IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Surgical decompression with or without fusion is the standard surgical treatment for patients with moderate to severe lumbar spinal stenosis. Lumbar interspinous process decompression (IPD), also known as interspinous distraction or posterior spinal distraction, and interlaminar stabilization have been proposed as minimally invasive alternatives to laminectomy and fusion.

- One type of interspinous process spacers are inserted between the spinous processes through a small (4–8 cm) incision. The supraspinous ligament is maintained and assists in holding the implant in place. No laminotomy, laminectomy or foraminotomy is performed. Other interspinous spacers require removal of the interspinous ligament and are secured around the upper and lower spinous processes.
- Interlaminar spacers are implanted midline between adjacent lamina and spinous processes following surgical decompression at the affected level(s). These implants have two sets of wings that are placed around the inferior and superior spinous processes.

These devices are intended to restrict painful motion while enabling otherwise normal motion. The devices theoretically enlarge the neural foramen, decompresses the cauda equina, and act as spacers between the spinous processes to maintain the flexion of the spinal interspace.

Proponents of these spacers list the advantages compared with standard surgical decompression
techniques to be the option of local anesthesia, shorter hospital stay and rehabilitation period, preservation of local bone and soft tissue, reduced risk of epidural scarring and cerebrospinal fluid leakage, and reversibility that does not limit future treatment options. The potential complications of spacers are implant dislodgement, incorrect positioning of implant, fracture of the spinous process, foreign body reaction (e.g., allergic reaction to titanium alloy), and mechanical failure of the implant.

**Regulatory Status**

There are a number of interspinous process and interlaminar spacers that are under investigation:

<table>
<thead>
<tr>
<th>Device name</th>
<th>Manufacturer</th>
<th>FDA Approved?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aperius™-PercLID™ System</td>
<td>Kyphon/Medtronic</td>
<td>No</td>
</tr>
<tr>
<td>Coflex® Interlaminar Stabilization Device* (formerly Interspinous U)</td>
<td>Paradigm Spine</td>
<td>As a stand-alone spacer – No; As adjunct to fusion - No</td>
</tr>
<tr>
<td>DIAM™ Spinal Stabilization System</td>
<td>Medtronic Sofamor Danek</td>
<td>No IDE only</td>
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<tr>
<td>Falena® Interspinous Decompression Device</td>
<td>Mikai Spine</td>
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<tr>
<td>FLEXUS™</td>
<td>Globus Medical</td>
<td>No IDE only</td>
</tr>
<tr>
<td>Helifix® Interspinous Spacer System</td>
<td>Alphatec Spine®</td>
<td>No</td>
</tr>
<tr>
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<td>Non-Linear Technologies</td>
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<td>Synthes®</td>
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</tr>
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<td>VertiFlex, Inc.</td>
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<tr>
<td>Wallis® System</td>
<td>Zimmer Spine (formerly Abbott Spine)</td>
<td>No IDE only</td>
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<tr>
<td>X-STOP® Interspinous Process Decompression (IPD®) System (discontinued in 2015)</td>
<td>Kyphon/Medtronic Spine</td>
<td>Yes</td>
</tr>
<tr>
<td>X-STOP® PEEK (polyetheretherketone)</td>
<td>Medtronic</td>
<td>Yes</td>
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</tbody>
</table>

**Note:** This policy addresses only IPD devices. Dynamic stabilization devices across pedicle screws are considered in separate medical policies (see Cross References below). *The Coflex-F device is a fusion device and is not address in this policy.

**MEDICAL POLICY CRITERIA**

Interspinous process and interlaminar distraction/stabilization devices are considered **investigational** for all indications.
SCIENTIFIC EVIDENCE

The primary beneficial outcomes of interest for treatment of low back pain are relief of pain and improved function. Both of these outcomes are subjective and can be influenced by nonspecific effects, placebo response, and the variable natural history of the disease. Therefore, data from large, blinded, randomized controlled trials (RCTs) with sufficient long-term follow-up are required to control for the placebo effect, determine its magnitude, and determine whether any treatment effect from interspinous process and interlaminar distraction/stabilization spacers provides a significant advantage over conventional surgical decompression or nonsurgical treatment. In addition, adverse effects related to complications, such as spinous process fracture and implant dislodgement or breakage, must be considered in evaluating the net health impact of spacers compared with conventional surgical decompression with or without fusion.

