MEDICAL POLICY

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

POLICY STATEMENT

Primary Lumbar Decompression for Neurogenic Claudication

I. Based upon our criteria and assessment of the peer-reviewed literature, an initial primary lumbar decompression has been medically proven to be effective for the treatment of neurogenic claudication and, therefore, is considered **medically appropriate** for spinal stenosis/spondylolisthesis, when **ALL** of the following criteria are met:

A. Subjective symptoms include **BOTH** of the following:
1. 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**
2. Pain, cramping, weakness, or tingling in the lower back, buttock(s), and leg(s) brought about by walking or positions that cause thecal sac or nerve root compression (e.g., standing, extension) and **EITHER** of the following occur:
   a. Symptoms worsen with standing and/or walking; **or**
   b. Symptoms are alleviated with sitting and/or forward flexion;

AND

B. The patient has not experienced clinically meaningful improvement with the following unless contraindicated:
1. Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for six (6) weeks; **and**
2. Prescription strength analgesics, steroids, gabapentinoids, or NSAIDS for six (6) weeks; **or**
3. Epidural steroid injection(s)/selective nerve root block(s);

AND

C. MRI/CT shows neural structure compression at the requested level (s) that is concordant with the individual's symptoms and physical examination findings and that is caused by **ANY** of the following:
1. Herniated disc(s) (retained disc material or a recurrent disc herniation);
2. Synovial cyst or arachnoid cyst;

3. Central/lateral/foraminal stenosis; **or**
4. Osteophytes

AND

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

AND

F. Documentation of nicotine-free status as evidenced by **EITHER** of the following:
   1. Patient is a never-smoker; **or**
   2. Patient has refrained from smoking, use of smokeless tobacco products, or nicotine replacement therapy for at least six (6) weeks prior to planned surgery as evidenced by blood cotinine lab results of ≤10 ng/nL.

Primary Lumbar Decompression for Radiculopathy

II. Based upon our criteria and assessment of the peer-reviewed literature, an initial primary lumbar decompression has been medically proven to be effective for the treatment of radiculopathy and, therefore, is considered medically appropriate when **ALL** of the following criteria are met:

A. The individual has subjective symptoms, including **BOTH** of the following:
   1. 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**
   2. Persistent, radiating pain into the buttock(s) or lower extremity(ies) on a daily basis that has a documented, negative impact on activities of daily living despite optimal conservative treatment as described below;

AND

B. The individual has objective physical exam-findings including **EITHER** of the following:
   1. Nerve root tension sign including **any** of the following:
      a. Positive straight leg raise;
      b. Crossed straight leg raise; **or**
      c. Femoral stretch test;

   OR

   2. Neurologic deficit including **any** of the following:
      a. Dermatomal sensory deficit;
      b. Functionally limiting motor weakness (e.g., foot drop, quadriceps weakness); **or**
      c. Reflex changes;

AND

C. The individual has not experienced clinically meaningful improvement with the following unless contraindicated:
   1. Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for six (6) weeks; **and**
   2. Prescription strength analgesics, steroids, gabapentinoids, or NSAIDS for six (6) weeks; **or**
   3. Epidural steroid injection(s)/selective nerve root block(s);

AND

D. MRI/CT findings identify neural structure compression at the requested level(s) that is concordant with the individual's symptoms and physical examination findings and that is caused by **ANY** of the following:
   1. Herniated disc(s) (retained disc material or a recurrent disc herniation);
   2. Synovial cyst or arachnoid cyst;
   3. Central/lateral/foraminal stenosis; **or**
   4. Osteophytes;

AND

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

AND

G. Documentation of nicotine-free status as evidenced by **EITHER** of the following:

1. Patient is a never-smoker; **or**
2. Patient has refrained from smoking, use of smokeless tobacco products, ~~and/~~or nicotine replacement therapy for at least six (6) weeks prior to planned surgery as evidenced by blood cotinine lab results of ≤10 ng/nL.

Repeat Lumbar Decompression

III. Based upon our criteria and assessment of the peer-reviewed literature, a repeat lumbar decompression at the same level has been medically proven to be effective and, therefore, is considered **medically appropriate** when **BOTH** of the following criteria are met:
   A. More than 12 weeks have elapsed since last decompression surgery; **and**
   B. Criteria for an initial lumbar decompression (Policy Statements I. or II.) met.

