



Louisiana

Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

Policy # 00221

Original Effective Date: 02/21/2007

Current Effective Date: 10/20/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Interspinous Fixation (Fusion) Devices is addressed separately in medical policy 00679.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers interspinous or interlaminar distraction devices as a stand-alone procedure as a treatment of spinal stenosis to be **investigational**.*

Based on review of available data, the Company considers the use of an interlaminar stabilization device following decompression surgery to be **investigational**.*

Background/Overview

Spinal Stenosis

Lumbar spinal stenosis, which affects over 200,000 people in the United States (U.S.), involves a narrowed central spinal canal, lateral spinal recesses, and/or neural foramina, resulting in pain as well as limitation of activities such as walking, traveling, and standing. In adults over 60 in the U.S., spondylosis (degenerative arthritis affecting the spine) is the most common cause. The primary symptom of lumbar spinal stenosis is neurogenic claudication with back and leg pain, sensory loss, and weakness in the legs. Symptoms are typically exacerbated by standing or walking and relieved with sitting or flexion at the waist.

Some sources describe the course of lumbar spinal stenosis as "progressive" or "degenerative," implying that neurologic decline is the usual course. Longer-term data from the control groups of clinical trials as well as from observational studies suggest that, over time, most patients remain stable, some improve, and some deteriorate.

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The lack of a valid classification for lumbar spinal stenosis contributes to wide practice variation and uncertainty about who should be treated surgically and which surgical procedure is best for each patient. This uncertainty also complicates research on spinal stenosis, particularly the selection of appropriate eligibility criteria and comparators.

Treatment

The largest group of patients with spinal stenosis is minimally symptomatic patients with mild back pain and no spinal instability. These patients are typically treated nonsurgically. At the other end of the spectrum are patients who have severe stenosis, concomitant back pain, and grade 2 or higher spondylolisthesis or degenerative scoliosis >25 Cobb angle who require laminectomy plus spinal fusion.

Surgical treatments for patients with spinal stenosis not responding to conservative treatments include decompression with or without spinal fusion. There are many types of decompression surgery and types of fusion operations. In general, spinal fusion is associated with more complications and a longer recovery period and, in the past, was generally reserved for patients with spinal deformity or moderate grade spondylolisthesis.

Conservative treatment for spinal stenosis may include physical therapy, pharmacotherapy, epidural steroid injections, and many other modalities. The terms "nonsurgical" and "nonoperative" have also been used to describe conservative treatment. Professional societies recommend that surgery for lumbar spinal stenosis should be considered only after a patient fails to respond to conservative treatment but there is no agreement about what constitutes an adequate course or duration of treatment.

The term "conservative management" may refer to "usual care" or to specific programs of nonoperative treatment, which use defined protocols for the components and intensity of conservative treatments, often in the context of an organized program of coordinated, multidisciplinary care. The distinction is important in defining what constitutes a failure of conservative treatment and what comparators should be used in trials of surgical versus nonsurgical management. The rationale for surgical treatment of symptomatic spinal stenosis rests on the Spine Patient Outcomes Research Trial (SPORT), which found that patients who underwent surgery for spinal stenosis and spondylolisthesis had better outcomes than those treated nonoperatively. The SPORT investigators did not require a specified program of nonoperative care but rather let each

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site decide what to offer. A subgroup analysis of the SPORT trial found that only 37% of nonsurgically treated patients received physical therapy in the first 6 weeks of the trial and that those who received physical therapy before 6 weeks had better functional outcomes and were less likely to cross over to surgery later. These findings provide some support for the view that, in clinical trials, patients who did not have surgery may have had suboptimal treatment, which can lead to a larger difference favoring surgery. The SPORT investigators asserted that their nonoperative outcomes represented typical results at a multidisciplinary spine center at the time, but recommended that future studies compare the efficacy of specific nonoperative programs to surgery.

