



## MEDICAL POLICY

Date Reviewed: 05/18/07, 05/15/08, 04/24/09, 04/28/10, 04/15/11

**Subject:** Interspinous Distraction Devices (Interspinous Process Decompression, Interspinous Process Distraction, IPD, X Stop, Dynamic Posterior Stabilization System; the Diam Spinal Stabilization System, and the Coflex Interspinous Implant)

**Description:** Interspinous distraction is a minimally invasive surgical procedure where a device is placed between the spinous processes of the lumbar vertebra to manage the symptoms of lumbar spinal stenosis in individuals who did not respond to conservative therapy. The devices do not need to be permanently affixed to the bone or other anatomy of the spine which may allow for increased motion when compared to other surgical procedures.

**Indications of Coverage:**

None

**Limitations of Coverage:**

Review contract and endorsements for exclusions and prior authorization or benefit requirements.

Interspinous distraction devices and procedures are considered investigational as there is insufficient peer-reviewed scientific literature supporting the effectiveness of the procedure.

**Documentation required:**

Procedure report

**Rationale:** Not all individuals who have evidence of narrowing of the spinal canal or the openings where the nerves exit the spinal canal (foramina) have symptoms. It is not clear why some individuals report no symptoms and some individuals report significant symptoms. A variety of non-invasive treatments (for example, medication and physical therapy) are available to treat the condition. In cases where these treatments fail, surgical treatments (for example, decompression or laminectomy) are frequently recommended. Because of the significant complications that may arise from these surgical procedures, less invasive procedures have been investigated. Interspinous distraction devices are placed between the levels of the spine to increase the spinal canal or foramina openings.

The X Stop device was approved by the Food and Drug Administration (FDA) with the requirement that further data be collected, since at the time of approval, there was no data evaluating effectiveness more than twenty four months after implantation. At this time, there are few studies comparing interspinous distraction devices to non-surgical and surgical treatment. The studies that are available include a small number of patients, have inadequate follow-up periods, frequently do not include control groups, and in several instances, lost many patients to follow-up. Much of the available literature is from Zucherman and colleagues, who are the developers of the X Stop device. Additionally, the individuals included in the Zucherman study were highly selected and typically had limited anatomical findings. Further studies incorporating controlled clinical trials and evaluating the long term effectiveness of interspinous distraction devices have been recommended.

References: Christie SD, Song JK, Fessler RG. Dynamic interspinous process technology. Spine. 2005 Aug 15;30(16 Suppl): S73-8.

Richards JC, Majumdar S, Lindsey DP, Beaupre GS, Yerby SA. The treatment mechanism of an interspinous process implant for lumbar neurogenic intermittent claudication. Spine. 2005 Apr 1;30(7):744-9.

U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health. X-Stop interspinous process distraction system. P040001. Summary of Safety and Effectiveness. Rockville, MD; FDA; Nov 21, 2005. Available at: [www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm078378.htm](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm078378.htm). Accessed: 12 Apr 10.

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*Approved by the Medical Director*