MEDICAL POLICY

Medical Policy Title	**Lumbar Decompression**
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Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Primary Lumbar Decompression for Neurogenic Claudication

I. Initial primary lumbar decompression for the treatment of neurogenic claudication is considered **medically appropriate** for spinal stenosis/spondylolisthesis, when **ALL** 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. Less than clinically meaningful improvement with at least TWO (2) of 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) performed at the same level(s) as the requested surgery;

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

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

Primary Lumbar Decompression for Radiculopathy

II. Initial primary lumbar decompression for the treatment of radiculopathy is considered **medically appropriate** when **ALL** 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);

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. Less than clinically meaningful improvement with at least two (2) 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) performed at the same level(s) as the requested surgery;

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).

Interlaminar Decompression Device in Open Lumbar Decompression

III. Use of an FDA-approved interlaminar decompression device (i.e., Coflex) is considered **medically appropriate** when used for an open lumbar decompression when **ALL** the following criteria are met:
   A. Meets initial lumbar decompression criteria for **EITHER** Neurogenic Claudication or Radiculopathy;
   B. The interlaminar decompression device will not be used in an open lumbar decompression performed with a lumbar fusion;
   C. The interlaminar decompression device will only be used in one (1) or two (2) lumbar levels between L1-L5;
   D. Meyerding Grade 1 degenerative spondylolisthesis with or without anticipated iatrogenic instability (created by disruption of the posterior elements due to facet joint excision that exceeds 50% bilaterally or 75% or more of a single facet during spinal decompression)

Repeat Lumbar Decompression

IV. Repeat lumbar decompression at the same level is considered **medically appropriate** when **BOTH** of the following criteria are met:
   A. More than 12 weeks have elapsed since prior lumbar decompression; **and**
   B. Criteria for an initial lumbar decompression (Policy Statements I. or II.) are met.

Not Medically Necessary and Investigational Procedures

V. 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.

VI. Use of an FDA-approved interlaminar decompression device (i.e., Coflex) is considered not **medically necessary** for **ANY** of the following scenarios:
   A. Used without meeting the decompression criteria in the applicable procedure specific section(s) (initial decompression or repeat decompression)
   B. Used in the presence of Meyerding Grade 2 or higher degenerative spondlylisthesis
   C. Used in the presence of spondylolysis or isthmic spondylolisthesis
   D. Used when a lumbar fusion is also being performed at the same level
   E. Used when a lumbar decompression is not performed as an open procedure

VII. Stabilization/distraction implants when used following decompression or as stand-alone procedures are considered **investigational**. The implants include, but are not limited to the following:
   A. Interspinous process spacer devices;
   B. Interspinous stabilization/distraction devices (e.g., Superion Indirect Decompression System);
   C. Interspinous process decompression (IPD) systems/devices (e.g., Superion ISS Interspinous Spacer System, X-STOP Interspinous Process Decompression System, and Total Posterior Spine [TOPS] System).

RELATED POLICIES

Corporate Medical Policy

7.01.16 Automated Percutaneous Discectomy and Image-Guided, Minimally Invasive Decompression

7.01.62 Intervertebral Disc Decompression: Laser (Laser Discectomy) and Radiofrequency Coblation (Disc Nucleoplasty) Techniques

7.01.117 Lumbar Fusion

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Minimum documentation requirements needed to complete a prior authorization request for spinal surgery include ALL 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;

B. Absence of unmanaged significant behavioral health disorders; **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 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/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).

SUPPORTIVE LITERATURE

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).

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 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 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 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.

In the American Society of Pain and Neuroscience (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.

PROFESSIONAL GUIDELINE(S)

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 2018, NASS published specific coverage policy recommendations on the lumbar interspinous device without fusion and with decompression. The 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 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.

REGULATORY STATUS

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.

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."

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 (Mikai).

CODE(S)

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

CPT Codes

Code	Description
22867 (E/I)	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level

Code	Description
22868 (E/I)	second level
22869 (E/I)	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level
22870 (E/I)	second level
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 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
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 (List separately in addition to code for primary procedure)
63052	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [e.g., spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; single vertebral segment (List separately in addition to code for primary procedure)

Code	Description
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
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)
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
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)
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
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)

HCPCS Codes

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

ICD10 Codes

Code	Description
C72.0	Malignant neoplasm of spinal cord
C79.40	Secondary malignant neoplasm of unspecified part of nervous system

Code	Description
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

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

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

PRODUCT DISCLAIMER

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

- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION	
Committee Approval Dates	
10/17/24, 06/26/25	
Date	**Summary of Changes**
10/15/25	• Annual review; Medically necessary and not medically necessary criteria added for Coflex and redundant policy statement criteria removed.
01/01/25	• Summary of changes tracking implemented.
02/01/25	• Original effective date