

MEDICAL POLICY



SUBJECT: INTERSPINOUS AND INTERLAMINAR STABILIZATION/ DISTRACTION IMPLANTS (SPACERS) POLICY NUMBER: 7.01.75 CATEGORY: Technology Assessment	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 PAGE: 1 OF: 6
<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i>• <i>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.</i>	

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

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patients in the control group and consistent use of outcome measurements. There are also questions about patient selection 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 Superior® 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. Superior® 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 Superior system or the commercially available X-STOP device and

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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

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KEY WORDS:

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