A recent trial by Delitto et al (2015) compared surgical decompression with a specific therapy program emphasizing physical therapy and exercise. Patients with lumbar spinal stenosis and from 0 to 5 mm of slippage (spondylolisthesis) who were willing to be randomized to decompression surgery versus an intensive, organized program of nonsurgical therapy were eligible. Oswestry Disability Index scores were comparable to those in the SPORT trial. A high proportion of patients assigned to nonsurgical care (57%) crossed over to surgery (in SPORT the proportion was 43%), but crossover from surgery to nonsurgical care was minimal. When analyzed by treatment assignment, Oswestry Disability Index scores were similar in the surgical and nonsurgical groups after 2 years of follow-up. The main implication is that about one-third of patients who were deemed candidates for decompression surgery but instead entered an intensive program of conservative care achieved outcomes similar to those of a successful decompression.

Diagnostic criteria for fusion surgery are challenging because patients without spondylolisthesis and those with grade 1 spondylolisthesis are equally likely to have predominant back pain or predominant leg pain. The SPORT trial did not provide guidance on which surgery is appropriate for patients who do not have spondylolisthesis, because nearly all patients with spondylolisthesis underwent fusion whereas nearly all those who did not have spondylolisthesis underwent decompression alone. In general, patients with predominant back pain have more severe symptoms, worse function, and less improvement with surgery (with or without fusion). Moreover, because back pain improved to the same degree for the fused spondylolisthesis patients as for the unfused spinal stenosis patients at 2 years, the SPORT investigators concluded that it was unlikely that fusion led to better surgical outcomes in patients with spondylolisthesis than those with no spondylolisthesis.

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Throughout the 2000s, decompression plus fusion became more widely used until, in 2011, it surpassed decompression alone as a surgical treatment for spinal stenosis. However, in 2016, findings from 2 randomized trials of decompression alone versus decompression plus fusion were published. The Swedish Spinal Stenosis Study found no benefit of fusion plus decompression compared with decompression alone in patients who had spinal stenosis with or without degenerative spondylolisthesis. The Spinal Laminectomy Versus Instrumented Pedicle Screw (SLIP) trial found a small but clinically meaningful improvement in the Physical Component Summary score of the 36-Item Short-Form Health Survey but no change in Oswestry Disability Index scores at 2, 3, and 4 years in patients who had spinal stenosis with grade 1 spondylolisthesis (3 to 14 mm). The patients in SLIP who had laminectomy alone had higher reoperation rates than those in Swedish Spinal Stenosis Study, and the patients who underwent fusion had better outcomes in SLIP than in Swedish Spinal Stenosis Study. While some interpret the studies to reflect differences in patient factors-in particular, Swedish Spinal Stenosis Study but not SLIP included patients with no spondylolisthesis, the discrepancy may also be influenced by factors such as time of follow-up or national practice patterns. As Pearson (2016) noted, it might have been helpful to have patient-reported outcome data on the patients before and after reoperation, to see whether the threshold for reoperation differed in the 2 settings. A small trial conducted in Japan, Inose et al (2018) found no difference in patient-reported outcomes between laminectomy alone and laminectomy plus posterolateral fusion in patients with 1-level spinal stenosis and grade 1 spondylolisthesis; about 40% of the patients also had dynamic instability. Certainty in the findings of this trial is limited because of its size and methodologic flaws.

Spacer Devices

Investigators have sought less invasive ways to stabilize the spine and reduce the pressure on affected nerve roots, including interspinous and interlaminar implants (spacers). These devices stabilize or distract the adjacent lamina and/or spinous processes and restrict extension in patients with lumbar spinal stenosis and neurogenic claudication.

Interspinous Implants

Interspinous spacers are small devices implanted between the vertebral spinous processes. After implantation, the device is opened or expanded to distract the neural foramina and decompress the nerves. One type of interspinous implant is inserted between the spinous processes through a small (4 to 8 cm) incision and acts as a spacer between the spinous processes, maintaining flexion of that spinal interspace. The supraspinous ligament is maintained and assists in holding the implant in

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place. The surgery does not include any laminotomy, laminectomy, or foraminotomy at the time of insertion, thus reducing the risk of epidural scarring and cerebrospinal fluid leakage. Other interspinous spacers require removal of the interspinous ligament and are secured around the upper and lower spinous processes.

