MEDICAL POLICY

Excellus

SUBJECT: INTERSPINOUS AND INTERLAMINAR STABILIZATION/ DISTRACTION IMPLANTS (SPACERS)	**EFFECTIVE DATE: 09/21/06** **REVISED DATE: 08/16/07, 07/17/08, 06/18/09, 11/30/10, 09/15/11, 09/20/12, 09/19/13, 08/21/14**
POLICY NUMBER: 7.01.75	
CATEGORY: Technology Assessment	**PAGE: 1 OF: 6**

- ***If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.***
- ***Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.***
- ***Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.***

POLICY STATEMENT:

I. Based upon our criteria and assessment of the peer-reviewed literature, interspinous distraction devices have not been proven to be medically effective and are considered **investigational** for all indications; including the treatment of neurogenic intermittent claudication.

II. Based upon our criteria and assessment of peer-reviewed literature , interlaminar stabilization devices (e.g., Coflex® implant) following decompression surgery have not been proven to be medically proven effective and are considered **investigational**.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Implanted interspinous/interlaminar blocking or spacer devices ~~is~~ are intended to relieve symptoms of neurogenic intermittent claudication secondary to lumbar spinal stenosis by theoretically enlarging the neural foramen and decompressing the cauda equina. They also limit extension of the spine in the affected area when the patient stands and walks. The interspinous implant is placed between the spinous processes of the symptomatic levels of the lumbar spine through a small incision under local or general anesthetic. Interspinous spacers can also be classified by design as static or dynamic. Static devices, such as the X STOP (Medtronic Spine), ExtenSure (NuVasive), and Wallis implants (Abbott Spine), are noncompressible spacers. Despite being made of different materials, the intention of the device is to maintain a constant degree of distraction between the spinous processes. As the lumbar spine is mobile, the degree of distraction varies with flexion and extension with a static device.

Other interspinous devices, such as the DIAM (Medtronic Spine) are dynamic in that they are made of elastomeric materials that act as a rubbery bumper between the bones. The DIAM system requires removal of the interspinous ligament and is secured with laces around the upper and lower spinous processes.

As another option, a dynamic interlaminar device has been developed. The Coflex device (Paradigm Spine), previously called the Interspinous U, is an axially compressible U-shaped piece of metal that is interposed between adjacent lamina and have two sets of wings that are placed around the inferior and superior spinous processes. By inserting it in a somewhat compressed or preloaded condition, the device can expand/distract further with flexion. Interlaminar stabilization with this device is performed after decompression of stenosis at the affected levels(s).

RATIONALE:

Interspinous and interlaminar implants (spacers) stabilize or distract the adjacent lamina and/or spinous processes and restrict extension in order to reduce pain in patients with lumbar spinal stenosis and neurogenic claudication. Although the randomized device trials report 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 section criteria; for instance, whether patients with any degree of spondylolisthesis should be excluded from this treatment. In addition, comparisons with decompressive surgery without an interlaminar implant are lacking, and recent case series indicate that outcomes may be less favorable than those reported in the multi-center randomized trial.

St. Francis Medical Technologies/Medtronic Spine LLC received FDA Premarket Approval for the X STOP® Interspinous Process Decompression (IPD) System on November 21, 2005 for use in patients who are moderately impaired in physical function and have a confirmed diagnosis of spinal stenosis, are 50 years of age or older, and experience relief in flexion from their leg/groin/buttock pain. No patient in the FDA study had spondylolisthesis score greater than 1. The device is approved for implantation in one or two lumbar levels in patients for whom operative treatment is indicated at no more than 2 levels. A multi-center trial with two-year outcomes compared the X STOP implant with non-operative care and demonstrated clinically significant improvement in symptom severity for 60.2% of the implanted patients vs. 15.5% of patients treated non-operatively. Clinically significant improvement in physical function was reported by 57% of implanted and 14.8% of non-operated patients. Re-operation was required in 6% of implanted patients.

