

Corporate Medical Policy

Spinal Surgery Using Interspinous Distraction Technology

File Name:	spinal_surgery_using_interspinous_distraction_technology
Origination:	7/2006
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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 foramen and decompress the nerves.

Interspinous spacers are devices implanted between vertebral spinous processes. These interspinous implants aim to restrict painful motion while otherwise enabling normal motion. The devices (spacers) distract the 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 posterior dynamic stabilization devices are pedicle screw/rod-based devices and total facet replacement systems; these are not covered in this policy.

The interspinous implant is inserted between the spinous processes through a small (4-8 cm) incision and acts as a space 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.

Regulatory Status

In November 2005, the X STOP® Interspinous Process Decompression (IPD®) System (Kyphon - now part of Medtronic Spine LLC) was approved by the U.S. Food and Drug Administration (FDA) for "treatment of patients aged 50 or older suffering from neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis." It is approved for patients with moderately impaired physical function who have had a regimen of at least 6 months of non-operative treatment, and who have relief of their pain when in flexion. The device is approved for implantation at 1 or 2 lumbar levels in patients whose condition warrants surgery at no more than 2 levels. The X-STOP PEEK (polyetheretherketone) received approval in 2006 and is a modified version of the X-STOP that includes a PEEK spacer and additional 16-mm spacer size. The indications are the same as for the X-STOP titanium model.

The FDA lists the following contraindications to use of the X-STOP:

- 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:
 - significant instability of the lumbar spine, e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1.0 (on a scale of 1 to 4);
 - an ankylosed segment at the affected level(s);
 - acute fracture of the spinous process or pars interarticularis;
 - significant scoliosis (Cobb angle greater than 25 degrees);
- cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder

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- dysfunction;
- diagnosis of severe osteoporosis, defined as bone mineral density (from DEXA scan or some comparable study) in the spine or hip that is more than 2.5 [standard deviations] SD below the mean of adult normals in the presence of one or more fragility fractures;
- active systemic infection or infection localized to the site of implantation.

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 a 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), Superior (Vertiflex) and FLEXUS (Globus Medical) devices; in the FLEXUS trial; the comparator in these trials is the X-STOP device.

The Coflex implant (Paradigm Spine) is used in Europe but is not currently FDA approved. ExtendSure and CoRoent (both from NuVasive) were launched in Europe in 2005 and 2006. The NL-Prow (Non-Linear Technologies), Aperius (Medtronic Spine) and Falena (Mikai) devices are in trials in Europe.

Related Policies

Total Facet Arthroplasty

****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

Spinal surgery using interspinous distraction technology 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 Spinal Surgery Using Interspinous Distraction Technology is covered

Not applicable

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When Spinal Surgery Using Interspinous Distraction Technology is not covered

Interspinous distraction devices are considered investigational as a treatment of neurogenic intermittent claudication including but not limited to the X-STOP®, the Wallis System®, the Coflex™, the Diam™, ExtendSure and CoRoent. BCBSNC does not provide coverage for investigational services.

Policy Guidelines

Interspinous implants (spacers) distract the spinous processes and restrict extension in order to reduce pain in patients with lumbar spinal stenosis and neurogenic claudication. Although the single randomized study of the X-STOP device reports short-term improvements in symptoms and functional status when compared to non-operative therapy, a number of questions remain. Overall, high-quality comparative data are limited. There is a need for longer-term (more than 2 years) outcome data on symptom relief, the need for repeat procedures, and implant survival. Future studies need to better control for potential biases and avoid other methodologic issues, including follow-up of patients in the control group and consistent use of outcome measurements. There are also questions about patient selection criteria; for instance, should patients with any degree of spondylolisthesis be excluded from this treatment? In addition, comparisons with decompressive surgery are lacking, and recent case series indicate that outcomes may be less favorable than those reported in the multi-center randomized trial. The impact of this technology on net health outcomes is not known.

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.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 0171T, 0172T

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

National Institute for Health and Clinical Excellence (NICE). (2005). Interventional Procedure Consultation Document - Interspinous distraction 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

Specialty Matched Consultant Advisory Panel - 5/2009

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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

Policy Implementation/Update Information

- 7/24/06 New policy. Spinal surgery using interspinous distraction 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.
- 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)

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