Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

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 (LSS) 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.

OBJECTIVE

The objective of this evidence review is to determine whether the use of an interspinous distraction device or interlaminar stabilization device improves the net health outcome in patients with lumbar spinal stenosis.

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**POLICY STATEMENT**

Interspinous or interlaminar distraction devices as a stand-alone procedure are considered **not medically necessary** as a treatment of spinal stenosis.

Use of an interlaminar stabilization device following decompression surgery is considered **not medically necessary**.

**POLICY GUIDELINES**

None

**BENEFIT APPLICATION**

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

**FDA REGULATORY STATUS**

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

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Manufacturer</th>
<th>Approval Date</th>
<th>PMA</th>
</tr>
</thead>
<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, 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 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:

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Instability of the lumbar spine, e.g., 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 six months of nonoperative treatment. The coflex "is intended to be implanted midline between the adjacent lamina of one or two 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 (e.g., 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 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 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**

**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 two randomized controlled trials (RCTs) of two spacers (Superion Indirect Decompression System (ISS), coflex interlaminar implant). The relevant outcomes are symptoms, functional outcomes, quality of life (QOL), 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 pivotal trial compared the Superion ISS 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 ISS on some measures. For example, the trial reported more than 80% of patients experienced improvements in certain QOL 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 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 composite clinical success (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 Oswestry Disability Index (ODI), visual analog scale (VAS) and Zurich Claudication Questionnaire (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 lumbar spinal stenosis (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 who receive an interlaminar spacer with spinal decompression surgery, the evidence includes an RCT. The relevant outcomes are symptoms, functional outcomes, QOL, 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 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 Swedish Spinal Stenosis Study (SSSS) and the Spinal Laminectomy versus Instrumented Pedicle Screw (SLIP), 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 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.

SUPPLEMENTAL INFORMATION

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 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

The NASS (2018) 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:

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 should consider offering the intervention)\(^{55,56}\). 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."\(^{57}\) The evidence reviewed consisted mainly of reports on X-STOP.

**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.

REFERENCES


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**POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 2012</td>
<td>New policy</td>
<td>Policy updated with literature review, references 7, 19, and 20 added and references reordered. Investigational policy statement added on interlaminar stabilization devices. Interlaminar stabilization added to title.</td>
</tr>
<tr>
<td>June 2015</td>
<td>Replace policy</td>
<td>Policy updated with literature review through February 23, 2017; references 7-8 and 14-16 added. Policy statements edited for clarification; the intent of the policy is unchanged.</td>
</tr>
<tr>
<td>June 2017</td>
<td>Replace policy</td>
<td>Policy updated after BCBSA Medical Advisory Panel (MAP) review and external consultation; A Structured Request for Clinical Input (SRCI) was sought after MPP approval of the policy in October and integration into the policy of the CI expert opinion was performed and presented during the December MPP Meeting; numerous references added. Policy statements unchanged.</td>
</tr>
<tr>
<td>March 2019</td>
<td>Replace policy</td>
<td>Policy updated after BCBSA Medical Advisory Panel (MAP) review and external consultation; A Structured Request for Clinical Input (SRCI) was sought after MPP approval of the policy in October and integration into the policy of the CI expert opinion was performed and presented during the December MPP Meeting; numerous references added. Policy statements unchanged.</td>
</tr>
<tr>
<td>June 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through March 6, 2019, references added. Policy statements unchanged.</td>
</tr>
<tr>
<td>December 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through July 9, 2019. Policy statements unchanged.</td>
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