MEDICAL POLICY

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, 07/16/15, 06/16/16, 06/15/17, 06/21/18**
POLICY NUMBER: 7.01.75	
CATEGORY: Technology Assessment	**PAGE: 1 OF: 6**

- ***If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.***
- ***If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.***
- ***If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.***

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 due to spinal stenosis.

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 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. RCTs that have compared the X-Stop device with nonoperative therapy reported greater short-term improvements in symptoms and functional status for the device groups. While this establishes that the use of this interspinous spacer can lead to better short-term symptom relief than continued conservative therapy, trials comparing this device with standard decompressive surgery reported that there is a higher reoperation rate for the devices compared with decompressive surgery. In addition, case series suggest a high complication rate, thereby creating uncertainty around the risk/benefit ratio. In 2015, Medtronic discontinued sales and distribution of the implant.

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®).

Vertiflex's Superion® interspinous spacer system won FDA premarket approval in May 2015 for the treatment of moderate stenosis. Per the manufacturer, FDA approval was based on a 470-patient, multicenter investigational device clinical trial that demonstrated safety, effectiveness and a favorable risk benefit profile. Superion® showed a greater than 80% clinical success in all major primary endpoint components at 24 months, maintaining durability of effect through 36 months. Patients were randomized 1:1 to either the Superion system or the commercially available X-STOP device and

followed for 2 years. The primary end point was a composite of clinically significant improvement in at least 2 of 3 ZCQ domain scores compared with baseline, freedom from reoperation, revision, removal, or supplemental fixation at the index level, freedom from epidural steroid injection or nerve block within 12 weeks of the 2-year visit, freedom from rhizotomy or spinal cord stimulator at any level, and freedom from major implant or procedure-related complications. The primary noninferiority end point was met, with a Bayesian posterior probability of 0.993. However, 111 patients (28%; 54 Superion, 57 XSTOP) were withdrawn from the study during follow-up due to a protocol-defined secondary intervention. Modified intention-to-treat analysis showed clinical success (improvement, ≥20 mm/100) for leg pain in 76% to 77% of patients and for back pain in 67% to 68% of patients, with no significant differences between groups. At 2 years, ODI success was achieved in 63% of Superion patients and 67% of XSTOP patients (p=0.061). Rates of complications and reoperations (44 [23.2%] Superion, 38 [18.9%] XSTOP) were similar between groups. Spinous process fractures, reportedly asymptomatic, occurred in 16.4% of Superion patients and 8.5% of XSTOP patients. Interpretation of this study is limited by the lack of a control group treated by surgical decompression (Patel, et al. 2015). 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. In 2014, Marsh and colleagues reported on a RCT that compared decompression alone (n=30) versus decompression with a Wallis implant (n=30). Follow-up at an average of 40 months showed no significant differences between the groups in VAS for back or leg pain or in the ODI. Improvement in back pain was 3.5 of 10 with the Wallis implant compared with 2.7 without (p<0.192). Improvement in ODI was 19.3 with the Wallis implant compared with 10.6 without (p=0.079). Additional study in a larger population is needed.

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) 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:	22867 (E/I)	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level
	22868 (E/I)	;second level
	22869 (E/I)	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level
	22870 (E/I)	:second 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.

Bae HW, et al. Therapeutic sustainability and durability of coflex interlaminar stabilization after decompression for lumbar spinal stenosis: a four year assessment. Int J Spine Surg 2015 May 11;9:15.

Bae HW, et al. Three-year follow-up of the prospective, randomized, controlled trial of coflex interlaminar stabilization vs instrumented fusion in patients with lumbar stenosis. Neurosurgery 2016 Aug;79(2):169-181.

*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. 2017 Apr 13.

*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.

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.

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].

Guyer R, et al. ISASS Recommendations/coverage criteria for decompression with interlaminar stabilization-coverage indications, limitations, and/or medical necessity. Int J Spine Surg 2016 Dec 5;10:41.

Hong P, et al. Comparison of the efficacy and safety between interspinous process distraction device and open decompression surgery in treating lumbar spinal stenosis: a meta-analysis. J Invest Surg 2015 Feb;28(1):40-9.

