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Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

Audience

Medical Management, Claims

Purpose

Medical policies provide general support for applying coverage decisions under the Mountain Health Co-Op member policy document and must reference the member-specific benefit plan document. The terms of the member-specific Policy document may differ from the standard benefit plan on which this medical policy is based. If there is a conflict between a member-specific policy document and the Mountain Health Co-Op medical policy, the member-specific policy document supersedes this medical policy. Any person(s) applying this medical policy must identify member eligibility, the member-specific policy document, and related policies or guidelines before applying this medical policy, including the existence of any state or federal guidance. Mountain Health Co-Op medical policies are intended for informational purposes only and are not an authorization, an explanation of benefits, or a contract. Receipt of benefits is subject to the satisfaction of all terms and conditions of the member-specific policy document coverage. Mountain Health Co-Op reserves the sole discretionary right to modify all policies and guidelines at any time.

Definition

N/A

Policy/Procedure

Mountain health Co-Op considers services and procedures listed in the current and future interspinous or interlaminar distraction devices as a stand-alone procedure are considered investigational as treatment of spinal stenosis.

Use of interlaminar stabilization device following decompression surgery is considered investigational.

Section 1862(a)(1)(A) of the Social Security Act is the basis for denying payment for types of care, specific items, services, or procedures, not excluded by any other statutory clause, meeting all technical requirements for coverage, but are determined to be any of the following:

- Not generally accepted in the medical community as safe and effective in the setting and for the condition for which it is used,
- Not proven to be safe and effective based on peer review or scientific literature
- Experimental
- Not medically necessary in the particular case
- Furnished at a level, duration or frequency that is not medically appropriate
- Not furnished in accordance with accepted standards of medical practice, or
- Not furnished in a setting appropriate to the patient's medical needs and condition.

Items and services must be established as safe and effective to be considered medically necessary. That is, the items and services must be:

- Consistent with the symptoms or diagnosis of the illness or injury under
- treatment; and
- Necessary for, and consistent with, generally accepted professional medical standards of care (e.g., not experimental or investigational);and
- Not furnished primarily for the convenience of the patient, the provider or
- supplier; and
- Furnished at the most appropriate level that can be provided safely and effectively to the patient.

Medical devices that are not approved for marketing by the Food and Drug Administration (FDA) are considered investigational by Medicare and are not considered reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve functioning of a malformed body member. Mountain Health Co-Op payments, therefore, may not be made for medical procedures and services performed using devices that have not been approved for marketing by the FDA or for those not included in an FDA-approved investigational (IDE) trial.

Background

Spinal Stenosis

Lumbar spinal stenosis, which affects over 200,000 people in the United States (U.S.), involves a narrowed central spinal canal, lateral spinal recesses, and/or neural foramina, resulting in pain as well as limitation of activities such as walking, traveling, and standing. In adults over 60 in the U.S., spondylosis (degenerative arthritis affecting the spine) is the most common cause. The primary symptom of lumbar spinal stenosis is neurogenic claudication with back and leg pain, sensory loss, and weakness in the legs. Symptoms are typically exacerbated by standing or walking and relieved with sitting or flexion at the waist.

Some sources describe the course of lumbar spinal stenosis as "progressive" or "degenerative," implying that neurologic decline is the usual course. Longer-term data from the control groups of clinical trials as well as from observational studies suggest that, over time, most patients remain stable, some improve, and some deteriorate.1,2,

The lack of a valid classification for lumbar spinal stenosis contributes to wide practice variation and uncertainty about who should be treated surgically and which surgical procedure is best for each patient.3,4, This uncertainty also complicates research on spinal stenosis, particularly the selection of appropriate eligibility criteria and comparators.5,

Treatment

The largest group of patients with spinal stenosis is minimally symptomatic patients with mild back pain and no spinal instability. These patients are typically treated nonsurgically. At the other end of the spectrum are patients who have severe stenosis, concomitant back pain, and grade 2 or higher spondylolisthesis or degenerative scoliosis >25 Cobb angle who require laminectomy plus spinal fusion.

Surgical treatments for patients with spinal stenosis not responding to conservative treatments include decompression with or without spinal fusion. There are many types of decompression surgery and types of fusion operations. In general, spinal fusion is associated with more complications and a longer recovery period and, in the past, was generally reserved for patients with spinal deformity or moderate grade spondylolisthesis.

Conservative treatment for spinal stenosis may include physical therapy, pharmacotherapy, epidural steroid injections, and many other modalities.6, The terms "nonsurgical" and "nonoperative" have also been used to describe conservative treatment. Professional societies recommend that surgery for lumbar spinal stenosis should be considered only after a patient fails to respond to conservative treatment but there is no agreement about what constitutes an adequate course or duration of treatment.

The term "conservative management" may refer to "usual care" or to specific programs of nonoperative treatment, which use defined protocols for the components and intensity of conservative treatments, often in the context of an organized program of coordinated, multidisciplinary care. The distinction is important in defining what constitutes a failure of conservative treatment and what comparators should be used in trials of surgical versus nonsurgical management. The rationale for surgical treatment of symptomatic spinal stenosis rests on the Spine Patient Outcomes Research Trial (SPORT), which found that patients who underwent surgery for spinal stenosis and spondylolisthesis had better outcomes than those treated nonoperatively. The SPORT investigators did not require a specified program of nonoperative care but rather let each site decide what to offer.7, A subgroup analysis of the SPORT trial found that only 37% of nonsurgically treated patients received physical therapy in the first 6 weeks of the trial and that those who received physical therapy before 6 weeks had better functional outcomes and were less likely to cross over to surgery later.8, These findings provide some support for the view that, in clinical trials, patients who did not have surgery may have had suboptimal treatment, which can lead to a larger difference favoring surgery. The SPORT investigators asserted that their nonoperative outcomes represented typical results at a multidisciplinary spine center at the time, but recommended that future studies compare the efficacy of specific nonoperative programs to surgery.

A recent trial by Delitto et al (2015) compared surgical decompression with a specific therapy program emphasizing physical therapy and exercise.9, Patients with lumbar spinal stenosis and from 0 to 5 mm of slippage (spondylolisthesis) who were willing to be randomized todecompression surgery versus an intensive, organized program of nonsurgical therapy were eligible. Oswestry Disability Index scores were comparable to those in the SPORT trial. A high proportion of patients assigned to nonsurgical care (57%) crossed over to surgery (in SPORT the proportion was 43%), but crossover from surgery to nonsurgical care was minimal. When analyzed by treatment assignment, Oswestry Disability Index scores were similar in the surgical and nonsurgical groups after 2 years of follow-up. The main implication is that about one-third of patients who were deemed candidates for decompression surgery but instead entered an intensive program of conservative care achieved outcomes similar to those of a successful decompression.10,

Diagnostic criteria for fusion surgery are challenging because patients without spondylolisthesis and those with grade 1 spondylolisthesis are equally likely to have predominant back pain or predominant leg pain.11, The SPORT trial did not provide guidance on which surgery is appropriate for patients who do not have spondylolisthesis, because nearly all patients with spondylolisthesis underwent fusion whereas nearly all those who did not have spondylolisthesis underwent decompression alone. In general, patients with predominant back pain have more severe symptoms, worse function, and less improvement with surgery (with or without fusion). Moreover, because back pain improved to the same degree for the fused spondylolisthesis patients as for the unfused spinal stenosis patients at 2 years, the SPORT investigators concluded that it was unlikely that fusion led to better surgical outcomes in patients with spondylolisthesis than those with no spondylolisthesis.12,13,