Interlaminar Spacers

Interlaminar spacers are implanted midline between the adjacent lamina and spinous processes to provide dynamic stabilization either following decompression surgery or as an alternative to decompression surgery. Interlaminar spacers have 2 sets of wings placed around the inferior and superior spinous processes. They may also be referred to as interspinous U. These implants aim to restrict painful motion while enabling normal motion. The devices (spacers) distract the laminar space and/or spinous processes and restrict extension. This procedure theoretically enlarges the neural foramen and decompresses the cauda equina in patients with spinal stenosis and neurogenic claudication.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Three interspinous and interlaminar stabilization and distraction devices have been approved by the U.S. Food Drug Administration (FDA) through the premarket approval (FDA product code: NQO) are summarized in Table 1.

Table 1. Interspinous and Interlaminar Stabilization/Distraktion Devices With Premarket Approval

Device Name	Manufacturer	Approval Date	PMA
X Stop Interspinous Process Decompression System	Medtronic Sofamor Danek	2005 (withdrawn 2015)	P040001
Coflex ^{®‡} Interlaminar Technology	Paradigm Spine (acquired by RTI Surgical)	2012	P110008

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Superion ^{®‡} Indirect Decompression System (previously Superion ^{®‡} Interspinous Spacer)	VertiFlex (acquired by Boston Scientific)	2015	P140004
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PMA: premarket approval.

The Superion Indirect Decompression System (formerly InterSpinous Spacer) is indicated to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs secondary to a diagnosis of moderate degenerative lumbar spinal stenosis, with or without grade 1 spondylolisthesis, confirmed by x-ray, magnetic resonance imaging (MRI), and/or computed tomography evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing. It is intended for patients with an impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, numbness, and/or cramping, with or without back pain, and who have undergone at least 6 months of nonoperative treatment.

FDA lists the following contraindications to use of the Superion Indirect Decompression System:

- "An allergy to titanium or titanium alloy.
- Spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable in situ, such as:
 - Instability of the lumbar spine, eg, isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1 (on a scale of 1 to 4)
 - An ankylosed segment at the affected level(s)
 - Fracture of the spinous process, pars interarticularis, or laminae (unilateral or bilateral);
 - Scoliosis (Cobb angle >10 degrees)
- *Cauda equina* syndrome, defined as neural compression causing neurogenic bladder or bowel dysfunction.
 - Diagnosis of severe osteoporosis, defined as bone mineral density (from DEXA [dual-energy x-ray absorptiometry] scan or equivalent method) in the spine or hip that is more than 2.5 S.D. [standard deviations] below the mean of adult normal.
- Active systemic infection, or infection localized to the site of implantation.
- Prior fusion or decompression procedure at the index level.
- Morbid obesity defined as a body mass index (BMI) greater than 40."

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The coflex Interlaminar Technology implant (Paradigm Spine) is a single-piece U-shaped titanium alloy dynamic stabilization device with pairs of wings that surround the superior and inferior spinous processes. The coflex (previously called the Interspinous U) is indicated for use in 1- or 2-level lumbar stenosis from the L1 to L5 vertebrae 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 6 months of nonoperative treatment. The coflex "is intended to be implanted midline between the adjacent lamina of 1 or 2 contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s).

FDA lists the following contraindications to use of the coflex:

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

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

At the time of approval, the FDA requested additional postmarketing studies to provide longer-term device performance and device performance under general conditions of use. The first was the 5-year follow-up of the pivotal investigational device exemption trial. The second was a multicenter

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trial with 230 patients in Germany who were followed for 5 years, comparing decompression alone with decompression plus coflex. The third, a multicenter trial with 345 patients in the U.S. who were followed for 5 years, compared decompression alone with decompression plus coflex. FDA product code: NQO.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Description

Interspinous and interlaminar implants (spacers) stabilize or distract the adjacent lamina and/or spinous processes and restrict extension to reduce pain in patients with lumbar spinal stenosis and neurogenic claudication. Interspinous spacers are small devices implanted between the vertebral spinous processes. After implantation, the device is opened or expanded to distract (open) the neural foramen and decompress the nerves. Interlaminar spacers are implanted midline between the adjacent lamina and spinous processes to provide dynamic stabilization either following decompression surgery or as an alternative to decompression surgery.