The Coflex® Interlaminar Technology implant (Paradigm Spine) was approved by the FDA in October 2012 (P110008). 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 1 or 2 contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s).

The pivotal investigational device exemption (IDE) trial for Coflex® Interlaminar Technology was a non-blinded randomized multi-center non-inferiority trial of Coflex® compared to posterolateral fusion with pedicle screw fixation. A total of 344 patients were randomized in a 2:1 ratio (215 Coflex® and 107 fusion controls, with 22 protocol violators). This study was conducted in a restricted population with numerous exclusion criteria. Compared to fusion, implantation of the Coflex® device required less operative time (98.0 vs. 153.2 minutes) and resulted in less blood loss (109.7 vs. 348.6 cc) and a shorter hospital stay (1.9 vs. 3.2 days). Composite clinical success (a combination of a minimum 15-point improvement in Oswestry Disability Index (ODI), no reoperations, no device-related complications, and no epidural steroid injections in the lumbar spine) at 24 months achieved non-inferiority compared to posterolateral fusion (66.2% Coflex® and 57.7% fusion). Secondary effectiveness criteria, which included the ZCQ, visual analog score (VAS) for leg and back pain, Short Form-12 (SF-12), time to recovery, patient satisfaction, and several radiographic endpoints, tended to favor the Coflex® group by Bayesian analysis. (In this analysis, non-overlapping confidence intervals imply statistically reliable group differences.) For example, ZCQ composite success was achieved in 78.3% of Coflex® patients (95% confidence interval [CI]: 71.9%, 84.7%) compared to 67.4% of controls (95% CI: 57.5%, 77.3%). The percentage of device-related adverse events was the same for the 2 groups (5.6% Coflex® and 5.6% control), and a similar percentage of asymptomatic spinous process fractures were observed. The FDA considered the data in this non-blinded study to support reasonable assurance of safety and effectiveness for device approval, but approval is conditional on 2 additional studies that will provide longer-term follow-up (in the IDE cohort) and evaluate device performance under actual conditions of use (decompression alone vs. decompression with Coflex®).

While other static and dynamic interspinous distraction and interlaminar stabilization implants are currently being studied in clinical trials, the long-term safety and efficacy of these devices are not yet known. 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. The DIAM Spinal Stabilization System (Medtronic Sofamor Danek) is also in a FDA-regulated clinical trial. Other clinical trials underway at U.S. centers are studying the In-Space (Synthes), Superion® (Vertiflex), and FLEXUS™ (Globus Medical) devices; the comparator in these trials is

the X-STOP device. 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.

CODES:	Number	Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

CPT:	0171T **(E/I)**	Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; single level
	0172T **(E/I)**	each additional level

HCPCS:	C1821 **(E/I)**	Interspinous process distraction device (implantable)
ICD-9	724.02	Spinal stenosis, lumbar region
	724.2	Low back pain
	729.5	Leg pain
ICD10:	M48.06-M48.07	Spinal stenosis (code range)
	M54.5	Low back pain
	M79.604-M79.609	Pain in leg/limb (code range)
	M79.651-M79.676	Pain in thigh/lower leg/foot/toes (code range)
	M99.23	Subluxation stenosis of neural canal of lumbar region
	M99.33	Osseous stenosis of neural canal lumbar region
	M99.43	Connective tissue stenosis of neural canal of lumbar region
	M99.53	Intervertebral disc stenosis of neural canal of lumbar region
	M99.63	Osseous and subluxation stenosis of intervertebral foramina of lumbar region
	M99.73	Connective tissue and disc stenosis of intervertebral foramina of lumbar region

REFERENCES:

Alexandre A, et al. One-year follow-up of a series of 100 patients treated for lumbar spinal canal stenosis by means of HeliFix interspinous process decompression device. Biomed Res Int 2014;176936.

