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Developed By: Medical Criteria Committee	



**Approved:**

**Robert Mills, MD**

**Date:** 07/28/11

**Description:**

The X-STOP Interspinous Process Decompression System is a minimally invasive surgical procedure designed to alleviate painful symptoms of lumbar spinal stenosis. It is a titanium implant that fits between the spinous processes of the vertebrae in the lumbar spine. The X-STOP is designed to remain permanently in place without attaching to the bone or ligaments in the back. It consists of two parts: a spacer assembly that fits between the spinous processes and a wing assembly that is designed to prevent the implant from moving. The X-STOP is designed to reduce extension of the spine in the affected area and thereby prevent motions that induce back pain.

**Criteria:**

- I. ODS will cover X-STOP to plan limitations when **all** of the following criteria are met:
  - A. The member is age 50 or older; and
  - B. Presence of neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis at no more than two levels (x-ray, CT or MRI is required); and
  - C. Member has no more than grade I spondylolisthesis or up to 20° of scoliosis; and
  - D. Member experiences moderately impaired physical function with relief of symptoms of leg, buttock or groin pain (with or without back pain) with spinal flexion or sitting; and
  - E. Member has failed 6 months of non-operative conservative treatment (e.g. nonsteroidal anti-inflammatory drugs (NSAIDS), muscle relaxants, physical therapy, epidural steroid injections); and
  - F. The X-STOP is planned for one or two lumbar levels in patients in whom operative treatment is indicated at no more than two levels.

**Limitations:**

- I. X-STOP is contraindicated and will **not** be covered if any of the following conditions apply:
  - A. Allergy to titanium or titanium alloy
  - B. Spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable such as:
    1. Significant instability of the lumbar spine such as spondylolisthesis greater than grade 1.0; or
    2. An ankylosed segment at the affected level(s); or
    3. Acute fracture of the spinous process or pars interarticularis; or
    4. Significant scoliosis (greater than 20°)
  - C. Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction
  - D. Severe osteoporosis, as defined by a bone mineral density in the spine or hip greater than 2.5 SD, with evidence of fragility fracture(s)
  - E. Active systemic infection or infection localized to the site of implantation
  - F. L5/S1 stenosis (the S1 spinous process is too small)

**Information to be Submitted with Pre-Authorization Request:**

- Medical records from the treating physician including subjective and objective findings

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- Imaging reports
- Conservative treatment attempts
- Prior history of spine surgery or other treatment

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