MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Interspinous and Interlaminar Stabilization/Distraction Implants (Spacers)**
Policy Number	**7.01.75**
Category	**Technology Assessment**
Original Effective Date	**09/21/06**
Committee Approval 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, 07/18/19, 08/20/20, 09/16/21, 09/15/22, 09/21/23, 09/19/24**
Current Effective Date	**09/19/24**
Archived Date	**N/A**
Archive Review Date	**N/A**
Product Disclaimer	• *Services are contract dependent; 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 or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) 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.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, interspinous distraction devices (e.g., Superion Indirect Decompression System) have not been proven to be medically effective and, therefore, 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, therefore, are considered **investigational** for all indications.

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

DESCRIPTION

Implanted interspinous/interlaminar blocking or spacer devices are intended to relieve symptoms of neurogenic intermittent claudication secondary to lumbar spinal stenosis, theoretically, by 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, which is secured with laces around the upper and lower spinous processes.

Another dynamic interlaminar device option has also 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. It has two sets of wings, which are placed around the inferior and superior spinous processes. By inserting the device 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 two 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, whether patients with any degree of spondylolisthesis should be excluded from the 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 one. The device is approved for implantation in one or two lumbar levels, in patients for whom operative treatment is indicated at no more than two 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 versus 15.5% of patients treated non-operatively. Clinically significant improvement in physical function was reported by 57% of implanted and 14.8% of non-operative patients. Re-operation was required in 6% of implanted patients. Randomized, controlled trials 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 one- to two-level lumbar stenosis from L1 to 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 six months of non-operative treatment. The Coflex is intended to be implanted midline between adjacent lamina of one to two 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 versus 153.2 minutes) and resulted in less blood loss (109.7 versus 348.6 cc) and a shorter hospital stay (1.9 versus 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 two 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 two 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, multi-center, 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 two years. The primary end point was a composite of clinically significant improvement in at least two of three 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 two-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 X-STOP) 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 two years, ODI success was achieved in 63% of Superion patients and 67% of X-STOP patients (p=0.061). Rates of complications and reoperations (44 [23.2%] Superion, 38 [18.9%] X-STOP) were similar between groups. Spinous process fractures, reportedly asymptomatic, occurred in 16.4% of Superion patients and 8.5% of X-STOP 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 an 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

- *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 Codes

Code	Description
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 Codes

Code	Description
C1821 **(E/I)**	Interspinous process distraction device (implantable)

ICD10 Codes

Code	Description
M43.10-M43.19	Spondylolisthesis (code range)
M48.00-M48.08	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 Article

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 or policies.