Title: Interspinous and Interlaminar Stabilization / Distraction Devices (Spacers)

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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.

**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.

**OBJECTIVE**

The objective of this policy is to assess whether the use of an interspinous distraction device or interlaminar stabilization device improves health outcomes in patients with lumbar spinal stenosis.

**BACKGROUND**

Spinal stenosis, which can involve a narrowed central spinal canal, lateral spinal recesses, and/or neural foramina, is a common cause of back pain and disability, particularly as individuals get older. It can result from a number of pathologic processes, but in adults over 60 in the United States, spondylosis (degenerative arthritis affecting the spine) is the most common cause. The primary symptom of lumbar spinal stenosis (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.

Conservative treatments for spinal stenosis include physical therapy, pharmacotherapy, and epidural steroid injections. If conservative treatments fail, surgical approaches for spinal stenosis may be used. They include decompression surgery with or without spinal fusion. Spinal fusion is associated with complications, and is generally reserved for patients with spinal instability or moderate grade spondylolisthesis, when a vertebral body slips forward relative to an adjacent vertebral body. The health benefit of fusion in patients with no or low grade spondylolisthesis who are undergoing decompression surgery for spinal stenosis has been questioned.\(^1,2\) Two studies published in 2016 reached different conclusions concerning the health benefit of spinal fusion in patients undergoing spinal decompression.\(^1,2\) The Swedish Spinal Stenosis Study (SSSS) included patients with spinal stenosis, with or without degenerative spondylolisthesis.\(^1\) Comparison of patients undergoing decompression surgery plus fusion to patients undergoing...
decompression surgery alone showed no benefit of fusion. In contrast, the Spinal Laminectomy versus Instrumented Pedicle Screw (SLIP) trial included patients with spinal stenosis and grade I spondylolisthesis, and found that some outcomes were improved with the addition of spinal fusion to decompression surgery, albeit at higher cost and an increase in complications.2

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 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. 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.

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 are implanted between adjacent lamina and 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. Other types of dynamic posterior stabilization devices are pedicle screw/rod-based devices and total facet replacement systems; they are not covered in this policy.

REGULATORY STATUS

In 2015 the Superion® Interspinous Spacer (ISS VertiFlex) was approved by FDA through the premarket approval process. The Superion ISS, as stated in the premarket approval, is 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. The Superion® ISS is indicated for those 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 nonoperative treatment. The Superion® ISS may be implanted at one or 2 adjacent lumbar levels in patients in whom treatment is indicated and at no more than 2 levels, from L1 to L5.

Continued FDA approval of the Superion device is contingent on reports from 2 postapproval studies, the Superion® Post-Approval Clinical Evaluation and Review (SPACER), a 60-month study comparing the Superion device with the X-STOP, and the Superion® New Enrollment Study, a new study comparing the Superion with decompression alone in at least 358 subjects.

In 2012, the coflex® Interlaminar Technology implant (Paradigm Spine) was approved by FDA through the premarket approval process (P110008). It 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 adjacent lamina of 1 or 2 contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s).”

The FDA lists the following contraindications to use of the 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 >25 degrees)
- 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 imaging (MRI) contrast agents
- Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction

"Contains Public Information"
The FDA labeling also contains multiple precautions and the following warning:
"Data has demonstrated that spinous process fractures can occur with coflex® implantation."

Continued FDA approval of the coflex® is contingent on annual reports of 2 post-approval studies to provide longer-term device performance and device performance under general conditions of use. One study will provide 5-year follow-up of the cohort in the pivotal investigational device exemption trial. The second will be a multi-center trial with 230 patients with follow-up at 5 years that compares decompression alone versus decompression plus coflex®. FDA product code: NQO.

The Wallis System (originally from Abbott Spine; currently from Zimmer Spine) was introduced in Europe in 1986. The first generation Wallis implant was a titanium block; the second generation device is composed of a plastic-like polymer that is inserted between adjacent processes and held in place with a flat cord that is wrapped around the upper and lower spinous processes. The Wallis System is currently being tested in a FDA-regulated clinical trial.

Also in an FDA-regulated clinical trial is the DIAM™ Spinal Stabilization System (Medtronic Sofamor Danek), which is a soft interspinous spacer with a silicone core. The DIAM™ system requires removal of the interspinous ligament and is secured with laces around the upper and lower spinous processes. Other clinical trials underway at U.S. centers are studying the In-Space (Synthes)-and FLEXUS™ (Globus Medical) devices; the comparator in these trials is the X-STOP device, which has been withdrawn from the market.

