Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

**MEDICAL POLICY – 7.01.107**

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

**BCBSA Ref. Policy: 7.01.107**

**Effective Date:** July 1, 2017  
**Last Revised:** Jan. 1, 2018  
**Replaces:** N/A

**RELATED MEDICAL POLICIES:**
- 7.01.120  
- 7.01.126  
- 7.01.130  
- 7.01.138  
- 7.01.551

**EVIDENCE REVIEW | REFERENCES | HISTORY**

Clicking this icon returns you to the hyperlinks menu above.

### Introduction

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

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

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

- X-STOP® Interspinous Process Decompression (IPD®) System
- Coflex® Interlaminar Technology implant (formerly known as Interspinous U)
- Superion® Interspinous Spacer (ISS, VertiFlex)

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

### Device

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

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

N/A

Evidence Review

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 such as decompression surgery with or without spinal fusion may be used.

Spinal fusion is associated with complications and is generally reserved for patients with spinal instability, including those with moderate grade spondylolisthesis (when a vertebral body slips forward relative to an adjacent vertebral body). The health benefit of adding fusion to decompression surgery in patients with no or low grade spondylolisthesis has been questioned. Two studies published in 2016 reached different conclusions concerning the health benefit of spinal fusion in patients undergoing spinal decompression. The Swedish Spinal Stenosis Study (SSSS) 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 Spinal Laminectomy versus Instrumented Pedicle Screw (SLIP) trial included patients with spinal stenosis and grade I spondylolisthesis. This study found that some outcomes were improved
when spinal fusion was added 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. One option is to insert interspinous or interlaminar implants (spacers) between the vertebrae, either following decompression surgery or as an alternative to decompression surgery. These small devices are placed midline between adjacent lamina and/or spinous processes and are then opened up or expanded. This helps prevent extension of the spine, thus reducing pinching of the nerve roots. The devices also enlarge the adjacent neural foramina, which also reduces pinching of the nerves as they exit through the foramen.

One type of interspinous implant is inserted between the spinous processes through a small (4-8 cm) incision. This acts as a spacer between the spinous processes, maintaining the 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 spinous processes. These implants aim to restrict painful motion while enabling normal motion. 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. However, they are not covered in this evidence review.

### Ongoing and Unpublished Clinical Trials

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

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

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<td></td>
<td></td>
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<tr>
<td>NCT03041896</td>
<td>Retrospective Evaluation of the Clinical and Radiographic Performance of Coflex®</td>
<td>5000</td>
<td>Oct 2017</td>
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Interlaminar Technology Versus Decompression With or Without Fusion

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<thead>
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<th>Title</th>
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<th>Enrollment Date</th>
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<tr>
<td>NCT01316211a</td>
<td>Comparative Evaluation of Clinical Outcome in the Treatment of Degenerative Spinal Stenosis With Concomitant Low Back Pain by Decompression With and Without Additional Stabilization Using the Coflex™ Interlaminar Technology</td>
<td>245</td>
<td>Dec 2017</td>
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<tr>
<td>NCT02555280a</td>
<td>A 2 and 5 Year Comparative Evaluation of Clinical Outcomes in the Treatment of Degenerative Spinal Stenosis With Concomitant Low Back Pain by Decompression With and Without Additional Stabilization Using the Coflex® Interlaminar Technology for FDA Real Conditions of Use Study (Post-Approval ‘Real Conditions of Use’ Study)</td>
<td>345</td>
<td>Jun 2022</td>
</tr>
<tr>
<td>NCT02457468</td>
<td>The Coflex®COMMUNITY Study: An Observational Study of Coflex® Interlaminar Technology</td>
<td>500</td>
<td>Jun 2023</td>
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</tbody>
</table>

