INTERSPINOUS DISTRACTION DEVICES (SPACERS)

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member’s specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

**Description:**

Interspinous process decompression limits extension of the spine in the affected area. It has been investigated as a means to relieve the symptoms of lumbar stenosis and improve the ability to function. Interspinous process decompression is achieved through implantation of a spinal distraction device. The procedure is minimally invasive and performed under local anesthesia.

The X-STOP® Interspinous Process Decompression (IPD®) System (Medtronic Spine LLC) received FDA approval through the premarket approval (PMA) process in 2005. The Coflex® Interlaminar Technology Implant (Paradigm Spine, LLC) received FDA approval through the premarket approval (PMA) process in 2012.

Several other devices are currently under investigation. The Wallis System (Abbott Spine) and the DIAM Spinal Stabilization System (Medtronic Sofamor Danek) are under investigation in FDA-regulated clinical trials. Other clinical trials underway at U.S. centers are investigating the In-Space (Synthes), the Superion (Vertiflex) and the FLEXUS (Globus Medical) devices. The NL-Prow (Non-Linear Technologies), Falena (Mikai) and Aperius (Medtronic Spine) devices are in trials in Europe. The ExtendSure and CoRoent (both from NuVasive) were launched in Europe in 2005 and 2006.
INTERSPINOUS DISTRACTION DEVICES (SPACERS) (cont.)

Criteria:

- Interspinous process decompression is considered experimental or investigational based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome.

Resources:


RESOURCES: (cont.)


FDA Premarket Approval Database for X STOP® Interspinous Process Decompression System:

- FDA-approved indication: Approval for the X STOP interspinous process decompression system. The device is indicated for treatment of patients aged 50 or older suffering from neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis (with x-ray, MRI, and/or CT evidence of thickened ligamentum flavum, narrowed lateral recess and/or central canal narrowing). The X STOP is indicated for those patients with moderately impaired physical function who experience relief in flexion from their symptoms of leg/buttock/groin pain, with or without back pain, and have undergone a regimen of at least 6 months of nonoperative treatment. The X STOP may be implanted at one or two lumbar levels in patients in whom operative treatment is indicated at no more than two levels.

FDA Premarket Approval Database for Coflex Interlaminar Technology:

- FDA-approved indication: Approval for the Coflex interlaminar technology. This device is indicated for use in one- or two-level lumbar stenosis from L1- L5 in skeletally mature patients with at least moderate impairment in function, who experience relief in flexion from their symptoms of leg/buttocks/ groin pain, with or without back pain, and who have undergone at least 6 month of non-operative treatment. The coflex is intended to be implanted midline between adjacent lamina of 1 or 2 contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s).