

X-STOP® Interspinous Spacer Procedure

Reimbursement Guide

HOSPITAL

Hospital Inpatient Coding

ICD-9-CM Procedure Code

- » 84.80 Insertion or replacement of interspinous process device(s)

ICD-9-CM Diagnosis Codes

Providers may wish to contact their Medicare contractor or third-party payers to determine coverage and ICD-9-CM diagnosis codes that support medical necessity for X-STOP® Interspinous Spacer procedures. The following diagnosis codes may apply to patients undergoing the X-STOP® Interspinous Spacer procedure:

- » 724.02 Spinal stenosis, lumbar region
- » Providers should report the ICD-9-CM code that most accurately describes a patient's condition. Please contact or refer to payer policy in your region for more information. Multiple diagnosis codes may be required.

Possible Medicare-Severity Diagnosis-Related Group (MS-DRG) Assignments

- » DRG 490 Back and neck procedures except spinal fusion with CC/MCC or disc devices or neurostimulator

Under the MS-DRG system, cases may be assigned to a number of other MS-DRGs based on individual patient diagnoses and presence or absence of additional surgical procedures performed. Additional MS-DRGs include, but are not limited to: MS-DRGs 028, 029, 030; MS-DRGs 907, 908, 909; MS-DRGs 957, 958, 959; and MS-DRGs 981, 982, 983.

Hospital Outpatient Coding

Procedure Codes

- » 0171T Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; single level
- » 0172T Insertion of posterior spinous process distraction device...lumbar; each additional level

HCPCS Level II Code

- » C1821 Interspinous process distraction device (implantable)

Medicare Ambulatory Payment Classification (APC)

- » APC 052 Level IV musculoskeletal procedures except hand and foot
- » Providers should contact or refer to the payer's policy to confirm coding.

Utilization Review

Physicians should confirm pertinent inpatient or outpatient admission criteria and make admission decisions based on medical necessity.

PHYSICIAN

CPT® Codes*

- » 0171T Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; single level
- » 0172T Insertion of posterior spinous process distraction device...lumbar; each additional level

*Providers should contact or refer to the payer's policy to confirm coding. Providers may also need to negotiate payment because Category III or "T" codes are not assigned relative value units.

ICD-9-CM Diagnosis Codes**

All claim forms must include ICD-9-CM diagnosis codes to report the patient's condition. These codes reflect the physician's assessment of a particular patient's condition. Providers may wish to contact their Medicare contractor, or third-party payers to determine coverage and ICD-9-CM diagnosis codes that support medical necessity for X-STOP® Interspinous Spacer procedures. The following diagnosis codes may apply to patients undergoing the X-STOP® Interspinous Spacer procedure:

- » 724.02 Spinal stenosis, lumbar region

**Providers should report the ICD-9-CM diagnosis code that most accurately describes a patient's condition. Please contact or refer to payer policy and ICD-9-CM diagnosis codes that support medical necessity in your region. Multiple diagnosis codes may be required.

Documentation Tips***

- » Medical record documentation is key to communicating essential information for making a decision as to whether a procedure was reasonable and necessary for a particular patient.
- » At minimum, the medical record should convey information about a patient's medical condition, the rationale for why the X-STOP® Interspinous Spacer procedure was needed, and the outcome of the procedure.
- » Medical record documentation should include a detailed history and physical, which enables billing personnel to verify that a claim is coded specifically and accurately. For example, payers may require documentation that conservative care has been tried and has failed.

***See payer policy for specific documentation and clinical coverage criteria.

Medical Necessity/Site of Service

The X-STOP® Interspinous Spacer procedure can be performed in either an inpatient or outpatient hospital setting. Medical necessity will dictate site of service for each individual patient. Please contact your medical facility for inpatient admission criteria.

