**MEDICAL POLICY – 7.01.107**

Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

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**Replaces:** N/A

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**Introduction**

Back pain is a common symptom and can cause disability in some people. Despite extensive knowledge of the bones, nerves, muscles, tendons and structures of the spine, it can still be very difficult to identify a specific cause of pain for many people. Scientists and physicians have felt that one cause may be pressure put on the nerves by the vertebrae (bones in the spine). Devices known as spacers have been designed to be positioned between the vertebrae. Spacers are intended to reduce pain. Generally speaking, a surgeon places the device and then expands it. This expansion lifts the part of the bone that’s pressing on the nerve. Some devices are used after surgery to take pressure off of nerves and some devices are used as a stand-alone treatment. These devices are considered unproven for all uses. Published scientific studies show high failure and complications rates.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Policy Coverage Criteria

Note: This policy applies only to the following FDA-approved devices:

- X-STOP® Interspinous Process Decompression (IPD®) System
- Coflex® Interlaminar Technology implant (previously known as Interspinous U)
- Superion® Indirect Decompression System (previously Superion® Interspinous Spacer)

This policy does not address other implanted interspinous/interlaminar spacer devices (see Regulatory Status and Related Policies).

<table>
<thead>
<tr>
<th>Device</th>
<th>Investigational</th>
</tr>
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<tbody>
<tr>
<td>Interspinous or interlaminar distraction device</td>
<td>Interspinous or interlaminar distraction devices as a stand-alone procedure are considered investigational as a treatment of spinal stenosis.</td>
</tr>
<tr>
<td>Interlaminar stabilization device</td>
<td>Use of an interlaminar stabilization device following decompressive surgery is considered investigational.</td>
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</table>

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<td>CPT</td>
<td></td>
</tr>
<tr>
<td>22867</td>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level</td>
</tr>
<tr>
<td>22868</td>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure)</td>
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<tr>
<td>22869</td>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level</td>
</tr>
<tr>
<td>22870</td>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)</td>
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</table>
Related Information

N/A

Evidence Review

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 adjacent lamina and spinous processes to provide dynamic stabilization either following decompressive surgery or as an alternative to decompressive surgery.

Background

Spinal Stenosis

Lumbar spinal stenosis (LSS), which affects over 200,000 people in the United States, 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 United States, spondylosis (degenerative arthritis affecting the spine) is the most common cause. The primary symptom of LSS 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 LSS 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.\textsuperscript{1,2}

The lack of a valid classification for LSS contributes to wide practice variation and uncertainty about who should be treated surgically and which surgical procedure is best for each patient.\textsuperscript{3,4} This uncertainty also complicates research on spinal stenosis, particularly the selection of appropriate eligibility criteria and comparators.\textsuperscript{5}

**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 treatments for spinal stenosis may include physical therapy, pharmacotherapy, and epidural steroid injections, and many other modalities.\textsuperscript{6} The terms "nonsurgical" and "nonoperative" have also been used to describe conservative treatment. Professional societies recommend that surgery for LSS 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 vs 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 site decide what to offer.\textsuperscript{7} 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 0 to 5 mm of slippage (spondylolisthesis) who were willing to be randomized to decompression surgery vs 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 the better surgical outcomes in patients with spondylolisthesis than those with no spondylolisthesis.

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 two randomized trials of decompression alone vs decompression plus fusion were published. The Swedish Spinal Stenosis Study (SSSS) 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 (3-14 mm). The patients in SLIP who had laminectomy alone had higher reoperation rates than those in SSSS, and the patients who underwent fusion had better outcomes in SLIP than in SSSS. While some interpret the studies to reflect differences in patient factors—in particular, SSSS 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 (4-8 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 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 adjacent lamina and spinous processes to provide dynamic stabilization either following decompression surgery or as an alternative to decompression surgery. Interlaminar spacers have two 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.