*Anderson PA, et al. Treatment of neurogenic claudication by interspinous decompression: application of the X STOP device in patients with lumbar degenerative spondylolisthesis. Neurosurg: Spine 2006 Jun;4:463-71.

Barbagallo GM, et al. Analysis of complications in patients treated with the X-Stop Interspinous Process Decompression System: proposal for a novel anatomic scoring system for patient selection and review of the literature. Neurosurg 2009 Jul;65(1):111-9.

Bini W, et al. Minimally invasive treatment of moderate lumbar spinal stenosis with the superion interspinous spacer. Open Orthop J 2011;5:361-7.

Bjorn S, et al. X-Stop versus decompressive surgery for lumbar neurogenic intermittent claudication: A randomized controlled trial with 2 years follow-up. Spine 2013 Feb 11 [Epub ahead of print].

BlueCross BlueShield Association. Interspinous and interlaminar stabilization/distraction devices (spacers). Medical Policy Reference Manual Policy #7.01.107. 2014 May 22.

Bonaldi G, et al. Posterior vertebral arch cement augmentation (spinoplasty) to prevent fracture of spinous processes after interspinous spacer implant. AJNR 2012 Mar;33(3):522-8.

*Bono CM, et al. Interspinous process devices in the lumber spine. J Spinal Disord Tech 2007 May;20(3):255-61.

Bowers C, et al. Dynamic interspinous process stabilization: review of complications associated with X-Stop device. Neurosurg Focus 2010 Jun;28(6):E8.

*Brussee P, et al. Self-rated evaluation of outcome of the implantation of interspinous process distraction (X-Stop) for neurogenic claudication. Eur Spine J 2008 Feb;17(2):200-3.

Burnett MG, et al. Cost-effectiveness of current treatment strategies for lumbar spinal stenosis: nonsurgical care, laminectomy, and X-STOP. J Neurosurg Spine 2010 Jul;13(1):39-46.

Cabraja M, et al. The short- and mid-term effect of dynamic interspinous distraction in the treatment of recurrent lumbar facet joint pain. Eur Spine J 2009 Nov;18(11):1686-94.

Chou R, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. Spine 2009 May 1;34(10):1066-77.

Davis R, et al. Can low-grade spondylolisthesis be effectively treated by either coflex interlaminar stabilization or laminectomy and posterior spinal fusion? Two-year clinical and radiographic results from the randomized, prospective, multicenter US investigational device exemption trial: clinical articles. J Neurosurg Spine 2013 Aug;19(2):174-84.

Davis RJ, et al. Decompression and Coflex interlaminar stabilization compared with decompression and instrumented spinal fusion for spinal stenosis and low-grade degenerative spondylolisthesis: two-year results from the prospective, randomized, multicenter, Food and Drug administration Investigational Device exemption trial. Spine 2013 Aug 15;38(18):1529-39.

Deyo RA, et al. Interspinous spacers compared with decompression or fusion for lumbar stenosis: complications and repeat operations in the Medicare population. Spine 2013 May 1;38(10):865-72.

Fabrizi AP, et al. Interspinous spacers in the treatment of degenerative lumbar spinal disease: our experience with DIAM and Aperius devices. Eur Spine J 2011 May;20 Suppl 1:S20-6.

*Floman Y, et al. Failure of the Wallis interspinous implant to lower incidence of recurrent lumbar disc herniations in patients undergoing primary disc excision. J Spinal Disord Tech 2007 Jul;20(5):337-41.

Hartjen CA, et al. Two-year evaluation of the X-STOP interspinous spacer in different primary patient populations with neurogenic intermittent claudication due to lumbar spinal stenosis. J Spinal Disord Tech 2012 Nov 16. [Epub ahead of print].

Grasso G, et al. Clinical analysis following lumbar interspinous devices implant: where we are and where we go. Spinal Cord 2014 Jun 10 [Epub ahead of print].