The NL-Prow™ (Non-Linear Technologies), Aperius® (Medtronic Spine) and Falena® (Mikai) devices are in trials in Europe.
POLICY

A. Interspinous or interlaminar distraction devices as a stand-alone procedure are considered experimental / investigational as a treatment of spinal stenosis.

B. Use of an interlaminar stabilization device following decompression surgery is considered experimental / investigational.

RATIONALE

The most recent literature review was performed through February 23, 2017.

The literature is dominated by reports from non-U.S. centers evaluating devices not approved by the U.S. Food and Drug Administration (FDA), though a number of them are in trials at U.S. centers. As of April 2017, only the X-STOP, coflex, and Superion Interspinous Spacer (ISS) devices had received FDA approval for use in the United States. Manufacturing of the X-STOP stopped in 2015. This review focuses on devices currently available for use in the United States. Following is a summary of the key literature to date.

Interspinous or Interlaminar Spacer as a Stand-Alone Treatment

A number of meta-analyses have compared interspinous distraction devices to traditional decompressive surgery for lumbar spinal stenosis (LSS). However, these meta-analyses include the X-STOP and other interspinous spacers not or no longer available in the United States. Therefore, they only reviewed here when discussed as a comparator to an indicated device with FDA approval.

Superion ISS Device vs X-STOP Device

In 2015, 2- and 3-year results were published from an FDA-regulated, industry-sponsored, multicenter randomized, investigational device exemption (IDE), noninferiority trial (10% margin) comparing the Superion ISS with the X-STOP. A total of 391 patients (190 Superion, 201 X-STOP) with intermittent neurogenic claudication despite 6 months of nonsurgical management were enrolled, randomized, and implanted with the Superion ISS or X-STOP spacers. The primary outcome was a composite of clinically significant improvement in at least 2 of 3 Zurich Claudication Questionnaire (ZCQ) domain scores compared with baseline; freedom from reoperation, epidural steroid injection, nerve block, rhizotomy, or spinal cord stimulator; and freedom from major implant or procedure-related complications.

The primary noninferiority end point was met, with a Bayesian posterior probability of 0.993. However, 111 (28%) patients (54 Superion ISS, 57 X-STOP) were withdrawn from the trial during follow-up due to a protocol-defined secondary intervention. Modified intention-to-treat analysis showed similar levels of clinical success for leg pain, back pain, and Oswestry Disability Index (ODI) scores. Rates of complications and reoperations were similar between groups. Spinous process fractures, reportedly asymptomatic, occurred in 16.4% of Superion ISS patients and 8.5% of X-STOP patients (see Table 1).
At 3-year follow-up, 120 patients in the Superion ISS group and 129 in the X-STOP group remained (64% [249/391]). Of these, composite clinical success was obtained in 52.5% of patients in the Superion ISS group and 38.0% of the X-STOP group (p=0.023). The 36-month clinical outcomes were reported for 82 patients in the Superion ISS group and 76 patients in the X-STOP group (40% [158/391]). It is not clear from the report whether the remaining patients were lost to follow-up or were considered treatment failures and censured from the results. In addition, study interpretation is limited by questions about the efficacy of the comparator and lack of a control group treated with surgical decompression.

coflex Device
An industry-sponsored, European, multicenter, randomized, double-blind trial (Foraminal Enlargement Lumbar InterSpinous distraXion: FELIX) compared implantation of coflex (without bony decompression) to bony decompression in 159 patients with intermittent neurogenic claudication due to LSS. Functional outcomes measured by the ZCQ and modified Roland-Morris Disability Questionnaire, and pain measured by a visual analog scale (VAS) and the McGill Pain Questionnaire, were similar in the 2 groups at 1-year follow-up; surgery times were shorter, but reoperation rates due to absence of recovery were higher in the coflex group (29%) than in the bony decompression group (8%; p<0.001). For patients with 2-level surgery, the reoperation rate was 38% for coflex versus 6% for bony decompression (p<0.05). At 2 years, reoperations due to absence of recovery had been performed in 33% of the coflex group and 8% of the bony decompression group. VAS back pain score at final follow-up was also higher in the coflex group (36 mm vs 28 mm; on a 100-point scale).

