Medical Coverage Policy | Interspinous Distraction Devices

EFFECTIVE DATE: 06|01|2015
POLICY LAST UPDATED: 04|07|2015

OVERVIEW
Interspinous spacers are small devices implanted between the vertebral spinous processes. After implantation, the device is opened or expanded to distract (open) the neural foramen and decompress the nerves.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
BlueCHiP for Medicare
Prior authorization is required for BlueCHiP for Medicare only and is obtained via the online tool for participating providers. See the Related Policies section.

Commercial
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare
Interspinous distraction devices are covered for BlueCHiP for Medicare. Preauthorization is required and obtained via the online tool for participating providers.

Commercial
Interspinous distraction devices are considered not medically necessary as a treatment of neurogenic intermittent claudication as there is insufficient published peer-reviewed medical literature to support long-term effectiveness compared to standard surgical treatment.

Removal for medical reasons (device failure, infection, etc.) is covered for all members. However, insertion of a replacement device after removal is not covered for Commerical members, as the insertion is considered not medically necessary.

NOTE:
Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates consideration of governmental regulations from Centers for Medicare and Medicaid Services (CMS), such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. Medicare and BCBSRI policies may differ. However, BlueCHiP for Medicare members must be offered, at least, the same services that Medicare offers.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for limitations of benefits/coverage for applicable surgery or when services are not medically necessary.

BACKGROUND

Interspinous spacers are devices implanted between vertebral spinous processes. These implants aim to restrict painful motion while otherwise enabling normal motion. The devices (spacers) distract the laminar space and/or spinous processes and restrict extension. This procedure theoretically enlarges the neural foramen and decompresses the cauda equina in patients with spinal stenosis and neurogenic claudication. Other types of dynamic posterior stabilization devices are pedicle screw/rod-based devices and total facet replacement systems; these are not covered in this policy.

One type of interspinous implant is inserted between the spinous processes through a small (4-8 cm) incision and acts as a spacer between the spinous processes, maintaining the flexion of that spinal interspace. The supraspinous ligament is maintained and assists in holding the implant in place. The surgery does not include any laminotomy, laminectomy, or foraminotomy at the time of insertion, thus reducing the risk of epidural scarring and cerebrospinal fluid leakage. Other interspinous spacers require removal of the interspinous ligament and are secured around the upper and lower spinous processes.

In November 2005, the X-STOP® Interspinous Process Decompression (IPD®) System (Kyphon-now part of Medtronic Spine LLC) was approved by the U.S. Food and Drug Administration (FDA) for "treatment of patients aged 50 or older suffering from neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis. It is approved for patients with moderately impaired physical function who have had a regimen of at least 6 months of non-operative treatment and who have relief of their pain when in flexion. The device is approved for implantation at 1 or 2 lumbar levels in patients whose condition warrants surgery at no more than 2 levels. The X-STOP PEEK (polyetheretherketone) received approval in 2006 and is a modified version of the X-STOP that includes a PEEK spacer and additional 16-mm spacer size. The indications are the same as for the X-STOP titanium model.

Because the impact of this technology on net health outcome is not known, these devices are considered not medically necessary.

CODING

Commercial

The following codes are not medically necessary:

0171T
0172T

RELATED POLICIES

Preauthorization Via Web-Based Tool for Procedures

PUBLISHED

Provider Update, June 2015
Provider Update, March 2013
Provider Update, March 2012
Provider Update, February 2010
Provider Update, February 2010
Provider Update, October 2008
Policy Update, February 2008

REFERENCES

1. Chou R, Baisden J, Carragee EJ et al. Surgery for low back pain: a review of the evidence for an American Pain Society Clinical Practice Guideline. Spine (Phila Pa 1976) 2009; 34(10):1094-109.
2. Zucherman JF, Hsu KY, Hartjen CA et al. A multicenter, prospective, randomized trial evaluating the X STOP interspinous process decompression system for the treatment of neurogenic intermittent claudication: two-year follow-up results. Spine (Phila Pa 1976) 2005; 30(12):1351-8.

3. Anderson PA, Tribus CB, Kitchel SH. Treatment of neurogenic claudication by interspinous decompression: application of the X STOP device in patients with lumbar degenerative spondylolisthesis. J Neurosurg Spine 2006; 4(6):463-71.
4. Kabir SM, Gupta SR, Casey AT. Lumbar interspinous spacers: a systematic review of clinical and biomechanical evidence. Spine (Phila Pa 1976) 2010; 35(25):E1499-506.
5. Kondrashov DG, Hannibal M, Hsu KY et al. Interspinous process decompression with the X-STOP device for lumbar spinal stenosis: a 4-year follow-up study. J Spinal Disord Tech 2006; 19(5):323-7.