Clinical Policy Title: Interspinous dynamic stabilization devices

AmeriHealth Caritas Pennsylvania Community HealthChoices has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania HealthChoices' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas Pennsylvania HealthChoices when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Pennsylvania HealthChoices' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Pennsylvania HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania HealthChoices will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania HealthChoices' clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas Pennsylvania HealthChoices considers the use of interspinous dynamic stabilization devices to be investigational and, therefore, not medically necessary. Medical necessity of requests for this device, therefore, will be considered on a case-by-case basis.

Limitations:

All other uses of interspinous dynamic stabilization devices are not medically necessary.
For Medicare members only:

AmeriHealth Caritas Pennsylvania HealthChoices considers the use of interspinous dynamic stabilization devices to be clinically proven and, therefore, medically necessary when using the X STOP® Interspinous Process Decompression System (Medtronic Sofamor Danek Inc., Memphis, Tennessee) for persons who meet all of the following criteria (Medicare coverage article A52693; Local Coverage Decisions [LCDs] L34006 and L35094):

- Age 50 or older and suffering from intermittent neurogenic claudication secondary to a confirmed diagnosis of lumbar spinal stenosis.
- Experiencing moderately impaired physical function and relief in flexion from their symptoms of leg, buttock, or groin pain, with or without back pain.
- Have undergone at least six months of non-operative treatment.

The X STOP is not medically necessary for persons with any of the following conditions:

- Allergy to titanium or titanium alloy.
- Spinal anatomy or disease that would prevent implant of the device or cause the device to be unstable in situ, such as significant instability of the lumbar spine (e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1.0 [on a scale of 1 to 4]); an ankylosed segment at the affected levels, or acute fracture of the spinous process or pars interarticularis.
- Significant scoliosis (Cobb angle greater than 25 degrees).
- Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction.
- Diagnosis of severe osteoporosis, defined as bone mineral density (from dual-energy X-ray absorptiometry scan or some comparable study) in the spine or hip that is more than 2.5 standard deviations below the mean of adult normals in the presence of one or more fragility fractures.
- Active systemic infection or infection localized at the site of implantation.
- Body mass index >40 kg/m².

Alternative covered services:

- Conservative nonsurgical treatments for lumbar spinal stenosis, including nonsteroidal anti-inflammatory drugs (NSAIDs), analgesics, muscle relaxants, epidural steroids, physical therapy, and bracing.
- Surgical options including decompressive procedures such as laminotomy, hemilaminotomy, laminectomy, hemilaminectomy, laminoplasty, foraminotomy, and facetectomy. Patients may undergo surgical spinal fusion.

Background

Spinal stenosis is a narrowing of the spinal canal resulting in pressure on the spinal cord and/or nerve roots. The narrowing may involve a small or large area of the spine. Causes can be inherited or acquired and most
often result from a gradual, degenerative aging process. The cervical and lumbar spinal regions are generally affected (National Institute of Arthritis and Musculoskeletal and Skin Diseases [NIAMS], 2016).

Lumbar spinal stenosis is a leading preoperative diagnosis in Americans, particularly those age 60 years or older. Neurogenic intermittent claudication is a common symptom of lumbar spinal stenosis. It includes weakness, cramping, pain or numbness in the legs, and, in more severe cases, bowel and bladder dysfunction and foot disorders.

First-line treatments for symptomatic lumbar spinal stenosis include rest, NSAIDs, muscle relaxants, corset use, physical therapy, and lumbar epidural steroid injections. For persons with moderate to severe symptoms, surgical decompression with or without spinal fusion and discectomy may be indicated but are associated with serious complications and high operative risk, particularly for elderly patients. The effectiveness of nonsurgical treatments, the extent of pain, and patient preferences may all factor into the decision to have surgery (NIAMS, 2016).

Interspinous dynamic stabilization is a minimally invasive technique that implants a titanium spacer or plate between the spinous processes or attaches to the spinous processes affected by stenosis (North American Spine Society [NASS], 2011). Interspinous dynamic stabilization achieves sagittal balance and segment stability by widening the spinal canal and decompressing the nerve, thereby reducing pain. Its theoretical advantages are using minimally invasive surgical techniques rather than direct decompression (e.g., laminotomy, laminectomy, or foraminotomy) at the time of insertion, reducing the risk of epidural scarring and cerebrospinal fluid leakage. Unlike conventional fusion that prevents spinal segment movement, interspinous dynamic stabilization restricts spinal movement in the direction that causes pain, while permitting mobility in the other directions, and may be performed alone or with surgical decompression.