Section Summary: Interspinous or Interlaminar Spacer as Stand-Alone Treatment
The evidence for the Superion ISS for LSS includes an FDA-regulated pivotal trial. This trial compared the Superion ISS with the X-STOP, but did not include comparison groups for conservative care or standard surgery. The trial reported significantly better outcomes on some measures. For example, the percentage of patients experiencing improvement in outcomes was reported as over 80%. However, this percentage was based on 40% of the original dataset. Interpretation of this trial is limited by questions about 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 was compared with decompression in the multicenter, double-blind FELIX trial. Functional outcomes and pain were similar in both groups at 1-year follow-up, but reoperation rates due to lack of recovery were substantially higher with the coflex implant.
(29%) compared with bony decompression (8%). It is not clear whether patients with reoperations were included in pain and function assessments; if they were, this would have decreased assessment scores at 1 year. For patients with 2-level surgery, the reoperation rate was 38% for coflex and 6% for bony decompression. At 2 years, reoperations due to absence of recovery had been performed in 33% of the coflex group compared with 8% of the bony decompression group.

**Interlaminar Stabilization Devices Used With Spinal Decompression Surgery**

**coflex Device**

The pivotal IDE trial for coflex Interlaminar Technology was a nonblinded, randomized, multicenter, noninferiority trial (-10% noninferiority margin) of decompression plus coflex compared to decompression plus posterolateral fusion and pedicle screw fixation in patients with stenosis and up to grade I spondylolisthesis.\(^7,8\) Detailed inclusion and exclusion criteria are described by Davis et al in 2013.\(^8\) Four-year follow-up was reported in 2015 and 3- and 5-year follow-ups in 2016.\(^9-11\) A total of 344 patients were randomized in a 2:1 ratio (230 coflex, 114 fusion controls). Twenty two patients were not included in the per protocol analysis due to protocol violations, resulting in 215 patients in the coflex group and 107 fusion controls. Compared with fusion, implantation of the coflex device required less operative time (98.0 minutes vs 153.2 minutes), resulted in less blood loss (109.7 mL vs 348.6 mL), and required a shorter hospital length of stay (1.9 days vs 3.2 days).

Composite clinical success at 24 months showed that coflex was noninferior to posterolateral fusion (-10% noninferiority margin). Secondary effectiveness criteria, which included ZCQ score, VAS scores for leg and back pain, 12-Item Short-Form Health Survey scores, time to recovery, patient satisfaction, and several radiographic end points, tended to favor the coflex group using Bayesian analysis. The percentages of device-related adverse events were similar for the 2 groups. In the subset of patients with grade I spondylolisthesis, the coflex and fusion groups had similar outcomes in ODI, VAS, and ZCQ scores.\(^12\) There was a 14.1% incidence of spinous process fractures, which were reported to be mostly asymptomatic. The FDA considered the data in this nonblinded trial to be sufficient to support reasonable assurance of safety and effectiveness for device approval, but approval was conditioned on 2 additional studies to provide longer term follow-up (in the IDE cohort; see Table 2) and evaluate device performance under actual conditions of use (decompression alone vs decompression with coflex; see Table 3 NCT02555280).

**Table 2. Results of the FDA-Regulated Noninferiority Trial Comparing Decompression Plus the coflex Device to Decompression Plus Posterolateral Spinal Fusion and Pedicle Screw Fixation**

