Medical Policy
Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

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- Policy: Medicare
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Policy Number: 584
BCBSA Reference Number: 7.01.107
NCD/LCD: NA

Related Policies
- Facet Arthroplasty, #174
- Interspinous Fixation - Fusion Devices, #436

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO Blue®SM and Medicare PPO Blue®SM Members

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.

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Outpatient</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>This is not a covered service.</td>
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<tr>
<td>Commercial PPO and Indemnity</td>
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<tr>
<td>Medicare HMO Blue®SM</td>
<td>This is not a covered service.</td>
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<tr>
<td>Medicare PPO Blue®SM</td>
<td>This is not a covered service.</td>
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CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code 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 as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

CPT Codes

<table>
<thead>
<tr>
<th>CPT codes</th>
<th>Code Description</th>
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<tbody>
<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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<tr>
<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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<tr>
<td>22869</td>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level</td>
</tr>
<tr>
<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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</table>

HCPCS Codes

<table>
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<tr>
<th>HCPCS codes</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>C1821</td>
<td>Interspinous process distraction device (implantable)</td>
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Description

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 evidence review.

**Summary**

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.

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 followup, 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.

Policy History

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<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>6/1/2017</td>
<td>BCBSA National medical policy review. Policy statements edited for clarity. The intent of the policy is unchanged. 6/1/2017</td>
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<tr>
<td>1/2017</td>
<td>Clarified coding information for the 2017 code changes.</td>
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<tr>
<td>5/2016</td>
<td>New references added from BCBSA National medical policy.</td>
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<td>6/2015</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>9/2014</td>
<td>New references added from BCBSA National medical policy.</td>
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Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References