Not Medically Necessary and Investigational Procedures

IV. Based upon our criteria and assessment of the peer-reviewed literature, lumbar decompression performed for **ANY** of the following sole indications is considered **not medically necessary**:
   A. Annular tears;
   B. Concordant discography;
   C. MR spectroscopy results;
   D. Degenerative disc disease.

V. Based upon our criteria and assessment of the peer-reviewed literature, percutaneous lumbar decompression (e.g., Vertos Medical Mild Surgical Procedure) has not been medically proven to be effective and, therefore, is considered **investigational**.

VI. Based upon our criteria and assessment of the peer-reviewed literature, stabilization/distraction implants when used following decompression or as stand-alone procedures, have not been medically proven to be effective and, therefore, are considered **investigational.** The implants include, but are not limited to the following:
   A. Interspinous/Interlaminar process spacer devices (ISS);
   B. Interspinous/Interlaminar stabilization/distraction devices (e.g., Superion Indirect Decompression System);
   C. Interspinous process decompression (IPD) systems/devices (e.g., Coflex Interlaminar Technology Implant, Superion ISS Interspinous Spacer System, X-STOP Interspinous Process Decompression System, and Total Posterior Spine [TOPS] System).

Refer to Corporate Medical Policy #7.01.16 Automated Percutaneous Discectomy and Image-Guided, Minimally Invasive Decompression

Refer to Corporate Medical Policy #7.01.62 Intervertebral Disc Decompression: Laser (Laser Discectomy) and Radiofrequency Coblation (Disc Nucleoplasty) Techniques

Refer to Corporate Medical Policy #7.01.83 Minimally Invasive/Minimal Access Techniques for Lumbar Interbody Fusion

Refer to Corporate Medical Policy #7.01.90 Lumbar Fusion for Adults

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

POLICY GUIDELINES

I. Minimum documentation requirements needed to complete a prior authorization request for spinal surgery include **ALL** of the following:
   A. CPT codes, disc level(s) or motion segments involved for planned surgery, and ICD-10 codes;
   B. Detailed documentation of the type, duration, and frequency of provider-directed non-surgical treatment (e.g., interventional pain management, physical therapy, chiropractic care, provider-directed active exercise program, etc.) and the response to each treatment including:

1. Detailed documentation explaining why a sufficient trial of non-surgical treatment was contraindicated (if applicable); and
2. Detailed documentation of less than clinically meaningful improvement for each treatment, Clinically meaningful improvement is defined as global assessment showing at least 50% improvement.

C. Written reports/interpretations of the most recent advanced diagnostic imaging studies (e.g., CT, MRI, Myelography) by an independent radiologist. Clinically significant discrepancies in interpretations between the surgeon and the radiologist need to be reconciled in the documentation submitted for prior authorization.
   1. Acceptable imaging modalities are CT scan, MRI, and myelography.
   2. Discography or magnetic resonance (MR) spectroscopy results will not be used as a determining factor of medical necessity for any requested procedures. Use is not endorsed.

II. URGENT/EMERGENT CONDITIONS: All patients being evaluated for spine surgery should be screened for indications of a medical condition that requires urgent/emergent treatment. The presence of such indications/conditions warrants definitive surgical treatment. Imaging findings noted in the applicable procedure section(s) are required.

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

A. acute/unstable traumatic spinal fractures or dislocations, with neural compression or traumatic cerebrospinal fluid leak;
B. cauda equina syndrome (CES);
C. documentation of progressive neurological deficit on two separate physical examinations;
D. **ANY** of the following due to a neurocompressive pathology:
   1. Motor weakness of grade 3/5 or less of specified muscle(s);
   2. Rapidly progressive symptoms of motor loss;
   3. Bowel incontinence; or
   4. Bladder incontinence/retention; **or**
E. epidural hematoma;
F. infection (e.g., discitis, epidural abscess, osteomyelitis);
G. primary or metastatic neoplastic disease causing pathologic fracture, cord compression or instability; or
H. A condition otherwise meeting criteria listed in the applicable procedure section(s) with documentation of severe debilitating pain and/or dysfunction to the point of being incapacitated.

