Clinical Review Criteria

Spinal Decompression Device

- Coflex
- DIAM
- Wallis
- X-Stop

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Criteria

For Medicare Members

Medicare will cover the placement of the X-Stop® Interspinous Process Decompression System for Medicare members for the treatment of neurogenic intermittent claudication secondary to lumbar spinal stenosis (LSS).

The system is indicated for use in patients aged 50 years and older who have undergone at least 6 months of non-surgical treatment with physical therapy, nonsteroidal anti-inflammatory drugs, and/or spinal injections. The maximum of two lumbar levels may be covered in accordance with FDA approval of the device.

The payment for X-Stop® using 22899 will be an inclusive payment, including all work and practice expenses. No additional codes for approach or hardware placement will be paid.

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* Spinal Distraction Devices (A-0494) for medical necessity determinations. This service is covered not per MCG guidelines.

MCG* are proprietary and cannot be published and/or distributed. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (orthosurgeon, orthopedics, chiro, physiatrist, neurosurgeon)
- Most recent back/spine imaging

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Lumbar spinal stenosis refers to the narrowing of the spinal canal resulting in compression of the spinal cord. The decrease in size of the spinal canal is believed to be due to a combination of degenerative processes including bulging of the intervertebral disc, hypertrophy of the liameterum flavum, facet joint hypertrophy with bone spurring and spondylolisthesis. Symptoms include pain and numbness in the lower back, legs and buttocks after lumbar extension and walking. Symptoms are generally relieved by flexion of the lower back or sitting. Spinal stenosis is the most prevalent diagnosis for spinal surgery; it affects approximately 0.5% of Americans older than 50 (Batt & Carlson, 2006; CTAF technology assessment).

Functional loss associated with lumbar spinal stenosis is typically slow and thus an initial course of non-surgical
therapy is recommended. Conservative management is particularly indicated for patients with mild to moderate symptoms. Initial recommended therapies are activity modification (e.g. avoiding aggravating activities) and use of oral medications such as NSAIDS and salicylates. Other medications that have been found to be helpful for some patients are oral corticosteroids, tricyclic antidepressants and salmon calcitonin. Epidural steroid injections are another commonly used conservative treatment. These can reduce the radicular pain associated with acute exacerbations of neurogenic claudication (leg or buttock pain). In addition to the various types of pain relief or pain reduction discussed above, physical therapy can be helpful, especially flexion-based exercises. Surgical treatment, specifically decompression surgery, may be appropriate for selected patients. Patients whose function is limited (e.g. limitations in walking and activities of daily living) are potential surgical candidates. Intractable pain, especially neurogenic claudication, not responding to non-surgical therapies, is another reason for considering surgery. Laminectomy is considered the “gold standard” for decompression in patients with lumbar spinal stenosis (Yuan et al., 2005).

The X-Stop Interspinous Process Decompression System (St. Francis Medical Technologies, Alameda, CA) is proposed as a minimally invasive alternative to surgical treatment of lumbar spinal stenosis in patients with a moderate level of symptoms. Patients with severe symptoms are not eligible to receive this device and may be candidates for laminectomy. X-Stop consists of an oval titanium implant that fits between the adjacent spinous processes at the level of spinal stenosis and a wing assembly that prevents the implant from moving from side-to-side. The spinal processes are thin projections from back of spinal bones to which muscles and ligaments are attached. X-Stop is designed to remain permanently in place without attaching to the bones and ligaments in the back. The device is intended to slightly flex the affected area and to prevent extension to avoid nerve root impingement (manufacturers’ materials; FDA materials; CTAF technology assessment).

The device is usually implanted under local anesthesia with fluoroscopy guidance. The procedure involves making a 4-5 cm midline incision over the spinous processes of the affected levels. An attempt is made to keep the supraspinous and interspinous ligaments intact. The implant size is determined (it is available in 5 sizes) and an appropriately sized implant is inserted. After fastening the wing assembly, the incision is closed (manufacturers’ materials; FDA materials; CTAF technology assessment).

X-Stop was approved by the FDA in November 2005. As specified in the FDA premarket application (PMA) approval letter, X-Stop:

- Is indicated for patients age 50 and older with neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis;
- Is indicated for patients with moderately impaired physical function who experience relief in flexion from leg, buttock and/or groin pain, with or without back pain, and have undergone at least 6 months of non-operative treatment;
- May be implanted at 1 or 2 lumbar levels in patients for whom surgery is indicated (no more than 2 levels).
- Is not currently indicated for patients with mildly impaired physical function.

As part of the approval agreement, the manufacturer agreed to conduct a study on the long-term safety and effectiveness of X-Stop.

Prior to FDA approval, the FDA’s Orthopedic and Rehabilitation Devices Advisory Panel recommended disapproval in August, 2004. A majority of committee members felt that the pivotal clinical trial (discussed below in evidence summary) had substantial threats to validity. After the panel decision, the company submitted additional data to the FDA and defended their study methodology including the use of a relatively new self-report instrument as the primary outcome.

Medical Technology Assessment Committee (MTAC)
X-stop Interspinous Process Decompression System
02/05/2007: MTAC REVIEW

Evidence Conclusion: There is one published RCT that evaluated the safety and effectiveness of the X-Stop system. This was the pivotal clinical trial presented to the FDA. The investigators, who included the device inventors, reported that patients who received the X-Stop had significantly better clinical outcomes than patients receiving non-operative treatment. The study had numerous threats to validity including a lack of blinding, use of subjective outcomes, an inappropriate comparison group and possibly inadequate randomization, and thus provides insufficient evidence for concluding that X-Stop is safe and effective. In addition, there is no comparative pain or functional outcome data beyond two years.
Articles: The safety and efficacy of the X-Stop system compared to standard treatment for patients with the FDA approved indication for device use. The ideal study would be a randomized, double-blind controlled trial comparing the X-Stop system to the best-accepted alternative treatment or a sham intervention. The search yielded one unblinded RCT that compared X-Stop with conservative management. There were no double-blind trials or trials comparing X-Stop to a sham intervention. Five publications were identified based on the single RCT. The two articles that reported primary clinical outcomes were critically appraised. Zucherman et al. (2004) reported 1 year outcomes and Zucherman et al., 2005 reported 2 year outcomes. Other publications using RCT data include a case series analysis on a sub-set of treated patients (Kondrashov 2006 ), another sub-analysis on patients with lumbar degenerative spondylolisthesis (Anderson et al., 2006 ) and an in-depth look at the quality of life outcomes that were reported in the main outcome papers (Hsu et al., 2006 ). The secondary publications from the RCT and small case series identified in the search were not reviewed. The articles that were critically appraised (in a single evidence table) were: Zucherman JF et al. A prospective randomized multi-center study for the treatment of lumbar spinal stenosis with the X-Stop interspinous implant: 1-year results. Eur Spine J 2004; 12:22-31. Zucherman JF et al. A multicenter, prospective, randomized trial evaluating the X-Stop interspinous process decompression system for the treatment of neurogenic intermittent claudication: 2-year follow-up results. Spine 2005; 30: 1351-1358. See Evidence Table.


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Codes: CPT: 0171T; 0172T; C1821, 22867, 22868, 22869, 22870