MEDICAL POLICY

POLICY TITLE	**INTERSPINOUS AND INTERLAMINAR STABILIZATION/DISTRACTION DEVICES (SPACERS) AND DYNAMIC STABILIZATION DEVICES.**
POLICY NUMBER	**MP- 1.111**

Original Issue Date (Created):	**5/1/2007**
Most Recent Review Date (Revised):	**9/26/2018**
Effective Date:	**1/1/2019** **RETIRED** – See policy history*

I. POLICY

Interspinous or interlaminar distraction devices as a stand-alone procedure are considered **investigational** as a treatment of spinal stenosis. As there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Use of an interlaminar stabilization device following decompressive surgery is considered **investigational**, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Dynamic stabilization devices including, but not limited to the Dynesys® Spinal System are considered **investigational**, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-reference:

MP-1.124 Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty

II. PRODUCT VARIATIONS

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO - Refer to FEP Medical Policy Manual MP-7.01.107 Interspinous Distraction Devices (Spacers). The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

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III. DESCRIPTION/BACKGROUND

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SPINAL STENOSIS

Spinal stenosis, which can involve a narrowed central spinal canal, lateral spinal recesses, and/or neural foramina, is a common cause of back pain and disability, particularly as individuals age. It can result from a number of pathologic processes, but in adults over 60 in the United States, spondylosis (degenerative arthritis affecting the spine) is the most common cause. The primary symptom of lumbar spinal stenosis is neurogenic claudication with back and leg pain, sensory loss, and weakness in the legs. Symptoms are typically exacerbated by standing or walking and relieved with sitting or flexion at the waist.

Treatment

Conservative treatments for spinal stenosis include physical therapy, pharmacotherapy, and epidural steroid injections. If conservative treatments fail, surgical approaches for spinal stenosis may be used. They include decompression surgery with or without spinal fusion. Spinal fusion is associated with complications and is generally reserved for patients with spinal instability or moderate grade spondylolisthesis when a vertebral body slips forward relative to an adjacent vertebral body. The Swedish Spinal Stenosis Study found no benefit of fusion plus decompression compared with fusion alone in patients who had spinal stenosis with or without degenerative spondylolisthesis.[1] The Spinal Laminectomy versus Instrumented Pedicle Screw trial found some improvements in patients who had spinal stenosis with grade 1 spondylolisthesis, but also more complications.[2] However, the different findings might have been influenced by factors such as time of follow-up and national practice patterns.[3-7]

Investigators have sought less invasive ways to stabilize the spine and reduce the pressure on affected nerve roots, including interspinous and interlaminar implants (spacers). These devices stabilize or distract the adjacent lamina and/or spinous processes and restrict extension in patients with lumbar spinal stenosis and neurogenic claudication. Interspinous spacers are small devices implanted between the vertebral spinous processes. After implantation, the device is opened or expanded to distract the neural foramina and decompress the nerves. Interlaminar spacers are implanted midline between adjacent lamina and spinous processes to provide dynamic stabilization either following decompression surgery or as an alternative to decompression surgery.

Interspinous Implants

One type of interspinous implant is inserted between the spinous processes through a small (4-8 cm) incision and acts as a spacer between the spinous processes, maintaining 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. Other

interspinous spacers require removal of the interspinous ligament and are secured around the upper and lower spinous processes.

Interlaminar Spacers

Interlaminar spacers are implanted between adjacent lamina and have 2 sets of wings placed around the inferior and superior spinous processes. They may also be referred to as interspinous U. These implants aim to restrict painful motion while enabling normal motion. The devices (spacers) distract the laminar space and/or 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 dynamic posterior stabilization devices are pedicle screw/rod-based devices and total facet replacement systems.

REGULATORY STATUS

Several interspinous and interlaminar stabilization and distraction devices have been approved by Food Drug Administration (FDA) through the premarket approval (FDA product code: NQO) are summarized in Table 1.

Table 1. Interspinous and Interlaminar Stabilization/Distraction Devices With Premarket Approval

Device Name	Manufacturer	Approval Date	PMA
X Stop Interspinous Process Decompression System	Medtronic Sofamor Danek	2005 (withdrawn 2015)	P040001
Coflex® Interlaminar Technology	Paradigm Spine	2012	P110008
Superion® Interspinous Spacer	VertiFlex	2015	P14004

PMA: premarket approval.

The Superion® Indirect Decompression System (formerly InterSpinous Spacer) is indicated to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs secondary to a diagnosis of moderate degenerative lumbar spinal stenosis, with or without grade 1 spondylolisthesis, confirmed by x-ray, magnetic resonance imaging, and/or computed tomography evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing. It is intended for patients with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, numbness, and/or cramping, with or without back pain, and who have undergone at least six months of nonoperative treatment.