Throughout the 2000s, decompression plus fusion became more widely used until, in 2011, it surpassed decompression alone as a surgical treatment for spinal stenosis.14,15,16, However, in 2016, findings from 2 randomized trials of decompression alone versus decompression plus fusion were published. The Swedish Spinal Stenosis Study found no benefit of fusion plus decompression compared with decompression alone in patients who had spinal stenosis with or without degenerative spondylolisthesis.17, The Spinal Laminectomy Versus Instrumented Pedicle Screw (SLIP) trial found a small but clinically meaningful improvement in the Physical Component Summary score of the 36-Item Short-Form Health Survey but no change in Oswestry Disability Index scores at 2, 3, and 4 years in patients who had spinal stenosis with grade 1 spondylolisthesis (3 to 14 mm).18, The patients in SLIP who had laminectomy alone had higher reoperation rates than those in Swedish Spinal Stenosis Study, and the patients who underwent fusion had betteroutcomes in SLIP than in Swedish Spinal Stenosis Study. While some interpret the studies to reflect differences in patient factors-in particular, Swedish Spinal Stenosis Study but not SLIP included patients with no spondylolisthesis, the discrepancy may also be influenced by factors such as time of follow-up or national practice patterns.19,20,21,22,23,24, As Pearson (2016) noted, it might have been helpful to have patient-reported outcome data on the patients before and after reoperation, to see whether the threshold for reoperation differed in the 2 settings.[25,] A small trial conducted in Japan, Inose et al (2018) found no difference in patient-reported outcomes between laminectomy alone and laminectomy plus posterolateral fusion in patients with 1-level spinal stenosis and grade 1 spondylolisthesis; about 40% of the patients also had dynamic instability.26, Certainty in the findings of this trial is limited because of its size and methodologic flaws.

Spacer Devices

Investigators have sought less invasive ways to stabilize the spine and reduce the pressure on affected nerve roots, including interspinous and interlaminar implants (spacers). These devices stabilize or distract the adjacent lamina and/or spinous processes and restrict extension in patients with lumbar spinal stenosis and neurogenic claudication.

Interspinous Implants

Interspinous spacers are small devices implanted between the vertebral spinous processes. After implantation, the device is opened or expanded to distract the neural foramina and decompress the nerves. One type of interspinous implant is inserted between the spinous processes through a small (4 to 8 cm) incision and acts as a spacer between the spinous processes, maintaining flexion of that spinal interspace. The supraspinous ligament is maintained and assists in holding the implant in place. The surgery does not include any laminotomy, laminectomy, or foraminotomy at the time of insertion, thus reducing the risk of epidural scarring and cerebrospinal fluid leakage.
Other interspinous spacers require removal of the interspinous ligament and are secured around the upper and lower spinous processes.

Interlaminar Spacers

Interlaminar spacers are implanted midline between the adjacent lamina and spinous processes to provide dynamic stabilization either following decompression surgery or as an alternative todecompression surgery. Interlaminar spacers have 2 sets of wings placed around the inferior and superior spinous processes. They may also be referred to as interspinous U. These implants aim to restrict painful motion while enabling normal motion. The devices (spacers) distract the laminar space and/or spinous processes and restrict extension. This procedure theoretically enlarges the neural foramen and decompresses the cauda equina in patients with spinal stenosis and neurogenic claudication.

Regulatory Status

Three interspinous and interlaminar stabilization and distraction devices have been approved by the U.S. Food Drug Administration (FDA) through the premarket approval (FDA product code: NQO) are summarized in Table 1.

Table 1. Interspinous and Interlaminar Stabilization/Distraction Devices With Premarket Approval

Device Name	Manufacturer	Approval Date	PMA
X Stop Interspinous Process Decompression System	Medtronic Sofamor Danek	2005 (withdrawn 2015)	P040001
Coflex® Interlaminar Technology	Paradigm Spine (acquired by RTI Surgical)	2012	P110008
Superion® Indirect Decompression System (previously Superion® Interspinous Spacer)	VertiFlex (acquired by Boston Scientific)	2015	P140004

PMA: premarket approval.

The Superion Indirect Decompression System (formerly InterSpinous Spacer) is indicated to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs secondary to

a diagnosis of moderate degenerative lumbar spinal stenosis, with or without grade 1 spondylolisthesis, confirmed by x-ray, magnetic resonance imaging (MRI), and/or computed tomography evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing. It is intended for patients with an impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, numbness, and/or cramping, with or without back pain, and who have undergone at least 6 months of nonoperative treatment.

FDA lists the following contraindications to use of the Superion Indirect Decompression System:

- "An allergy to titanium or titanium alloy.
- Spinal anatomy or disease that would prevent implantation of the device or cause the
- device to be unstable in situ, such as:
  - Instability of the lumbar spine, e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1 (on a scale of 1 to 4)
  - An ankylosed segment at the affected level(s)
  - Fracture of the spinous process, pars interarticularis, or laminae (unilateral or bilateral);
  - Scoliosis (Cobb angle >10 degrees)
- Cauda equina syndrome, defined as neural compression causing neurogenic bladder or bowel dysfunction.
  - Diagnosis of severe osteoporosis, defined as bone mineral density (from DEXA [dual-energy x-ray absorptiometry] scan or equivalent method) in the spine or hip that is more than 2.5 S.D. [standard deviations] below the mean of adult normal.
- Active systemic infection, or infection localized to the site of implantation.
- Prior fusion or decompression procedure at the index level.
- Morbid obesity defined as a body mass index (BMI) greater than 40."

The coflex Interlaminar Technology implant (Paradigm Spine) is a single-piece U-shaped titanium alloy dynamic stabilization device with pairs of wings that surround the superior and inferior spinous processes. The coflex (previously called the Interspinous U) is indicated for use in 1- or 2-level lumbar stenosis from the L1 to L5 vertebrae 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 months of nonoperative treatment. The coflex "is intended to be implanted midline between the adjacent lamina of 1 or 2 contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s).

FDA lists the following contraindications to use of the coflex:

- "Prior fusion or decompressive laminectomy at any index lumbar level.
- Radiographically compromised vertebral bodies at any lumbar level(s) caused by current or past trauma or tumor (e.g., compression fracture).
- Severe facet hypertrophy that requires extensive bone removal which would cause instability.
- Grade II or greater spondylolisthesis.
- Isthmic spondylolisthesis or spondylolysis (pars fracture).
- Degenerative lumbar scoliosis (Cobb angle greater than 25°).

- Osteoporosis.
- Back or leg pain of unknown etiology.
- Axial back pain only, with no leg, buttock, or groin pain.
- Morbid obesity defined as a body mass index > 40.
- Active or chronic infection - systemic or local.

Known allergy to titanium alloys or MR [magnetic resonance] contrast agents. Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction."

The FDA labeling also contains multiple precautions and the following warning: "Data has demonstrated that spinous process fractures can occur with coflex® implantation."
At the time of approval, the FDA requested additional postmarketing studies to provide longer-term device performance and device performance under general conditions of use. The first was the 5-year follow-up of the pivotal investigational device exemption trial. The second was a multicenter trial with 230 patients in Germany who were followed for 5 years, comparing decompression alone with decompression plus coflex. The third, a multicenter trial with 345 patients in the U.S. who were followed for 5 years, compared decompression alone with decompression plus coflex.27, FDA product code: NQO.

Rationale
This evidence review was created in October 2006 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through February 28, 2024.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.
The largest group of patients with spinal stenosis is minimally symptomatic patients with mild back pain and no spinal instability. These patients are typically treated nonsurgically. At the other end of the spectrum are patients who have severe stenosis, concomitant back pain, and grade 2 or higher

spondylolisthesis, spinal instability, or degenerative scoliosis >25 Cobb angle who require laminectomy plus spinal fusion.