Literature Appraisal

The literature on this technology is dominated by reports from non-U.S. centers on devices that have not received U.S. Food and Drug Administration (FDA) approval, though a number of them are in trials at U.S. centers. The focus of this literature appraisal is on systematic reviews, randomized trials, and nonrandomized comparative studies on devices that are approved for use in the United States. The published clinical trial data are relatively sparse and consist largely of small, non-randomized, uncontrolled studies with short-term follow-up. Of the few studies with a control group, most compare spacers with conservative medical management.

Systematic Reviews

Two systematic reviews of studies that compared spacers to traditional decompression surgery for lumbar spinal stenosis were published in 2010.[1,2] Both noted that outcomes seem promising, but that the level of evidence is low. The authors call for well-designed, large randomized studies with long-term follow-up and consistent outcome measures.

In 2014, Wu et al[3] conducted a meta-analysis of 2 RCTs[4,5] and 3 non-randomized prospective comparative studies.[6-8]. There were 204 patients in the interspinous spacer group and 217 patients in the decompressive surgery group. The interspinous spacers that were studied were the X-STOP, Aperius, Coflex, DIAM, and distraXion. Pooled analysis showed no significant difference at 12 and 24 months between the spacer and decompression groups for low back pain, leg pain, Oswestry Disability Index (ODI), Roland Disability Questionnaire (RDQ) or complications. However, the traditional decompressive surgery group had a significantly lower incidence of reoperation, with 11 of 160 cases requiring reoperation compared to 31 of 161 cases in the interspinous spacer group (relative risk [RR] 3.34; 95% CI: 1.77, 6.31). Several limitations to this meta-analysis were listed, with the primary concern being the small number of studies in the published literature comparing spacers and traditional decompression surgery. Although risk of bias was analyzed, no narrative critical appraisal of the included articles was provided. The authors noted the high reoperation rate associated with spacer use and stated that the indications, risks, and benefits of these devices required careful consideration before surgery.

A 2015 meta-analysis by Hong et al. included 20 studies with 3,155 patients in the interspinous spacers group and 50,983 patients treated with open decompression.[9] Devices studied were the X-STOP, DiAM, Aperius, Coflex, Wallis, and SPIRE. Results of this meta-analysis were similar to those obtained
in the more selective analysis by Wu et al. There was no significant difference between the 2 procedures for improvement rate, ODI, or visual analog scale (VAS) for back or leg pain. Although secondary outcomes such as operative and hospitalization time, perioperative blood loss, and postoperative complication rate were superior in the spacer group, reoperation rate was higher in that group (16.5% vs 8.7%). Because of the higher reoperation rate the authors concluded that, while the use of spacers may be a viable technique, they could not conclude that it had replaced open decompression surgery as the gold standard for treatment of lumbar spinal stenosis.

Randomized Controlled Trials (RCTs)

Spacers Compared with Nonoperative Treatment

The U.S. Food and Drug Administration (FDA) approval of the X STOP Interspinous Process Decompression System was based on laboratory, mechanical and cadaver studies, and a multi-center, prospective randomized controlled clinical study.[10-12] In this clinical study, patients were randomized to either the XSTOP® at one (n=64) or two (n=36) levels or to a control group (n=91) which received continued non-operative therapy which included bed rest, a lumbar corset and a varied number of epidural injections. The Symptom Severity and Physical Function scores were measured at six weeks, six months, one year and two years. The scores for the X STOP patients were significantly higher than the scores for the control group at each follow-up point. At two years, the mean Symptom Severity score for the X-STOP and the control groups was 45.4% above baseline scores and 7.4 (p<0.001), respectively. The mean Physical Function score changes were 44.3% and -0.4% (p<0.001), respectively. While these short-term results are promising, the study precludes scientific conclusions related to long-term health outcomes.

The following are additional reports on various subsets of the participants in this RCT:

A subsequent article was been published by the same authors using the 2-year quality of life date (SF-36) data from this trial.[13] As with other reports, the X STOP group showed improvements (by single-factor ANOVA or t-test) in both physical and mental component scores compared to both baseline and control subjects. However, in this report the authors considered the patients from both treatment and control groups who went on to have laminectomy within the 2-year follow-up period as lost to follow-up rather than as treatment failures; thus, the beneficial outcomes reported are misleadingly inflated. The article also notes a conflict of interest for the two primary authors of these articles.