Holinka J, et al. Stabilizing effect of dynamic interspinous spacers in degenerative low-grade lumbar instability. Int Orthop 2011 Mar;35(3):395-400.

*Hsu KY, et al. Quality of life of lumbar stenosis-treated patients in whom the X STOP interspinous device was implanted. J Neurosurg Spine 2006 Dec;5:500-7.

Kabir SM, et al. Lumbar interspinous spacers: a systematic review of clinical and biomechanical evidence. Spine 2010 Dec 1;35(25):E1499-506.

*Kim KA, et al. Dynamic intraspinous spacer technology for posterior stabilization: case-control study on the safety, sagittal angulation, and pain outcome at 1-year follow-up evaluation. Neurosurg Focus 2007 Jan 15;22(1):E7.

Kim DH, et al. Occult spinous process fractures associated with interspinous process spacers. Spine 2011 Jul 15;36(16):E1080-5.

Kim DH, et al. Association between degenerative spondylolisthesis and spinous process fracture after interspinous process spacer surgery. Spine J 2012 Jun;12(6):466-72.

*Kondrashov DG, et al. Interspinous process decompression with the X-STOP device for lumbar spinal stenosis – a 4-year follow-up study. J Spinal Disor Tech 2006 Jul;19(5):323-7.

Korovessis P, et al. Does Wallis implant reduce adjacent segment degeneration above lumbosacral instrumented fusion? Eur Spine J 2009 Jun;18(6):830-40.

Kuchta J, et al. Two-year results of interspinous spacer (X-STOP) implantation in 175 patients with neurologic intermittent claudication due to lumbar spinal stenosis. Eur Spine J 2009 Apr 22 [Epub ahead of print].

*Liu G, et al. Endoscopic decompression combined with interspinous process implant fusion for lumbar spinal stenosis. Chin J Traumatol 2008 Dec;11(6):364-7.

Loguidice V, et al. Rationale, design and clinical performance of the Superion® Interspinous Spacer: a minimally invasive implant for treatment of lumbar spinal stenosis. Expert Rev Med Devices 2011 Jul;8(4):419-26.

Miller LE, et al. Interspinous spacer implant in patients with lumbar spinal stenosis: preliminary results of a multicenter, randomized, controlled trial. Pain Res Treat 2012:823509 [Epub 2012 Feb 7].

Moojen WA, et al. Interspinous process device versus standard conventional surgical decompression for lumbar spinal stenosis: a randomized controlled trial. BMJ 2013 Nov 14;f6415.

Nandakumar A, et al. Two-year results of X-STOP interspinous implant for the treatment of lumbar spinal stenosis: a prospective study. J Spinal Disord Tech 2013 Feb;26(1):1-7.

Nardi P, et al. Aperius PerLID Stand Alone Interspinous System for the treatment of degenerative lumbar stenosis: experience on 152 cases. J Spinal Disord Tech 2010 Jan 10 [Epub ahead of print].

National Institute for Health and Clinical Excellence (NICE). Interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication. 2010 Nov [http://www.nice.org.uk/guidance/index.jsp] accessed 7/14/14.

*North American Spine Society Clinical Guidelines. Degenerative Lumbar Spinal Stenosis. 2007. [http://www.spine.org/Douments/NASSCG_stenosis.pdf] accessed 8/1/13.

Patel VV, et al. Two-year clinical outcomes of a multicenter randomized controlled trial comparing two interspinous spacers for treatment of moderate lumbar spinal stenosis. MBC Musculoskeletal Disord 2014 Jul 5;15(1):221.

Patil S, et al. Evaluation of interspinous process distraction device (X-STOP) in a representative patient cohort. World Neurosurg 2013 Jul-Aug;80(1-2):213-7.

Richter A, et al. Does an interspinous device (Coflex) improve the outcome of decompressive surgery in lumbar spinal stenosis? One-year follow up of a prospective case control study of 60 patients. Eur Spine J 2010 Feb;19(2):283-9.