The literature is dominated by reports from non-U.S. centers evaluating devices not approved by the U.S. Food and Drug Administration (FDA), although a number of them are in trials at U.S. centers. As of April 2018, only the X-STOP® Interspinous Process Decompression System, coflex Interlaminar Stabilization, and Superion Interspinous Spacer devices had received the FDA approval for use in the U.S. Manufacturing of the X-STOP device stopped in 2015. This review focuses on devices currently available for use in the U.S.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Interspinous or Interlaminar Spacer as a Stand-Alone Treatment

Clinical Context and Therapy Purpose
The purpose of the interspinous or interlaminar spacer in individuals with spinal stenosis and no spondylolisthesis or grade 1 spondylolisthesis is to provide a treatment option that is better than lumbar spinal decompression surgery. Although not tested in trials, another potential purpose could be to provide an alternative to conservative therapy in individuals who are medically unsuitable for undergoing general anesthesia for more invasive lumbar surgery or nonsurgical conservative therapy.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with spinal stenosis and no spondylolisthesis or grade 1 spondylolisthesis.

Interventions
The treatment being considered is the placement of an interspinous or interlaminar spacer as a stand-alone treatment.

Comparators
The following practices are currently being used to treat spinal stenosis with no spondylolisthesis or grade 1 spondylolisthesis: lumbar spinal decompression surgery and nonsurgical conservative therapy.

Outcomes
The general outcomes of interest are whether the placement of an interspinous or interlaminar spacer improves pain, function, and quality of life.

The visual analog scale for pain is a continuous scale that depicts pain intensity along a line that is anchored by 2 verbal descriptors. For pain intensity, the scale is most commonly anchored by "no pain" (score of 0) and "worst imaginable pain" (score of 10) on 10 cm (100 mm) scale.

Function can be measured by a 15-point improvement in the Oswestry Disability Index scores. Other measures such as 36-Item Short-Form (SF-36) Health Survey or 12-item Short-Form (SF-12) Health Survey to assess the quality of life, and the Zurich Claudication Questionnaire also to assess the quality of life for patients with lumbar spinal stenosis. The SF-12 and SF-36 Health Survey is a measure of perceived health that describes the degree of general physical health status and mental health distress. The SF-12 is a shorter alternative to the SF-36 and has at least 1 question from each of the SF-36's original 8 domains. Both scales are scored such that the adult population mean is 50, with a standard deviation of 10, and higher scores represent a better function.

Freedom from secondary interventions is also of interest to determine whether the placement of an interspinous or interlaminar spacer improves the net health outcome. In addition, the adverse events of treatment need assessment. The window to judge treatment success is a minimum of 2 years post procedure.

Zurich Claudication Questionnaire
The Zurich Claudication Questionnaire was designed specifically for use in the evaluation of physical function in patients with lumbar spinal stenosis. Subscales of the questionnaire may be used separately. For example, the 5-item Physical Function Scale is used primarily to evaluate walking capacity. These 5 items assess the distance walked and activities of daily living that involve walking. The Physical Function Scale has been used to assess walking as an outcome for surgical and nonsurgical treatment in patients with lumbar spinal stenosis.

The Zurich Claudication Questionnaire consists of 3 subscales:

1. Symptom severity scale (questions I to VII) [further subdivided into pain domain (questions I to IV) and a neuro-ischemic domain (questions V to VII)]: Possible range of the score is 1 to 5.
2. Physical function scale (questions VIII to XII): Possible range of scores is 1 to 4.
3. Patient's satisfaction with treatment scale (questions XIII to XVIII): The range of the scale is 1 to 4.

Scoring Method/Interpretation: The result is expressed as a percentage of the maximum possible score. The score increases with worsening disability.

Oswestry Disability Index
The Oswestry Disability Index is a self-administered questionnaire used by clinicians and researchers to quantify disability for low back pain. The maximum score is 50. The Minimum Detectable Change (at 90% confidence) is 10 percentage points.
Interpretation of the Oswestry Disability Index:

1. 0% to 20%: Minimal disability: This group can cope with most living activities. Usually, no treatment is indicated, apart from advice on lifting, sitting posture, physical fitness, and diet.

In this group, some patients have particular difficulty with sitting, and this may be important if their occupation is sedentary (e.g., a typist or truck driver).

2. 20% to 40% Moderate disability: This group experiences more pain and problems with sitting, lifting, and standing. Travel and social life are more difficult and they may well be off work. Personal care, sexual activity, and sleeping are not grossly affected, and the back condition can usually be managed by conservative means.
3. 40% to 60%: Severe disability: Pain remains the main problem in this group of patients, but travel, personal care, social life, sexual activity, and sleep are also affected. These patients require detailed investigation.
4. 60% to 80%: Crippled: Back pain impinges on all aspects of these patients' lives, both at home and at work, and positive intervention is required.
5. 80% to 100%: These patients would be bed-bound.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Interspinous Spacer Devices Versus Decompression Surgery

Systematic Reviews

A systematic review and meta-analysis of RCTs comparing interspinous spacer devices (ISDs) to decompressive surgery for patients with lumbar spinal stenosis was conducted by Xin et al (2023).[28,] Eight RCTs including patients (N=852) with lumbar spinal stenosis who received either ISD or decompressive surgery were included (Table 2). Follow-up duration of trials ranged from 6 to 40 months. Characteristics of the included patients are summarized in Table 3. The pooled data indicated that patients in the ISD group experienced shorter operation time (p=.003) and otherwise similar hospital stay time and dural violation compared to decompressive surgery.

After initial ISD or decompressive surgery, there was a significantly higher rate or reoperation after ISD compared to decompression (odds ratio [OR], 3.21; 95% confidence interval [CI], 1.91 tp 5.40; p<.0001). Additionally, in terms of clinical efficacy endpoints, there was no significant difference in mean visual analog scale leg and back pain scores, Oswestry Disability Index scores, or Zurich Claudication Questionnaire symptom severity subscores between groups who received ISD or decompression. There was a significantly lower Zurich Claudication Questionnaire physical function subscore with ISD compared to decompression (mean difference, -0.27; 95% CI, -0.53 to -0.02; p=.03), but the clinical significance is unknown. Table 4 summarizes relevant clinical efficacy outcomes from the systematic review. The studies included X-STOP ISD devices or other, non-FDA

approved ISD devices, which contributed to heterogeneity. Additionally, there was no discussion or stratification of patients based on severity of lumbar spinal stenosis.

Table 2. Comparison of Studies Included in SR & M-A

Study	Xin et al (2023)[28,]
Moojen et al (2013)	●
Strömqvist et al (2013)	●
Marsh et al (2014)	●
Lonne et al (2015)	●
Mohar et al (2016)	●
Meyer et al (2017)	●
Schmidt et al (2018)	●
Borg et al (2021)	●

M-A: meta-analysis; SR: systematic review

Table 3. SR & M-A Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Xin et al (2023)[28,]	Through 2023	8	Patients with symptomatic LSS receiving either ISD or decompressive surgery	852 (12 to 230)	RCT	range, 6 to 40 months

ISD: interspinous spacer device; LSS: lumbar spinal stenosis; M-A: meta-analysis; RCT: randomized controlled trial; SR: systematic review.

Table 4. SR & M-A Results

Study	VAS leg pain	VAS back pain	ODI	ZCQ physical function	ZCQ symptom severity
Xin et al (2023)[28,]					
Total N	3 studies (n=212)	4 studies (n=242)	3 studies (n=371)	2 studies (n=244)	2 studies (n=244)
Pooled effect (95% CI)	SMD, -0.08 (-0.27 to 0.11)	SMD, -0.20 (-0.55 to 0.15)	SMD, -0.81 (-1.70 to 0.09)	SMD, -0.27 (-0.53 to -0.02)	SMD, -0.67 (-2.62 to 1.27)

I2 (p)	0% (.38)	72% (.01)	93% (<.00001)	0% (.34)	98% (<.00001)

CI: confidence interval; M-A: meta-analysis; ODI: Oswestry Disability Index; SMD: standardized mean difference; SR: systematic review; VAS: visual analog scale; ZCQ: Zurich Claudication Questionnaire.