**Summary of Evidence**

For individuals who have spinal stenosis and no spondylolisthesis or grade 1 who receive an interspinous or interlaminar spacer as a stand-alone procedure, the evidence includes two randomized controlled trials (RCTs) of two spacers (Superion Indirect Decompression System, coflex interlaminar implant). The relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Overall, use of interspinous or interlaminar distraction devices (spacers) as an alternative to spinal decompression has shown a high failure and complication rates. A pivotal trial compared the Superion Interspinous Spacer with the X-STOP (which is no longer marketed), without conservative care or standard surgery comparators. The trial reported significantly better outcomes with the Superion® 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 were similar in the 2 groups at 1-year follow-up, but reoperation rates due to 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 two years, reoperations due to absence of recovery had been performed in 33% of the coflex® group and in 8% of the bony decompression group. The evidence is insufficient to determine the effects of the technology on health outcomes.
For individuals who have severe spinal stenosis and grade 1 spondylolisthesis who have failed conservative therapy who receive an interlaminar spacer with spinal decompression surgery, the evidence includes two RCTs with a mixed population of patients. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Use of the coflex interlaminar implant as a stabilizer after surgical decompression has been studied in two 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 vs 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 CCS 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; \( p < 0.001 \)) and blood loss (106 vs 336 ml, \( p < 0.001 \)). There were no statistically significant differences between the coflex and fusion groups in ODI, VAS, and ZCQ scores after two 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 ODI or VAS between the patients with pseudoarthrosis or solid fusion, but ZCQ 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 (\( p = 0.18 \)), 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 LSS with significant back pain and up to grade 1 spondylolisthesis, there was no difference in the primary outcome measure, the ODI, between the patients treated with coflex plus decompression vs. decompression alone. CCS, defined as a minimum 15-point improvement in ODI 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 CCS 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 knowledge of the patient’s treatment. Consequently, including this component in the CCS 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. Limitations of the published evidence preclude determining the effects of the technology on net health outcome, and evidence reported through 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. 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 the effect of the technology on health outcomes.

For individuals who have spinal stenosis and no spondylolisthesis or grade I spondylolisthesis who receive an interlaminar spacer with spinal decompression surgery, the evidence includes an RCT. The relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The pivotal randomized controlled trial, 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 CCS 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 SSSS and the SLIP, two 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 vs 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 IDE trial have been published, but comparison with decompression alone in this population has not been reported. Limitations of the published evidence preclude determining the effects of the technology on net health outcome. Evidence reported through clinical input is not generally supportive of a clinically meaningful improvement in net health outcome, with clinical experts noting an increase in complications and need for additional surgery compared to laminectomy.
alone. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this policy are listed in Table 1.

**Table 1. Summary of Key Active Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
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<tr>
<td>NCT02555280*</td>
<td>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)</td>
<td>345</td>
<td>Jun 2022</td>
</tr>
<tr>
<td>NCT02457468</td>
<td>The Coflex®COMMUNITY Study: An Observational Study of Coflex® Interlaminar Technology</td>
<td>500</td>
<td>Jun 2023</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT03041896*</td>
<td>Retrospective Evaluation of the Clinical and Radiographic Performance of Coflex® Interlaminar Technology Versus Decompression With or Without Fusion</td>
<td>5000</td>
<td>Aug 2018 (completed)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

* Denotes industry-sponsored or cosponsored trial.

**Clinical Input Received 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

In response to requests, clinical input on the use of interlaminar spacer with spine decompression in individuals with spinal stenosis, predominant back pain, and no or grade 1 spondylolisthesis who failed conservative treatment 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, while this policy was under review in 2018. Evidence from clinical input is integrated within the Summary of Evidence section.

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 March 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 investigational, stating the technology 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

International Society for the Advancement of Spine Surgery

The International Society for the Advancement of Spine Surgery (2016) 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 I 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

The North American Spine Society (NASS; 2018) published specific coverage policy recommendations on lumbar interspinous device without fusion and with decompression.\textsuperscript{54} 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:

1. Degenerative spondylolisthesis of Grade 2 or higher.

2. Degenerative scoliosis or other signs of coronal instability.

3. Dynamic instability as detected on flexion-extension views demonstrating at least 3 mm of change in translation.

4. Iatrogenic instability or destabilization of the motion segment.

5. A fusion is otherwise not indicated for a Grade 1 degenerative spondylolisthesis and stenosis as per the NASS Coverage Recommendations for Lumbar Fusion.

6. A laminectomy for spinal stenosis is otherwise not indicated as per the NASS Coverage Recommendations for Lumbar Laminectomy.

**American Pain Society**

The guidelines from the American Pain Society (2009) indicated that interspinous spacer devices, based on fair evidence, have a B recommendation (clinicians consider offering the intervention).\textsuperscript{55,56} The net benefit was considered moderate through two years, with insufficient evidence to estimate the net benefit for long-term outcomes.

**National Institute for Health and Care Excellence**

The National Institute for Health and Care Excellence (2010) 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.”\textsuperscript{57} The evidence reviewed consisted mainly of reports on X-STOP.