Richter A, et al. 2-year follow-up after decompressive surgery with and without implantation of an interspinous device for lumbar spinal stenosis: a prospective controlled study. J Spinal Disord Tech 2012 [Epub ahead of print].

Rolfe KW, et al. Scoliosis and interspinous decompression with the X-STOP: prospective minimum 1-year outcomes in lumbar spinal stenosis. Spine J 2010 Nov;10(11):972-8.

Senegas J, et al. Clinical evaluation of a lumbar interspinous dynamic stabilization device (the Wallis system) with a 13-year mean follow-up. Neurosurg Rev 2009 Apr 22 [Epub ahead of print].

Schulte LM, et al. Change in sagittal balance with placement of an interspinous spacer. Spine 2011 Sep 15;36(20):E1302-5.

Shabat S, et al. Minimally invasive treatment of lumbar spinal stenosis with a novel interspinous spacer. Clin Interv Aging 2011.6:227-33.

*Siddiqui M, et al. One-year results of X Stop interspinous implant for the treatment of lumbar spinal stenosis. Spine 2007 May 20;32(12):1345-8.

Skidmore G, et al. Cost-effectiveness of the X-STOP® interspinous spacer for lumbar spinal stenosis. Spine 2011 Mar 1;36(5):E345-56.

Sobottke R, et al. Interspinous implants (X-Stop, Wallis, Diam) for the treatment of LSS: is there a correlation between radiological parameters and clinical outcome? Eur Spine J 2009 Oct;18(10):1494-503.

Stromqvist BH, et al. X-stop versus decompressive surgery for lumbar neurogenic intermittent claudication: randomized controlled trial with 2-year follow-up. Spine 2013 Aug 1;38(17):1436-1442.

Tian NF, et al. Incidence of heterotopic ossification after implantation of interspinous process devices. Neurosurg Focus 2013 Aug;35(2):E3.

Tuschel A, et al. Implant survival analysis and failure modes of the X STOP interspinous distraction device. Spine 2013 Oct 1;38(21):1826-31.

US Food and Drug Administration. Summary and safety effectiveness data. Coflex® Interlaminar technology. [http://www.accessdata.fda.gov/cdrh_docs/pdf11/P110008b.pdf] accessed 7/14/14.

*Verhoof, et al. High failure rate of the interspinous distraction device (X-Stop) for the treatment of lumbar spinal stenosis caused by degenerative spondylolisthesis. Eur Spin J 2008 Feb;17(2):188-92.

*Watters WC 3rd, et al. Degenerative lumbar spinal stenosis: an evidence-based clinical guideline for the diagnosis and treatment of degenerative lumbar spinal stenosis. Spin J 2008 Mar-Apr;8(2):305-10.

*Weinstein, et al. Surgical versus non surgical therapy for lumbar spinal stenosis. NEJM 2008 Feb 21;358:794-810.

Wu AM, et al. Interspinous spacer versus traditional decompressive surgery for lumbar spinal stenosis: a systematic review and meta-analysis. PLoS One 2014 May 8;9(5):e97142.

*Zucherman JF, et al A multicenter, prospective randomized trial evaluating the X STOP interspinous decompression system for the treatment of neurogenic intermittent claudication: two-year results. Spine 2005;20(12)1351-8.

KEY WORDS:

Coflex®, Interlaminar stabilization, Interspinous spacer, Spinal Decompression, Spinal Distraction, Spinal Stenosis, X-STOP

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, interspinous process decompression devices are not specifically addressed in National or Regional Medicare coverage determinations. However, National Government Services (Regional CMS) has the following coverage determination and article (A46075) related to Category III CPT codes and specifically addresses coverage for 0171T and 0172T: http://apps.ngsmedicare.com/lcd/LCD_L25275.htm and http://apps.ngsmedicare.com/sia/ARTICLE_A46075.htm.