Retrospective Observational Studies

Hagedorn et al (2022) conducted a retrospective study to determine the incidence of lumbar decompression surgery following minimally invasive lumbar decompression or treatment with the Superion interspinous spacer.29, Of the 199 patients included in the final analysis, 57 patients underwent minimally invasive lumbar decompression only, 124 patients underwent treatment with the Superion interspinous spacer only, and 18 patients underwent minimally invasive lumbar decompression followed by treatment with the Superion interspinous spacer. After 2 years of follow-up, subsequent spine surgery was received by 3 patients who initially underwent minimally invasive lumbar decompression and 1 patient who initially underwent treatment with the Superion interspinous spacer. All patients who underwent subsequent surgery were noted to have severe lumbar spine stenosis.

Whang et al (2023) conducted a retrospective, comparative claims analysis using Medicare claims data to compare rates of subsequent interventions between patients with lumbar spinal stenosis treated initially with ISD and open surgery (such as decompression or fusion).30, Patients were included in the analysis if they were at least 50 years of age with lumbar spinal stenosis and a qualifying procedure during 2017 to 2021 in the Medicare database. Once identified, patients were reviewed from the qualifying procedure until the end of data availability, up to a 3-year follow-up period. Claims data reflected inpatient hospital, outpatient hospital, skilled nursing facility, or home health encounters for Medicare beneficiaries, but not medication coverage. A total of 400,685 patients (mean age, 71.5 years; 50.7% male) received a qualifying procedure (4183 [10%] treated with ISD; 211,014 [52.7%] with decompression alone;76,935 [19.2%] with decompression + fusion; and 108,553 [27.1%] with fusion alone) and were included in the analysis. Patients who received ISD were older at baseline compared to open surgery groups (p<.0001 vs all 3 surgery groups) and had increased prevalence of comorbidities, including hypertension, osteoarthritis, diabetes, obesity, chronic obstructive pulmonary disease, atrial fibrillation, osteoporosis, and congestive heart failure.

Investigators found that individuals with initial ISD treatment were significantly less likely to receive surgical interventions than comparators in the 3-year follow-up period. Patients receiving open surgery initially were 1.5 to 2.5 times more likely to have subsequent fusion (ISD vs decompression alone: hazard ratio [HR], 1.49; 95% CI, 1.17 to 1.89; p=.001; ISD vs decompression + fusion: HR, 1.78; 95% CI, 1.40 to 2.27; p<.0001; ISD vs fusion alone: HR, 2.54; 95% CI, 2 to 3.23; p<.0001). Patients in the surgery cohorts were also more likely to have other lumbar spine surgeries (all comparisons p<.001), but less likely to have a drug delivery implant (all comparisons p<.001). In patients with at least 3 months of follow-up, the re-operation rates at 3 months were 1.7%, 1.6%, and 2.5% for the decompression, decompression + fusion, and fusion cohorts, respectively, compared to 0.6% re-operation rate for the ISD cohort (all p<.001). Adjusted logistic regression demonstrated that patients receiving decompression initially (with or without fusion) were 2.6 to 2.8 times more likely to have a re-operation at 3 months compared to ISD patients, and patients receiving initial fusion were 3.9 times more likely to receive re-operation compared to ISD. Short-term life-threatening events within 30 days were 2.4 to 6.4 times more likely to occur in the open surgery cohorts compared to ISD, driven primarily by blood loss associated with fusion procedures

and re-admission (all p<.001). Additionally, patients in the open surgery cohorts were 1.3 to 2.4 times more likely to have a long-term complication (all p<.001) and 1.6 to 3 times more likely to have sustained a spinous process fracture compared to ISD (all p<.001). This study has many limitations. Firstly, there are many limitations inherent to claims analyses, including the possibility of coding or data entry errors and the omission of clinical details not needed to justify payment. For example, diagnosis codes identified in claims data lack clinical context, such as the severity of lumbar spinal stenosis or postoperative complications, as well as other prior therapies. Claims data also does not capture patient-reported outcomes, such as visual analog scale scores or Zurich Claudication Questionnaire scores, limiting the ability to determine true efficacy. It is unknown if authors were able to see when a patient was lost to follow-up due to death or end of

Medicare coverage, as these rates were not reported. Additionally, since the baseline characteristics of patients receiving ISD indicated that these patients may be inherently sicker than those receiving open surgery, we need clinical context to infer if the reason they did not receive additional surgical procedures post initial ISD placement is because they truly didn't require intervention or they were too sick to tolerate the procedure.

Rosner et al (2024) also conducted a retrospective Medicare claims analysis to determine rates of subsequent spinal procedures between individuals receiving ISD alone versus minimally invasive lumbar decompression (MILD) during 2017 to 2021.31, Patients receiving ISD and MILD were matched 1:1 using propensity score matching based on demographics and clinical characteristics. A total of 3614 patients from each group were included after matching (mean age, 74 years; mean follow-up, 20 months). At 20 months of follow-up, the ISD cohort showed lower rates of any subsequent surgical intervention (13.9% vs 17.2%; p<.001) and lumbar spinal stenosis surgical intervention (11% vs 14.8%; p<.001) compared to the MILD cohort. There were no significant differences in safety endpoints between the cohorts, including postoperative complications or life-threatening complications. Authors concluded that the safety was comparable between procedures, with a lower re-operation rate at 20 months after ISD compared to MILD. Limitations are similar to the other claims analysis, since the study did not examine changes in symptoms, functionality, or pain. Because the enrollment criteria was the same as that in Whang et al (2023), there may have been patients included in both analyses. Patients were also not randomized to treatment groups and MILD and ISD do not always have identical clinical indications, which could increase the risk of implicit bias in patient selection.

While claims data gives us some information related to re-operation rates, direct or indirect comparative studies using clinical data and validated outcomes measures are required to draw conclusions on the utility of ISDs compared to open surgery.

Superion Interspinous Spacer Device Versus X-STOP Device (Interspinous)

Randomized Controlled Trials

Patel et al (2015) reported on the results of a multicenter randomized noninferiority trial (10% margin) comparing the Superion interspinous spacer with the X-STOP.32, Trial characteristicsand results are summarized in Tables 5 and 6. The primary outcome was a composite of a clinically significant improvement in at least 1 of 3 Zurich Claudication Questionnaire domain scores compared with baseline; freedom from reoperation, epidural steroid injection, nerve block,

rhizotomy, or spinal cord stimulator; and freedom from a major implant or procedure-related complications.

The results at 2 years of follow-up indicated that the primary noninferiority endpoint was met, with a Bayesian posterior probability of 0.993. However, 111 (28%) patients (54 Superion interspinous spacer, 57 X-STOP) withdrew from the trial during follow-up because they received a protocol-defined secondary intervention. Modified intention-to-treat analysis showed similar levels of clinical success for leg pain, back pain, and Oswestry Disability Index scores. Rates of complications and reoperations were similar between groups. Spinous process fractures, reported as asymptomatic, occurred in 16.4% of Superion interspinous space patients and 8.5% of X-STOP patients. Subsequently, long-term follow-up results were reported. At 3 years, 120 patients in the Superion interspinous process spacer group and 129 in the X-STOP group remained (64% [249/391]). Of them, composite clinical success was achieved in 52.5% of patients in the Superion interspinous spacer group and 38.0% of the X-STOP group (p=.023).