The following criteria are **NOT** required for confirmed urgent/emergent conditions:

A. Provider-directed, non-surgical management (Statements I.C. and II.C);
B. Absence of unmanaged significant behavioral health disorders (Statement I. E and II.E); **and**
C. Timeframe for repeat procedure.

DESCRIPTION

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:

I. 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.

II. 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.
III. 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.
IV. 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.

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 is 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/Distraction 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 levels(s).

RATIONALE

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)

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 (Asghar, 2012; Weinstein, 2006a; Weinstein, 2006b; Weinstein, 2007; Weinstein, 2009).

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). The Society 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 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.

Percutaneous Image-Guided Spinal Decompression

In 2006, the X-Sten MILD Tool Kit (now the mild device kit, X-Sten Corp. renamed Vertos Medical) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for treatment of various spinal conditions using percutaneous lumbar decompressive procedures. Vertos's mild instructions state that the device is not intended for disc procedures but rather for tissue resection at the perilaminar space, within the interlaminar space, and at the ventral aspect of the lamina. The device is not intended for use near the lateral neural elements and remains dorsal to the dura using image guidance and anatomic landmarks.

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.

The MOTION study was a prospective, multicenter, randomized controlled trial that aimed to provide outcome data for patients with lumbar spinal stenosis (LSS) suffering from neurogenic claudication secondary to hypertrophic ligamentum flavum. A total of 177 patients were randomized to either conventional medical management (CMM alone) or minimally invasive lumbar decompression in combination with CMM (mild +CMM). Baseline function was evaluated with the ODI, Numerical Pain Rating Scale (NPRS), and ZCQ scores. MRI or CT images (when MR imaging was not possible) of the spine were assessed. The primary efficacy endpoint was mean improvement in ODI score at one-year follow-up compared with baseline. Secondary endpoints included ZCQ and NPRS patient-reported outcomes. Mean improvement from baseline to one-year follow-up for all outcome measures demonstrated statistical significance in favor of mild + CMM versus CMM alone. The authors concluded that the results of this study confirm the use of the mild Procedure as a safe and effective first-line treatment for the indicated LSS patient population. Although results of this study are promising, further research is warranted examining long term follow up of outcomes (Deer, 2022).

Stabilization/Distraction Implants

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 in one or two lumbar levels, in patients for whom operative treatment is indicated at no more than two levels.

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 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.

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 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 allows or MR contrast agents
13. Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder disfunction."

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

The FDA approved coflex based on an open-label, randomized, multicenter, noninferiority trial that compared coflex plus decompression to decompression plus posterolateral fusion in patients who had stenosis, significant back pain, and either no spondylolisthesis or grade 1 spondylolisthesis (Davis et al., 2013). The control group was treated with pedicle screw and rod fixation with autograft but without an interbody cage or bone morphogenetic protein. A total of 398 patients were randomized, of whom 322 were included in the per-protocol analysis. Composite clinical success was defined as a minimum 15-point improvement in ODI score, no reoperations, no device-related complications, no epidural steroid injections at the lumbar spine, and no new or worsening sensory or motor deficit at 24 months. At two years, overall success was similar for patients treated with coflex at 1 or 2 levels (68.9% and 69.4%). A secondary analysis of 150 patients with grade 1 spondylolisthesis comparing coflex and fusion results demonstrated no statistically significant differences in ODI, VAS, and ZCQ. 18% of the coflex group (18/99) resulted in spinous process fractures. Reoperation rates were 6% in the fusion group and 14% in the coflex group.

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

Grinberg et al. (2020) conducted a post-hoc analysis of the pivotal RCT, assessing the use of the coflex device in patients 65 years or older. Results were measured out to 60 months. Patients who received the implant with decompression had clinical outcomes that were not significantly different to patients who received decompression and fusion. Coflex was ruled as non-inferior however, the benefit of the comparator is uncertain, and therefore, there cannot be a meaningful interpretation of the net benefit.

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. Superion showed a 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).

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.

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 (Mikai).