**Regulation:**

While the U.S. Food and Drug Administration (FDA) does not regulate surgical procedures, it does regulate the spacer implants as class III devices requiring pre-market approval. FDA has approved three interspinous spacers or plates for treating neurogenic intermittent claudication caused by radiologically-confirmed lumbar spinal stenosis (FDA, 2017):

- X STOP interspinous dynamic stabilization system.
- Superion® InterSpinous Spacer (ISS) (Vertiflex® Inc., San Clemente, CA).
- Coflex® Interlaminar Technology (Paradigm Spine LLC, New York, NY).

These devices are intended for patients with at least moderately impaired physical function who experience relief in flexion from their symptoms of leg, buttock, or groin pain, with or without back pain, and have undergone a regimen of at least six months of unsuccessful non-operative treatment. X STOP and Superion are stand-alone devices that may be implanted at one or two lumbar levels in patients in whom operative treatment is indicated. Coflex is intended to be implanted midline between adjacent lamina of one or two contiguous lumbar motion segments after surgical decompression of stenosis at the affected levels.
Continued approval of these class III devices is contingent upon the submission of periodic reports and the results of post-market studies assessing long-term safety and effectiveness.

**Searches**

AmeriHealth Caritas Pennsylvania HealthChoices searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on November 15, 2017. Search terms were: “back” (MeSH), “back pain” (MeSH), and “prostheses and implants” (MeSH), along with free text terms “interspinous process spacer” and “interspinous” combined with “device” and “space.”

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

We identified four systematic reviews, three evidence-based guidelines, three cost-effectiveness analyses, and one additional randomized controlled trial (RCT) for this policy. Overall, the quality of the evidence is low to moderate. The evidence consists of largely non-comparative, observational studies. The systematic reviews identified six RCTs comparing patient outcomes of an interspinous dynamic stabilization device to surgical decompression with or without fusion in persons with lumbar spinal stenosis; four RCTs assessed the X STOP, and two examined the Coflex implant. One additional RCT compared the three-year clinical outcomes of X STOP and Superion spacers (Patel, 2015).

The implant procedure using any of the three devices is relatively safe. X STOP and Superion spacers can be inserted using local anesthesia, whereas the Coflex is usually performed after surgical decompression. The most common implant-related adverse events were device migration, spinous process fracture, and malpositioned implant. Other adverse events were sensitivity or allergy to the implant material, pain and discomfort associated with the operative site or presence of implants, formation of scar tissue at the implant site, and degradation of the implant, all of which may require revision surgery.
Contraindications to interspinous dynamic stabilization devices include anatomy that prevents implantation due to significant lumbar instability, ankylosis, acute fracture of the spinous process or pars interarticularis, allergy to titanium or titanium alloy, significant scoliosis, fixed motor deficit, cauda equina syndrome, neural compression causing neurogenic bowel or bladder dysfunction, previous lumbar surgery, significant peripheral neuropathy, degenerative spondylolisthesis at the affected level, sustained pathological fractures, severe osteoporosis of the vertebrae or hips, severe foraminal stenosis, obesity, active infection or systemic disease, Paget's disease or metastasis to the vertebrae, and steroid use for more than one month within 12 months preceding surgery. A relative contraindication is adjacent-level disease.

Results of the systematic reviews suggest interspinous dynamic stabilization offers greater short-term improvement in symptoms and functional status than nonsurgical therapy. Symptomatic outcomes for interspinous dynamic stabilization and surgical decompression were similar, but interspinous dynamic stabilization was associated with a higher reoperation rate and higher cost. One RCT comparing Superion to X STOP found greater durable clinical improvement with Superion after three years in the treatment of patients with moderate degenerative lumbar spinal stenosis (Patel, 2015). Long-term (i.e., more than two years) outcome data on durability of symptom relief, the need for repeat procedures, and implant survival compared to other surgical options are inadequate. Longer-term studies are in progress as part of FDA post-approval requirements (ClinicalTrials.gov identifiers NCT00534235 and NCT02555280).

The American Academy of Orthopaedic Surgeons (AAOS) makes no specific recommendation for or against interspinous dynamic stabilization devices but acknowledges them as a minimally invasive option for appropriately selected patients who experience relief of buttock and leg pain when sitting or bending forward but return of pain when standing (AAOS, 2015). The NASS (2011) found insufficient evidence to recommend for or against interspinous dynamic stabilization devices for treatment of lumbar spinal stenosis or degenerative lumbar spondylolisthesis.