FDA lists the following contraindications to use of the Superion® Indirect Decompression System:

- "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:
    - Instability of the lumbar spine, e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1 (on a scale of 1 to 4)
    - An ankylosed segment at the affected level(s)

  - Fracture of the spinous process, pars interarticularis, or laminae (unilateral or bilateral);
  - Scoliosis (Cobb angle >10 degrees)
- *Cauda equina* syndrome defined as neural compression causing neurogenic bladder or bowel dysfunction.
  - Diagnosis of severe osteoporosis, defined as bone mineral density (from DEXA [dual-energy x-ray absorptiometry] scan or equivalent method) in the spine or hip that is more than 2.5 S.D. below the mean of adult normal.
- Active systemic infection, or infection localized to the site of implantation.
- Prior fusion or decompression procedure at the index level.
- Morbid obesity defined as a body mass index (BMI) greater than 40."

The coflex® Interlaminar Technology implant (Paradigm Spine) is a single-piece U-shaped titanium alloy dynamic stabilization device with pairs of wings that surround the superior and inferior spinous processes. The coflex® (previously called the Interspinous U) is indicated for use in 1- or 2-level lumbar stenosis from the L1 to L5 vertebrae 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 nonoperative 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)."

FDA lists the following contraindications to use of the coflex®:

- "Prior fusion or decompressive laminectomy at any index lumbar level.
- Radiographically compromised vertebral bodies at any lumbar level(s) caused by current or past trauma or tumor (e.g., compression fracture).
- Severe facet hypertrophy that requires extensive bone removal which would cause instability.
- Grade II or greater spondylolisthesis.
- Isthmic spondylolisthesis or spondylolysis (pars fracture).
- Degenerative lumbar scoliosis (Cobb angle greater than 25°).
- Osteoporosis.
- Back or leg pain of unknown etiology.
- Axial back pain only, with no leg, buttock, or groin pain.
- Morbid obesity defined as a body mass index > 40.
- Active or chronic infection – systemic or local.
- Known allergy to titanium alloys or MR [magnetic resonance] contrast agents.
- Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction."

The FDA labeling also contains multiple precautions and the following warning: "Data has demonstrated that spinous process fractures can occur with coflex® implantation."

At the time of approval, FDA requested additional postmarketing studies to provide longer-term device performance and device performance under general conditions of use. The first was the 5-year follow-up of the pivotal investigational device exemption trial. The second, a multicenter trial with 230 patients in Germany who were followed for 5 years, compared decompression alone with decompression plus coflex®. The third, also a multicenter trial with 345 patients in the United States who were followed for 5 years, compared decompression alone with decompression plus coflex®.[8] FDA product code: NQO.

Dynamic Stabilization Devices

Dynamic stabilization, also known as soft stabilization or flexible stabilization, has been proposed as an adjunct or alternative to spinal fusion for the treatment of severe refractory pain due to degenerative spondylolisthesis, or continued severe refractory back pain following prior fusion, sometimes referred to as failed back surgery syndrome. Dynamic stabilization uses flexible materials rather than rigid devices to stabilize the affected spinal segment(s). These flexible materials may be anchored to the vertebrae by synthetic cords or by pedicle screws. Unlike the rigid fixation of spinal fusion, dynamic stabilization is intended to preserve the mobility of the spinal segment.

IV. RATIONALE

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SUMMARY OF EVIDENCE

For individuals who have spinal stenosis and no spondylolisthesis or grade 1 spondylolisthesis who receive an interspinous or interlaminar spacer as a stand-alone procedure, the evidence includes RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Overall, use of interspinous or interlaminar distraction devices (spacers) as an alternative to spinal decompression has shown a high failure and complication rates. Two devices are considered: the Superion Interspinous Spacer and the coflex interlaminar implant. A pivotal trial compared the Superion Interspinous Spacer with the X-STOP (which is no longer marketed), without conservative care or standard surgery comparators. The trial reported significantly better outcomes with the Superion Interspinous Spacer on some outcome measures. For example, the percentage of patients experiencing improvements in certain quality of life outcome domains was reported at over 80%. Interpretation of this trial is limited by questions about the number of patients used to calculate success rates, the lack of efficacy of the comparator, and the lack of an appropriate control group treated by surgical decompression. The coflex interlaminar implant (formerly called the interspinous U) was compared with decompression in the multicenter, double-blind trial FELIX trial. Functional outcomes and pain levels were similar in the 2 groups at 1-year follow-up, but reoperation rates due to the absence of recovery were substantially higher with the coflex implant (29%) than with bony

