• New Policy