Policy updates:

We identified two updates of previously included systematic reviews comparing interspinous dynamic stabilization versus decompression surgery (Hayes, 2016; Machado, 2016) and one new Cochrane review comparing interspinous dynamic stabilization to non-surgical treatment (Zaina, 2016) for lumbar spinal stenosis. The new evidence confers no clear outcome advantage of adding interspinous dynamic stabilization to decompression surgery compared to either decompression surgery alone (with or without fusion) or conservative treatment. These results do not change previous findings. Therefore, no policy changes are warranted.

In 2018, we added updates to a systematic review of the Coflex interspinous dynamic stabilization (Hayes, 2017) and five-year outcomes from the Superion treatment arm of a FDA noninferiority RCT comparing two interspinous dynamic stabilization devices (Nunley, 2017; ClinicalTrials.gov identifier: NCT00692276). Forty-eight of 88 patients underwent revision surgery, and 38 of the 48 patients required revision within the initial two postoperative years. These results suggest that patients who demonstrate early clinical improvement with spacer implantation will maintain that benefit over time, but direct comparison to
Laminectomy is lacking. Forty-one adverse events related to interspinous dynamic stabilization devices have been reported to the FDA Manufacturer and User Facility Device Experience (MAUDE) database since October 1, 2016 (FDA, 2017). The new information confirms previous findings. No policy changes are warranted.