The 36-month clinical outcomes were reported for 82 patients in the Superion interspinous spacer group and 76 patients in the X-STOP group (40% [158/391]). It is unclear from the reporting whether the remaining patients were lost to follow-up or were considered treatment failures and censored from the results. Also, trial interpretation is limited by questions about the efficacy of the comparator and the lack of a control group treated with surgical decompression. At the 4-year and 5-year follow-ups, only data for the Superion arm were reported, which included data for 90% and 65% of originally randomized patients, respectively. Of these, success on at least 2 of 3 Zurich Claudication Questionnaire domains was observed in 84% of patients at years 4 and 5. Nunley et al (2018) reported a decrease in opioid use (n=107) and improvement in the quality of life (n=68) at 5 years, however, results were reported only for patients who had not undergone reoperation or revision, limiting interpretation of these results.33,34,

The purpose of Tables 7 and 8 is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of the evidence supporting the position statement.

Table 5. Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Patel et al (2015);[32,] NCT00692276	U.S.	29	2008-2011	Patients with intermittent neurogenic claudication despite 6 mo of nonsurgical management (N=440)	Superion interspinous spacer (n=218)	X-STOP spacers (n=222)

NCT00692276: Randomized Study Comparing the VertiFlex® Superion® interspinous process spacer to the X-STOP® Interspinous Process Decompression (IPD®) System in Patients With Moderate Lumbar Spinal Stenosis.

Table 6. Results of Noninferiority Trials Comparing Superion With X-STOP

Study	Group	n	Success Rates	VAS Leg Pain[a]	VAS Back Pain[a]	ODI Scores[b]	Spinous Process Fractures	Reoperation Rates
2 years								
Patel et al (2015)35,32,35,	Superion	136	75%[c]	76%	67%	63%	16.4%	44 (23.2%)
	X-STOP	144	75%[c]	77%	68%	67%	8.5%	38 (18.9%)
3 years								
Patel et al (2015)[35],	Superion	120	52.5%[c]	69/82	63/82	57/82		
	X-STOP	129	38.0%[c]	53/76	53/76	55/77		
4 years								
Nunley et al (2017)[36],	Superion	122	84.3%[d]	67/86	57/86	55/89		
5 years								
Nunley et al (2017)[37],	Superion	88	84%[d]	68/85	55/85	57/88		

ODI: Oswestry Disability Index; VAS: visual analog scale.
a Percentage achieving at least a 20 mm improvement on a 100-mm VAS score.
b Percentage achieving at least a 15% improvement in ODI scores.
c Composite outcome based on 4 components: improvement in 2 of 3 domains of the Zurich Claudication Questionnaire, no reoperations at the index level, no major implant/procedure-related complications, and no clinically significant confounding treatments.
d Clinical success on at least 2 of 3 Zurich Claudication Questionnaire domains.

Review of Evidence

Table 7. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Patel et al (2015)[32],					

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms;
4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 8. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Patel et al (2015)[32]	3. Allocation concealment unclear	1. Not blinded to treatment assignment 2. Not blinded outcome assessment 3. Outcome assessed by treating physician		1. High loss to follow-up and/or missing data: 11% of patients not randomized; and data for 28% missing at 2 y; 36% at 3 y.	3. Unclear why a 10% noninferiority margin selected	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Coflex Device (Interlaminar) Versus Decompression Surgery

Randomized Controlled Trials

A European, multicenter, randomized, double-blind trial (Foraminal Enlargement Lumbar Interspinous distraXion; FELIX) assessed the superiority of coflex (without bony decompression) over bony decompression in 159 patients who had intermittent neurogenic claudication due to lumbar spinal stenosis.38, The primary outcome at 8-week and 1-year follow-ups was the Zurich Claudication Questionnaire score. The score increases with increasing disability. Trial characteristics and results are summarized in Tables 9 and 10. At 8 and 52 weeks, the primary outcome efficacy measure in the coflex arm was not superior to that for standard decompression. In addition, more coflex recipients required reoperation than the standard decompression patients at the 1- and 2-

year follow-ups. Given the substantially higher frequency of reoperation in the absence of statistically significant improvements in the efficacy outcome, further summarization of study limitations was not done for this trial.

Table 9. Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Moojen et al (2013)38,;FELIX	Netherlands	5	2008 - 2011	Patients with intermittent neurogenic claudication due to lumbar stenosis with an indication for surgery (N=159)	Coflex (n80)	Decompression (n=79)

FELIX: Foraminal Enlargement Lumbar Interspinous distraXion.

Table 10. Summary of Key Randomized Controlled Trial Outcomes

Study	*Proportions of Patients Achieving ZCQ Success, [a]% (95% CI)*		*Reoperations, n (%)*
	8 Weeks	*52 Weeks*	
Moojen et al (2013; 2014)[38,39]; FELIX (1-yr follow-up)	*142*	*144*	*Not reported*
Coflex	*63 (51 to 73)*	*66 (54 to 74)*	*21 (29)*
Decompression alone	*72 (60 to 81)*	*69 (57 to 78)*	*6 (8)*
Odds ratio (p)	*0.73 (.44)*	*0.90 (.77)*	*p<.001*
Moojen et al (2015)[40]; FELIX (2-yr follow-up)	*145*		*Not reported*
Coflex	*69*		*23 (33)*
Decompression alone	*60*		*6 (8)*
Odds ratio (p)	*0.65 (.20)*		*p<.001*

CI: confidence interval; FELIX: Foraminal Enlargement Lumbar Interspinous distraXion; ZCQ: Zurich Claudication Questionnaire.

a Reductions in ZCQ scores were categorized as successful if at least 2 domain subscales were judged as "success." The ZCQ has 3 domains: symptoms severity, physical function, and patient's satisfaction. Success in the domains was defined as a decrease of at least 0.5 points on the symptom severity scale and on the physical function scale or a score of less than 2.5 on the patient's satisfaction subscale.

Section Summary: Interspinous or Interlaminar Spacer as Stand-Alone Treatment

A systematic review of RCTs comparing ISD and decompression surgery in patients with lumbar spinal stenosis found that ISD resulted in an increased rate of reoperation compared to decompression, as well as no statistically significant differences in pain, functional, and quality of life outcomes. Additional longitudinal retrospective comparative claims analyses found that there was a significantly lower rate of reoperation in patients with lumbar spinal stenosis who received ISD compared to open surgery. However, there are many limitations inherent to claims analyses, including the possibility of coding or data entry errors and the omission of clinical details not needed to justify payment. For example, diagnosis codes identified in claims data lack clinical context, such as the severity of lumbar spinal stenosis or postoperative complications, as well as other prior therapies. Claims data also does not capture patient-reported outcomes, such as visual analog scale scores or Zurich Claudication Questionnaire scores, limiting the ability to determine true efficacy. It is unknown if authors were able to see when a patient was lost to follow-up due to death or end of Medicare coverage, as these rates were not reported. Additionally, in 1 of the studies, since the baseline characteristics of patients receiving ISD indicated that these patients may be inherently sicker than those receiving open surgery, we need clinical context to infer if the reason they did not receive additional surgical procedures post initial ISD placement is because they truly didn't require intervention, or they were too sick to tolerate the procedure. While claims data gives us some information related to re-operation rates, direct or indirect comparative studies using clinical data and validated outcomes measures are required to draw conclusions on the utility of ISDs compared to open surgery.

The evidence for the Superion interspinous spacer for lumbar spinal stenosis includes a pivotal trial. This trial compared the Superion interspinous spacer with the X-STOP Interspinous Process Decompression System but did not include comparison groups for conservative treatment or standard surgery. The trial reported significantly better outcomes on some measures. For example, the percentage of patients experiencing improvements in certain quality of life outcome domains was reported at over 80%. However, this percentage was based on 40% of the original dataset. Interpretation of this trial is limited by uncertainty about the number of patients used to calculate success rates, the lack of efficacy of the comparator, and the lack of an appropriate control group treated by surgical decompression.

