KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Spinal Decompression Device

- Coflex
- Vertiflex Superion

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis (150.13)
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* **Spinal Distraction Devices** (A-0494) for medical necessity determinations. This service is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

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 or access the MCG Guideline Index using the link provided above.

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

- Last 6 months of clinical notes from requesting provider &/or specialist (orthopedic surgeon, 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 provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information 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 ligamentum 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

Back to Top

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 another 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.

Back to Top

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.

The use of X-stop Interspinous Process Decompression System in the treatment of lumbar spinal stenosis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Not Medically Necessary

CPT® or HCPC Codes	Description
C1821	Interspinous process distraction device (implantable)
22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level
22868	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure)
22869	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level
22870	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
03/21/2007	02/05/2007, 05/21/2007 MPC, 04/29/2008 MPC, 02/9/2009 MPC, 12/18/2009 MPC, 09/07/2010 MPC, 07/05/2011 MPC, 05/01/2012 MPC, 03/05/2013 MPC, 01/07/2014 MPC, 11/04/2014 MPC, 09/01/2015 MPC, 07/05/2016 MPC, 05/02/2017 MPC, 03/06/2018 MPC, 02/05/2019 MPC, 02/04/2020 MPC, 02/02/2021 MPC, 02/07/2023 MPC, 06/04/2024 MPC, 06/03/2025 MPC	02/02/2021

MPC Medical Policy Committee

Revision History	Description
04/12/2019	Added Coflex to Medicare Covered Criteria

Back to Top

02/02/2021	Added Vertiflex Superion product to criteria; removed products that are no longer in the market (DIAM, Wallis, X-Stop) from criteria. Added NCD (150.13) Percutaneous image-guided lumbar decompression for lumbar spinal stenosis for Medicare Members.

Back to Top