In the ASPN (Deer et al., 2022) consensus guideline outlining best practices for minimally invasive lumbar spinal stenosis treatment, the following recommendation was provided with regard to the use of to the use of interspinous spacers, "Interspinous spacers should be considered for treatment of symptomatic spinal stenosis at the index level with mild-to-moderate spinal stenosis, with less than or equal to grade 1 spondylolistheses, in the absence of dynamic instability or micro-instability represented as fluid in the facets on advanced imaging. Grade A; Level of certainty high; Quality of Evidence 1-A"

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.

CODES

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

CPT Codes

Code	Description
22867 **(E/I)**	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level (*effective 01/01/17*)
22868 **(E/I)**	second level (*effective 01/01/17*)
22869 **(E/I)**	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level (*effective 01/01/17*)
22870 **(E/I)**	second level (*effective 01/01/17*)
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 (*effective 01/01/17*)
63005	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), 1 or 2 vertebral segments; lumbar, except for spondylolisthesis
63011	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), 1 or 2 vertebral segments; sacral
63012	Laminectomy with removal of abnormal facets and/or pars inter-articularis with decompression of cauda equina and nerve roots for spondylolisthesis, lumbar (Gill type procedure)
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
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

Code	Description
63048	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; each additional segment, cervical, thoracic, or lumbar
63052	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [e.g., spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; single vertebral segment (List separately in addition to code for primary procedure)
63053	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [e.g., spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; each additional vertebral segment (List separately in addition to code for primary procedure)
63087	Vertebral corpectomy (vertebral body resection), partial or complete, combined thoracolumbar approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic or lumbar; single segment (*effective 01/01/93*)
63088	Vertebral corpectomy (vertebral body resection), partial or complete, combined thoracolumbar approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic or lumbar; each additional segment (List separately in addition to code for primary procedure) (*effective 01/01/93*)
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 (*effective 01/01/93*)
63091	Vertebral corpectomy (vertebral body resection), partial or complete, transperitoneal or retroperitoneal approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic, lumbar, or sacral; each additional segment (List separately in addition to code for primary procedure) (*effective 01/01/93*)
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 (*effective 01/01/04*)
63103	Vertebral corpectomy (vertebral body resection), partial or complete, lateral extracavitary approach with decompression of spinal cord and/or nerve root(s) (e.g., for tumor or retropulsed bone fragments); thoracic or lumbar, each additional segment (List separately in addition to code for primary procedure) (*effective 01/01/04*)

HCPCS Codes

Code	Description
C1821 (E/I)	Interspinous process distraction device (implantable)

ICD10 Codes

Code	Description
C72.0	Malignant neoplasm of spinal cord

Code	Description
C79.40	Secondary malignant neoplasm of unspecified part of nervous system
G06.1	Intraspinal abscess and granuloma
M43.10-M43.19	Spondylolisthesis (code range)
M48.00-M48.08	Spinal stenosis (code range)
M54.5	Low back pain
M79.604-M79.609	Pain in leg/limb (code range)
M79.651-M79.676	Pain in thigh/lower leg/foot/toes (code range)
M99.23	Subluxation stenosis of neural canal of lumbar region
M99.33	Osseous stenosis of neural canal lumbar region
M99.43	Connective tissue stenosis of neural canal of lumbar region
M99.53	Intervertebral disc stenosis of neural canal of lumbar region
M99.63	Osseous and subluxation stenosis of intervertebral foramina of lumbar region
M99.73	Connective tissue and disc stenosis of intervertebral foramina of lumbar region

REFERENCES

*Andreisek G, et al. Uncertainties in the diagnosis of lumbar spinal stenosis. Radiology 2011;261(3):681-4.

Aggarwal N and Chow R. Real world adverse events of interspinous spacers using Manufacturer and User Facility Device Experience data. Anesth Pain Med (Seoul) 2021 Apr;16(2):177-183.

Austevoll IM, et al. Decompression with or without fusion in degenerative lumbar spondylolisthesis. N Engl J Med 2021 Aug; 385(6): 526-38.

