

Private Health Insurance Plan

Prior Authorization/Pre-Determination Process and Appeals

If your physician determines that you require a procedure such as the X-STOP® IPD®, you may need to contact the health plan to request a prior authorization or pre-determination (approval) for coverage. **Prior authorization** is a process that health plans have developed to review certain medical and surgical health services to ensure medical necessity prior to services being rendered. **Pre-determination** is a review process conducted by the health plan to verify the medical necessity of a planned procedure. Pre-determination is often a condition of plan payment. The prior authorization and appeals process will vary from plan to plan. Thus, it is important to follow the individual plan process outlined in the provider manual. A brief overview is provided below. For more information, contact the health plan or provider manual. You may also contact your Medtronic Provider Relations Specialist at (888) 865-9512 for more information.

1 First Step – Submit request for prior authorization for the X-STOP® IPD® procedure before scheduling surgery.

- Generally, allow a minimum of 14 days for review and consideration by the health plan.
- **Include:** patient name and plan (insurance) ID number; provider name and billing number; anticipated date of service; diagnosis (by ICD-9-CM code and narrative); and the CPT codes that describe the procedure. For X-STOP, the codes are 0171T Insertion of posterior spinous process distraction device (including necessary removal of bone...), single level, and 0172T Insertion of posterior spinous process distraction device...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.*
- A letter of medical necessity to document that the patient has met the medical criteria per the FDA indications.
- It is helpful to note that X-STOP is generally covered by traditional Medicare.

After obtaining prior authorization, the surgery may be scheduled.

Health plans may have a disclaimer stating that prior authorization is not a guarantee of payment and additional information may be requested post surgery. If the plan denies coverage for the X-STOP® IPD® procedure, the decision may be appealed.

Appeal Process – If a request for prior authorization is denied, health plans provide an appeal process to address the specific reasons for denying a request. Contact the health plan and request the appropriate guidelines for the appeal.

Initial Appeal and/or Re-determination

If the request for surgery is denied, the patient or provider (depending on the plan) may appeal by filing a written request for a re-determination (generally within 30-90 days). Some payers require that the patient file the appeal although the physician may still need to submit evidence and/or support a request for an expedited re-determination. The re-determination is the **first level** of the appeal process. It is generally a good idea to request the re-determination in writing.

Generally, the following information should be included in the appeal:

- The patient's name, address, phone number; the reason for the appeal, a copy of the initial denial letter and any additional documents/clinical literature supporting the appeal
- Check the payer's plan - the physician may request an expedited appeal within 72 hours of the denial.

- Request a peer-to-peer review. Personnel reviewing the re-determination generally must be different from the personnel involved in making the initial coverage determination. On a re-determination, the reviewer generally must be a physician with expertise in the field if the procedure was determined to be not medically necessary.
- The timeline for a decision is usually 15-30 days. If the re-determination decision is unfavorable, generally the denial notice must explain the process for requesting a "reconsideration."

2 Second Level Appeal – Reconsideration

Reconsideration can be requested following an adverse determination from the insurer. This second appeal involves submitting additional medical and clinical documentation to the healthcare plan. Also...

- The physician can request that the independent physician reviewing the case is of the same specialty. This is also known as a school-to-school review.
- Patients may contact their employer or patient advocacy groups for support and assistance in addressing the health plan's denial and copy the state insurance commissioner on correspondence with the health plan.

Second level appeal timeline is usually 30 - 45 days.

Be persistent. In some instances, requests for surgery are authorized after several levels of appeals.

