X Stop: Interspinous Process Decompression System

Origionation: November 2007
Review Date: October 18, 2017
Next Review: October, 2019

DESCRIPTION OF PROCEDURE OR SERVICE
Interspinous Process Decompression (IPD®) is a surgical procedure for the treatment of spinal stenosis that is less invasive than traditional surgery, in which a titanium metal implant is placed between the spinous processes of the symptomatic lumbar disc levels. The implant may be placed at two levels if necessary.

IPD® is performed as an alternative to laminectomy for patients diagnosed with lumbar spinal stenosis who exhibit symptoms of intermittent neurogenic claudication and are able to relieve their symptoms when bending forward or when the spine is in a flexed position such as when sitting. The implant is designed to limit pathologic extension of the spinal segments and maintain them in a neutral or slightly flexed position which may allow patients to resume their normal posture rather than flex the entire spine to gain symptom relief.

IPD® is performed in the operating room under local, spinal or general anesthesia. It is typically done as an outpatient procedure depending upon the number of levels performed. The member is usually encouraged to get up and walk the same day as the surgery, as walking helps the healing and recovery process.

POLICY STATEMENT
Coverage will be provided for X-stop when it is determined to be medically necessary, as outlined in the below guidelines and medical criteria.

BENEFIT APPLICATION
Please refer to the member’s individual Evidence of Coverage (EOC) for benefit determination. Coverage will be approved according to the EOC limitations if the criteria are met.

Coverage decisions will be made in accordance with:
- The Centers for Medicare & Medicaid Services (CMS) national coverage decisions;
- General coverage guidelines included in original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.
Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member’s particular Evidence of Coverage (EOC), the EOC always governs the determination of benefits.

**INDICATIONS FOR COVERAGE**

1. Preauthorization by the Plan is required;

2. IPD® is considered medically reasonable and necessary for patients who meet ALL of the following criteria:
   a. Age 50 or older suffering from intermittent neurogenic claudication secondary to a confirmed (eg. MRI or CT scan) diagnosis of lumbar spinal stenosis;
      
      AND
   
   b. Members with moderately impaired physical function who experience relief from their symptoms of leg/buttock/groin pain (with or without back pain) in flexion;
      
      AND
   
   c. Have undergone at least six (6) months of non operative conservative treatment including non-steroidal therapy, a series of epidural injections, and physical therapy exercises to help stabilize the spine and help to build endurance and increase flexibility.

3. IPD® may be implanted at 1 or 2 lumbar levels, but at no more than 2 levels.

**WHEN COVERAGE WILL NOT BE APPROVED**

IPD® will not be considered medically reasonable and necessary with ANY of the following conditions:

1. Allergy to titanium or titanium alloy;
2. Spinal anatomy or disease that would prevent implant 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;
3. Significant scoliosis (Cobb angle greater than 25 degrees);
4. Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction;
5. Active systemic infection or infection localized at the site of implantation;
6. Diagnosis of severe osteoporosis.

**BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION**

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee reimbursement.

*Applicable codes:* 0171T, 0172T
The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

**SPECIAL NOTES**

It is expected that the members have not previously received a laminotomy or laminectomy at the same level of the spine as the IPD®.

Services performed on members who have received another spinal procedure such as any spinal instrumentation (CPT codes 22840-22849) and laminectomy or laminotomy (CPT codes 63001-63048) may be subject to denial and will be reviewed by the medical director on an individual case basis.

If inpatient level of care is requested for this procedure, the request will need to be reviewed by the Medical Director for medical necessity.

**References:**
1. Wisconsin Local Coverage Determination Category III Codes (Part A); L35490; Effective date 10/01/2015; Located at [www.cms.gov](http://www.cms.gov); viewed on 10/03/2017.
2. FDA Approved Devices: X STOP Interspinous Decompression System-P040001, viewed online at [http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm078378.htm](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm078378.htm); viewed on 10/3/2017.

**Policy Implementation/Update Information:**
Revision Date: February 2008; September 2009: Formatting changes and code review only.
Revision Date: 3/25/11: Under Indications for Coverage section, item c; added language referencing conservative treatment and included language pertaining to physical therapy/exercise for spine stabilization, build endurance and increase flexibility. Removed language pertaining to, “Examples of non operative treatments” per updated CMS policy. Removed language, “at the same time” from Special Notes section pertaining to ‘services performed on patients who have received another spinal procedure’ and updated the word patient for member.
Revision Date: 10/07/2013; Annual Review, no changes.
Revision Date: 09/09/2015; Annual Review; Reworded information under Description of Procedure/Service for clarity based on FDA summary; Added item #3 to Indications For Coverage per FDA guidelines; When Coverage Will Not Be Approved – corrected item #6 as referenced in FDA Approved Devices conditions for coverage, BMI is not an indication for noncoverage; Special Notes – added Medical Director review is required for inpatient level of care requests; updated reference section.
Revision Date: 10/18/17: Annual Review; No CMS or FDA updates. Minor Revisions Only.

**Approval Dates:**

Medical Coverage Policy Committee: October 18, 2017

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