Kamal TT, et al. Reported clinical outcomes of coflex dynamic stabilization device vs instrumented decompression and fusion in degenerative lumbar stenosis. MOJ Orthoped Rheumat 2016;5(6):00200.

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

Lee SH, et al. A systematic review of interspinous dynamic stabilization. Clin Orthop Surg 2015 Sep;7(3):323-9.

Lee N, et al. Paradoxical radiographic changes of Coflex Interspinous Device with minimum 2-year follow-up in lumbar spinal stenosis. World Neurosurg 2016 Jan;85:177-184.

Li AM, et al. Decompression and coflex interlaminar stabilization compared with conventional surgical procedures for lumbar spinal stenosis: A systematic review and meta-analysis. Int J Surg 2017 April;40:60-67.

*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.

Lonne G, et al. Minimally invasive decompression versus x-stop in lumbar spinal stenosis: a randomized controlled multicenter study. Spine 2015 Jan 15;40(2):77-85.

Lonne G, et al. Comparing cost-effectiveness of x-stop with minimally invasive decompression in lumbar spinal stenosis: A randomized controlled trial. Spine 2015 Apr 15;40(8):514-20.

Marsh GD, et al. A prospective randomized controlled trial to assess the efficacy of dynamic stabilization of the lumbar spine with the Wallis ligament. Eur Spine J 2014 Oct;23(10):2156-60.

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.

Moojen WA, et al. IPD without bony decompression versus conventional surgical decompression for lumbar spinal stenosis: 2-year results of a double-blind randomized controlled trial. Eur Spine J 2015 Jan 14 [Epub ahead of print].

Moojen WA, et al. Interspinous process device versus standard conventional surgical decompression in lumbar spinal stenosis: randomized controlled trial. Br J Sports Med 2015 Jan;49(2):135.

Musacchio MJ, et al. Evaluation of decompression and interlaminar stabilization compared with decompression and fusion for the treatment of lumbar spinal stenosis: 5-year follow-up of a prospective, randomized, controlled trial. Int J Spine Surg 2016 Jan 26;10:6.

*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 5/8/17.

*North American Spine Society Clinical Guidelines. Degenerative Lumbar Spinal Stenosis. 2007. Updated 2014. [http://www.spine.org/Douments/NASSCG_stenosis.pdf] accessed 5/8/17.

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.

Patel VV, et al. Superion interspinous process spacer for intermittent neurogenic claudication secondary to moderate lumbar spinal stenosis: two-year results from a randomized controlled FDA-IDE pivotal trial. Spine 2015 Mar 1;40(5):275-82.

Patel VV, et al. Superion® Interspinous Spacer for treatment of moderate degenerative lumbar spinal stenosis: durable three-year results of a randomized controlled trial. J Pain Res 2015 Oct 3;8:657-62.

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.

Puzzilli F, et al. Interspinous spacer decompression (X-STOP) for lumbar spinal stenosis and degenerative disk disease: a multicenter study with a minimum 3-year follow-up. Clin Neurol Neurosurg 2014 Sep;124:166-74.

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 2014 Aug;27(6):336-41.

Roder C, et al. Superior outcomes of decompression with an interlaminar dynamic device versus decompression alone in patients with lumbar spinal stenosis and back pain: a cross registry study. Eur Spine J 2015 Oct;24(10):2228-35.

*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].

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):1436-42.

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 5/8/17.

*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.

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.

Xu C, et al. Application of the Coflex interlaminar stabilization in patients with L5/S1 degenerative diseases: minimum 4-year follow-up. Am J Ther 2016 Nov/Dec;23(6):e1813-e1818.

Zhao XW, et al. Interspinous process devices (IPD) alone versus decompression surgery for lumbar spinal stenosis (LSS): a systematic review and meta-analysis of randomized controlled trials. Int J Surg 2017 March;39:57-64.

KEY WORDS:

Coflex®, Interlaminar stabilization, Interspinous spacer, Spinal Decompression, Spinal Distraction, Spinal Stenosis, Superion®, 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.