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

**Summary of Evidence**

The evidence for interspinous or interlaminar spacers as a stand-alone treatment in individuals who have spinal stenosis and up to grade I spondylolisthesis includes several 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) used as an alternative to spinal decompression show 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 evidence for coflex interlaminar spacer in individuals who have spinal stenosis includes an RCT. The coflex
interlaminar implant was compared with decompression in the multicenter, double-blind FELIX trial. Functional outcomes and pain were similar in the 2 groups at 1-year follow-up, but reoperation rates due to absence of recovery were substantially higher with the coflex implant compared with bony decompression (29% vs 8%). It is not clear whether patients with reoperations were included in the pain and function assessments, which would have decreased the scores at 1-year. For patients with 2-level surgery, the reoperation rate was 38% for coflex versus 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for interlaminar spacers in individuals who are undergoing surgical decompression for spinal stenosis and up to grade I spondylolisthesis includes RCTs and non-randomized 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 different situations, as an alternative to spinal fusion after decompression or as an adjunct to decompression compared to decompression alone. The pivotal RCT, which was conducted in a population with grade 1 or lower spondylolisthesis, showed that outcomes following stabilization of a decompression with the coflex implant were not different than 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. Non-randomized 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 benefit of this device may be obtained when a recently completed and moderately sized RCT on decompression with and without the coflex implant is published. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Clinical Input Received From Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may provide appropriate reviewers who collaborate with and make recommendations during this process, 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. 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, NASS published specific coverage policy recommendations on lumbar interspinous device without fusion. 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 states 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 indicate that interspinous spacer devices, based on fair evidence, have a B recommendation (panel recommends that clinicians consider offering the intervention). 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 United Kingdom’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.

**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.

**Regulatory Status**

In 2015 the Superion® Interspinous Spacer (ISS, VertiFlex), was approved by the FDA through the premarket approval process. The device is approved 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. Spinal stenosis must have been confirmed by X-ray, MRI and/or have CT evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing. The
Superion® ISS is intended for patients with impaired physical function who experience relief from symptoms of leg/buttock/groin pain, numbness, and/or cramping, with or without back pain, with flexion and who have undergone at least 6 months of nonoperative treatment. The Superion® ISS may be implanted at one or two adjacent lumbar levels in patients in whom treatment is indicated and at no more than two levels, from L1 to L5.

Continued FDA approval of the Superion® device is contingent on reports from 2 post-approval studies. These are 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 the 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. This device was previously called the Interspinous U.

The coflex® is indicated for use in 1- or 2-level lumbar stenosis from L1-L5 in skeletally mature patients with at least moderate impairment in function, who experience relief from their symptoms of leg/buttocks/groin pain, with or without back pain, when they flex and who have undergone at least 6 months of non-operative treatment. The coflex® is intended to be implanted midline between adjacent lamina of 1 or 2 contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s).

FDA lists the following contraindications to use of the coflex®:

- Prior fusion or decompressive laminectomy at any index lumbar level
- Radiographically compromised vertebral bodies at any lumbar level(s) caused by current or past trauma or tumor (eg, compression fracture)
- Severe facet hypertrophy that requires extensive bone removal which would cause instability.
- Grade II or greater spondylolisthesis
- Isthmic spondylolisthesis or spondylolysis (pars fracture)
- Degenerative lumbar scoliosis (Cobb angle greater than 25°)
- Osteoporosis
- Back or leg pain of unknown etiology
• Axial back pain only, with no leg, buttock, or groin pain
• Morbid obesity defined as a body mass index greater than 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

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 information on 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 Abbott Spine; currently Zimmer Spine) was introduced in Europe in 1986. The first-generation Wallis implant was a titanium block; the second-generation device is a plastic-like polymer inserted between adjacent processes and held in place with a flat cord wrapped around the upper and lower spinous processes. The Wallis System is currently being tested in an 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.

References


### History

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<td>08/22/12</td>
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<td>01/21/14</td>
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<td>Annual Review, approved June 6, 2017. Policy updated with literature review through February 23, 2017; references 7-8 and 14-16 added. Removed CPT code 22899. Policy statements edited for clarification; the intent of the policy is unchanged.</td>
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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at

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