*Backstrom KM, et al. Lumbar spinal stenosis-diagnosis and management of the aging spine. Manual Therapy 2011;16(4):308-17.

*Bjorn S, et al. X-Stop versus decompressive surgery for lumbar neurogenic intermittent claudication: A randomized controlled trial with 2 years follow-up. Spine 2013 Feb 11 [Epub ahead of print].

*Brox JI, et al. Four-year follow-up of surgical versus non-surgical therapy for chronic low back pain. Annals of the Rheumatic Diseases 2010;69(9):1643-8.

Boonstra AM, et al. Cut-off points for mild, moderate, and severe pain on the visual analogue scale for pain in patients with chronic musculoskeletal pain. Pain 2014 Sep;155(2014):2545-2550.

*Burnett MG, et al. Cost-effectiveness of current treatment strategies for lumbar spinal stenosis: nonsurgical care, laminectomy, and X-STOP. J Neurosurg Spine 2010 Jul;13(1):39-46.

*Choi D, et al. Review of metastatic spine tumour classification and indications for surgery: the consensus statement of the Global Spine Tumour Study Group. European Spine Journal 2010;19(2):215-22.

*Chou R, et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. Annals of Internal Medicine 2007;147(7):478-91.

*Chou R, et al. Medications for acute and chronic low back pain: a review of the evidence for an American Pain Society/ American College of Physicians clinical practice guideline. Annals of Internal Medicine 2007;147(7):505-14.

*Chou R, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. Spine 2009;34(10):1066-77.

*Cohen SP, Hanling S, Bicket MC, et al. Epidural steroid injections compared with gabapentin for lumbosacral radicular pain: multicenter randomized double blind comparative efficacy study. BMJ 2015;350:h1748-h1748.

*Conn A, et al. Systematic review of caudal epidural injections in the management of chronic low back pain. Pain Physician 2009;12(1):109-35.

Costa F, et al. Decompressive surgery for lumbar spinal stenosis: WFNS spine committee recommendations. World Neurosurg X 2020 Mar 10;7:100076.

*Darouiche RO. Spinal epidural abscess. New England Journal of Medicine 2006;355(19):2012-20.

*Davis RJ, et al. Decompression and Coflex interlaminar stabilization compared with decompression and instrumented spinal fusion for spinal stenosis and low-grade degenerative spondylolisthesis: two-year results from the prospective, randomized, multicenter, Food and Drug administration Investigational Device exemption trial. Spine 2013 Aug 15;38(18):1529-39.

Deer TR, et al. The MIST guidelines: the lumbar spinal stenosis consensus group guidelines for minimally invasive spine treatment. Pain Pract 2019 Mar;19(3):250-274.

Deer TR, et al. The MOTION study: a randomized controlled trial with objective real-world outcomes for lumbar spinal stenosis patients treated with the mild procedure: One-year results. Pain Medicine 2022 Apr 8;23(4):625-634.

*Deyo RA, et al. Trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults. Journal of the American Medical Association 2010;303(13):1259-65.

Du MR, et al. Coflex interspinous process dynamic stabilization for lumbar spinal stenosis: Long-term follow-up. J Clin Neurosci 2020 Nov;81:462-468.

*Eliyas JK, et al. Surgery for degenerative lumbar spine disease. Disease-a-Month 2011;57(10):592-606.

*Errico TJ, et al. Survivorship of coflex interlaminar-interspinous implant. SAS Journal 2009;3(2): 59-67.

Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): coflex InterlaminarTechnology 2012 [https://www.accessdata.fda.gov/cdrh_docs/pdf11/P110008b.pdf] accessed 09/05/24.

*Fu KM, et al. Morbidity and mortality in the surgical treatment of 10,329 adults with degenerative lumbar stenosis. Journal of Neurosurgery: Spine 2010;12(5):443-6.

Gadjradj PS, et al. Percutaneous transforaminal endoscopic discectomy versus open microdiscectomy for lumbar disc herniation: a systematic review and meta-analysis. Spine 2021 Apr 15;46(8):538-549.

*Grinberg SZ, et al. Interlaminar stabilization for spinal stenosis in the Medicare population. Spine J 2020 Dec;20(12):1948-1959.