The coflex interlaminar implant was compared with decompression in the multicenter, double-blind FELIX trial. Functional outcomes and pain levels between the 2 groups at 1-year follow-up did not differ statistically but reoperation rates due to lack of recovery were statistically higher with the coflex implant (29%) compared with bony decompression (8%). It is not clear whether patients with reoperations were included in pain and function assessments; if they were, this would have decreased assessment scores at 1 year. For patients with 2-level surgery, the reoperation rate was 38% for coflex and 6% for bony decompression. At 2 years, reoperations due to the absence of recovery had been performed in 33% of the coflex group compared with 8% of the bony decompression group. This is an off-label use of the device. Use consistent with the FDA label is reviewed in the next section.

Interlaminar Stabilization Devices Used With Spinal Decompression Surgery in Individuals With Severe Spinal Stenosis and Grade 1 Spondylolisthesis or Instability

Clinical Context and Therapy Purpose

The purpose of placement of an interlaminar spacer in individuals with severe spinal stenosis and grade 1 spondylolisthesis or instability is to provide a treatment option that is less invasive than lumbar spinal decompression surgery with fusion and more effective for back pain than lumbar spinal decompression surgery alone. Lumbar spinal stenosis has a broad clinical spectrum. Features that may affect the choice of the surgical procedure include the severity of leg pain, back pain, and instability; the presence of facet hypertrophy, diminished disc height, or deformity; the risk of general anesthesia, and the individual's preferences.10,

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with severe spinal stenosis and grade 1 spondylolisthesis or instability who have not responded to conservative treatment.

Interventions
The treatment being considered is the placement of an interlaminar spacer as an adjunct to spinal decompression.

Comparators
The comparators are lumbar spinal decompression with spinal fusion and lumbar spinal decompression surgery without fusion.

Outcomes
The main outcomes of interest are (1) improvements in symptoms of spinal stenosis (e.g., claudication, leg pain), (2) reductions in back pain, and (3) reductions in limitations on activities related to symptoms. Symptoms can be measured by scores of validated instruments such as the Oswestry Disability Index and the Zurich Claudication Questionnaire, as well as the visual analog scale for back and leg pain. Other measures such as the SF-36 to assess the quality of life are relevant. Other key outcome measures are reoperations, including fusion procedures, and adverse events. The window to judge treatment success is a minimum of 2 years post-procedure.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer

periods of follow-up and/or larger populations were sought.

- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Coflex Device Plus Decompression Versus Decompression Plus Fusion

Randomized Controlled Trials

The FDA approved coflex on the basis of an open-label, randomized, multicenter, noninferiority trial (-10% noninferiority margin) that compared coflex plus decompression to decompression plus posterolateral fusion in patients who had stenosis, significant back pain, and either no spondylolisthesis or grade 1 spondylolisthesis.27,41,42, The control group was treated with pedicle screw and rod fixation with autograft but without an interbody (intervertebral) cage or bone morphogenetic protein. A total of 398 patients were randomized, of whom 322 were included in the per-protocol analysis. Of 215 coflex patients in the per-protocol analysis, 11 were lost to follow-up at the 2-year endpoint. In the fusion group, 3 of 107 were lost to follow-up. Results of long-term follow-up to 5 years were reported subsequently.43,44,45,46,47,

Trial characteristics and results are summarized in Tables 11 and 12. Composite clinical success (a minimum 15-point improvement in Oswestry Disability Index score, no reoperations, no device-related complications, no epidural steroid injections in the lumbar spine, and no persistent new or worsening sensory or motor deficit) at 24 months showed that coflex was noninferior to screw and rod fixation (-10% noninferiority margin). Secondary effectivenesscriteria, which included Zurich Claudication Questionnaire score, visual analog scale scores for leg and back pain, SF-12 scores, time to recovery, patient satisfaction, and several radiographic endpoints, tended to favor the coflex group. The percentages of device-related adverse events (5.6%) did not differ statistically between the 2 groups. Wound problems were more frequent in the coflex group (14% vs. 6.5%) but all of these were resolved by 3 months. There was a 14% incidence of spinous process fractures in the coflex arm, which were reported to be mostly asymptomatic. The reported follow-up rates through 5 years were at least 85%.45, At 2 years, overall success was similar for patients treated with the coflex device at 1 or 2 levels (68.9% and 69.4%, respectively). At 60 months, the composite clinical success was achieved in 48.3% of 1 level and 60.9% of 2 level patients.47,

A secondary (unplanned) analysis of patients with grade 1 spondylolisthesis (99 coflex patients and 51 fusion patients) showed a decrease in operative time (104 vs. 157 minutes; p<.001) and blood loss (106 vs. 336 mL;p<.001). There were no statistically significant differences between the coflex and fusion groups in Oswestry Disability Index, visual analog scale, and Zurich Claudication Questionnaire scores after 2 years.42, In that analysis, 59 (62.8%) of 94 coflex patients and 30 (62.5%) of 48 fusion patients met the criteria for operative success. Fusion was obtained in 71% of the control group, leaving nearly a third of patients with pseudoarthrosis.

The authors reported no significant differences in Oswestry Disability Index or visual analog scale between the patients with pseudoarthrosis or solid fusion, but Zurich Claudication Questionnaire scores were not reported. There were 18 (18%) spinous process fractures in the coflex group, of which 7 had healed by the 2-year follow-up. Reoperation rates were 6% in the fusion group (p=.18) and 14% in the coflex group, including 8 (8%) coflex cases that required conversion to fusion.

Another post-hoc analysis of the pivotal RCT evaluated the use of the device in patients 65 years or older.48, Clinical outcomes (e.g., Oswestry Disability Index, visual analog score, Zurich Claudication Questionnaire, epidural injections) were measured out to 60 months. Patients age 65 years or older who received the interlaminar implant with decompression (n=84) had clinical outcomes that were not significantly different to patients 65 years or older who received decompression and fusion (n=57), and to patients younger than 65 who received the interlaminar implant with decompression

(n=131). In contrast, perioperative outcomes such asoperative time (100 vs. 153 min ; p<.001), blood loss (106 vs. 358 mL; p<.001), and hospital stay (2.1 vs. 3.3 days ; p<.001) were improved with the interlaminar implant compared to posterolateral fusion.

Table 11. Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Davis et al (2013);[41] NCT00534235[a]	U.S.	21	2006-2008	Patients with spinal stenosis with up to grade 1 spondylolisthesis, 1 or 2 levels with VAS ≥50 and ODI ≥20 (N=344)	Decompression plus coflex (n=262)	Decompression plus pedicle screw and rod fixation (n=136)

NCT00534235: Post-Approval Study to Investigate The Long Term (5-Year) Survivorship of Coflex Compared to Control Fusion Study Patients;
ODI: Oswestry Disability Index; VAS: visual analog score
[a] Noninferiority study.

Table 12. Summary of Key Randomized Controlled Trial Outcomes

Study	CCS[a]	15-Point Improvement in ODI Score	No Secondary Surgical Intervention or Lumbar Injection	No Secondary Surgical Intervention	No Secondary Lumbar Injection
2-year follow-up					
Davis et al (2013)[41]					
N	308	248	322	215	215
coflex	135 (66)	139 (86)	173 (81)	192 (89)	190 (88)
Fusion	104 (58)	66 (77)	89 (83)	99 (93)	94 (88)
% D (95% CI)	8.5[b] (-2.9 to 20.0)	9 (NR)	2 (NR)	-4 (NR)	0
3-year follow-up					
Bae et al (2016)[45]					
N	290	214	Unclear	NR	NR
coflex	(62)	129 (90)	(76)	NR	NR
Fusion	(49)	53 (76)	(79)	NR	NR
% D (95% CI) or p	13.3 (1.1 to 25.5)	.008	NR	NR	NR
4-year follow-up					
Bae et al (2015)[43]					
N	274	181	NR	NR	NR
coflex	106 (58)	106 (86)	NR	NR	NR
Fusion	42 (47)	42 (72)	NR	NR	NR
% D (95% CI) or p	10.9 (-1.6 to 23.5)	.038	NR	NR	NR
5-year follow-up					
Musacchio et al (2016)[44]					
N	282	179	322	322	322
coflex	96 (50)	100 (81)	148 (69)	179 (83)	173 (81)
Fusion	40 (44)	41 (75)	71 (66)	89 (83)	82 (77)
% D (95% CI) or p	6.3 (NR); >.90	>.40	>.70	>.90	>.40

Values are n or n (%.)
CCS: composite clinical success; CI: confidence interval; D: decompression; ODI: Oswestry Disability Index (reported as mean score or percent
with at least 15-point improvement); NR: not reported.
[a] CCS was composed of a minimum 15-point improvement in ODI score, no reoperations, no device-related complications, no epidural steroid injections in the lumbar spine, and no persistent new or worsening sensory or motor deficit.
[b] The lower bound of Bayesian posterior credible interval for the device group difference in CCS was equal to -2.9%, which is within the ed noninferiority margin of -10%.