Prior Authorization

For assistance with a prior authorization or denial, please contact Medtronic's Therapy Access Solutions at (866) 446-3873. Prior authorization requests for the X-STOP® Interspinous Spacer procedure may require the following items:

- » X-ray and/or MRI reports
- » Medicare or other coverage policies
- » Clinical literature (available from Medtronic upon request)

PROCEDURE

Indications for Use: The X-STOP® Interspinous Process Decompression (IPD®) System is indicated for treatment of patients aged 50 or older suffering from neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis (with X-ray, MRI and/or CT evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal narrowing). The X-STOP is indicated for those patients with moderately impaired physical function who experience relief in flexion from their symptoms of leg/buttock/groin pain, with or without back pain, and have undergone a regimen of at least 6 months of nonoperative treatment. The X-STOP may be implanted at one or two lumbar levels in patients in whom operative treatment is indicated at no more than two levels.

Contraindications: The device is contraindicated in patients with: an allergy to titanium or titanium alloy; spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable *in situ*, such as: significant instability of the lumbar spine, e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1.0 (on a scale of 1 to 4), an ankylosed segment at the affected level(s), acute fracture of the spinous process or pars interarticularis and significant scoliosis (Cobb angle greater than 25 degrees); cauda equina syndrome, defined as neural compression causing neurogenic bowel or bladder dysfunction; diagnosis of severe osteoporosis, defined as bone mineral density (from DEXA scan or some comparable study) in the spine or hip that is more than 2.5 SD below the mean of adult normals in the presence of one or more fragility fractures; and active systemic infection or infection localized to the site of implantation.

Warnings: The X-STOP implant must be placed in the concavity between the spinous processes. Posterior positioning of the implant may result in dislodgement. If correct placement of the implant cannot be achieved due to variant anatomy, the surgeon should consider aborting the procedure because incorrect placement may result in device dislodgement, particularly if the patient experiences a traumatic event.

Precautions: Radiological evidence of stenosis must be correlated with the patient's symptoms before the diagnosis can be confirmed; if the spinous processes at the affected level are not distracted in flexion, the X-STOP system may not be indicated; the safety and effectiveness of the X-STOP device has not been studied in patients with the following conditions: axial back pain without leg, buttock or groin pain, symptomatic lumbar spinal stenosis at more than 2 levels, prior lumbar spine surgery, significant peripheral neuropathy, acute denervation secondary to radiculopathy, Paget's disease, vertebral metastases, morbid obesity, pregnancy, a fixed motor deficit, angina, active rheumatoid arthritis, peripheral vascular disease and advanced diabetes or any other systemic disease that may affect the patient's ability to walk; surgeons should not implant the X-STOP implant until receiving adequate training regarding surgical technique because inadequate training may result in poor patient outcomes and/or increased rates of adverse events; and a stress fracture of the spinous process may occur if strenuous physical activity is resumed too soon postoperatively.

Potential Adverse Events: The following potential adverse events may occur as a result of interspinous process decompression with the X-STOP system; some of these adverse events were reported in the Pivotal Clinical Trial. X-STOP system related: implant dislodgement/migration; implant not positioned correctly; fracture of the spinous process; additional surgery, which could include removal of the X-STOP implant; foreign body reaction; mechanical failure of the device; failure of the device/procedure to improve symptoms and/or function. Surgery related: reactions to anesthesia; myocardial infarction; infection; blood vessel damage/bleeding; deep vein thrombosis; hematoma; pneumonia; neurological system compromise; stroke; nerve injury or spinal cord damage; paralysis; thrombus formation; wound dehiscence or delayed healing; pain/discomfort at the operative site; and death.

Note: Medication or additional surgery may be necessary to correct some of these potential adverse events.

www.medtronicsofamordanek.com/spine

Medtronic

Spinal and Biologics Business
Worldwide Headquarters

2600 Sofamor Danek Drive
Memphis, TN 38132

1800 Pyramid Place
Memphis, TN 38132

1221 Crossman Avenue
Sunnyvale, CA 94089

(901) 396-3133
(800) 876-3133
Customer Service: (800) 933-2635

For more information visit
www.myspinetools.com

For additional coding information
contact the SpineLine® Coding
Support Line at (877) 690-5353.

Provider Relations Specialist:
(888) 865-9512
www.kyphon.com/us/reimbursement

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