Interspinous Process Devices With Open Decompression - Single Service

Clinical Guidelines for Medical Necessity Review

Version: 2
Effective Date: July 25, 2024

Important Notices

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Other Notices:

Guideline Information:

Specialty Area: Diseases & Disorders of the Musculoskeletal System (M00-M99)
Guideline Name: Interspinous Process Devices with Open Decompression (Single Service)

Literature review current through: 7/25/2024
Document last updated: 7/25/2024
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Interspinous Devices with Open Decompression

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach:** Designed as an alternative to lumbar fusion or decompression, interspinous spacers were developed to provide a less invasive surgical treatment for LSS with intermittent neurogenic claudication (NC).[1] These devices do not alter the bony anatomy of the spinal column; yet via indirect methods, they can both stabilize and decompress the local anatomy and offer treatment for lumbar stenosis. As the name suggests, interspinous spacers are positioned between the spinous processes. This reduces lumbar extension at the treated levels but allows preserved lateral and rotational movement. By fixing the stenotic segment in a slightly flexed position, the interspinous spacer decreases the symptoms of NC. The first of these devices was given US Food and Drug Administration (FDA) approval in 2005.[2] The Superion® Interspinous Spacer, also known as Vertiflex®, is an FDA-approved titanium implant that is delivered percutaneously to relieve back pain caused by lumbar spinal stenosis.
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **Interspinous process devices** are considered appropriate if **ALL** of the following are **TRUE**[4-6]:

- ◆ Skeletally mature patients suffering from pain, numbness, or cramping in the legs (intermittent neurogenic claudication) secondary to a diagnosis of moderate degenerative lumbar spinal stenosis, with or without grade 1 spondylolisthesis; **AND**
- ◆ Failure of conservative management for greater than 3 months, including **ALL** of the following:
  - Oral steroids, anti-inflammatory medications, or analgesics; **AND**

- Physical therapy; **AND**
- Epidural steroid injection (ESI); **AND**
- **ANY** of the following:
  - Corticosteroid injection if medically appropriate; **OR**
  - Corticosteroid injection is contraindicated; **AND**

◆ Advanced imaging (MRI or CT) demonstrates **ALL** of the following:
- Evidence of mild to moderate (50% or less) central canal stenosis; **AND**
- The stenosis is confined to one or two lumbar levels.

Non-Indications

➔ **Interspinous process devices** are not considered appropriate if **ANY** of the following are **TRUE**[5-7]:

◆ Advanced stenosis is defined by **ANY** of the following:
- Greater than 2 levels of moderate lumbar stenosis; **OR**
- One level of severe stenosis; **OR**

◆ Previous decompression at the planned level for surgery; **OR**

◆ An allergy to titanium or titanium alloy; **OR**

◆ Spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable in situ, such as **ANY** of the following:
- Instability of the lumbar spine (e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1 [on a scale of 1 to 4]); **OR**
- An ankylosed segment at the affected level(s); **OR**
- Fracture of the spinous process, pars interarticularis, or laminae (unilateral or bilateral); **OR**
- Scoliosis (Cobb angle greater than 10 degrees); **OR**

◆ Cauda equina syndrome, defined as neural compression causing neurogenic bladder or bowel dysfunction; **OR**

◆ Diagnosis of severe osteoporosis, defined as bone mineral density (from DEXA scan or equivalent method) in the spine or hip that is more than 2.5 SD below the mean of adult normals; **OR**

◆ Active systemic infection, or infection localized to the site of implantation; **OR**

◆ Prior fusion or decompression procedure at the index level; **OR**

◆ Morbid obesity (body mass index [BMI] greater than 40).

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description/Definition
22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed with open decompression, lumbar; single level
22868	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure)
C1821	Interspinous process distraction device (implantable)

Medical Evidence

The United States Food and Drug Administration (FDA) approved the VertiFlex Superion interspinous spacer in 2015, intended for moderate degenerative lumbar spinal stenosis.[5-6]

Deer et al. (2018) formulated several recommendations for minimally invasive spine treatment related to lumbar spinal stenosis. The systematic review concluded that such treatments must be used in a judicious and algorithmic fashion. There were 11 consensus recommendations made throughout the document including obtaining radiographic evidence, differentiating between neurogenic claudication and other claudication sources as well as following anticoagulation recommendations.[4]

The North American Spine Society (NASS) conditionally recommended in their 2014 coverage policy that in a select group of patients, interspinous distraction devices without direct decompression or fusion would be appropriate. They discuss the benefits of operative versus nonoperative treatment, that surgical intervention has been proven superior in a number of studies.[1]

Onggo et al. (2021) concluded in a systematic review that interspinous spacers, compared to open decompression with interbody fusion, similar outcomes were achieved with reduced operative time, length of stay, blood loss and improved segment mobility. Future directions may include implantation of interspinous spacers with open decompression as an alternative to decompression and interbody fusion for stable grade 1 spondylolisthesis and central stenosis. Future studies are recommended by the group.[7]

References

1. North American Spine Society (NASS). Coverage policy recommendations: Interspinous devices without fusion. Published May 2014. Accessed July 1, 2024. https://www.spine.org.
2. Deyo RA, Martin BI, Ching A, et al. Interspinous spacers compared with decompression or fusion for lumbar stenosis: complications and repeat operations in the Medicare population. *Spine*. 2013;38(10):865–872. doi: 10.1097/BRS.0b013e31828631b8. PMID: 23324936; PMCID: PMC3855445.
3. Tapp SJ, Martin BI, Tosteson TD, et al. Understanding the value of minimally invasive procedures for the treatment of lumbar spinal stenosis: the case of interspinous spacer devices. *Spine J*. 2018;18(4):584–592. doi: 10.1016/j.spinee.2017.08.246. PMID: 28847740.
4. Deer T, Grider J, Pope J, et al. The MIST guidelines: The Lumbar Spinal Stenosis Consensus Group guidelines for minimally invasive spine treatment. *Pain Pract*. 2019 Mar;19(3):250-274. doi: 10.1111/papr.12744. PMID: 30369003.
5. United States Food and Drug Administration (FDA). Summary of safety and effectiveness data (SSED): Superion® InterSpinous Spacer (ISS). Published May 15, 2015. Accessed July 1, 2024. https://www.accessdata.fda.gov/cdrh_docs/pdf14/p140004b.pdf.
6. United States Food and Drug Administration (FDA). Premarket approval (PMA): Superion Interspinous Spacer. Published June 18, 2015. Accessed July 1, 2024. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140004.
7. Onggo J, Nambiar M, Maingard J, et al. The use of minimally invasive interspinous process devices for the treatment of lumbar canal stenosis: a narrative literature review. *J Spine Surg.* 2021 Sep;7(3):394-412. doi: 10.21037/jss-21-57. PMID: 34734144.

Clinical Guideline Revision History/Information

Original Date: December 15, 2023		
Review History		
Version 2	7/25/2024	Updated language regarding conservative treatment.