FEP 7.01.107 Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

Effective Date: July 15, 2017

Related Policies:
7.01.120 Facet Arthroplasty
7.01.138 Interspinous Fixation (Fusion) Devices

Description
Interspinous and interlaminar implants (spacers) stabilize or distract the adjacent lamina and/or spinous processes and restrict extension to reduce pain 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 (open) the neural foramen and decompress the nerves. Interlaminar spacers are implanted midline between adjacent lamina and spinous processes to provide dynamic stabilization either following decompressive surgery or as an alternative to decompressive surgery.

FDA REGULATORY STATUS
In 2015 the Superion® InterSpinous Spacer (ISS; VertiFlex) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. The Superion® ISS 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. The Superion® ISS 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 6 months of nonoperative treatment. The Superion® ISS may be implanted at 1 or 2 adjacent lumbar levels in patients in whom treatment is indicated and at no more than 2 levels, from L1 to L5.

Continued FDA approval of the Superion device is contingent on reports from 2 postapproval studies, the Superion® Post-Approval Clinical Evaluation and Review (SPACER), a 60-month study comparing the Superion device with the X-STOP, and the Superion® New Enrollment Study, a new study comparing the Superion with decompression alone in at least 358 subjects.

In 2012, the coflex® Interlaminar Technology implant (Paradigm Spine) was approved by FDA through the premarket approval process (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. 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
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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.”

Continued FDA approval of the coflex® is contingent on annual reports of 2 postapproval studies to provide longer term device performance and device performance under general conditions of use. One study provides 5-year follow-up of the cohort in the pivotal investigational device exemption trial. The second is a multicenter trial with 230 patients, followed for 5 years, that compares decompression alone with decompression plus coflex®. FDA product code: NQO.

The Wallis® System (originally Abbott Spine; currently Zimmer Spine) was introduced in Europe in 1986. The first-generation Wallis implant was a titanium block; the second-generation device is a plastic-like polymer inserted between adjacent processes and held in place with a flat cord wrapped around the upper and lower spinous processes. The Wallis System is currently being tested in an FDA-regulated clinical trial.

Also in an 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) and FLEXUS™ (Globus Medical) devices; the comparator in these trials is the X-STOP device, which has been withdrawn from the market.

The NL-Prow™ (Non-Linear Technologies), Aperius® (Medtronic Spine), and Falena® (Mikai) devices are in trials in Europe.

POLICY STATEMENT

Interspinous or interlaminar distraction devices as a stand-alone procedure are considered not medically necessary as a treatment of spinal stenosis.

Use of an interlaminar stabilization device following decompression surgery is considered not medically necessary.
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BENEFIT APPLICATION

Services, drugs, or supplies that are not medically necessary are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

For individuals who have spinal stenosis and up to grade I spondylolisthesis who receive an interspinous or interlaminar spacer as a stand-alone procedure, the evidence includes randomized controlled trials (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 (ISS) and the coflex interlaminar implant. A pivotal trial regulated by the U.S. Food and Drug Administration compared the Superion ISS to the X-STOP (which is no longer marketed), without conservative care or standard surgery comparators. The trial reported significantly better outcomes with the Superion ISS on some outcome measures. For example, the percentage of patients experiencing improvement was reported as 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 (also called the interspinous U) was compared with decompression in the multicenter, double-blind trial FELIX trial. Functional outcomes and pain were similar in the 2 groups at 1-year followup, but reoperation rates due to 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 absence of recovery had been performed in 33% of the coflex group and in 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 up to grade I 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 alternative to spinal fusion after decompression or as an adjunct to decompression compared to decompression alone. The pivotal RCT, conducted in a patient population with grade 1 or lower spondylolisthesis, showed that stabilization of decompression with the coflex implant was noninferior to decompression with spinal fusion. However, evidence of a health benefit for fusion in this population is inconclusive, calling into question the validity of the noninferiority trial. Because of this uncertainty, a key question is whether decompression plus a coflex device improves health outcomes compared to decompression alone in this population. Nonrandomized comparative studies have reported mixed results on whether use of the implant in combination with decompression improves outcomes compared with decompression alone. Greater certainty about the net health outcome of this device might be obtained when results of an RCT on decompression with and without the coflex implant are published. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

International Society for the Advancement of Spine Surgery

In 2016, the International Society for the Advancement of Spine Surgery (ISASS) published recommendations and coverage criteria for decompression with interlaminar stabilization. ISASS

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
concluded, based in part on a conference presentation of a level I study, that an interlaminar spacer in combination with decompression can provide stabilization in patients who do not present with greater than grade I instability. Recommended indications and limitations were presented. The document did not address interspinous and interlaminar distraction devices without decompression.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

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POLICY HISTORY

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<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>June 2012</td>
<td>New</td>
<td>Policy updated with literature review, references 7, 19, and 20 added and references reordered. Investigational policy statement added on interlaminar stabilization devices. Interlaminar stabilization added to title.</td>
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<tr>
<td>September 2013</td>
<td>Revise Policy</td>
<td>Policy updated with literature review, references 7, 19, and 20 added and references reordered. Investigational policy statement added on interlaminar stabilization devices. Interlaminar stabilization added to title.</td>
</tr>
<tr>
<td>June 2017</td>
<td>Revise Policy</td>
<td>Policy updated with literature review through February 23, 2017; references 7-8 and 14-16 added. Policy statements edited for clarification; the intent of the policy is unchanged.</td>
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