Tables 13 and 14 display notable limitations identified in each study.

Another limitation in the study, not listed in the limitations tables, is that other published evidence about the use of coflex as an alternative to fusion is sparse. The results of a single randomized trial do not always correspond with the rates of treatment response, complications, and reoperations in actual practice. Although thousands of coflex operations have been performed in the U.S. and elsewhere, there are few data on the performance of coflex plus decompression surgery other than in randomized trials. A retrospective cohort study, Evaluation of the Clinical and Radiographic Performance of Coflex® Interlaminer Technology Versus Decompression With or Without Fusion (NCT03041896) trial, undertaken by the manufacturer was completed, but only limited descriptive results are published on Clinicaltrials.gov and a full publication of the trial is not available. Per the website, the proportion of participants undergoing secondary surgical interventions at 6 months was 8.8% (126/1428) with decompression, 6.1% (125/2058) with coflex, and 9.8% (99/1009) with fusion. Additionally, a large registry study , The Coflex® COMMUNITY Study: An Observational Study of Coflex® Interlaminar Technology (NCT02457468), has been completed but results are not published.

Table 13. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Davis et al (2013)[41,]; NCT00534235	4. Study population combines no and grade 1 spondylolisthesis		2. Noninferiority to a comparator whose benefit is uncertain does not permit meaningful interpretation of the net benefit.	1. Outcomes did not include success of the fusion procedure	
Davis et al (2013)[42,]; NCT00534235			2. The benefit of the comparator is uncertain. Fusion was not obtained in 29% of cases. Intervertebral cages and BMP were not allowed in the FDA IDE study.		

BMP: bone morphogenetic protein; IDE: investigational device exemption; FDA: U.S. Food and Drug Administration; NCT00534235: Post-
Approval Study to Investigate The Long Term (5-Year) Survivorship of Coflex Compared to Control Fusion Study Patients.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms;
4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 14. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]	
Davis et al (2013)[41,]; NCT00534235		4. No independent adjudication or preset criteria for subsequent intervention	3. Evidence of selective reporting				
Davis et al (2013)[42,]; NCT00534235			3. Evidence of selective reporting. ZCQ scores were not reported for the comparison of pseudoarthrosis and solid fusion.				1. Secondary (unplanned) superiority testing in patients with grade 1 spondylolisthesis patients from the pivotal non-inferiority trial. 3. A non-inferiority margin for the subgroup analysis was not defined or discussed and confidence intervals weren't not reported

NCT00534235: Post-Approval Study to Investigate The Long Term (5-Year) Survivorship of Coflex Compared to Control Fusion Study Patients; ZCQ: Zurich Claudication Questionnaire. The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.4 No independent adjudication or preset criteria for subsequent intervention.

[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intention-to-treat analysis (per protocol for noninferiority trials).

[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important

difference.

Nonrandomized Studies

Zheng et al (2021) retrospectively compared the long-term outcomes of coflex plus decompression to decompression plus fusion for lumbar degenerative disease.49, The coflex group was comprised of 39 patients and the decompression plus posterior lumbar interbody fusion group (PLIF) was comprised of 43 patients. Both groups had a mean follow-up period of 104 months (about 8.7 years). Both the Oswestry disability index and visual analog scale leg and back pain scores of both groups significantly improved compared to the baseline (p<.05 for all), with no difference detected between groups. Compared to the PLIF group, the coflex group displayed preserved mobility (p<.001), shorter duration of surgery (p=.001), decreased amount of blood loss (p<.001), and shorter hospital stay (p=.040).

Subsection Summary: Coflex Device Plus Decompression Versus Decompression Plus Posterolateral Fusion

The FDA's approval of coflex was based on an open-label, randomized, noninferiority trial that compared the noninferiority of coflex plus decompression to decompression plus posterolateral fusion in patients who had spinal stenosis, significant back pain, and up to grade 1 spondylolisthesis. Use of the noninferiority framework by the FDA assumed that decompression plus fusion was the standard of care for patients with spinal stenosis with up to grade 1 spondylolisthesis and because fusion is a more invasive procedure that requires longer operative time and has a potential for higher surgical and postsurgical complications, demonstrating noninferiority with a less invasive procedure such as coflex would be adequate to demonstrate a net benefit in health outcomes. However, subsequent to the approval of coflex, 2 RCTs, the Swedish Spinal Stenosis Study, and the Spinal Laminectomy versus Instrumented Pedicle Screw (SLIP) trial assessing the superiority of adding fusion to decompression over decompression alone reported a lack of or marginal benefit. The Swedish Spinal Stenosis Study trial, which was adequately powered to detect a 12-point difference in Oswestry Disability Index score, showed no difference in Oswestry Disability Index scores between the 2 treatment arms. Hence, the results generated from a noninferiority trial using a comparator whose net benefit on health outcomes is uncertain confound meaningful interpretation of its results. A secondary (posthoc) comparison of the subgroup of patients with grade 1 spondylolisthesis, which may be a more relevant analysis, found similar outcomes between the coflex and fusion groups. However, almost a third of the fusion group had unsuccessful fusion with pseudoarthrosis which raises additional questions about the efficacy of the comparator. Oswestry Disability Index and visual analog scale did not significantly differ between the pseudoarthrosis and solid fusion groups, but the Zurich Claudication Questionnaire results were not reported. In addition, posthoc analysis is considered hypothesis-generating. Given the multiple concerns, a prospective trial that compares coflex to fusion in patients with severe spinal stenosis and grade 1 spondylolisthesis is needed.

Coflex Device Plus Decompression Versus Decompression Alone

Randomized Controlled Trials

Schmidt et al (2018) reported on results of an RCT in patients with moderate-to-severe lumbar spinal stenosis and back pain with or without spondylolisthesis randomized to open microsurgical decompression with interlaminar stabilization using the coflex device (n=110) or open microsurgical decompression alone (n=115).50, Trial characteristics and results at 24 months are summarized in Tables 15 and 16. The proportion of patients who met the criteria for composite clinical success at 24 months was statistically significantly higher in the coflex arm (58.4%) than in the decompression alone arm (41.7%; p=.017), with a treatment difference of 16.7% (95% CI , 3.1% to 30.2%). This result was driven primarily by the lower proportion of patients who received an epidural steroid injection in the coflex arm (4.5%) versus the decompression alone arm (14.8%; p=.010) at 24 months.

The proportion of patients with Oswestry Disability Index success among those censored for subsequent secondary interventions was not statistically significant between the treatment (75.6%) and the control arms (70.4%; p=.47). The difference in the proportion of patients overall who had Oswestry Disability Index success in the overall sample was also not statistically significant (55% vs. 44% ; p=.091).None of the other outcomes (data not shown) showed statistically significant differences between the treatment and control arms; outcomes included success measured on the Zurich Claudication Questionnaire (success was defined as an improvement in 2 or 3 Zurich Claudication Questionnaire criteria), success measured on a visual analog scale for pain (success defined as a >20-mm change from baseline), reduction in visual analog scale leg pain, success on a walking distance test (either ≥8-minute walk improvement or the ability to walk to the maximum 15-minute limit), the proportion of patients receiving secondary surgical interventions, or 1- and 2-year survival (Kaplan-Meier) estimates without secondary surgical interventions or survival curves for time to first secondary intervention.