**Medicare National Coverage**

There is no national coverage determination.
**Regulatory Status**

Three interspinous and interlaminar stabilization and distraction devices have been approved by Food Drug Administration (FDA) through the premarket approval (FDA product code: NQO) are summarized in Table 2.

**Table 2. Interspinous and Interlaminar Stabilization/Distraction Devices with Premarket Approval**

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Manufacturer</th>
<th>Approval Date</th>
<th>PMA</th>
</tr>
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<tbody>
<tr>
<td>Coflex® Interlaminar Technology</td>
<td>Paradigm Spine</td>
<td>2012</td>
<td>P110008</td>
</tr>
<tr>
<td>Superion® Indirect Decompression System (previously Superion® Interspinous Spacer)</td>
<td>VertiFlex</td>
<td>2015</td>
<td>P14004</td>
</tr>
</tbody>
</table>

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 have computed tomography (CT) evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing. It is intended for patients with 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 six 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. 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."

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 non-operative treatment. The coflex® “is intended to be implanted midline between 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 magnetic resonance (MR) 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, FDA requested additional postmarketing studies to provide longer-term device performance and device performance under general conditions of use. The first was the five-year follow-up of the pivotal investigational device exemption trial. The second was a multicenter trial with 230 patients in Germany who were followed for five years, comparing decompression alone with decompression plus coflex®. The third, a multicenter trial with 345 patients in the United States who were followed for five years, compared decompression alone with decompression plus coflex®. 27 FDA product code: NQO.

References


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/13/07</td>
<td>New Policy – Add to Surgery section.</td>
</tr>
<tr>
<td>08/23/07</td>
<td>Codes updated; no other changes.</td>
</tr>
<tr>
<td>11/11/08</td>
<td>Codes updated; 84.58 removed from policy.</td>
</tr>
<tr>
<td>07/14/09</td>
<td>Replace policy – Policy updated with literature search; no change to the policy statement. References added.</td>
</tr>
<tr>
<td>09/14/10</td>
<td>Related Policies updated.</td>
</tr>
<tr>
<td>06/13/11</td>
<td>Replace policy – Policy updated with literature review, reference numbers 10-17 added, clinical input reviewed, policy statement unchanged.</td>
</tr>
<tr>
<td>02/27/12</td>
<td>Related policies updated; 7.01.130 added.</td>
</tr>
<tr>
<td>08/22/12</td>
<td>Update Related Policies – Change title to 7.01.116.</td>
</tr>
<tr>
<td>12/19/12</td>
<td>Replace policy. References 18, 19, 20 added. No change to policy statement.</td>
</tr>
<tr>
<td>07/24/13</td>
<td>Replace policy. Interlaminar stabilization added to title. New policy statement added “Use of an interlaminar stabilization device following decompressive surgery is considered investigational”. New, approved device, added to regulatory surgery section. Rationale updated with literature review through April 4, 2013; references 7, 19, 20 added; others renumbered/removed. Policy statement changed as noted.</td>
</tr>
<tr>
<td>09/30/13</td>
<td>Update Related Policies. Change title to 7.01.120.</td>
</tr>
<tr>
<td>12/06/13</td>
<td>Update Related Policies. Add 7.01.138.</td>
</tr>
<tr>
<td>01/21/14</td>
<td>Update Related Policies. Add 7.01.551</td>
</tr>
<tr>
<td>05/20/14</td>
<td>Update Related Policies. Remove 7.01.116 as it was deleted, and replace with 7.01.555.</td>
</tr>
<tr>
<td>11/10/15</td>
<td>Annual Review. In the Regulatory Status section under Coflex® contraindications for degenerative lumbar scoliosis, the Cobb angle was corrected to greater than 25°. Clinical trials reformatted into a table. Policy updated with literature review through March 11, 2015; references 1-2, 7, 9-12, 27 added. HCPCS code C1821 removed from policy as not used for adjudication. Policy statements unchanged.</td>
</tr>
<tr>
<td>07/01/16</td>
<td>Annual Review, approved June 14, 2016. Policy updated with literature review through February 22, 2016; references 21, 26-27, and 29 added. Rationale section revised; policy statements unchanged.</td>
</tr>
<tr>
<td>10/11/16</td>
<td>Policy moved into new format; no change to policy statements.</td>
</tr>
<tr>
<td>01/01/17</td>
<td>Coding update, added new CPT codes 22867-22870 effective 1/1/17.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
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<td>------------</td>
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</tr>
<tr>
<td>07/01/17</td>
<td>Annual Review, approved June 6, 2017. Policy updated with literature review through February 23, 2017; references 7-8 and 14-16 added. Removed CPT code 22899. Policy statements edited for clarification; the intent of the policy is unchanged.</td>
</tr>
<tr>
<td>01/01/18</td>
<td>Coding update; removed CPT codes 0171T and 0172T as they terminated 1/1/17.</td>
</tr>
<tr>
<td>07/01/19</td>
<td>Annual Review, approved June 20, 2019. Policy updated with literature review through March 2019, references added. Policy statements unchanged.</td>
</tr>
<tr>
<td>12/01/19</td>
<td>Interim Review, approved November 6, 2019. Policy updated with literature review through July 2019. Policy statements unchanged.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2019 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5952. TTY 800-537-5767 (TDD)
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-5767 (TDD)
Email AppealsDepartmentInquiries@Premera.com