Anderson and colleagues reported two year outcomes of a subset of patients in the original randomized trial reported above.[14] This subset consisted of patients in the randomized trial whose symptoms were due to degenerative spondylolisthesis at one or two levels. The overall success was defined as a case in which all outcome measures (i.e., Zurich Claudication Questionnaire (ZCQ), Patient Satisfaction Survey, Short Form-36 (SF-36) scores, and additional surgery) were met. In the X-STOP® group (n=42) 63.4% of patients met success criteria while 12.9% of the control group (n=33) met success criteria. The difference was statistically significant. Five patients (12%) in the X-STOP® group and four patients (12%) in the control group underwent laminotomy during the follow-up period. Again, short-term results were encouraging but long-term outcomes are needed.

In 2006, Kondrashov and Zucherman published the four year outcomes of another subset of patients in the randomized trial noted above.[15] Eighteen patients from one center were selected from the original nine-center sample based on the availability of preoperative Oswestry Disability Index (ODI) scores and willingness to complete the ODI at four years following surgery. Using a 15 point improvement from
baseline ODI score as a success criterion, 14 out of 18 patients (78%) had successful outcomes at the 4-year follow-up. The outcomes of the original control group were not included in this article. This intermediate-term study suffered from the same design flaws noted previously, specifically, the small size, lack of a control group for comparison, and lack of long-term health outcomes.

In 2014 Puzzilli et al. reported a multicenter controlled trial of X-STOP versus non-surgical management.[16] A total of 542 patients with lumbar spinal stenosis (LSS) and intermittent claudication relieved on flexion were enrolled. All patients had failed a 6-month trial of conservative therapy (medical and/or physical). Initially patients were randomized, but randomization to conservative management was terminated after the first 120 patients due to poor outcomes. These patients were followed for a minimum of 3 years. By 3 years, the overall failure rate was 12.3% of X-STOP patients, with 24 of 422 requiring device removal, compared to 50% of patients with continued non-surgical management with 38 of 120 patients having decompression and/or spinal fixation surgery.

### Spacers Compared with Decompression Surgery

In 2015 and 2016, the four- and five-year outcomes of the investigational device exemption (IDE) trial for the coflex® Interlaminar Technology.[17,18] The reported rate of follow-up at five years ranged from 40% to 100%, depending on the outcome measured. For example, the ODI at six months was reported for 56% of patients, while major device-related complications and composite clinical success were reported for 100% of patients. Interpretation of the five-year results is limited by the variable loss to follow-up in outcomes.

Roder et al reported a cross registry study that compared lumbar decompression plus coflex (SWISSspine registry) to lumbar decompression alone (Spine Tango registry) in 50 pairs matched by a multifactorial propensity score.[19] SWISSspine is a governmentally mandated registry from Switzerland for coverage with evidence development. Spine Tango is a voluntary registry from the Spine Society of Europe. Both registries use the numeric rating scale (NRS) for back and leg pain and the Core Outcome Measures Index (COMI) as the patient-based outcome instrument. The COMI consists of 7 questions to evaluate pain, function, wellbeing, quality of life, and disability. At 7 to 9 months follow-up, the coflex group had greater reduction in NRS back pain (3.8 vs 2.5, p=0.014), NRS leg pain (4.3 vs 2.5, p<0.001), NRS maximum pain (4.1 vs 2.3, p=0.002) and greater improvement in the COMI score (3.7 vs 2.5, p = 0.029).

In 2015, Lonne et al. reported a trial of X-STOP versus minimally invasive decompression in 96 patients with symptoms of neurogenic intermittent claudication relieved on flexion.[20] Intention-to-treat analysis showed no significant differences between the groups in primary and secondary outcome measures at up to 2-year follow-up. However, the number of patients having secondary surgery due to persistent or recurrent symptoms was significantly higher in the X-STOP group (25% vs 5%, odds ratio = 6.5). In addition, 2 patients had fracture of the spinous process and 1 had dislocation of the implant.[21] Three patients in the decompression group had secondary surgery during the first hospital stay due to hematoma. Mean days of rehabilitation were 66 for X-STOP and 48 for surgical decompression. The study was terminated after planned mid-term analysis due to the higher reoperation rate with X-STOP.

