**Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)**

**Medical Benefit**

*Effective Date: 10/01/17  
Next Review Date: 07/20*

**Preauthorization**

*Review Dates: 07/07, 07/08, 09/09, 09/10, 07/11, 07/12, 07/13, 07/14, 07/15, 07/16, 07/17, 07/18, 07/19*

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*This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.*

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

<table>
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<th>Populations</th>
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<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
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| • With spinal stenosis and no spondylolisthesis or grade I spondylolisthesis | • Interspinous or interlaminar spacer as a stand-alone procedure | • Lumbar spinal decompression surgery  
• Nonoperative treatment | • Symptoms  
• Functional outcomes  
• Quality of life  
• Treatment-related morbidity |
| Individuals:              | Interventions of interest are:             | Comparators of interest are:                | Relevant outcomes include:                  |
| • With spinal stenosis, and no or to grade I spondylolisthesis who failed conservative treatment | • Interlaminar spacer with spinal decompression surgery | • Lumbar spinal decompression with spinal fusion  
• Lumbar spinal decompression alone | • Symptoms  
• Functional outcomes  
• Quality of life  
• Treatment-related morbidity |

**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.

**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 of two 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 decom-
pression. The coflex interlaminar implant (formerly called the interspinous U) was compared with decompres-
sion in the multicenter, double-blind Foraminal Enlargement Lumbar Interspinous distraX ion trial. Functional
outcomes and pain levels were similar in the two groups at one 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 two 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 spondylolisthesis or grade 1 spondylolisthesis 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 two situations as an adjunct to decompression compared with decompression alone (supe-
riority) and as an alternative to spinal fusion after decompression (noninferiority). 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 spondylolisthesis, there was no difference in the primary outcome measure, the Oswes-
try 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 reoper-
a tions, 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. How-
ever, 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 compo-
site 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 cer-
tainty about the net health outcome of adding coflex to decompression surgery might be demonstrated when
the five-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 five years.

For decompression with coflex vs. decompression with spinal fusion, 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 spi-
nal 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 spondylolisthesis. 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.
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, 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.

POLICY

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

Use of an interlaminar stabilization device following decompressive surgery is considered investigational.

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.\(^1,2\)

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.\(^3,4\) This uncertainty also complicates research on spinal stenosis, particularly the selection of appropriate eligibility criteria and comparators.\(^5\)

Treatment

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

Conservative treatment for spinal stenosis may include physical therapy, pharmacotherapy, epidural steroid injections, and many other modalities.\(^6\) 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. A sub-group analysis of the SPORT trial found that only 37% of nonsurgically treated patients received physical therapy in the first six weeks of the trial and that those who received physical therapy before six weeks had better functional outcomes and were less likely to cross over to surgery later. These findings provide some support for the view that, in clinical trials, patients who did not have surgery may have had suboptimal treatment, which can lead to a larger difference favoring surgery. The SPORT investigators asserted that their nonoperative outcomes represented typical results at a multidisciplinary spine center at the time, but recommended that future studies compare the efficacy of specific nonoperative programs to surgery.

A recent trial by Delitto et al (2015) compared surgical decompression with a specific therapy program emphasizing physical therapy and exercise. Patients with lumbar spinal stenosis and from zero to five mm of slippage (spondylolisthesis) who were willing to be randomized to decompression surgery versus an intensive, organized program of nonsurgical therapy were eligible. Oswestry Disability Index scores were comparable to those in the SPORT trial. A high proportion of patients assigned to nonsurgical care (57%) crossed over to surgery (in SPORT the proportion was 43%), but crossover from surgery to nonsurgical care was minimal. When analyzed by treatment assignment, Oswestry Disability Index scores were similar in the surgical and nonsurgical groups after two 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 two 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 two, three, and four 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.
son (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 two 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.

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.

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 (four to eight 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.

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>
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<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>
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PMA: premarket approval.
The Superion® Indirect Decompression System (formerly InterSpinous Spacer) is indicated to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs secondary to a diagnosis of moderate degenerative lumbar spinal stenosis, with or without grade 1 spondylolisthesis, confirmed by x-ray, magnetic resonance imaging, 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 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, 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 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 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.
  o Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunc-
  tion.”

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 per-
formance and device performance under general conditions of use. The first was the five year follow-up of the piv-
otal 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 decompres-
sion alone with decompression plus coflex®.27, FDA product code: NQO.

RELATED PROTOCOLS
Facet Arthroplasty
Interspinous Fixation (Fusion) Devices
Lumbar Spinal Fusion

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are
considered investigational. For explanation of experimental and investigational, please refer to the Technology
Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to
conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced
procedures. Some of this protocol may not pertain to the patients you provide care to, as it may relate to
products that are not available in your geographic area.

REFERENCES
We are not responsible for the continuing viability of web site addresses that may be listed in any references
below.

1. Lurie J, Tomkins-Lane C. Management of lumbar spinal stenosis. BMJ. Jan 4 2016;352:h6234. PMID
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