Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

Medical Benefit

Effective Date: 10/01/13

Next Review Date: 07/17

Preauthorization: No

Review Dates: 07/07, 07/08, 09/09, 09/10, 07/11, 07/12, 07/13, 07/14, 07/15, 07/16

This Protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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</table>
| Individuals:  
  - With spinal stenosis | Interventions of interest are:  
  - Interspinous or interlaminar spacer as a stand-alone procedure | Comparators of interest are:  
  - Conservative therapy  
  - Lumbar spinal decompression surgery | Relevant outcomes include:  
  - Symptoms  
  - Functional outcomes  
  - Quality of life  
  - Treatment-related morbidity |
| Individuals:  
  - With spinal stenosis | Interventions of interest are:  
  - Interlaminar spacer with spinal decompression surgery | Comparators of interest are:  
  - Conservative therapy  
  - Lumbar spinal decompression surgery, with or without spinal fusion | Relevant outcomes include:  
  - Symptoms  
  - Functional outcomes  
  - Quality of life  
  - Treatment-related morbidity |

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.

Summary of Evidence

The evidence for an interspinous or interlaminar spacer as a stand-alone procedure in individuals who have spinal stenosis includes randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Overall, use of interspinous or distraction devices (spacers) used as an alternative to spinal decompression have shown a high failure and complication rates. Three devices are considered: X-STOP and Superion Interspinous Spacer (ISS) and the coflex interlaminar implant. RCTs that compared the X-STOP device with nonoperative therapy have 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 have reported higher reoperation rates for the devices than for decompressive surgery. In addition, case series suggest high complication rates, thereby creating uncertainty around the risk-benefit ratio. In 2015, sales and distribution of the device were discontinued. A pivotal trial regulated by U.S. Food and Drug Administration compared the Superion ISS to the X-STOP, without conservative care or standard surgery comparators. The study reported significantly better outcomes on some outcome measures. For example, the percentage of patients experiencing improvement was reported as over 80%. Interpretation of this study 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 FELIX trial. Functional outcomes and pain were similar in the two groups at one-year follow-up, but reoperation rates due to absence of recovery were substantially higher with the coflex implant (29%) than with bony decompression (8%). For patients with two-level surgery, the reoperation rate was 38% for coflex and 6% for bony decompression. At two years, reoperations due to 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.

The evidence for interlaminar spacers in individuals who have spinal decompression surgery for spinal stenosis 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 two different 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 very selective patient population, showed that outcomes following stabilization of a decompression with the coflex implant did not differ from decompression with spinal fusion. This study was not blinded and had a high rate of missing data for patient-reported measures. There are also two non-RCTs, and they reported mixed results on whether use of the implant in combination with decompression improves outcomes compared with decompression alone. The different comparators used in these trials and the very selective patient population in the pivotal trial limit conclusions about the generalizability of these results. Greater certainty about the net health benefit of this device may be obtained when a recently completed and moderately sized RCT on decompression with and without the coflex implant is published. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Policy**

Interspinous distraction devices are considered **investigational** as a treatment of neurogenic intermittent claudication.

Use of an interlaminar stabilization device following decompressive surgery is considered **investigational**.

**Medicare Advantage**

For Medicare Advantage a spinous process distraction device will be considered **medically necessary** under the conditions as allowed in the Food and Drug Administration (FDA) pre-market approval (for a spinous process distraction device). The device is indicated for treatment of patients aged 50 and older suffering from neurogenic intermittent claudication secondary to confirmed diagnosis of lumbar spinal stenosis (with x-ray, MRI, and/or CT evidence of thickened ligamentum flavum, narrowed lateral recess and/or central canal narrowing).
It is indicated for those patients with moderately impaired physical function, symptom relief of leg/buttock/groin pain, with or without back pain, with flexion, and persistence of symptoms after at least six months of non-operative treatment.

For use of an interlaminar stabilization device see above general business investigational statement.

**Background**

Interspinous spacers are devices implanted between vertebral spinous processes. Interlaminar spacers are implanted between adjacent lamina and have two sets of wings placed around the inferior and superior spinous processes. 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; they are not covered in this evidence review.

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. These may be referred to as interlaminar implants or an interspinous U.

**Regulatory Status**

In 2005, the X-STOP® Interspinous Process Decompression (IPD®) System (Kyphon, now part of Medtronic Spine) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process 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 six months of nonoperative treatment and who have relief of their pain when in flexion. In 2015, Medtronic discontinued sales and distribution of the implant.

In 2015 the Superion® Interspinous Spacer (ISS VertiFlex) was approved by FDA through the premarket approval process. The Superion ISS, as stated in the premarket approval, is 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 indicated for those 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. The Superion® ISS may be implanted at one or two adjacent lumbar levels in patients in whom treatment is indicated and at no more than two levels, from L1 to L5.

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. This device was previously called the Interspinous U.
The coflex® is indicated for use in one- or two-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 six months of nonoperative treatment. The coflex® is intended to be implanted midline between adjacent lamina of one or two 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 > 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, both systemic or local.
- Known allergy to titanium alloys or 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 warnings:

“The 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 two postapproval studies to provide longer term device performance and device performance under general conditions of use. One study will provide five-year follow-up of the cohort in the pivotal investigational device exemption trial. The second will be a multicenter trial with 230 patients with follow-up at five years that compares decompression alone versus decompression plus coflex®. FDA product code: NQO.

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 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.

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.

Related Protocols

Facet Arthroplasty
Interspinous Fixation (Fusion) Devices

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


36. National Government Services, Inc. Local Coverage Determination (LCD): Category III CPT® Codes (L33392), Revision Effective Date for services performed on or after 02/08/2016.