A 2-year outcomes of double-blind RCT (the FELIX trial) comparing the use of the coflex® spacer without bony decompression to surgical decompression were reported in 2015.[22] Functional outcomes were measured by ZCQ and Modified Roland-Morris Disability Questionnaire (RMDS), and pain was measured with VAS and McGill Pain Questionnaire. All 159 participants had intermittent neurogenic claudication due to lumbar spinal stenosis. Surgery time was shorter, but reoperation rates due to
absence of recovery were higher in the coflex group compared with the bony decompression group (29% vs 8%, p<0.001). For patients with 2-level surgery, the reoperation rate was 38% for coflex versus 6% for bony decompression (p<0.05). At 2 years, reoperations due to absence of recovery had been performed in 33% of the coflex group compared with 8% of the bony decompression group. VAS back pain at final follow-up was also higher in the coflex group (36 mm vs 28 mm/100). A number of methodological limitations were reported that limit interpretation and generalizability of the study findings. Differences may not have been found due to the lack of power, though the authors were not certain that a larger sample size would lead to a different study result. “To the contrary, the higher reoperation rate and the higher intensity of [low back pain] in the [spacer] group do suggest inferiority compared to classical decompression.”

In 2014 Marsh et al reported a randomized controlled trial that compared decompression alone (n=30) versus decompression with a Wallis implant (n=30).[23] Follow-up at an average of 40 months showed no significant differences between the groups in VAS for back or leg pain or in the ODI. Improvement in back pain was 3.5 out of 10 with the Wallis implant compared with 2.7 without (p=0.1926). Improvement in ODI was 19.3 with the Wallis implant compared with 10.6 without (p=0.0787). Additional study in a larger population is needed.

The 2-year outcomes of the pivotal investigational device exemption (IDE) trial for the coflex® Interlaminar Technology were published in 2013. This was a non-blinded randomized multi-center non-inferiority trial that compared implantation of the coflex spacer with decompression and posterolateral fusion with pedicle screw fixation.[24,25] The condition treated was back pain due to spinal stenosis or low-grade degeneration spondylolisthesis. A total of 322 patients were randomized to undergo either laminectomy and coflex insertion (n=215) or laminectomy and fusion (n=107).

At a minimum of 2 years follow-up, non-inferiority was reported, with 66.2% success with coflex and 57.7% success with fusion (p=0.999). There was no statistically significant between-group differences in pain and function scores. The percentage of device-related adverse events was the same (5.6%) for both groups, and the rate of spinous process fractures was not significantly different between the groups (14% for coflex and 12% for fusion). The vast majority of spinous process fractures were asymptomatic. A separate article reported similar outcomes for the spondylolisthesis subgroup in the study.[26] The overall reoperation rate was 10.7% in the coflex group and 7.5% in the fusion control (p=0.426). One limitation of this study was the lack of participant blinding to the treatment allocation; however, since the postoperative protocols are different for these procedures, blinding can be difficult to maintain. In addition, the 2-year follow-up does not permit conclusion about long-term outcomes.

In 2013, Stromqvist et al. reported the 2-year outcomes of a noninferiority randomized trial of 100 patients with symptomatic one- or two-level lumbar spinal stenosis with neurogenic claudication relieved on flexion.[4] Patients were randomized in a 1:1 ratio to undergo either X-STOP implantation or conventional surgical decompression. At 6, 12, and 24 months follow-up, there was no significant difference in scores for symptoms and function, or for complication rates. Reoperation rates were significantly higher (p<0.04) in the X-STOP group (n=13; 26%) than in the decompression group (n=3; 6%). (The X-STOP patients who later underwent decompression were not considered to be treatment failures.) For the reasons noted above, longer-term data is needed to determine the durability of treatment effects and to compare the long-term reoperation rates.

Richter et al. also published 2-year follow-up for 60 patients who underwent decompressive surgery with or without implantation of the Coflex device.[6,27] Though comparative, this study was not a randomized trial; treatment was allocated at the discretion of the surgeon. The authors reported no
significant between-group differences in any outcome measures, and concluded that “additional placement of a Coflex™ interspinous device does not improve the already good clinical outcomes after decompression surgery for LSS in this 24-month follow up interval.”

