VENTURA COUNTY HEALTH CARE PLAN

Medical Policy: Superion Interspinous Spacer for Spinal Stenosis

Effective Date: 11/14/19
Created by: Dr. Robert Sterling
Reviewed/No Updates: 2/13/20

Superion Interspinous Spacer for Spinal Stenosis Medical Policy

Policy

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 and adjacent structures.

In 2015, the Superion Interspinous Spacer (VertiFlex) Decompression System was approved by the U.S Food and Drug Administration (FDA) through the premarket approval process.

It's purpose is to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs secondary to diagnosis of moderate degenerative lumbar spinal stenosis (with or without Grade 1 spondylolisthesis) confirmed by x-ray, magnetic resonance imaging, and/or computed tomography, after at least 6 months of nonoperative treatment. It may be implanted at one or two adjacent lumbar levels in at no more than two levels, from L1 to L5.

Indications:

- Age 50 or older suffering from moderately severe intermittent neurogenic claudication secondary to a clinically and radiographically confirmed diagnosis of lumbar spinal stenosis.
- Note: Neurogenic claudication is defined as leg/buttock/groin pain induced by position (extension) and/or moderate activity with relief of symptoms in flexion and/or rest.
- Note: Moderate is defined as ability to sit with minimal discomfort for 50 minutes without pain and to walk 50 feet or more.
- Note: Moderate stenosis is defined as >25% reduction of the anteroposterior dimension compared with the next adjacent normal level, with nerve root crowding compared with the normal level, as determined by CT scanning or MRI.
- Patient who have undergone at least 6 months of non-operative treatment [consisting of NSAIDs and at least one of: rest, restricted ADLs, PT or steroid injections]
- Vascular cause of claudication is absent or considered a minimal contributor to symptoms
- In the judgement of the provider, a poor candidate for more invasive or extensive surgery (e.g. bad reaction to general anesthetic, morbidly obese*, unusual airway, unique anatomy, etc.)
  *In this case, with severe symptoms and having failed a weight reduction program

Contraindications:

- Spinal anatomy or disease that would prevent proper implant of the device or cause it to be unstable after implant
- Degenerative spondylolisthesis of Grade 2 or higher [Scale: 1-4], including isthmic spondylolisthesis
- Degenerative or other scoliosis [Cobb angle >25 degrees]
- Boney fracture(s) or metastases
- Ankylosed segment at the affected level(s)
- Cauda equina syndrome (defined as neural compression causing neurogenic bladder or bowel dysfunction)
- Severe osteoporosis (defined as bone mineral density from DEXA scan or equivalent method in the spine or hip that is more than 2.5 S.D below the mean of adult normal)
- Prior fusion/decompression procedure or other surgery in the area of concern
- Significant instability of the lumbar spine as detected on flexion-extension views

Note: Instability is based on standing flexion/extension radiographs and defined as sagittal plane translation >4.0 mm or 15% - or- local sagittal plan rotation >15% at L1-2, 2-3 and 3-4; >20% at L4-5

- Active systemic infection, or infection localized to the site of implantation
- Axial back pain only, with no leg, buttock or groin pain
- Back or leg pain of unknown etiology
- Body mass index (BMI) >40kg/m2 (morbid obesity)
- Failure of a prior FDA approved interspinous spacer
- Fusion or laminectomy is otherwise contraindicated
- Allergy to titanium or titanium alloy

CPT Codes:

22867: placement without fusion, with open decompression, including image guidance; single level

22868: second level

22869: placement without open decompression or fusion, including image guidance; single level

22870: second level

HCPCS Code:

C1821: Interspinous process distraction device (implantable)

A. Attachments: None

B. History:

Created by: Robert Sterling, MD

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Reviewed/No Updates by**:** Howard Taekman, MD & Robert Sterling, MD
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2/13/20	No	Howard Taekman, MD; Robert Sterling, MD	Annual Review