

**SAMPLE LETTER PRE-AUTHORIZATION AND MEDICAL NECESSITY FOR
X-STOP® Interspinous Process Decompression (IPD®) Procedure**

Name of Medical Director or Medical Reviewer
Payer Name
Address
City, State, Zip

Re: Patient Name
SS#
Policy, Group or Claim # (identifying data for the carrier)
Date of birth

Dear Director of Medical Review:

I am recommending lumbar back surgery for [insert patient name]. Specifically I am recommending the insertion of a spinous process distraction device at L [insert level]. This procedure is also sometimes referred to as the X-STOP® IPD® procedure and it has been assigned a new CPT code, 0171T – Insertion of posterior spinous process distraction device. I am requesting that you review, authorize, and assign payment for 0171T, which as a new code has not been assigned a relative value unit.

[Insert description supporting authorization and payment; a sample is provided below]:

SAMPLE: [Insert patient name] is a [50+] year old patient who presents with a history of severe leg, buttock and groin pain for over 6 months, and because of the pain, has moderately impaired physical function [insert time frame]. MJ also complains of severe back pain. MJ obtains relief from pain when bending forward or when seated. Medical management and conservative therapy, administered over the last 6 months, has failed.

Physical examination and radiographic imaging including CT scans confirm neurogenic intermittent claudication secondary to spinal stenosis [1 or 2 levels]. Spinal stenosis is a narrowing of the spinal canal diameter in the lumbar area resulting in compression of the nerve roots. As you may know, compression of these nerve roots can create severe pain in the buttocks or lower legs.

Until recently the only surgical option for spinal stenosis was a laminectomy to increase the space between interspinous structures and to reduce neural compression. When

spinal instability could result from a laminectomy, a fusion is also performed. However, unlike a laminectomy, the X-STOP Procedure, can be performed using a local anesthetic so that patients with comorbidities that prohibit the use of general anesthesia can be treated. Also, with the X-STOP procedure there usually is no tissue or bone resection and the procedure does not preclude the patient from having other treatment at a later time.

The X-STOP[®] IPD[®] procedure is a minimally invasive procedure in which an implant is placed between the interspinous processes of the symptomatic lumbar level(s). The X-STOP Implant is designed to limit pathological extension of the treated spinal segments and maintain them in a neutral or slightly flexed position with the goal of reducing the symptoms of spinal stenosis. The clinical effectiveness of this minimally invasive surgical procedure is documented by the results from a prospective, randomized, multi-center trial that was conducted under an Investigational Device Exemption (IDE) done in support of a Premarket Approval (PMA). Results of the study have been published in U.S. peer-reviewed journals.¹ The overall treatment success was analyzed at 24 months and required all of the following conditions: Zurich Claudication Questionnaire (ZCQ) success, no additional operation for stenosis symptoms, and for the X-STOP System patients only, distraction maintained at 24 months, no implant dislodgement, and no device-related complications. It was found that patients undergoing the X-STOP[®] IPD[®] procedure had significantly better outcomes at 24 month follow-up than patients randomized to conservative care. In the Indicated Population,² success rates in each ZCQ domain (Symptom Severity, Physical Function and Patient Satisfaction) as well as overall success were statistically significantly higher in the X-STOP Device group when compared to the control group.

The X-STOP[®] Interspinous Process Decompression (IPD[®]) system was approved in the United States on November 21, 2005 (FDA PMA # PO40001). Over 1,000 surgeons have been trained across the country to implant the X-STOP[®] IPD[®] devices and over 3,500 patients have been treated as of January 2007. 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[®] IPD[®] procedure 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 non-operative treatment. The X-STOP[®] IPD[®] device may be implanted at one or two lumbar levels in patients in whom operative treatment is indicated at no more than two levels.

As an additional consideration, the Centers for Medicare and Medicaid Services (CMS) thoroughly evaluated the clinical data associated with the X-STOP[®] IPD[®] procedure and

¹ Zucherman JF, et. al., A multicenter, prospective randomized trial evaluation the X STOP interspinous decompression system for the treatment of neurogenic intermittent claudication: two-year results, *Spine* 2005;30(12)1351-1358.

² The subset of patients most likely to benefit from the X-STOP Implant which include those patients with moderately impaired physical function at baseline.

determined that this technology provided a significant clinical benefit to patients. Because the technology met Medicare's strict criteria for new technology, CMS designated the X-STOP® IPD® device as eligible for additional pass-through payment when the procedure is done on an outpatient basis.

In closing, based on the patient's condition as well as the scientific and clinical evidence documenting the benefits of X-STOP® device, it is my professional opinion that the X-STOP® IPD® procedure is reasonable and necessary at this time and I am requesting written approval to perform the procedure on this patient.

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| Diagnosis: | |
| 724.02 | Spinal stenosis, lumbar region |
| Surgical recommendations: | |
| 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 |

I appreciate your timely review and approval of this matter.

Sincerely,

[Physician name]

Other References available:

Anderson PA, et. al., Treatment of neurogenic claudication by interspinous decompression; application of the X STOP device in patients with lumbar degenerative spondylolisthesis. Neurosurg: Spine 2006 Jun;4:463-71.

Kondrashov DG, et. al., Interspinous process decompression with the X STOP device for lumbar spinal stenosis – a 4-year follow-up study. J Spinal Disor Tech 2006 Jul;19(5):323-27.

Medtronic, Inc. cannot guarantee coverage or reimbursement for X-STOP® IPD® procedure, and Kyphon Inc. makes no other representations as to selecting codes for procedures or compliance with any other billing protocols or prerequisites. As with all claims, individual physicians and hospitals are responsible for exercising their independent clinical judgment in selecting the codes that most accurately reflect the patient's condition and procedures performed for a patient. Physicians and hospitals should refer to current, complete, and authoritative publications such as AMA CPT lists or insurer policies for selecting codes and completing claims forms based on the care rendered to an individual patient, and may wish to contact individual carriers, fiscal intermediaries, or other third-party payers as needed.

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 non-operative 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.

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