Interspinous Distraction Devices are considered investigational as a treatment of neurogenic intermittent claudication 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-1.104 Laminoplasty
- MP-1.093 Artificial Intervertebral Disc
- MP-1.123 Automated Percutaneous Discectomy
- MP-1.125 Decompression of the Intervertebral Disc Using laser Energy (Laser Discectomy) or Radiofrequency Coblation
- MP-1.021 Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD) for Spinal Stenosis
- MP-1.124 Percutaneous Intradiscal Electrothermal (IDET) Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty
II. **PRODUCT VARIATIONS**

[N] = No product variation, policy applies as stated  
[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids  
[N] PPO  
[N] HMO  
[N] SeniorBlue PPO  
[N] SeniorBlue HMO  
[N] Indemnity  
[N] SpecialCare  
[N] POS  
[Y] 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: www.fepblue.org

III. **DESCRIPTION/BACKGROUND**

Interspinous implants aim to restrict painful motion while otherwise enabling normal motion. The interspinous distraction devices (spacers) distract the spinous processes and restrict extension. This theoretically enlarges the neural foramen in patients with 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 (open) the neural foramen and decompress the nerves. Interlaminar spacers are implanted midline between adjacent lamina and spinous processes to provide dynamic stabilization following decompressive surgery.

Interspinous spacers are devices implanted between vertebral spinous processes. Interlaminar spacers are implanted between adjacent lamina and have 2 sets of wings that are placed around the inferior and superior spinous processes. These implants aim to restrict painful motion while otherwise 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; these are not covered in this policy.

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 the 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 implants are inserted between the adjacent lamina and spinous processes following decompressive surgery.

Regulatory Status

In November 2005, the X-STOP® Interspinous Process Decompression (IPD®) System (Kyphon-now part of Medtronic Spine LLC) was approved by the U.S. Food and Drug Administration (FDA) for “treatment of patients aged 50 or older suffering from neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis.” It is approved for patients with moderately impaired physical function who have had a regimen of at least 6 months of non-operative treatment and who have relief of their pain when in flexion. The device is approved for implantation at 1 or 2 lumbar levels in patients whose condition warrants surgery at no more than 2 levels. The X-STOP PEEK (polyetheretherketone) received approval in 2006 and is a modified version of the X-STOP that includes a PEEK spacer and additional 16-mm spacer size. The indications are the same as for the X-STOP titanium model.

The FDA lists the following contraindications to use of the X-STOP:

- 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:
  - significant instability of the lumbar spine, e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1.0 (on a scale of 1 to 4);
  - an ankylosed segment at the affected level(s);
  - acute fracture of the spinous process or pars interarticularis;
  - significant scoliosis (Cobb angle greater than 25 degrees);
- cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction;
- diagnosis of severe osteoporosis, defined as bone mineral density (from DEXA scan [dual energy x-ray absorptiometry] or some comparable study) in the spine or hip that is more than 2.5 [standard deviations] SD below the mean of adult normals in the presence of one or more fragility fractures;
- active systemic infection or infection localized to the site of implantation.
The Coflex® Interlaminar Technology implant (Paradigm Spine) was approved by the FDA in 2012 (P110008). It is a single-piece U-shaped titanium alloy dynamic stabilization device with pairs of wings that surround the superior and inferior spinous processes. This device was previously called the Interspinous U.

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 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 of greater than 250 degrees).
- 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 magnetic resonance imaging (MRI) 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 warnings:

Coflex® Interlaminar Technology should only be used by surgeons who are experienced and have undergone hands-on training in the use of this device. Only surgeons who are familiar with the implant components, instruments, procedure, clinical applications,
biomechanics, adverse events, and risks associated with the coflex® Interlaminar Technology should use this device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events. Data has demonstrated that spinous process fractures can occur with coflex® implantation. Potential predictors for spinous process fractures include:

- Over-decompression during surgery leading to instability in the spine,
- Resection of the spinous process to: 14 mm,
- Height of the spinous process 23 mm pre-operatively,
- Osteopenia or osteoporosis, and
- "Kissing" spinous processes.

If a spinous process fracture occurs during the surgical procedure, the surgeon should assess if sufficient bone stock exists for Coflex® implantation.

Continued FDA approval of the Coflex® is contingent on annual reports of 2 post-approval studies to provide longer-term device performance and device performance under general conditions of use. One study will provide 5-year follow-up of the cohort in the pivotal investigational device exemption (IDE) trial. The second will be a multi-center trial with 230 patients with follow-up at 5 years that compares decompression alone versus decompression plus Coflex®.

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. Also in a FDA-regulated clinical trial is the DIAM Spinal Stabilization System (Medtronic Sofamor Danek), which is a soft interspinous spacer with a silicone core. The DIAM system requires removal of the interspinous ligament and is secured with laces around the upper and lower spinous processes. Other clinical trials underway at U.S. centers are studying the In-Space (Synthes), Superion® (Vertiflex), and FLEXUSTM (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.

Dynamic stabilization devices such as the Dynesys use flexible material to stabilize the spine and alter load transmission without the purpose of fusing the segment. These non-rigid spinal stabilization devices are surgically implanted at the affected level of the spine.
to support the spinal motion segment without fusion, preserving a fuller range of motion. Other terms used to describe non-rigid implants are soft, dynamic and flexible. Dynamic stabilization has been proposed as an adjunct or alternative to fusion. The FDA granted 510 (k) approval of the Dynesys® Spinal System in 2003.

IV. DEFINITIONS

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.

V. BENEFIT VARIATIONS

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 for benefit information.
VI. DISCLAIMER

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

VII. REFERENCES


[Note: Final page is signature page and is kept on file, but not issued with Policy.]


### VIII. CODING INFORMATION

**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/Not Covered/Not Medically Necessary:

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<th>CPT Codes ®</th>
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MEDICAL POLICY

POLICY TITLE
INTERSPINOUS DISTRACTION DEVICES AND INTERLAMINAR STABILIZATION/DISTRACTION DEVICES (SPACERS), AND DYNAMIC STABILIZATION DEVICES

POLICY NUMBER
MP- 1.111

HCPCS Code | Description
--- | ---
C1821 | INTERSPINOUS PROCESS DISTRACTION DEVICE (IMPLANTABLE)

IX. POLICY HISTORY

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<tr>
<th>MP- 1.111</th>
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<td>CAC 4/26/11 Consensus</td>
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<td>CAC 6/26/12 Consensus review; no changes, references updated.</td>
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<td>7/18/13 Admin code review complete. rsb</td>
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<td>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.</td>
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