Gross D, et al. Acute opioid administration improves work-related exercise performance in patients with chronic back pain. The Journal of Pain: Official Journal of the American Pain Society 2008; 9(9):856-62 .

*Guyer R, et al. ISASS Recommendations/coverage criteria for decompression with interlaminar stabilization-coverage indications, limitations, and/or medical necessity. Int J Spine Surg 2016 Dec 5;10:41.

Hayden J, et al. Exercise treatment effect modifiers in persistent low back pain: an individual participant data meta-analysis of 3514 participants from 27 randomised controlled trials. British Journal of Sports Medicine 2019;54:1277-1278.

*Hsu KY, et al. Quality of life of lumbar stenosis-treated patients in whom the X STOP interspinous device was implanted. J Neurosurg Spine 2006;5: 500-7.

Jung JM, et al. The long-term reoperation rate following surgery for lumbar stenosis: a nationwide sample cohort study with a 10-year follow-up. Spine (Phila Pa 1976) 2020 Sep 15;45(18):1277-1284.

*Kalichman L, Hunter DJ. Diagnosis and conservative management of degenerative lumbar spondylolisthesis. European Spine Journal 2008;17(3):327-35.

*Kanayama M, et al. Effective prevention of surgical site infection using a Centers for Disease Control and Prevention guideline-based antimicrobial prophylaxis in lumbar spine surgery. Journal of Neurosurgery: Spine 2007;6(4):327-9.

Karlson, Thomas, et al. Decompression alone or decompression with fusion for lumbar spinal stenosis: a randomized clinical trial with two-year MRI follow-up. Bone Joint J 2022 Dec;104-B(12):1343-1351.

*Kim DH, et al. Occult spinous process fractures associated with interspinous process spacers. Spine 2011 Jul 15;36(16):E1080-5.

*Klein G, et al. Nonoperative treatment of spondylolysis and grade I spondylolisthesis in children and young adults: a meta-analysis of observational studies. Journal of Pediatric Orthopedics 2009;29(2):146-56.

*Kreiner DS, et al. Diagnosis and treatment of degenerative lumbar spinal stenosis. Evidence-based clinical guidelines for multidisciplinary spine care. North American Spine Society. 2011. [https://www.spine.org/Portals/0/assets/downloads/ResearchClinicalCare/Guidelines/LumbarStenosis.pdf] accessed 09/05/2024.

*Kumar N, Shah SM, Ng YH, et al. Role of coflex as an adjunct to decompression for symptomatic lumbar spinal stenosis. Asian Spine Journal 2014;8(2): 161-169.

*Kushchayev SV, et al. ABCs of the degenerative spine. Insights Imaging 2018;9(2):253-274.

*Lee BS, et al. Utility of repeat magnetic resonance imaging in surgical patients with lumbar stenosis without disc herniation. Spine J 2019;19(2):191-198.

*Loguidice V, et al. Rationale, design and clinical performance of the Superion Interspinous Spacer: a minimally invasive implant for treatment of lumbar spinal stenosis. Expert Rev Med Devices 2011 Jul;8(4):419-26.

*Lurie JD, et al. Long-term outcomes of lumbar spinal stenosis: eight-year results of the spine patient outcomes research trial (SPORT). Spine (Phila Pa 1976) 2015;40(2): 63-76.

Manzur MK, et al. Indirect Lumbar decompression combined with or without additional direct posterior decompression: A systematic review. Global Spine Journal 2021: 1-10.

*Moojen WA, et al. Interspinous process device versus standard conventional surgical decompression for lumbar spinal stenosis: a randomized controlled trial. BMJ 2013 Nov 14;f6415.

*Musacchio MJ, et al. Evaluation of decompression and interlaminar stabilization compared with decompression and fusion for the treatment of lumbar spinal stenosis: 5-year follow-up of a prospective, randomized, controlled trial. Int J Spine Surg 2016 Jan 26;10:6.

*Nandakumar A, et al. The increase in dural sac area is maintained at 2 years after X-stop implantation for the treatment of spinal stenosis with no significant alteration in lumbar spine range of movement. The Spine Journal 2010;10: 762-8.