Summary of Evidence

For individuals who have spinal stenosis and no spondylolisthesis or grade 1 spondylolisthesis who receive an interspinous or interlaminar spacer as a stand-alone procedure, the evidence includes 1 systematic review of randomized controlled trials (RCTs) of X-STOP spacer devices (which is no longer marketed) or other devices not approved in the US, observational retrospective claims data analyses, and 2 RCTs of 2 spacers compared to each other (Superion Indirect Decompression System, coflex interlaminar implant). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Overall, the use of interspinous or interlaminar distraction devices (spacers) as an alternative to spinal decompression has shown high failure and complication rates. A systematic review of RCTs comparing interspinous spacer devices (ISDs) and decompression surgery in patients with lumbar spinal stenosis found that ISD resulted in an increased rate of reoperation compared to decompression, as well as no statistically significant

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differences in pain, functional, and quality of life outcomes. Additional longitudinal retrospective comparative claims analyses found that there was a significantly lower rate of reoperation in patients with lumbar spinal stenosis who received ISD compared to open surgery. However, there are many limitations inherent to claims analyses, including the possibility of coding or data entry errors and the omission of clinical details not needed to justify payment. For example, diagnosis codes identified in claims data lack clinical context, such as the severity of lumbar spinal stenosis or postoperative complications, as well as other prior therapies. Claims data also does not capture patient-reported outcomes, such as visual analog scale scores or Zurich Claudication Questionnaire scores, limiting the ability to determine true efficacy. It is unknown if authors were able to see when a patient was lost to follow-up due to death or end of Medicare coverage, as these rates were not reported. Additionally, in 1 of the studies, since the baseline characteristics of patients receiving ISD indicated that these patients may be inherently sicker than those receiving open surgery, we need clinical context to infer if the reason they did not receive additional surgical procedures post initial ISD placement is because they truly didn't require intervention, or they were too sick to tolerate the procedure. While claims data gives us some information related to re-operation rates, direct or indirect comparative studies using clinical data and validated outcomes measures are required to draw conclusions on the utility of ISDs compared to open surgery. A pivotal trial compared the Superior Interspinous Spacer with the X-STOP Interspinous Process Decompression System (which is no longer marketed), without conservative care or standard surgery comparators. The trial reported significantly better outcomes with the Superior Interspinous Spacer on some measures. For example, the trial reported more than 80% of patients experienced improvements in certain quality of life outcome domains. Interpretation of this trial is limited by questions about the number of patients used to calculate success rates, the lack of efficacy of the comparator, and the lack of an appropriate control group treated by surgical decompression. The coflex interlaminar implant (formerly called the interspinous U) was compared with decompression in the multicenter, double-blind FELIX trial. Functional outcomes and pain levels were similar in the 2 groups at 1 year follow-up, but reoperation rates due to the absence of recovery were substantially higher with the coflex implant (29%) than with bony decompression (8%). For patients with 2-level surgery, the reoperation rate was 38% for coflex and 6% for bony decompression. At 2 years, reoperations due to the absence of recovery had been performed in 33% of the coflex group and 8% of the bony decompression group. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have severe spinal stenosis and grade 1 spondylolisthesis or instability who have failed conservative therapy who receive an interlaminar spacer with spinal decompression