**Comparisons of Different Devices**

At three-year follow-up of the IDE non-inferiority trial comparing the Superion interspinous spacer to the X-STOP, there were 120 patients in the Superion ISS group and 129 in the X-STOP group remaining (64% of 391). Of these, composite clinical success was obtained in 52.5% of patients in the Superion ISS group and 38.0% of the X-STOP group (p=0.023). The 36-month clinical outcomes were reported for 82 patients in the Superior ISS group and 76 patients in the X-STOP group (40% of 391). It is not clear from the report whether the remaining patients were lost to follow-up or were considered treatment failures and censured from the results. In addition, interpretation of this study is limited by questions about the efficacy of the comparator and lack of a control group treated by surgical decompression.

Preliminary and two-year follow-up results have been published from an FDA-regulated multicenter randomized IDE non-inferiority trial comparing the Superion interspinous spacer to the X-STOP. At baseline, all patients (N=391) had intermittent neurogenic claudication despite 6 months nonsurgical management. The FDA-mandated primary endpoint of this trial was non-inferiority to X-STOP at 2 years, with additional postmarket surveillance for 10 years. The reported outcome was a composite of clinically significant improvement in at least 2 of 3 ZCQ domain scores compared with baseline, freedom from reoperation, revision, removal, or supplemental fixation at the index level, freedom from epidural steroid injection or nerve block within 12 weeks of the 2-year visit, freedom from rhizotomy or spinal cord stimulator at any level, and freedom from major implant or procedure-related complications.

The primary non-inferiority endpoint was met, with a Bayesian posterior probability of 0.993. However, 111 patients (28%, 54 Superion and 57 XSTOP) were withdrawn from the study during follow-up due to a protocol-defined secondary intervention. Modified intent-to-treat analysis showed clinical success (improvement ≥ 20 mm/100) for leg pain in 76% to 77% of patients and for back pain in 67% to 68% of patients, with no significant differences between groups. At two-years, ODI success was achieved in 63% of Superion patients and 67% of XSTOP patients (p=0.061). Rates of complications and reoperations (44 [23.2%] Superion and 38 [18.9%] XSTOP) were similar between groups. Spinal process fractures, reportedly asymptomatic, occurred in 16.4% of Superion patients and 8.5% of XSTOP patients. Interpretation of this study is limited by the lack of blinding and lack of control groups treated by surgical decompression or medical management.

**Clinical Practice Guidelines**

**North American Spine Society**

The 2014 revised clinical guidelines from the North American Spine Society (NASS) on lumbar spinal stenosis concluded that “there is insufficient evidence at this time to make a recommendation for or against the placement of an interspinous process spacing device in patients with lumbar spinal stenosis” (Grade of Recommendation I - Insufficient Evidence)

The 2014 revised NASS clinical guidelines on degenerative lumbar spondylolisthesis concluded that “there is insufficient and conflicting evidence to make a recommendation for or against the efficacy of interspinous spacers versus medical/interventional treatment in the management of degenerative lumbar
spondylolisthesis patients.” (Grade of Recommendation I - Insufficient Evidence) [32]

Summary

Current evidence is insufficient to permit conclusions about whether any beneficial effect from interspinous process distraction or interlaminar stabilization spacers provides a significant advantage over surgical decompression, which is the current standard of care for surgical treatment of lumbar spinal stenosis. The evidence consists of several randomized controlled trials (RCTs) and nonrandomized comparative studies and overall, these studies show a high failure and complication rates compared to surgical decompression. In addition, longer-term studies are now reporting high reoperation rates. Current clinical practice guidelines state that interspinous process distraction or interlaminar stabilization spacers may be indicated in a very small, select patient population, but acknowledge that failure may occur and further surgery may be needed. Therefore, use of interspinous process and interlaminar stabilization/distraction spacers is considered investigational.

REFERENCES


CROSS REFERENCES

- **Dynamic Stabilization of the Spine**, Surgery, Policy No. 143
- **Total Facet Arthroplasty**, Surgery, Policy No. 171
- **Interspinous Fixation (Fusion) Devices**, Surgery, Policy No. 172
- **Image-Guided Minimally Invasive Spinal Decompression (IG-MSD) for Spinal Stenosis**, Surgery, Policy No. 176
- **Lumbar Spinal Fusion**, Surgery, Policy No. 187

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<td>Insertion of posterior spinous process distraction device (including necessary</td>
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