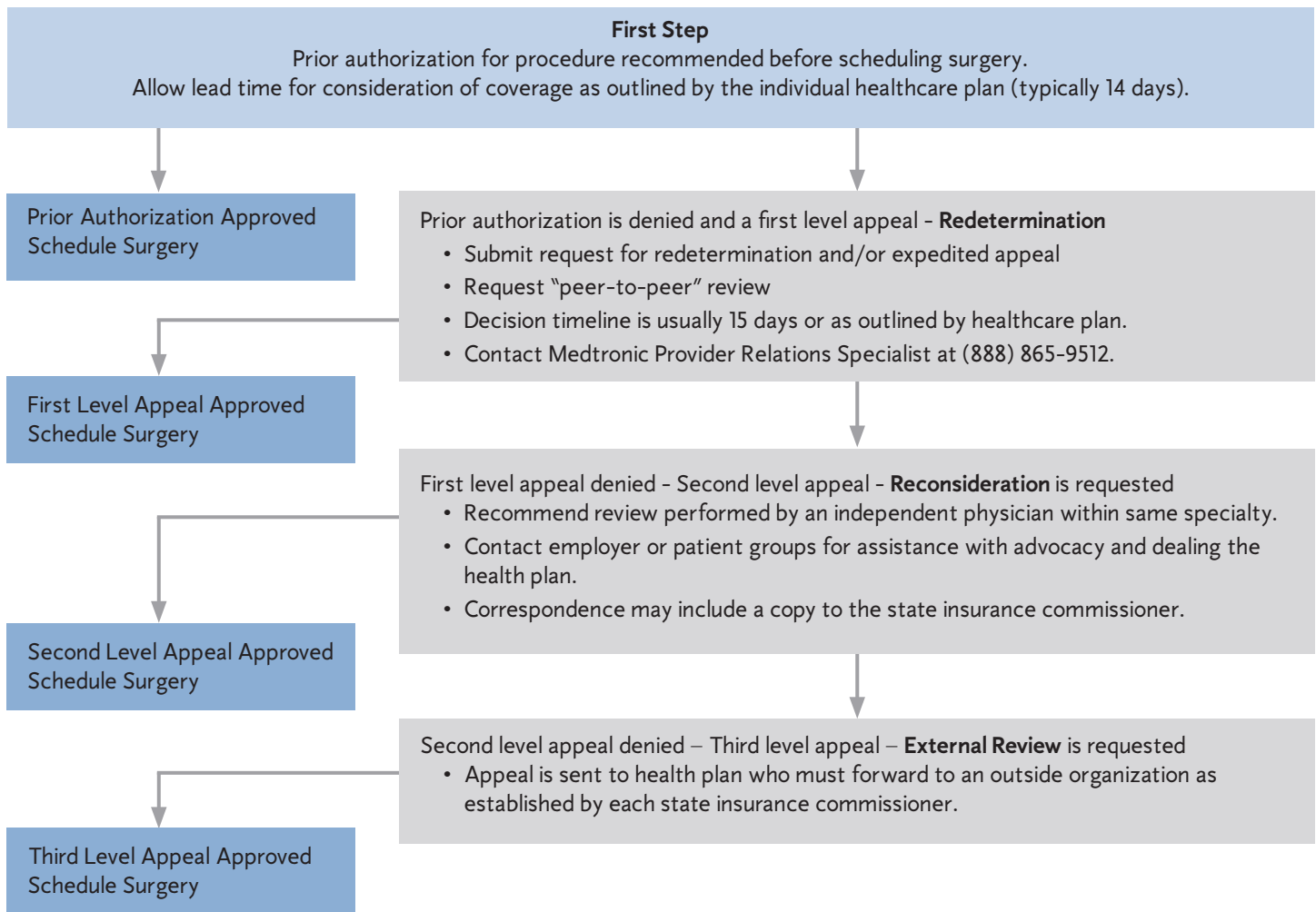
3 Third Level Appeal – External Independent Appeals

If the reconsideration (coverage) is denied, you may request a review by an external independent review organization (IRO) as established by each state insurance commissioner. An external independent review (IR) requires that someone, who is not employed by the health plan, review the request for treatment and make a decision independent of the health plan. The IR process and time frames vary from plan-to-plan and from state to state. Generally –

- The request to an IR must be made within a certain period and should be sent directly to the health plan.
- The health plan will send the request for an IR with all of your information, to the State's Department of Insurance.
- There is no charge to you for the external independent review.
- The independent physician who reviews the case generally has 21 days to make a decision.
- The Department of Insurance generally will send the decision within a week or two following receipt of the decision.
- If you disagree with the IR, you may have the right to an Administrative hearing to further your appeal.

Success builds future success – It is recommended that the physician maintain a file with all successful prior authorizations and appeals for healthcare plans as this information can facilitate and assist with future requests.

Prior Authorization Process and Appeal Flowchart



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.

This procedure is not for everyone. A prescription is required. Please consult your physician for a full discussion of risks and whether this procedure is right for you. For more information about the products and procedures please visit www.kyphon.com or call Customer Service at 1-866-959-7466.

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