*National Institute for Health and Clinical Excellence (NICE). Interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication. IPG365. 2010 Nov [https://www.nice.org.uk/guidance/ipg365] accessed 09/05/24.

*North American Spine Society. Coverage policy recommendations. Lumbar decompression: laminectomy, laminotomy and foraminotomy. 2022 Sep [https://www.spine.org/coverage] accessed 09/05/24.

*North American Spine Society. Coverage policy recommendations. Lumbar interspinous device without fusion and with decompression. 2018 May [https://www.spine.org/coverage] accessed 09/05/24.

*North American Spine Society. Coverage policy recommendations. Interspinous devices without fusion. 2014 May [https://www.spine.org/coverage] accessed 09/05/24.

*North American Spine Society (NASS). Evidence-based clinical guidelines for multidisciplinary spine care: diagnosis & treatment of low back pain. 2020 Aug. [https://www.spine.org/Portals/0/assets/downloads/ResearchClinicalCare/Guidelines/LowBackPain.pdf] accessed 09/05/24.

*Panagopoulos J, et al. Do mri findings change over a period of up to 1 year in patients with low back pain and/or sciatica? Spine 2017;42(7):504-512.

*Park S, et al. Minimum 2-year follow-up result of degenerative spinal stenosis treated with interspinous U (Coflex™). J Korean Neurosurg 2009;46: 292-9.

*Patel VV, et al. Superion interspinous process spacer for intermittent neurogenic claudication secondary to moderate lumbar spinal stenosis: two-year results from a randomized controlled FDA-IDE pivotal trial. Spine 2015 Mar 1;40(5):275-82.

*Patel VV, et al. Superion® Interspinous Spacer for treatment of moderate degenerative lumbar spinal stenosis: durable three-year results of a randomized controlled trial. J Pain Res 2015 Oct 3;8:657-62.

*Patil CG, et al. Interspinous device versus laminectomy for lumbar spinal stenosis: a comparative effectiveness study. The Spine Journal 2014;14: 1484-92.

Pazarlis K, et al. Lumbar spinal stenosis with degenerative spondylolisthesis treated with decompression alone. a cohort of 346 patients at a large spine unit. clinical outcome, complications and subsequent surgery. Spine 2022 Mar 15;47(6):470-475.

Podet, AG., et al. Minimally invasive lateral corpectomy for thoracolumbar traumatic burst fractures. Neurosurg Focus 2020 Sep;49(3):E12.

*Pearson A, et al. Who should have surgery for spinal stenosis?: treatment effect predictors in SPORT. Spine (Phil Pa 1976) 2012;37(21): 1791-1802.

*Pintauro M, et al. Interspinous implants: are the new implants better than the last generation? A review. Curr Rev Musculoskelet Med 2017;10: 189-98.

*Richter A, et al. Does an interpsinous device (Coflex™) improve the outcome of decompressive surgery in lumbar spinal stenosis? One-year follow up of a prospective case control study of 60 patients. Eur Spine J 2010;19: 283-9.

*Ries ZG, Glassman SD, Vasilyev I, Metcalfe L, Carreon LY. Updated imaging does not affect revision rates in adults undergoing spine surgery for lumbar degenerative disease. J Neurosurg Spine 2019;30(2):228-223.

*Sansur CA, et al. Morbidity and mortality in the surgical treatment of 10,242 adults with spondylolisthesis. Journal of Neurosurgery: Spine 2010;13(5):589-93.

*Schmidt S, et al. Prospective, randomized, multicenter study with 2-year follow-up to compare the performance of decompression with and without interlaminar stabilization. J Neurosurg Spine 2018 Apr;28(4):406-415.

*Senegas J, et al. Clinical evaluation of a lumbar interspinous dynamic stabilization device (the Wallis system) with a 13-year mean follow-up. Neurosurg Rev 2009 Apr 22 [Epub ahead of print].

Shafshak T, et al. Epidural steroid injection versus conservative measures in treatment of chronic axial low back pain, a prospective randomized controlled study. European Journal of Medical and Health Sciences 2022;4(5):47-51.

*Shafshack TS, and Elnemr R. The visual analog scale versus numerical rating scale in measuring pain severity and predicting disability in low back pain. JClinRheum 2021 Oct;27(7):282-285.