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs.
You have the right to get this information and help in your language at no cost.
Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Arabic):
يوجد هذا الإشعار معلومات هامة. قد يوجد هذا الإشعار معلومات مهمة بصيغة تفريغية، أو معلومات تتعلق إجمالاً بجميع الموضوعات المتعلقة بإصلاحات الإشراحت. قد تلعب الإشراحت دورًا هامًا في توفير معلومات عن تأمينات الصحة أو المساعدة في تدخل التأمين. يرجى مراجعة الإشراحت على هذه المعلومات السماحة ينطلق اختصارًا: 800-722-1471 (TTY: 800-842-5357).

中文 (Chinese):
本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知內容可能會有重要日期。您可能需要在截止日期之前採取行動。以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).

Kreyòl ayisyen (Creole):

Deutsche (German):

Oromoo (Cushite):

Italiano (Italian):
Japanese (Japanese):
この通知には重要な情報が含まれています。この通知には、Premera Blue Crossの申請または補償範囲に関する重要な情報が含まれている場合があります。この通知に記載されている可能性のある重要な日付をご確認ください。健康保険または補償を維持するには、特定の期日にまでに行動を取らなければならない場合があります。この言語による情報は、電話で提供されます。800-722-1471 (TTY: 800-842-5357)までお電話ください。

한국어 (Korean):
본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관한 하관된 Premera Blue Cross를 통해 보낼 커버리지에 관한 정보를 포함하고 있습니다. 본 통지서는 책임이 있는 빌패이나 있을 수 있습니다. 귀하의 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하의 신용 또는 보험의 만료 여부가 있을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357)로 전화하십시오.

Lao (Lao):
ພາສາລາວ: ລາວພາສານ້ອການຕັ້ງການຂອງທ່ານໂດຍບໍ່ວ່າມີຄວາມຄ່າຍຄ່າຍ. ສັງກວ່າທ່ານມີການບັນລະບາຍເລື່ອງທີ່ມີຄວາມຄ່າຍຫຼາຍທີ່ມີຄວາມຄ່າຍ ໃນການບັນລະບາຍເລື່ອງທີ່ມີຄວາມຄ່າຍ. ເນື້ອທີ່ມີຄວາມຄ່າຍຂອງທ່ານໄດ້ຮັບການບັນລະບາຍເລື່ອງທີ່ມີຄວາມຄ່າຍ. ຄຳ້ນທ່ານການບັນລະບາຍເລື່ອງທີ່ມີຄວາມຄ່າຍ. ສັງກວ່າທ່ານມີການບັນລະບາຍເລື່ອງທີ່ມີຄວາມຄ່າຍ. 800-722-1471 (TTY: 800-842-5357)

Punjabi (Punjabi):
ਈਸਾਈ ਤੋਂ ਕਊਕ੍ਰਮ ਵਧਾਈ ਸਦੀ ਕਰਦੇ ਹਨ। ਈਸਾਈ ਤੋਂ ਕਊਕ੍ਰਮ ਵਧਾਈ ਸਦੀ ਕਰਦੇ ਹਨ। ਈਸਾਈ ਤੋਂ ਕਊਕ੍ਰਮ ਵਧਾਈ ਸਦੀ ਕਰਦੇ ਹਨ। 

Romanian (Romanian):

Russian (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

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Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud de cobertura a través de Premera Blue Cross. Es posible que haya fechas claves en este aviso. Es posible que deba tomar algunas medidas antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):
Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon. Ang paunawa na ito ay naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagkaisakap sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring may mahalagang petsa dito sa paunawa. Maaaring may mga mahalagang petsa dito sa paunawa. 800-722-1471 (TTY: 800-842-5357).