

INTERSPINOUS PROCESS DECOMPRESSION (X-STOP®)

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Overview

Many people in the fifth and sixth decade of life begin to suffer from progressive lumbar spinal stenosis with symptomatic neurogenic intermittent claudication. Lumbar spinal stenosis is a narrowing of the spinal canal or neural foramina that generally occurs as a result of age-related spinal degeneration. The hallmark clinical features include radicular symptoms (i.e., pain, tingling, numbness, and weakness) that are provoked when the patient assumes positions that place the spine in extension, such as standing and walking. Conversely, symptoms are relieved when the patient assumes a position that flexes the spine, such as sitting or leaning forward; this is a differential diagnostic characteristic relative to other causes of neurogenic claudication.

There is a continuum of care for patients with neurogenic intermittent claudication associated with lumbar spinal stenosis that begins with non-surgical treatment, e.g., activity modification, medications such as NSAIDs, physical therapy and epidural steroid injections. The condition is progressive in many cases, however, and when symptoms become severe, patients are often confronted with the dilemma of living with persistent pain and functional impairment or electing one of several surgical options, including decompressive laminectomy with or without fusion.

Interspinous process decompression is a minimally invasive surgical procedure in which a spacer is inserted between contiguous spinous processes. The spacer reduces extension at the symptomatic level, preventing narrowing of the spinal canal while preserving natural, unrestricted motion in flexion, lateral bending, and axial rotation. The X-Stop® Interspinous Process Decompression System (Medtronic Spine, LLC) is currently the only FDA-approved interspinous process spacer. The X-Stop® device received FDA approval on November 21, 2005.

The effectiveness of this device is based solely on 24-month outcome data from the FDA pivotal study. This study has been published by Zucherman et al. (2005). In this prospective, multicenter study, 191 patients were randomized to interspinous process decompression or non-operative therapy over a 15-month period from May 2000 to June 2001. Patients had to be at least 50 years old and have moderate symptoms of neurogenic intermittent claudication (leg, buttock, or groin pain with or without back pain) that was relieved during flexion. Assessments were made at baseline, and at 6 weeks, 6 months, 1 year and 2 years following treatment. The mean age was 70 years in the X-Stop® group and 69.1 years in the control group.

At 2-years follow-up, data from 93 of the 100 X-Stop® patients and 81 of the 91 control patients were available for analysis. At 2 years, the mean symptom severity



scores improved by 45.4% from baseline in the X-Stop™ group and by 7.4% in the control group. At the same time, the mean physical function scores improved by 44.3% in the X-Stop™ group and by -0.4% in the control group. Distraction was maintained in 96% of the levels implanted with X-Stop® defined as no measurable change in the distance between the spinous processes when radiographs were taken over the 2-year follow-up period. Undergoing this procedure does not eliminate the possibility of more invasive surgery at a later time if symptoms persist. Six patients in the X-Stop® group (6%) and 24 patients in the control group underwent decompressive surgery (laminectomy) for unresolved stenosis symptoms during the 2-year follow-up period.

While the results of this study are encouraging, the published evidence is insufficient to make a determination on the long-term safety and efficacy of interspinous process decompression. Until there is quality published data on long-term safety and efficacy, interspinous process decompression remains experimental/investigational.

Definitions

Spinous process – the spinous process is the protrusion on the center of the back of a vertebral body. It is the site for the attachment of many spinal muscles. The spinous process is the only part of the vertebral column you can touch with your hands – it creates the "bumps" you feel in the middle of your back.

Policy

Commercial plans

FCHP does not cover interspinous process decompression (or the X-Stop® interspinous process decompression device) for commercial plan members.¹ This procedure has not been proven to improve patient outcomes in the peer-reviewed published literature and is considered experimental/investigational.

Fallon Senior Plan™

Interspinous process decompression (X-Stop®) is covered for Fallon Senior Plan™ members. Interspinous process decompression (X-Stop®) requires preauthorization by FCHP.

Interspinous process decompression is covered for Fallon Senior Plan™ members when all of the following criteria are met:

1. The plan member has 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); AND

¹ Although FCHP's Technology Assessment Committee has determined that interspinous process decompression is experimental/investigational, the Federal Employees Health Benefits Program (FEHBP) requires coverage for all FDA-approved drugs, devices or biological products. Therefore, interspinous process decompression is covered for FEHBP members if an FCHP Medical Director determines that the procedure is medically necessary. (FEHBP Carrier Letter No. 2001-27).



2. The plan member has moderately impaired physical function who experience relief in flexion from their symptoms of leg/buttock/groin pain, with or without back pain; AND
3. The plan member has undergone at least 6 months of conservative treatment which includes physical therapy, bracing, systematic and/or injected medications.

The interspinous process decompression device may be implanted at one or two lumbar levels in plan members in whom operative treatment is indicated at no more than two levels.

Codes

Claims for interspinous process decompression for commercial plan members will be denied vendor liable.

Codes	Number	Description
CPT	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 (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; each additional level

Note: CMS assigned pass-through payment status to HCPCS code C1821 effective January 1, 2007 through December 31, 2008. HCPCS code C1821 is not eligible for Medicare-reimbursement, effective January 1, 2009. CMS determined the separate cost-based pass-through payment for the X-Stop® device will expire and reassigned the procedure to a higher paying APC with the costs of the device folded into the payment for the procedure.

References

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Products to Which This Policy Applies

- ⊕ FCHP Direct & Select Care
- ⊕ Fallon Preferred Care (PPO)
- ⊕ Major Medical
- ⊕ MassHealth
- ⊕ Companion Care
- ⊕ Commonwealth Care
- ⊕ Fallon Senior Plan™

Committee review dates:

Technology Assessment Subcommittee: 01/26/09

Technology Assessment Committee: 06/10/09, 09/30/09



IMPORTANT NOTE

Not all services are covered for all products or employer groups. This medical policy expresses FCHP's determination of whether certain services or supplies are medically necessary, experimental or investigational or cosmetic. FCHP has reached these conclusions based upon the regulatory status of the technology and a review of clinical studies published in peer-reviewed medical literature. Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. Members and their providers need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and the plan of benefits, the provisions of the benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this medical policy.