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surgery, the evidence includes 2 RCTs with a mixed population of patients. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Use of the coflex interlaminar implant as a stabilizer after surgical decompression has been studied in 2 situations—as an adjunct to decompression compared with decompression alone (superiority) and as an alternative to spinal fusion after decompression (noninferiority). For decompression with coflex versus decompression with lumbar spinal fusion, the pivotal RCT, conducted in a patient population with spondylolisthesis no greater than grade 1 and significant back pain, showed that stabilization of decompression with the coflex implant was noninferior to decompression with spinal fusion for the composite clinical success measure. A secondary (unplanned) analysis of patients with grade 1 spondylolisthesis (99 coflex patients and 51 fusion patients) showed a decrease in operative time (104 vs. 157 minutes; $p < .001$) and blood loss (106 vs. 336 mL; $p < .001$). There were no statistically significant differences between the coflex and fusion groups in Oswestry Disability Index, visual analog scale, and Zurich Claudication Questionnaire scores after 2 years. In that analysis, 62.8% of coflex patients and 62.5% of fusion patients met the criteria for operative success. The efficacy of the comparator in this trial is uncertain because successful fusion was obtained in only 71% of the control group, leaving nearly a third of patients with pseudoarthrosis. The report indicated no significant differences in Oswestry Disability Index or visual analog scale between the patients with pseudoarthrosis or solid fusion but Zurich Claudication Questionnaire scores were not reported. There were 18 (18%) spinous process fractures in the coflex group, of which 7 had healed by the 2-year follow-up. Reoperation rates were 6% in the fusion group and 14% in the coflex group ($p = .18$), including 8 (8%) coflex cases that required conversion to fusion. This secondary analysis is considered hypothesis-generating, and a prospective trial in patients with grade 1 spondylolisthesis is needed. In an RCT conducted in a patient population with moderate-to-severe lumbar spinal stenosis with significant back pain and up to grade 1 spondylolisthesis, there was no difference in the primary outcome measure, the Oswestry Disability Index, between the patients treated with coflex plus decompression versus decompression alone. Composite clinical success defined as a minimum 15-point improvement in Oswestry Disability Index score, no reoperations, no device-related complications, no epidural steroid injections in the lumbar spine, and no persistent new or worsening sensory or motor deficit was used to assess superiority. A greater proportion of patients who received coflex plus decompression instead of decompression alone achieved the composite endpoint. However, the superiority of coflex plus decompression is uncertain because the difference in the composite clinical success was primarily driven by a greater proportion of patients in the control arm who received a secondary rescue epidural steroid injection. Because the trial was open-label, surgeons' decision to use epidural steroid injection could have been affected by their

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knowledge of the patient's treatment. Consequently, including this component in the composite clinical success measure might have overestimated the potential benefit of treatment. Analysis was not reported separately for the group of patients who had grade 1 spondylolisthesis, leaving the question open about whether the implant would improve outcomes in this population. Consideration of existing studies as indirect evidence regarding the outcomes of using spacers in this subgroup is limited by substantial uncertainty regarding the balance of potential benefits and harms. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have spinal stenosis and no spondylolisthesis or instability who receive an interlaminar spacer with spinal decompression surgery, the evidence includes an RCT and a retrospective study. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The pivotal RCT, conducted in a patient population with spondylolisthesis no greater than grade 1 and significant back pain, showed that stabilization of decompression with the coflex implant was noninferior to decompression with spinal fusion for the composite clinical success measure. However, in addition to concerns about the efficacy of fusion in this study, there is uncertainty about the net benefit of routinely adding spinal fusion to decompression in patients with no spondylolisthesis. Fusion after open decompression laminectomy is a more invasive procedure that requires longer operative time and has a potential for higher procedural and postsurgical complications. When the trial was conceived, decompression plus fusion was viewed as the standard of care for patients with spinal stenosis with up to grade 1 spondylolisthesis and back pain; thus demonstrating noninferiority with a less invasive procedure such as coflex would be adequate to result in a net benefit in health outcomes. However, the role of fusion in the population of patients represented in the pivotal trial is uncertain, especially since the publication of the Swedish Spinal Stenosis Study, and the Spinal Laminectomy versus Instrumented Pedicle Screw study, 2 RCTs comparing decompression alone with decompression plus spinal fusion that were published in 2016. As a consequence, results generated from a noninferiority trial using a comparator whose net benefit on health outcome is uncertain confounds meaningful interpretation of trial results. Therefore, demonstrating the noninferiority of coflex plus spinal decompression versus spinal decompression plus fusion, a comparator whose benefit on health outcomes is uncertain, makes it difficult to apply the results of the study. Outcomes from the subgroup of patients without spondylolisthesis who received an interlaminar device with decompression in the pivotal Investigational Device Exemption trial have been published, but comparison with decompression

