FEP 7.01.107 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 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 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. Other types of dynamic posterior stabilization devices are pedicle screw/rod-based devices and total facet replacement systems; they are not discussed in this evidence review.

**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.

**BENEFIT APPLICATION**

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).
FEP 7.01.107 Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

FDA 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 1.

Table 1. 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>
</thead>
<tbody>
<tr>
<td>Decompression System</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coflex® Interlaminar Technology</td>
<td>Paradigm Spine</td>
<td>2012</td>
<td>P110008</td>
</tr>
<tr>
<td>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 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 non-operative 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, 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,
Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

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 (e.g., compression fracture).
- Severe facet hypertrophy that requires extensive bone removal which would cause instability.
- Grade II or greater spondylolisthesis.
- Isthmic spondylolisthesis or spondyloysis (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, FDA requested additional post-marketing 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 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 United States who were followed for 5 years, compared decompression alone with decompression plus coflex®,27 FDA product code: NQO.

RATIONAL

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 2 randomized controlled trials of 2 spacers (Superion Interspinous Spacer, 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 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 Foraminal Enlargement Lumbar Interspinous distraX ion 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 spinal stenosis and no spondylothesis or grade 1 spondylothesis who receive an interlaminar spacer with spinal decompression surgery, the evidence includes randomized controlled trials and nonrandomized comparative studies. 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 (non-inferiority). In a randomized controlled trial conducted in a patient population with moderate-to-severe lumbar spinal stenosis with significant back pain and up to grade 1 spondylothesis, there was no difference in the primary outcome measure, the Oswestry Disability Index (ODI), between the patients treated with coflex plus decompression vs. decompression alone. “Composite clinical success” (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 composite clinical success measure might have overestimated the potential benefit of treatment. This bias could have been mitigated using protocol-mandated standard objective clinical criteria to guide decisions about secondary interventions and subsequent adjudication of these events by an independent blinded committee. Greater certainty about the net health outcome of adding coflex to decompression surgery might be demonstrated when the 5-year follow-up results of these trials and an ongoing trial (NCT02555280) on decompression with and without the coflex implant in the United States are published. To be useful for clinical decision-making, this study should report the patient-reported effectiveness measures for both back pain (ODI and/or back visual analog scale) and the claudication (Zurich Claudication Questionnaire and/or leg visual analog scale) in all patients at 5 years.

For decompression with coflex vs decompression with spinal fusion, the pivotal randomized controlled trial, conducted in a patient population with spondylothesis no greater than grade 1 and significant back pain, showed that stabilization of decompression with the coflex implant was non-inferior to decompression with spinal fusion for the composite clinical success measure. However, there is uncertainty about the net benefit of routinely adding spinal fusion to decompression in patients with no or low-grade spondylothesis. Therefore, demonstrating the non-inferiority 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.

Clinical input supplements and informs the interpretation of the published evidence. Clinical input respondents were mixed in the level of support of this indication. While some of the expert opinion supported a potential benefit in carefully selected individuals, other experts were not confident of a clinically meaningful benefit or use in generally accepted medical practice, citing long-term complications leading to removal of the device. Some clinical input suggested that spacers may have utility in patients who are high risk for general anesthesia. 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 main source of uncertainty about the benefits versus risks of using coflex plus laminectomy in patients who are not able to have general anesthesia is whether revisions,
FEP 7.01.107 Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

removals, and other secondary surgical procedures can be conducted safely if they are needed. 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, based in part on a conference presentation of a level 1 study, that an interlaminar spacer in combination with decompression can provide stabilization in patients who do not present with greater than grade 1 instability. 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 the lumbar interspinous device without fusion and with decompression. 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.
FEP 7.01.107 Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

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).\textsuperscript{53} \textsuperscript{54} The net benefit was considered moderate through 2 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{55} 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 (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

FEP 7.01.107 Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)


FEP 7.01.107 Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)


FEP 7.01.107 Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)


POLICY HISTORY

<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>Update 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>
</tbody>
</table>

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
<table>
<thead>
<tr>
<th>March 2019</th>
<th>Update Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td></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>
</tbody>
</table>