Cohere Medical Policy - Interspinous Process Devices without Open Decompression

Clinical Guidelines for Medical Necessity Review

Version: 5
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Important Notices

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Guideline Information:

Specialty Area: Disorders of the Musculoskeletal System
Guideline Name: Cohere Medical Policy - Interspinous Process Devices without Open Decompression

Date of last literature review: 11/14/2024
Document last updated: 12/19/2024
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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Service: Interspinous Devices without Open Decompression

Recommended Clinical Approach

Designed as an alternative to lumbar fusion or decompression, interspinous spacers were developed to provide a less invasive surgical treatment for lumbar spinal stenosis (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 LSS. 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 approval in 2005 by the United States Food and Drug Administration (FDA).[2] The Superion® Interspinous Spacer, also known as Vertiflex®, is a titanium implant that is delivered percutaneously to relieve back pain caused by LSS.

Medical Necessity Criteria

Indications

- ➔ **Interspinous process devices** are considered appropriate if **ALL** of the following are **TRUE**[3-7]:
  - ◆ The patient is skeletally mature with ANY of the following related to intermittent neurogenic claudication (NC)5:
    - Refractory pain; OR
    - Numbness; OR
    - Cramping in the legs; AND
  - ◆ Symptoms are secondary to a diagnosis of moderate degenerative lumbar spinal stenosis (LSS), with or without grade 1 spondylolisthesis[5]; **AND**
  - ◆ Failure of conservative management for greater than 3 months, including **ALL** of the following:
    - Anti-inflammatory medications, analgesics, or prescription

medications (e.g., oral steroids, narcotics, neuropathic pain medications) if not contraindicated; **AND**
    - Physical therapy; **AND**
    - **ANY** of the following:
        - Corticosteroid injection if medically appropriate; **OR**
        - Corticosteroid injection is contraindicated; **AND**
- Advanced imaging (magnetic resonance imaging [MRI] or computed tomography [CT]) demonstrates **ALL** of the following:
    - Evidence of mild to moderate (50% or less) central canal stenosis; **AND**
    - The stenosis is confined to 1 or 2 lumbar levels; **AND**
- The patient is deemed a non-surgical candidate by a surgeon.

Non-Indications

➔ **Interspinous process devices** are not considered appropriate if **ANY** of the following is **TRUE**[5-8]:

- 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, including but not limited to **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; **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

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description/Definition
22869	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level
22870	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)
C1821	Interspinous process distraction device (implantable)

Medical Evidence

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 the 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.[8]

Deer et al. (2018) formulated several recommendations for minimally invasive spine treatment related to lumbar spinal stenosis (LSS). 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.[4]

The United States Food and Drug Administration (FDA) approved the Superion Interspinous Spacer (ISS) by VertiFlex, Inc. in 2015. The spacer is intended for patients with moderate degenerative LSS and impaired physical function who experience relief in flexion from symptoms (e.g., pain, numbness, or cramping) affecting the legs, buttocks, or groin. The symptoms may be accompanied with or without back pain. The device "may be implanted at one or two adjacent lumbar levels in patients in whom treatment is indicated at no more than two levels, from L1 to L5".[5-6]

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]

References

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8. 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: June 15, 2023		
Review History		
Version 2	9/29/2023	
Version 3	12/15/2023	
Version 4	9/20/2024	Updated language regarding conservative treatment.
Version 5	12/19/2024	• Annual review. • Updated references. • Added indication - "The patient is deemed a non-surgical candidate by a surgeon." • The indications for this policy match the indications of the Interspinous Process Devices with Open Decompression policy.