**Summary of clinical evidence:**

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<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td><strong>Hayes (2017)</strong></td>
<td><strong>Key points:</strong></td>
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<tr>
<td>Safety and efficacy of Coflex for lumbar spinal stenosis</td>
<td>• Systematic review of one RCT and two prospective cohort studies (46 to 322 total patients per study). &lt;br&gt;• Overall quality: low due to inadequate follow-up time, small sample size; retrospective design; lack of a control group; and heterogeneous patient populations, study designs, treatment protocols, and comparators. &lt;br&gt;• Results suggest Coflex device with decompression surgery (laminectomy or laminotomy) may result in similar improvements in pain, disability, function, and quality of life compared with decompression surgery alone or decompression with fusion. &lt;br&gt;• Adverse events between groups were similar. &lt;br&gt;• More comparative data are needed to identify long-term reoperation rates, biomechanical effects on the spine, and optimal patient selection criteria. &lt;br&gt;• Update: no new information added.</td>
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<td><strong>Nunley (2017)</strong></td>
<td><strong>Key points:</strong></td>
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<td>Five-year durability of stand-alone interspinous process decompression for lumbar spinal stenosis using Superion</td>
<td>• FDA noninferiority trial of 88 patients with moderate lumbar spinal stenosis treated with the Superion device. Reporting results at five years. &lt;br&gt;• Clinical success = 84% of patients on ≥ two of three Zurich Claudication Questionnaire (ZCQ) domains. &lt;br&gt;• Leg and back pain success rates = 80% and 65%, respectively. &lt;br&gt;• Oswestry Disability Index (ODI) success rate = 65%. &lt;br&gt;• Percentage improvements over baseline = 42%, 39%, 75%, 66%, and 58% for ZCQ symptom severity, ZCQ physical function, leg and back pain visual analog scale, and ODI, respectively (all P &lt; 0.001). &lt;br&gt;• Within-group effect sizes were classified as very large for four of five clinical outcomes (i.e., &gt; 1.0; all P &lt; 0.0001). &lt;br&gt;• Free from reoperation, revision, or supplemental fixation = 75%. &lt;br&gt;• Revision required in 48 patients; 38 of them underwent revision within the initial two years of the procedure. Of the remaining 10 reoperations, one occurred during the fifth year of observation, suggesting a decreasing risk of revision surgery with time.</td>
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<td><strong>Machado (2016)</strong></td>
<td><strong>Key points:</strong></td>
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<td>Comparative effectiveness of different surgical techniques for lumbar spinal stenosis</td>
<td>• Systematic review and meta-analysis of three RCTs of interspinous dynamic stabilization vs. conventional bony decompression. &lt;br&gt;• Overall quality: low (two RCTs), high (one RCT). &lt;br&gt;• Compared to decompression, interspinous dynamic stabilization was associated with: &lt;br&gt;  – Similar reductions in pain (mean difference [MD] -0.55, 95% confidence interval [CI] -8.08 to 6.99) and disability (MD 1.25, 95% CI -4.48 to 6.98).</td>
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<td>Citation</td>
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| Zaina (2016) Cochrane review Surgical versus non-surgical treatment for lumbar spinal stenosis | Key points:  
- Systematic review of one RCT of interspinous dynamic stabilization vs. usual conservative treatment (191 total participants).  
- Overall quality: low.  
- Side effects: conservative care 0% vs. interspinous dynamic stabilization 11% (spinous process fracture, coronary ischemia, respiratory distress, hematoma, and death due to pulmonary edema).  
- Significant treatment effect favored surgery on the SF-36 scale for bodily pain, with an MD in change from baseline of 7.8 (95% CI, 1.5 to 14.1).  
- No significant difference in scores on physical function or disability.  
- Significant advantage for surgery at three months for all primary outcomes that remained significant at two years. |
| Lee (2015) Safety and efficacy of interspinous dynamic stabilization | Key points:  
- Systematic review of 20 studies of the DIAM<sup>®</sup> (Medtronic, Tolochenaz, Switzerland), X STOP (two RCTs), Wallis, and Coflex devices (two RCTs).  
- Overall quality: low to moderate with three- to 41-month follow-up.  
- Complication rate: X STOP alone was 0% to 11%. Spinal process fracture, implant displacement, and foreign body reaction to polyethylene were noted, but no permanent disability. Coflex and traditional decompressive surgery was 32.3% and. traditional decompressive surgery alone was 6.5%, but no complication that significantly affected treatment results was noted.  
- Efficacy: interspinous dynamic stabilization produced slightly better clinical outcomes than conservative treatments.  
- Coflex produced comparable treatment outcomes to traditional decompressive surgery or fusion alone.  
- Long-term results are lacking. |
| Parker (2015) Cost-effectiveness analysis of conservative care, TDS, and Superion spacer for lumbar spinal stenosis | Key points:  
- Markov model using three strategies of care for lumbar spinal stenosis.  
- Conservative care had the lowest cost at $10,540, while spacers and TDS were nearly identical at about $13,950. |
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| Patel (2015)      | - Quality-adjusted life year (QALY): conservative care had the lowest increase (0.06), while spacers and traditional decompressive surgery were nearly identical (.28).  
                    - Results suggest surgical alternatives provide superior value versus sustained conservative care.                                                                                                                                 |
| Superion spacer vs. X STOP | **Key points:**  
                    - Multisite RCT of Superion (N = 190 patients) versus X STOP (n = 201 patients) with three-year follow-up.  
                    - Overall quality: moderate. Blinding not reported.  
                    - Primary composite endpoint: Improvement in two of three domains of the Zurich Claudication Questionnaire, no reoperations at the index level, no major implant- or procedure-related complications, and no clinically significant confounding treatments.  
                    - At three years, Superion (63/120, 52.5%) versus X STOP (49/129, 38.0%) (P = 0.023) achieved the desired endpoint and maintained improvements in back and leg pain.  
                    - Success rates > 80% for each component of the primary endpoint in the Superion group (range: 81% – 91%). |
| Hayes (2014)      | **Key points:**  
                    - Systematic review of four RCTs, two retrospective comparative studies, four prospective studies, three retrospective case series, and two cost-effectiveness analyses (Skidmore, 2011; Burnett, 2010).  
                    - Overall quality: low with high risk of bias. Uncontrolled and/or retrospective, and small or moderate in size (n = 30 to 285 patients). Limited follow-up.  
                    - Implant procedure is relatively safe and can be performed using local anesthesia. System-related adverse events include: revision surgery (2% to 7%), device migration (1% to 5%), spinous process fracture (1% to 4%), and malpositioned implant (1%).  
                    - X STOP device is associated with short-term decreased pain, increased function, and improved quality of life. There were statistically significant improvements from baseline in both groups (P <0.001), but no significant differences between groups.  
                    - Traditional decompressive surgery and X STOP were more cost effective than conservative care.  
                    - Well-designed, long-term clinical trials vs. standard treatment and other alternatives are needed to further evaluate the efficacy, safety, and durability of the device. |

**References**

**Professional society guidelines/other:**


FDA Manufacturer and User Facility Device Experience (MAUDE) database searched from October 1, 2016 to the present using product code NQO. FDA website.


Peer-reviewed references:


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.


**Local Coverage Determinations (LCDs):**


**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<tr>
<th>CPT Code</th>
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<tr>
<td>0171T</td>
<td>Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; single level</td>
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<tr>
<td>0172T</td>
<td>Each additional level (list separately in addition to code for primary procedure)</td>
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<td>G95.89</td>
<td>Disease of the spinal cord, other specified</td>
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<td>M48.06</td>
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<tr>
<td>M48.07</td>
<td>Spinal stenosis, lumbosacral region</td>
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