Interspinous Process Devices With Open Decompression - Single Service

Clinical Guidelines for Medical Necessity Review

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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: 12/15/2023
Document last updated: 12/15/2023
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17yo)

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Single Services & 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**
- ◆ These patients must have undergone at least 3 months of nonoperative treatment, including **ALL** of the following:
  - Oral steroids or anti-inflammatory medication; **AND**

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- Physical therapy; **AND**
- Epidural Steroid Injection; **AND**

◆ Advanced imaging (MRI or CT) demonstrating **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 that 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, defined as a body mass index (BMI) greater than 40.

Site of Service Criteria

Outpatient.

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Procedure Codes (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)

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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.

Deer, et al. (2018) formulated several recommendations for minimally invasive spine treatment related to lumbar spinal stenosis. Their 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.

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.

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.

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Clinical Guideline Revision History/Information

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