<table>
<thead>
<tr>
<th>Year</th>
<th>Group</th>
<th>N (%)</th>
<th>Success Rates(^a)</th>
<th>Diff</th>
<th>95% CI</th>
<th>VAS Leg Score(^b)</th>
<th>VAS Back Score(^b)</th>
<th>ODI Score(^b)</th>
<th>Secondary Surgeries/Injections</th>
</tr>
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<tbody>
<tr>
<td>2(^8)</td>
<td>coflex</td>
<td>215</td>
<td>66.2%</td>
<td></td>
<td></td>
<td>20.6</td>
<td>23.6</td>
<td>22.0</td>
<td>10.7%</td>
</tr>
<tr>
<td></td>
<td>Fusion</td>
<td>107</td>
<td>57.7%</td>
<td>8.5%(^c)</td>
<td>NR</td>
<td>24.1</td>
<td>27.0</td>
<td>26.7</td>
<td>7.5%</td>
</tr>
<tr>
<td>3(^11)</td>
<td>coflex</td>
<td>196 (91%)</td>
<td>62.2%</td>
<td></td>
<td></td>
<td>83%</td>
<td>83%</td>
<td>89.6%(^e)</td>
<td>24%</td>
</tr>
<tr>
<td></td>
<td>Fusion</td>
<td>94 (88%)</td>
<td>48.9%</td>
<td>13.3%(^c) (_{,d})</td>
<td>1.1% to 25.5%</td>
<td>83%</td>
<td>78%</td>
<td>75.7%</td>
<td>21%</td>
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<tr>
<td>4(^9)</td>
<td>coflex</td>
<td>184 (86%)</td>
<td>57.6%</td>
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<td></td>
<td></td>
<td></td>
<td>33.2%</td>
</tr>
<tr>
<td></td>
<td>Fusion</td>
<td>90 (86%)</td>
<td>46.7%</td>
<td>10.9%(^c)</td>
<td>-1.6% to 23.5%</td>
<td></td>
<td></td>
<td></td>
<td>35.6%</td>
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<tr>
<td>5(^10)</td>
<td>coflex</td>
<td>191 (89%)</td>
<td>50.3%</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>31.2%</td>
</tr>
<tr>
<td></td>
<td>Fusion</td>
<td>91 (85%)</td>
<td>44.0%</td>
<td>6.3%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>33.6%</td>
</tr>
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</table>

\(^a\) p=NS

\(^b\) Includes ZCQ score, VAS scores for leg and back pain, 12-Item Short-Form Health Survey scores, time to recovery, patient satisfaction, and several radiographic end points.

\(^c\) Includes spinous process fractures.

\(^d\) Includes patients with grade I spondylolisthesis.

\(^e\) Includes patients with grade II spondylolisthesis.
CI: confidence interval; Diff: difference between success rate of coflex and fusion groups; FDA: Food and Drug Administration; ODI: Oswestry Disability Index (reported as mean score or percent with at least 15-point improvement); NR: not reported; VAS: visual analog score (reported as mean score out of 100 or percent with at least 20-mm improvement).

\(^a\) Composite clinical success was composed of 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.

\(^b\) Patients with secondary procedures were censored from results at 4 and 5 years.

\(^c\) Bayesian posterior probability of noninferiority >0.999.

\(^d\) Bayesian posterior probability of superiority of 0.984.

\(^e\) \(p=0.008\).

The reported follow-up rates through 5 years were at least 85\%. Evaluation of VAS and ODI scores in the follow-up study was limited due to the censoring of patients who received a secondary surgical intervention or injection. The authors reported that, in the uncensored data, the percentage of patients with ODI success was significantly higher in coflex group than in the fusion group over the 5 years of the study (data not reported). Overall, success rates for the coflex group achieved noninferiority through 5 years and were statistically higher in the coflex group at the 3-year follow-up, with no significant differences between groups in secondary interventions.

In 2015, Roder et al reported on a cross registry study that compared lumbar decompression plus coflex (SWISSspine registry) to lumbar decompression alone (Spine Tango registry) in 50 pairs matched by a multifactorial propensity score. SWISSspine is a governmentally mandated registry from Switzerland for coverage with evidence development. Spine Tango is a voluntary registry from the Spine Society of Europe. Both registries use the numeric rating scale (NRS) for back and leg pain and the Core Outcome Measures Index (COMI) as the patient-based outcome instrument. The COMI consists of 7 questions to evaluate pain, function, well-being, quality of life, and disability. At 7- to 9-month follow-up, the coflex group had greater reductions in NRS back pain score (3.8 vs 2.5, \(p=0.014\)), NRS leg pain score (4.3 vs 2.5, \(p<0.001\)), NRS maximum pain score (4.1 vs 2.3, \(p=0.002\)), and greater improvement in COMI score (3.7 vs 2.5; \(p=0.029\)).

In 2010, Richter et al reported on a prospective case-control study of the coflex device in 60 patients who underwent decompression surgery. Two-year follow-up was published in 2014. The surgeon determined whether the midline structures were preserved or resected and whether the coflex device was implanted (1 or 2 levels). The indications for the 2 groups were identical, and use of the device was considered incidental to the surgery. At 1- and 2-year follow-ups, placement of a coflex device did not significantly improve the clinical outcome compared to decompression surgery alone.

