

Corporate Medical Policy

Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

File Name:	interspinous_and_interlaminar_stabilization-distraction_devices
Origination:	7/2006
Last CAP Review:	5/2018
Next CAP Review:	5/2019
Last Review:	5/2018

Description of Procedure or Service

Interspinous spacers are small devices implanted between the vertebral spinous processes. After implantation the device is opened or expanded to distract (open) the neural foramina and decompress the nerves. Interlaminar spacers are implanted midline between adjacent lamina and spinous processes to provide dynamic stabilization following decompressive 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 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 have 2 sets of wings that are placed around the inferior and superior spinous processes. These may be referred to as interlaminar implants or an interspinous U. These implants aim to restrict painful motion while otherwise enabling normal motion. The devices (spacers) distract the lamina 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; these are not covered in this policy.

Regulatory Status

In 2015 the Superior® Interspinous Spacer (ISS VertiFlex) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. The Superior® 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 Superior® 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 Superior® 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 Superior device is contingent on reports from two postapproval studies, the Superior® Post-Approval Clinical Evaluation and Review (SPACER), a 60-month study

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comparing the Superior device with the X-STOP, and the Superior® New Enrollment Study, a new study comparing the Superior with decompression alone in at least 358 subjects.

The coflex® Interlaminar Technology implant (Paradigm Spine) was approved by the FDA in 2012 (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 in flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least 6 months of non-operative 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).

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 (e.g., 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 of greater than 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.

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 (IDE) 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®.

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 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 US 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.

Related Policies

Total Facet Arthroplasty

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Interspinous Fixation (Fusion) Devices

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

Interspinous or interlaminar distraction devices as a stand-alone procedure are considered investigational for all applications. Use of an interlaminar stabilization device following decompressive surgery is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Interspinous and Interlaminar Stabilization/Distraktion Devices (Spacers) are covered

Not applicable

When Interspinous and Interlaminar Stabilization/Distraktion Devices (Spacers) are not covered

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 for all applications.

Policy Guidelines

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 high failure and complication rates. Two devices are considered: the Superior Interspinous Spacer (ISS) and the coflex interlaminar implant. A pivotal trial regulated by the U.S. Food and Drug Administration compared the Superior 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 Superior 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-

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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 two 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 22867, 22868, 22869, 22870, 22899, C1821

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Spinal Surgery Using Interspinous Distraktion Technology

National Institute for Health and Clinical Excellence (NICE). (2005). Interventional Procedure Consultation Document - Interspinous distraktion procedures for spinal stenosis causing neurogenic claudication in the lumbar spine. Retrieved 6/15/06 from <http://www.nice.org.uk/page.aspx?o=ip191consultation>.

BCBSA TEC-Medical Policy Clearinghouse News [electronic] - 6/16/2006

Specialty Matched Medical Consultant 6/2006

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.107, 10/10/2006

Specialty Matched Consultant Advisory Panel - 5/2007

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.107, 9/18/2007

Interspinous and Interlaminar Stabilization/Distractor Devices (Spacers)

Specialty Matched Consultant Advisory Panel - 5/2009

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.107, 3/10/2011

Specialty Matched Consultant Advisory Panel - 5/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.107, 12/8/2011

Medical Director – 3/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.107, 12/13/2012

Specialty Matched Consultant Advisory Panel – 5/2013

Interspinous and Interlaminar Stabilization/Distractor Devices (Spacers) – Name change

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.107, 5/9/2013

Senior Medical Director – 8/2013

Specialty Matched Consultant Advisory Panel – 5/2014

North American Spine Society. Interspinous device without fusion. 2014. Available online at: <https://www.spine.org/Documents/PolicyPractice/CoverageRecommendations/InterspinousFixationWithFusion.pdf> . Last accessed October, 2014.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.107, 5/22/2014

Specialty Matched Consultant Advisory Panel – 5/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.107, 4/23/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.107, 4/14/2016

Specialty Matched Consultant Advisory Panel – 5/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.107, 4/13/2017

Specialty Matched Consultant Advisory Panel – 5/2017

Specialty Matched Consultant Advisory Panel – 5/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.107, 6/14/2018

Policy Implementation/Update Information

Spinal Surgery Using Interspinous Distractor Technology

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|----------|--|
| 7/24/06 | New policy. Spinal surgery using interspinous distractor technology is considered investigational. Notification given 7/24/06. Effective date 10/2/06. |
| 10/30/06 | Added statement indicating "Until a specific code is created for this procedure, it is anticipated that providers will use the unlisted code, 22899, when submitting claims." to the "Billing/Coding" section. |
| 1/17/07 | Added new 2007 CPT codes 0171T and 0172T to "Billing/Coding" section. |
| 6/18/07 | Specialty Matched Consultant Advisory Panel review 5/23/2007. No changes to policy statement. References added. |

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- 7/6/09 Specialty Matched Consultant Advisory Panel review 5/28/2009. "Description" revised. No change to policy statement. Updated rationale in "Policy Guidelines" section. References added. (btw)
- 6/22/10 Policy Number(s) removed (amw)
- 6/21/11 Specialty Matched Consultant Advisory Panel review 5/25/2011. "Description" section revised. "Policy Guidelines" updated. No change to policy intent. References added. (btw)
- 4/17/12 Description section revised. Reworded the When Not Covered statement for consistency, no change to policy intent. Policy Guidelines updated. Reference added. Medical Director review 3/21/2012. (btw)
- 2/12/13 Reference added. (btw)
- 7/1/13 Description section and Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 5/15/2013. No change to policy intent. (btw)
- Interspinous and Interlaminar Stabilization/Distractio n Devices (Spacers) – Name change**
- 8/27/13 Policy name changed from "Spinal Surgery Using Interspinous Distractio n Technology" to "Interspinous and Interlaminar Stabilization/Distractio n Devices (Spacers)". Description section updated. Policy statement updated to indicate: "Interspinous distractio n devices and interlaminar stabilization devices are considered investigational for all applications." Added new statement under the When Not Covered section; "Use of an interlaminar stabilization device following decompressive surgery is considered investigational for all applications." Senior Medical Director review 8/6/2013. Reference added. (btw)
- 4/15/14 CPT code 22899 added to Billing/Coding section. (btw)
- 6/10/14 Specialty Matched Consultant Advisory Panel review 5/27/2014. No change to policy. (btw)
- 10/28/14 References added. (sk)
- 7/1/15 Specialty Matched Consultant Advisory Panel review 5/26/2015. (sk)
- 9/1/15 Reference added. (sk)
- 7/1/16 Reference added. Policy Guidelines updated. Regulatory Status updated. Specialty Matched Consultant Advisory Panel review 5/25/2016. (sk)
- 12/30/16 Codes 22867, 22868, 22869, and 22870 added to Billing/Coding section. Codes 0171T and 0172T removed from policy. (sk)
- 6/30/17 Reference added. Description section updated. Policy Statement revised for clarity. Policy Guidelines updated. Regulatory Status updated. Specialty Matched Consultant Advisory Panel review 5/31/2017. (sk)
- 8/11/17 Code C1821 added to Billing/Coding section. Notification given 8/11/2017 for effective date 10/13/2017. (sk)
- 6/29/18 Specialty Matched Consultant Advisory Panel review 5/23/2018. (sk)
- 9/28/18 Reference added. Policy Guidelines updated. Regulatory Status updated. (sk)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment

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and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.