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alone in this population has not been reported. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2018 Input

Clinical input was sought to help determine whether the use of interlaminar spacer with spinal decompression surgery for individuals with spinal stenosis, predominant back pain, and no or grade 1 spondylolisthesis who failed conservative treatment would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 6 respondents, including 2 specialty society-level responses and 4 physician-level responses, including 2 identified through a specialty society and 2 through an academic medical center.

For individuals who have severe spinal stenosis and grade 1 spondylolisthesis or instability who have failed conservative therapy who receive an interlaminar spacer with spinal decompression surgery, clinical input is not universally supportive of a clinically meaningful improvement in net health outcome. While some respondents considered the shorter recovery time and lower complication rate to be an advantage compared to fusion, others noted an increase in complications and the need for additional surgery with the device.

For individuals who have spinal stenosis and no spondylolisthesis or instability who receive an interlaminar spacer with spinal decompression surgery, clinical input is not universally supportive of a clinically meaningful improvement in net health outcomes, with clinical experts noting an increase in complications and need for additional surgery compared to laminectomy alone.

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2011 Input

In response to requests, input was received from 2 physician specialty societies and 2 academic medical centers while this policy was under review in 2011. Two of those providing input agreed this technology is investigational due to the limited high-quality data on long-term outcomes (including durability). Two reviewers did not consider this technology investigational, stating that it has a role in the treatment of selected patients with neurogenic intermittent claudication.

2009 Input

In response to requests, input was received from 1 physician specialty society and 3 academic medical centers while this policy was under review in 2009. Differing input was received; several reviewers indicated data were sufficient to demonstrate improved outcomes.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Society of Pain and Neuroscience

In 2022, the American Society of Pain and Neuroscience (ASPN) 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 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"

In 2022, ASPN also published evidence-based clinical guidelines informed by a systematic review of randomized controlled trials on interventional treatments for low back pain. The following recommendation was provided with regard to the use of interspinous spacers:

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- "Stand-alone interspinous spacers for indirect decompression are safe and effective for the treatment of mild to moderate lumbar spinal stenosis if no contraindications exist. Grade A; Level of certainty high; Quality of Evidence: I-A."

Department of Health & Human Services

In 2019, a Department of Health & Human Services inter-agency task force released a report on pain management best practices. The report provides best practices for development of effective pain management plans using a patient-centered approach in the diagnosis and treatment of acute and chronic pain. All of their statements are on generalized pain and their recommendations relate to gaps in comprehensive pain plan development. In their report, regarding interspinous process spacer devices, they state: "research has shown that interspinous process spacer devices can provide relief for patients with lumbar spinal stenosis with neuroclaudication." The guidelines do not compare therapies to each other and is not informed by a systematic review, it only offers various options to consider when building a pain management plan for a patient.

International Society for the Advancement of Spine Surgery

In 2016, the International Society for the Advancement of Spine Surgery published recommendations and coverage criteria for decompression with interlaminar stabilization. The Society concluded that an interlaminar spacer in combination with decompression can provide stabilization in patients who do not present with greater than grade 1 instability. Criteria included:

1. Radiographic confirmation of at least moderate lumbar stenosis.
2. Radiographic confirmation of the absence of gross angular or translatory instability of the spine at index or adjacent levels.
3. Patients who experience relief in flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least 12 weeks of non-operative treatment.

The document did not address interspinous and interlaminar distraction devices without decompression.