Some radiologic findings with the coflex device require additional study to determine their clinical significance. In 2013, Tian reported a high rate (81.2\%) of heterotopic ossification (HO) at follow-up (range, 24-57 months) in patients who had received a coflex device. In 16 (50\%) of 32 patients, HO was detected in the interspinous space but had not bridged the space, while in 2 (6.3\%) patients there was interspinous fusion. In the 9 patients followed for more than 3 years, class II (interspinous space but not bridging) and class III (bridging) HO were detected in all 9. In 2016, Lee et al reported erosion around the spinous process and reductions in disc height and range of motion in patients treated with a coflex device and spinal decompression and were at least 24 months of follow-up. Erosion around the coflex device, which was observed in 47\% of patients, has the potential to result in spinous process fracture or device malposition. Continued follow-up is needed.
Section Summary: Interlaminar Stabilization Devices With Spinal Decompression Surgery
The use of the coflex interlaminar implant as a stabilizer after surgical decompression has been studied in 2 situations: as an alternative to spinal fusion after decompression or as an adjunct to decompression compared to spinal decompression alone. The pivotal RCT, conducted in a patient population with spinal stenosis and grade I or lower spondylolisthesis, showed that stabilization of spinal decompression with the coflex implant was noninferior to spinal decompression and fusion. However, the evidence of a health benefit for adding fusion to decompression in this population is inconclusive, which raises concern that decompression plus fusion is not necessarily an appropriate comparator, particularly in a noninferiority trial. Two studies published in 2016 reached different conclusions on the health benefit of spinal fusion in patients undergoing spinal decompression. The SSSS trial included patients with spinal stenosis, with or without degenerative spondylolisthesis. Comparison of patients undergoing decompression surgery plus fusion to patients undergoing decompression surgery alone showed no benefit of fusion. In contrast, the SLIP trial included patients with spinal stenosis and grade I spondylolisthesis and found that some outcomes were improved with the addition of spinal fusion to decompression surgery, albeit at higher cost and an increase in complications. Because the health benefit of spinal fusion as an adjunct to decompression in this population is uncertain, a noninferiority comparison of decompression plus coflex is not an appropriate comparator to demonstrate the value of adding coflex to decompression. The more appropriate comparison would be a trial to determine whether decompression plus a coflex device improves health outcomes compared to decompression alone in this population. Nonrandomized comparative studies have reported mixed results on whether use of the implant in combination with decompression improves outcomes compared with decompression alone. Greater certainty about the net health outcome of adding coflex to decompression surgery may be obtained when results of an ongoing RCT on decompression with and without the coflex implant are published.

SUMMARY OF EVIDENCE
For individuals who have spinal stenosis and up to grade I spondylolisthesis who receive an interspinous or interlaminar spacer as a stand-alone procedure, the evidence includes randomized controlled trials (RCTs). 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. Two devices are considered: the Superion Interspinous Spacer (ISS) and the coflex interlaminar implant. A pivotal trial regulated by the U.S. Food and Drug Administration compared the Superion ISS to 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 outcome measures. For example, the percentage of patients experiencing improvement was reported as over 80%. 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 (also called the interspinous U) was compared with decompression in the multicenter, double-blind trial 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 2 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 spinal stenosis and up to grade I spondylolisthesis who receive an interlaminar spacer with spinal decompression surgery, the evidence includes RCTs 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 alternative to spinal fusion after decompression or as an adjunct to decompression compared to decompression alone. The pivotal RCT, conducted in a patient population with grade 1 or lower spondylolisthesis, showed that stabilization of decompression with the coflex implant was noninferior to decompression with spinal fusion. However, evidence of a health benefit for fusion in this population is inconclusive, calling into question the validity of the noninferiority trial. Because of this uncertainty, a key question is whether decompression plus a coflex device improves health outcomes compared to decompression alone in this population. Nonrandomized comparative studies have reported mixed results on whether use of the implant in combination with decompression improves outcomes compared with decompression alone. Greater certainty about the net health outcome of this device might be obtained when results of an RCT on decompression with and without the coflex implant are published. The evidence is insufficient to determine the effects of the technology on health outcomes.

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.

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 but felt the technology had 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 felt data were sufficient to demonstrate improved outcomes.

PRACTICE GUIDELINES AND POSITION STATEMENTS
International Society for the Advancement of Spine Surgery
In 2016, the International Society for the Advancement of Spine Surgery (ISASS) published recommendations and coverage criteria for decompression with interlaminar stabilization.18 ISASS concluded, based in part on a conference presentation of a level I study, that an interlaminar spacer in combination with decompression can provide stabilization in patients who do not
present with greater than grade I instability. Recommended indications and limitations were presented. The document did not address interspinous and interlaminar distraction devices without decompression.