decompression (8%). For patients with 2-level surgery, the reoperation rate was 38% for coflex and 6% for bony decompression. At 2 years, reoperations due to the absence of recovery had been performed in 33% of the coflex group and 8% of the bony decompression group. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have spinal stenosis and no spondylolisthesis or grade 1 spondylolisthesis who receive an interlaminar spacer with spinal decompression surgery, the evidence includes RCTs and nonrandomized comparative studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Use of the coflex interlaminar implant as a stabilizer after surgical decompression has been studied in 2 situations—as an adjunct to decompression compared with decompression alone (superiority) and as an alternative to spinal fusion after decompression (noninferiority). As an adjunct to decompression vs decompression alone, an RCT conducted in a patient population with moderate-to-severe lumbar spinal stenosis with or without spondylolisthesis, showed that a greater proportion of patients who received coflex plus decompression achieved the primary end point of composite clinical success compared with decompression alone. This composite end point was primarily driven by a greater proportion of patients who received a secondary rescue epidural steroid injection in the control arm while there was no difference in the proportion of patients who achieved a meaningful reduction of 15 points in ODI score in the treatment and the control arms. However, the decision to use rescue epidural steroid injection introduces possible bias because this trial was open-label. Bias could have been mitigated using protocol-mandated standard objective clinical criteria to guide decisions about secondary interventions and subsequent adjudication of these events by an independent blinded committee. These gaps in trial design and conduct raised concerns that trial results might have overestimated the potential benefit of treatment. Greater certainty about the net health outcome of adding coflex to decompression surgery may be demonstrated when the 5-year follow-up results of these trials and an ongoing RCT (NCT02555280) on decompression with and without the coflex implant in the United States are published. For decompression with spacer vs decompression with spinal fusion, the pivotal RCT, conducted in a patient population with spondylolisthesis assessed as at most grade 1, showed that stabilization of decompression with the coflex implant was noninferior to decompression with spinal fusion. However, there is uncertainty about the net benefit of routinely adding spinal fusion to decompression in patients with no or low-grade spondylolisthesis. Therefore, demonstrating the noninferiority of coflex plus spinal decompression vs spinal decompression plus fusion as a comparator whose benefit on health outcomes is uncertain, makes it difficult to interpret the result of such a comparison. The evidence is insufficient to determine the effects of the technology on health outcomes.

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V. DEFINITIONS

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FORAMEN is a passage or opening; an orifice, a communication between two cavities of an organ, or a hole in a bone for passage of vessels or nerves.

FORAMINOTOMY is surgical enlargement of the intervertebral foramen.

LAMINA is a thin flat layer or membrane or the flattened part of either side of the arch of the vertebra.

LAMINECTOMY is the excision of a vertebral posterior arch, usually to remove a lesion or herniated disk.

LAMINOTOMY is a division of one of the vertebral laminae.

NEUROGENIC CLAUDICATION is leg pain or numbness that occurs with standing or walking and is relieved by sitting or resting with the spine flexed. It is typically caused by lumbar disk disease.

SPINOUS PROCESS is the prominence at the posterior part of each vertebra.

STENOSIS is the constriction or narrowing of a passage or orifice.

VERTEBRAE are any of the thirty-three (33) bony segments of the spinal column.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If

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there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore, not covered:

CPT Codes ®							
22867	22868	22869	22870	22899			

HCPCS Code	Description
C1821	Interspinous process distraction device (implantable)

IX. REFERENCES

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Dynamic Stabilization Devices

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Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

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X. POLICY HISTORY

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MP- 1.111	**CAC 11/28/06**
	CAC 1/29/08
	CAC 1/27/09
	CAC 1/26/10 Consensus
	CAC 4/26/11 Consensus
	CAC 6/26/12 Consensus review; no changes, references updated.
	7/18/13 Admin code review complete.
	CAC 11/26/13 Minor revision. Added an additional investigational statement that use of an interlaminar stabilization device following decompressive surgery is considered investigational. Policy title revised to Interspinous Distraction Devices and Interlaminar Stabilization/Distraction Devices (Spacers), and Dynamic Stabilization Devices. References updated. Background updated. FEP variation revised to refer to the FEP manual. Medicare variation removed. Policy coded.
	CAC 11/25/14 Consensus review. No changes to the policy statements. References updated. Rationale added**.** Consensus Coding - 11/14/2014

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	CAC 11/24/15 Consensus review. No changes to the policy statements. In the contraindications for X-STOP in the regulatory status section, the 4th and 5th bullets were combined, and in the contraindications for coflex in the same section the Cobb angle in the 6th bullet was corrected to >25 degrees. Background, reference and rationale update. LCD number changed from L31686 to L35094 due to Novitas update to ICD 10. Coding updated.
	CAC 9/27/16 Consensus review. No change to the policy statements. References, and rationale updated**.** Variations reformatted. Coding reviewed.
	Administrative Update 1/1/17: Removed NOC code (22899) and deleted codes (0171T-0172T); added new codes (22867-22870) effective 1/1/17.
	CAC 9/26/17 Minor. Added the following statement "Interspinous or interlaminar distraction devices as a stand-alone procedure are considered investigational as a treatment of spinal stenosis". Deleted "Interspinous Distraction Devices are considered investigational as a treatment of neurogenic intermittent claudication". Changed title. Formerly Interspinous Distraction Devices and Interlaminar Stabilization/Distraction Devices (Spacers) and Dynamic Stabilization Devices. Updated background, rationale and references. Coding Reviewed.
	6/28/18 Consensus review. No change to policy statements. Rationale condensed. References updated.
	9/26/18 Retirement. Please refer to TurningPoint Healthcare for management of these services effective 1/1/2019.*

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