North American Spine Society

In 2018, the North American Spine Society (NASS) published specific coverage policy recommendations on the lumbar interspinous device without fusion and with decompression. The NASS recommended that:

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"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*."

Of note, clinical guidelines from NASS are no longer freely available.

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National Institute for Health and Care Excellence

In 2010, NICE published guidance that indicated "Current evidence on interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication shows that these procedures are efficacious for carefully selected patients in the short and medium-term, although failure may occur and further surgery may be needed." The evidence reviewed consisted mainly of reports on X-STOP^{®‡} Interspinous Process Decompression System.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT02555280 ^a	A 2 and 5 Year Comparative Evaluation of Clinical Outcomes in the Treatment of Degenerative Spinal Stenosis With Concomitant Low Back Pain by Decompression With and Without Additional Stabilization Using the Coflex ^{®‡} Interlaminar Technology for FDA Real Conditions of Use Study (Post-Approval 'Real Conditions of Use' Study)	300	Nov 2027
NCT04192591 ^a	A 5-year Superior ^{®‡} IDS Clinical Outcomes Post-Approval Evaluation (SCOPE)	214	May 2032

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<i>Unpublished</i>			
NCT02457468 ^a	The Coflex ^{®‡} COMMUNITY Study: An Observational Study of Coflex ^{®‡} Interlaminar Technology	325	Dec 2019
NCT04087811 ^a	Postmarket Registry for Evaluation of the Superion ^{®‡} Spacer	1672	Mar 2021
NCT04563793 ^a	Postmarket Outcomes Study for Evaluation of the Superion Spacer	129	Mar 2023

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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Policy History

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- 02/07/2007 Medical Director review
- 02/21/2007 Medical Policy Committee approval.
- 02/04/2009 Medical Director review
- 02/19/2009 Medical Policy Committee approval. No change to coverage.
- 02/04/2010 Medical Policy Committee review
- 02/17/2010 Medical Policy Implementation Committee approval. No change to coverage.
- 02/03/2011 Medical Policy Committee review
- 02/16/2011 Medical Policy Implementation Committee approval. No change to coverage.
- 02/02/2012 Medical Policy Committee review
- 02/15/2012 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 06/06/2013 Medical Policy Committee review
- 06/25/2013 Medical Policy Implementation Committee approval. Title changed from “Interspinous Distraction Devices (Spacers)” to “Interspinous and Interlaminar Stabilization/Distracton Devices (Spacers)”. Removed “secondary to lumbar stenosis” from the first investigational statement. Added that the use of an interlaminar device following decompressive surgery is considered to be investigational. Updated FDA section with new approval for Coflex.
- 06/05/2014 Medical Policy Committee review
- 06/18/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
- 09/03/2015 Medical Policy Committee review
- 09/23/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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09/08/2016	Medical Policy Committee review
09/21/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes and CPT coding update
02/01/2017	Coding adjustment
07/06/2017	Medical Policy Committee review
07/19/2017	Medical Policy Implementation Committee approval. Coding update. Coverage eligibility unchanged.
07/05/2018	Medical Policy Committee review
07/11/2018	Medical Policy Implementation Committee approval. Clarified the first investigational statement to read, “the Company considers interspinous or interlaminar distraction devices as a stand-alone procedure as a treatment of spinal stenosis to be investigational.” Coverage intent and eligibility unchanged.
07/03/2019	Medical Policy Committee review
07/18/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/02/2020	Medical Policy Committee review
07/08/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/01/2021	Medical Policy Committee review
07/14/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/07/2022	Medical Policy Committee review
07/13/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/06/2023	Medical Policy Committee review
07/12/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/02/2024	Medical Policy Committee review
07/10/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 07/2025

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Interspinous and Interlaminar Stabilization/Distraktion Devices (Spacers)

Policy # 00221

Original Effective Date: 02/21/2007

Current Effective Date: 10/20/2024

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	22867, 22868, 22869, 22870
HCPCS	C1821
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into

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Louisiana

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standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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