**North American Spine Society**
In 2014, the North American Spine Society (NASS) published specific coverage policy recommendations on lumbar interspinous device without fusion.19 NASS recommended that interspinous distraction devices may be indicated for degenerative lumbar stenosis with the following criteria: (a) associated with neurogenic claudication that is relieved by lumbar flexion, (b) patients older than 50 years old, (c) failure of nonoperative treatment, (d) no more than 25° of degenerative scoliosis, (e) no more than a grade I degenerative spondylolistheses, and (f) open surgery (eg, laminectomy) is not a medically safe treatment option because of comorbidities. NASS stated that interspinous distraction devices are not indicated in cases that do not fall within these parameters.

**American Pain Society**
The 2009 guidelines from the American Pain Society indicated that interspinous spacer devices, based on fair evidence, have a B recommendation (panel recommends that clinicians consider offering the intervention).20,21 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 U.K.’s National Institute for Health and Care Excellence published guidance in November 2010 stating that “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.22

**U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS**
Not applicable.

**ONGOING AND UNPUBLISHED CLINICAL TRIALS**
Some currently unpublished trials that might influence this policy are listed in Table 3.

**Table 3. Summary of Key Active Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<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>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>Oct 2017</td>
</tr>
</tbody>
</table>
CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

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

22868 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)

22869 Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level

22870 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)

22899 Unlisted procedure, spine

C1821 Interspinous process distraction device (implantable)

- Effective January 1, 2017, there are specific CPT category I codes for this procedure: 22867, 22868.
- Effective January 1, 2007, there is also a HCPCS “C” Medicare pass-through code for the device: C1821

DIAGNOSES

Experimental / Investigational for all diagnoses related to this medical policy.

REVISIONS

02-08-2010 The Interspinous Distraction Devices (Spacers) medical policy is a new freestanding policy developed from the Minimally Invasive Procedures for Spine Pain medical policy which was

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
<th>Rationale</th>
<th>Coding Section</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>06-27-2011</td>
<td>Description updated.</td>
<td>Rationale updated.</td>
<td>Removed CPT code 22899 as there are specific codes for this service.</td>
<td>References updated.</td>
</tr>
<tr>
<td>02-24-2012</td>
<td>Description updated.</td>
<td>Rationale updated.</td>
<td>References updated.</td>
<td>References updated.</td>
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<tr>
<td>03-19-2013</td>
<td>Description updated.</td>
<td>Rationale updated.</td>
<td>References updated.</td>
<td>References updated.</td>
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<tr>
<td>01-23-2015</td>
<td>Updated Title to &quot;Interspinous and Interlaminar Stabilization / Distraction Devices (Spacers)&quot; from &quot;Interspinous Distraction Devices (Spacers)&quot;</td>
<td>Description updated</td>
<td>In Policy section: ▪ Added new experimental / investigational indication of &quot;Use of an interlaminar stabilization device following decompressive surgery is considered experimental / investigational.&quot;</td>
<td>Rationale updated</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>In Coding section: ▪ Added CPT Code: 22899 (for interlaminar stabilization)</td>
<td>References updated</td>
</tr>
<tr>
<td>07-21-2015</td>
<td>Updated Description section.</td>
<td>Updated Rationale section.</td>
<td>Updated References section.</td>
<td>Updated References section.</td>
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<tr>
<td>06-08-2016</td>
<td>Updated Description section.</td>
<td>Updated Rationale section.</td>
<td>Updated References section.</td>
<td>Updated References section.</td>
</tr>
</tbody>
</table>
| 06-09-2017 | Updated Description section. | In Policy section: ▪ In Item A, added "or interlaminar", "as a stand-alone procedure", and "spinal stenosis" and removed "neurogenic intermittent claudication" to read, "Interspinous or interlaminar distraction devices as a stand-alone procedure are considered experimental / investigational as a treatment of spinal stenosis."
▪ In Item B, changed "decompressive" to "decompression" to read, "Use of an interlaminar stabilization device following decompression surgery is considered experimental / investigational."
| Updated Rationale section. | In Coding section: ▪ Added coding bullet. | Updated References section. | Updated References section. |
REFERENCES