Shariff S, et al. Acute back pain: the role of medication, physical medicine and rehabilitation: WFNS spine committee recommendations. World Neurosurgery 2024 July;23:1-11.

*Siddiqui M, et al. Influence of X-Stop on neural foramina and spinal canal area in spinal stenosis. Spine 2006;31(25): 2958-62.

*Siddiqui M, et al. The positional magnetic resonance imaging changes in the lumbar spine following insertion of a novel interspinous process distraction device. Spine 2005;30(23): 2677-82.

*Tekmyster G, et al. Interspinous process decompression with the Superion® spacer for lumbar spinal stenosis: real-world experience from a device registry. Med Devices (Auckl) 2019 Oct 3;12:423-427.

*Thome C, et al. Outcome after less-invasive decompression of lumbar spinal stenosis: a randomized comparison of unilateral laminotomy, bilateral laminotomy, and laminectomy. Journal of Neurosurgery: Spine 2005;3(2):129-41.

*Tran de QH, Duong S, Finlayson RJ. Lumbar spinal stenosis: a brief review of the nonsurgical management. Canadian Journal of Anaesthesia 2010;57(7):694-703.

*US Food and Drug Administration. Summary and safety effectiveness data. Coflex Interlaminar technology. [https://www.accessdata.fda.gov/cdrh_docs/pdf11/P110008B.pdf] accessed 09/05/24.

*Verhoof, et al. High failure rate of the interspinous distraction device (X-Stop) for the treatment of lumbar spinal stenosis caused by degenerative spondylolisthesis. Eur Spin J 2008 Feb;17(2):188-92.

*Watters WC, et al. An evidence-based clinical guideline for the diagnosis and treatment of degenerative lumbar spondylolisthesis. Spine Journal 2009;9(7):609-14.

Wei FL, et al. Management for lumbar spinal stenosis: a network meta-analysis and systematic review. Int J Surg 2020 Nov 27;85:19-28.

*Weinstein JN, et al. Surgical compared with nonoperative treatment for lumbar degenerative spondylolisthesis. four-year results in the Spine Patient Outcomes Research Trial (SPORT) randomized and observational cohorts. Journal of Bone and Joint Surgery American Volume 2009;91(6):1295-304.

*Weinstein JN, et al. Surgical versus nonsurgical therapy for lumbar spinal stenosis. N Engl J Med 2008 Feb 21;358(8):794-810.

Welton L, et al. Comparison of adverse outcomes following placement of Superion interspinous spacer device versus laminectomy and laminotomy. Int J Spine Surg 2021 Feb;15(1):153-160.

*Xin JH, et al. Effectiveness and safety of interspinous spacer versus decompressive surgery for lumbar spinal stenosis: A meta-analysis of randomized controlled trials. Medicine (Baltimore) 2023 Nov;102(46): e36048.

*Yaksi A, Özgönenel L, Özgönenel B. The efficiency of gabapentin therapy in patients with lumbar spinal stenosis. Spine 2007;32(9):939-942.

Zhang Y, et al. Which is the most effective treatment for lumbar spinal stenosis: Decompression, fusion, or interspinous process device? A Bayesian network meta-analysis. J Orthop Translat 2020 Sep 26;26:45-53.

Zheng, Xiaoqing, et al. A minimum 8-year follow-up comparative study of decompression and coflex stabilization with decompression and fusion. Exp Ther Med Jun 2021; 21(6): 595.

Zhong J, et al. Patient outcomes after single-level Coflex interspinous implants versus single-level laminectomy. Spine (Phila Pa 1976) 2021 Jul 1;46(13):893-900.

*Key Article

KEY WORDS

Lumbar foraminotomy, Lumbar decompression, Lumbar laminectomy, Spinal stenosis, Spondylolisthesis, Coflex, Interlaminar stabilization, Interspinous spacer, Spinal Decompression, Spinal Distraction, Spinal Stenosis, Superion, X-STOP

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based upon review, lumbar decompression and interspinous process decompression devices are not specifically addressed in National or Regional Medicare coverage determinations or policies.