Interspinous Distraction Devices

Last Review Date: May 12, 2017	Number: MG.MM.SU.48C6

Definitions

X-STOP® Interspinous Process Decompression (IPD®) System — 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

Members are eligible for coverage of interspinous distraction with an FDA-approved implanted blocking or spacer device (e.g., the X-STOP IPD) when all of the following criteria are met[*]:

1. Confirmed diagnosis of lumbar spinal stenosis (as evidenced by X-Ray, MRI and/or CT confirmation of thickened ligamentum flavum, narrowed lateral recess and/or central canal narrowing)
2. ≥ 50 years of age 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)

[*] The X-STOP package insert indicates that radiological evidence of stenosis must be correlated with symptoms before the diagnosis can be confirmed. If the spinous processes at the affected level are not distracted in flexion, the X-STOP may not be indicated. The X-STOP is suitable for implantation at either 1 or 2 lumbar levels when operative treatment is indicated at no > 2 levels

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 (New Code: 01/01/2017)
22868	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level (New Code: 01/01/2017)
22869	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level (New Code: 01/01/2017)
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) (New Code: 01/01/2017)
~~0171T~~	~~Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; single level~~ (Deleted 01/01/2017)
~~0172T~~	~~Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; each additional level (List separately in addition to code for primary procedure)~~ (Deleted 01/01/2017)
C1821	Interspinous process distraction device (implantable)

Applicable ICD-10 Diagnosis Codes

M48.06	Spinal stenosis, lumbar region
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

Limitations/Exclusions

X-STOP 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.

References

X STOP® Interspinous Process Decompression (IPD) System [product insert]. St. Francis Medical Technologies. Alameda, CA http://www.accessdata.fda.gov/cdrh_docs/pdf4/P040001c.pdf. Accessed May 15, 2017.

Specialty-matched clinical peer review.