EmblemHealth

Interspinous Distraction Devices

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Definitions

Superion® InterSpinous Spacer — used to relieve symptoms of lumbar spinal stenosis, a narrowing of the passages for the spinal cord and nerves. The implant is made from titanium alloy and consists of two components: a spacer assembly and a wing assembly. The device is placed between the spinous processes of the lumbar levels to limit spine extension in the affected area, which may relieve the symptoms of lumbar spinal stenosis.

Guideline

The Superion IPD is considered medically necessary when all of the following criteria are met:

1. Confirmed diagnosis of lumbar spinal stenosis with or without Grade 1 spondylolisthesis (as evidenced by X-Ray, MRI and/or CT confirmation of thickened ligamentum flavum, narrowed lateral recess and/or central canal narrowing)
2. Skeletally mature with symptoms of neurogenic intermittent claudication
3. Members with moderately impaired physical function who experience relief in flexion from their symptoms of leg/buttock/groin pain (with or without back pain)
4. Failed nonoperative treatment for ≥ 6 months (e.g. non-steroidal anti-inflammatory medications, analgesics, oral and epidural steroids, an initial period of rest, physical therapy and bracing)

Limitations/Exclusions

Superion is not considered medically reasonable and necessary with any of the following conditions:

1. Allergy to titanium or titanium alloy
2. Spinal anatomy or disease that would prevent implant of the device or cause it to be unstable in situ (e.g., isthmic spondylolisthesis or degenerative spondylolisthesis > grade 1.0 [on a scale of 1–4]; an ankylosed segment at the affected level[s]; acute fracture of the spinous process or pars interarticularis)
3. Significant scoliosis (Cobb angle > 25 degrees)

4. Cauda equina syndrome (defined as neural compression causing neurogenic bowel or bladder dysfunction)
5. Diagnosis of severe osteoporosis (defined as bone mineral density [from DEXA scan or some comparable study] in the spine or hip that is > 2.5 SD below the mean of adult normals in the presence of ≥ 1 fragility fracture)
6. Active systemic infection or infection localized at implantation site

Coflex® Interlaminar Technology is considered investigational, as substantial uncertainty remains regarding the safety, efficacy, and durability of coflex. Additional rigorous adequately powered studies are needed to establish patient selection criteria and to compare the benefit of coflex relative to other surgical approaches for lumbar spinal stenosis.

Revision History

6/8/2018 — Superion substituted for X-Stop (no longer available) and Coflex added to Limitations/Exclusions as investigational

Applicable Procedure Codes

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; single level
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 fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure)

Applicable ICD-10 Diagnosis Codes

M48.061	Spinal stenosis, lumbar region without neurogenic claudication
M48.062	Spinal stenosis, lumbar region with neurogenic claudication
M48.07	Spinal stenosis, lumbosacral region
M99.23	Subluxation stenosis of neural canal of lumbar region
M99.33	Osseous stenosis of neural canal of lumbar region
M99.43	Connective tissue stenosis of neural canal of lumbar region
M99.53	Intervertebral disc stenosis of neural canal of lumbar region
M99.63	Osseous and subluxation stenosis of intervertebral foramina of lumbar region
M99.73	Connective tissue and disc stenosis of intervertebral foramina of lumbar region

References

Hayes Inc. coflex Interlaminar Stabilization Device (Paradigm Spine LLC) for Treatment of Lumbar Spinal Stenosis. Health Technology Brief. January 2018, annual review October 2020.

Specialty-matched clinical peer review.