

SAMPLE APPEAL LETTER

X-STOP[®] Interspinous Process Decompression (IPD[®]) Procedure

Name of Medical Director or Medical Reviewer

Payer Name

Address

City, State, Zip

Re: Patient Name

Policy #

Claim or Reference #

Date of Birth

Dear Director of Medical Review:

[insert physician name], M.D. is requesting an expedited appeal for medically necessary surgical services prescribed to [insert patient name] for the X-STOP[®] Interspinous Process Decompression (IPD[®]) device.

[Patient Name], who is [enter age] years old suffers from intermittent neurogenic claudication with moderate physical impairment that is caused by lumbar spinal stenosis (LSS). The patient's pain is relieved when in flexion. This diagnosis has been confirmed on [X-Ray, MRI, and/or CT scan]. A course of conservative medical management including pain medication, NSAIDS, physical therapy and epidural steroid injections has been unsuccessful in treating [his/her] debilitating back pain over the last 7 months. I determined that the best course of action to prevent extension related compression of nerves in the foraminal, spinal canal space and to reduce pain is to use the X-STOP[®] Interspinous Process Decompression (IPD[®]) system.

The X-STOP[®] IPD[®] system was approved in the United States on November 21, 2005 (FDA PMA#PO400001). The X-STOP[®] IPD[®] system provides a minimally invasive and effective surgical treatment for patients suffering from symptoms due to LSS, and is an alternative to both conservative care and decompressive lumbar spinal surgery.

To date I have successfully performed this procedure on a number of patients. (Physician to include appropriate historical outcome information.)

Should you have any questions or need additional information, please contact me by phone at [office number] or via fax at [fax number].

Sincerely

Medtronic 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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