

Protocol

Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

(701107)

Medical Benefit		Effective Date: 10/01/17	Next Review Date: 07/19
Preauthorization	No	Review Dates: 07/07, 07/08, 09/09, 09/10, 07/11, 07/12, 07/13, 07/14, 07/15, 07/16, 07/17, 07/18	

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.

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none">• With spinal stenosis and up to grade I spondylolisthesis	Interventions of interest are: <ul style="list-style-type: none">• Interspinous or interlaminar spacer as a stand-alone procedure	Comparators of interest are: <ul style="list-style-type: none">• Conservative therapy• Lumbar spinal decompression surgery	Relevant outcomes include: <ul style="list-style-type: none">• Symptoms• Functional outcomes• Quality of life• Treatment-related morbidity
Individuals: <ul style="list-style-type: none">• With spinal stenosis and up to grade I spondylolisthesis	Interventions of interest are: <ul style="list-style-type: none">• Interlaminar spacer with spinal decompression surgery	Comparators of interest are: <ul style="list-style-type: none">• Conservative therapy• Lumbar spinal decompression surgery	Relevant outcomes include: <ul style="list-style-type: none">• 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

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 high failure and complication rates. Two devices are considered: the Superior Interspinous

Spacer (ISS) and the coflex interlaminar implant. A pivotal trial regulated by the U.S. Food and Drug Administration compared the Superior 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 Superior 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 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 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 two 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.

POLICY

Interspinous or interlaminar distraction devices as a stand-alone procedure are considered **investigational** as a treatment of spinal stenosis.

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

BACKGROUND

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 get older. 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 (LSS) 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.

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 health benefit of fusion in patients with no or low grade spondylolisthesis who are undergoing decompression surgery for spinal stenosis has been questioned.^{1,2} Two studies published in 2016 reached different conclusions concerning the health benefit of spinal fusion in patients undergoing spinal decompression.^{1,2}

The Swedish Spinal Stenosis Study (SSSS) included patients with spinal stenosis, with or without degenerative spondylolisthesis.¹ Comparison of patients undergoing decompression surgery plus fusion to patients undergoing decompression surgery alone showed no benefit of fusion. In contrast, the Spinal Laminectomy versus Instrumented Pedicle Screw (SLIP) trial included patients with spinal stenosis and grade I spondylolisthesis, and found that some outcomes were improved with the addition of spinal fusion to decompression surgery, albeit at higher cost and an increase in complications.²

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.

One type of interspinous implant is inserted between the spinous processes through a small (four to eight 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 are implanted between adjacent lamina and have two 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; they are not covered in this protocol.

REGULATORY STATUS

In 2015 the Superior[®] InterSpinous Spacer (ISS; VertiFlex) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. The Superior[®] 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 Superior[®] 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 six months of nonoperative treatment. The Superior[®] 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.

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

In 2012, the coflex® Interlaminar Technology implant (Paradigm Spine) was approved by FDA through the pre-market 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 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 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 two postapproval studies to provide longer term device performance and device performance under general conditions of use. One study provides five-year follow-up of the cohort in the pivotal investigational device exemption trial. The second is a multicenter trial with 230 patients, followed for five 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.

RELATED PROTOCOLS

Facet Arthroplasty

Interspinous Fixation (Fusion) Devices

Lumbar Spinal Fusion

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.

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