Table 15. Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Schmidt et al (2018)[50,]; NCT01316211	Germany	7	2008-2014	Patients with moderate-to-severe LSS with or without spondylolisthesis and significant back pain (N=255)	Decompression with interlaminar stabilization (n=129)	Open microsurgical decompression alone (n=131)

NCT01316211: Comparative Evaluation of Clinical Outcome in the Treatment of Degenerative Spinal Stenosis With Concomitant Low Back Pain ithout Additional Stabilization Using the Coflex™ Interlaminar Technology; LSS: lumbar spinal stenosis.

Table 16. Summary of Key Randomized Controlled Trial Outcomes

Study	CCS[a]	15-Point Improvement in ODI Score (all patients)	15-Point Improvement in ODI Score (those not receiving a secondary intervention)	No Secondary Surgical Intervention or Lumbar Injection	No Secondary Surgical Intervention	No Secondary Lumbar Injection
Schmidt et al (2018)[50,]						

N	204	255	132	225	225	225
D plus ILS	59 (58)	69 (55)	62 (76)	91 (83)	96 (87)	105 (96)
D alone	43 (42)	57 (44)	50 (70)	84 (73)	98 (85)	98 (85)
%D (95% CI)	16.7 (3.1 to 30.2)	10.6 (-1.6 to 22.8)	5.2 (-8.9 to 19.3)	9.7 (-1.1 to 20.4)	2.1 (-6.9 to 11.0)	10.2 (2.7 to 17.8)
p	.017	.091	.470	.081	.655	.010

Values are n, n (%), or %.

CCS: composite clinical success; CI: confidence interval; D: decompression; ILS: interlaminar stabilization; ODI: Oswestry Disability Index.

[a] CCS defined as meeting all 4 criteria: (1) ODI success with improvement >15 points; (2) survivorship with no secondary surgical intervention or lumbar injection; (3) neurologic maintenance or improvement without worsening; and (4) no device- or procedure-related severe adverse ents.

The purpose of Tables 17 and 18 is to display notable limitations identified in each study. Major limitations are discussed below.

- Based on the reporting by Schmidt et al (2018), 254 patients were randomized but data for only 204 patients were analyzed for the primary outcome measure.50, Thus, data of 20% of patients were excluded. While the proportion of patients excluded was comparable in both arms, the investigators did not explain the missing data of these 50 patients. Lack of a consistent approach in reporting and handling of missing data (patients who remained in the trial but for whom data for repeated longitudinal measures were missing), including describing methods to minimize missing data, reporting reasons for missing data, and using appropriate multiple imputation statistical techniques and sensitivity analysis51, to handle missing data, makes interpretation of trial results challenging.
- The observed treatment effect on the primary composite outcome was primarily driven by a reduction in the use of rescue epidural steroid injection. One concern is a bias that could have been introduced by the open-label design where the treating surgeon also made the assessment that additional intervention with lumbar steroid was needed. The trial design did not include features commonly used to address this problem, such as preset criteria for subsequent intervention, or independent blinded adjudication to verify that subsequent intervention was merited.
- The inclusion of epidural and facet joint injections in the endpoint may be inappropriate for this trial. Epidural injections are less invasive than reoperations, revisions, removal, and supplemental fixations. Nonsurgical therapy, including epidural or facet injections, would be an expected adjunct to decompression alone in patients with predominant back pain. In this context, epidural injections may be offered to provide temporary pain relief that allows a patient to progress with a rehabilitative stretching and exercise program. Censoring patients who undergo particular components of nonsurgical back care may beinappropriate in this context. A better approach would be to measure and report Oswestry Disability Index for all patients, or Oswestry Disability Index success in all patients except for those who have revisions or reoperations, at 24 months.
- Because of concerns about potential bias, inconsistent reporting of analysis as intention-to-treat, and a lack of critical discussion of the number, timing, pattern, and reason for and possible implications of missing values, the magnitude of difference might have been overestimated.

Table 17. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Schmidt et al (2018)[50,]			1. In the control arm, nonsurgical treatment for back pain after decompression should be described	3. No CONSORT reporting of harms	1, 2. Present study reports 2-y follow-up

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms;
4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 18. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Schmidt et al (2018)[50,]		1. 1. Not blinded to treatment assignment 4. No independent adjudication or preset criteria for subsequent intervention		2. High Loss to follow up or missing data 3. Inadequate handling of missing data. LOCF may not be the most appropriate approach 4. Not intention-to-treat analysis		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment. LOCF: last observation carried forward.

[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician. 4. No independent adjudication or preset criteria for subsequent intervention.

[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intention-to-treat analysis (per protocol for noninferiority trials).

[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important
difference.

[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for
multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Nonrandomized Studies

Zhong et al (2021) evaluated perioperative outcomes in a comparative study of 83 patients.52, Patients who had the coflex interlaminar implant in combination with laminectomy (n=46) had higher estimated blood loss (97.50 ± 77.76 vs. 52.84 ± 50.63 mL; p=.004), longer operative time (141.91 ± 47.88 vs. 106.81 ± 41.30 min; p=.001), and longer length of stay (2.0 ± 1.5 vs. 1.1 ± 1.0 days; p=.001) compared to laminectomy alone (n=37). Total perioperative complications (21.7% vs. 5.4%; p=.035) and instrumentation-related complications (10.9% vs. 0%; p=.039) were also higher in the interlaminar implant cohort.

Röder et al (2015) reported on a small cross-registry study that compared lumbar decompression plus coflex (SWISS spine Registry) with lumbar decompression alone (Spine Tango Registry) in 50 pairs matched by a multifactorial propensity score.53, The SWISS spine 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 for back and leg pain, as well as the Core Outcome Measures Index as the patient-based outcome instrument. The Core Outcome Measures Index consists of 7 questions to evaluate pain, function, well-being, quality of life, and disability. At 7- to 9-month follow-up, the coflex group had greater reductions in numeric rating scale back pain score (3.8 vs. 2.5; p=.014), numeric rating scale leg pain score (4.3 vs. 2.5; p<.001), numeric rating scale maximum pain score (4.1 vs. 2.3; p=.002), and greater improvement in Core Outcome Measures Index score (3.7 vs. 2.5; p=.029). Back pain improved by the minimum clinically relevant change in about 60% of patients in the decompression alone group versus 78% in the coflex plus decompression group.
Because of substantial baseline differences between the compared groups, small sample size, and short follow-up time, there is a high risk that the Röder et al (2015) study's estimate of the effect of decompression alone versus decompression plus coflex is biased. Decompression alone had better outcomes than those reported by Röder et al (2015) in a larger, well-conducted, 12-month European registry study of patients with spinal stenosis, significant back, and no spondylolisthesis.54,

Richter et al (2010) reported on a prospective case-control study of the coflex device in 60 patients who underwent decompression surgery.55, Richter et al (2014) also published a 2-year follow-up.56, The surgeon determined whether the midline structures were preserved or resected and whether the coflex device was implanted (1 or 2 levels). The indications for the 2 groups were identical and the use of the device was considered incidental to the surgery. At 1-and 2-year follow-ups, placement of a coflex device did not significantly improve the clinical outcome compared with decompression surgery alone.

Some radiologic findings with the coflex device require additional study to determine their clinical significance. Tian et al (2013) reported a high rate (81.2%) of heterotopic ossification at follow-up (range, 24 to 57 months) in patients who had received a coflex device.57, In 16 (50%) of 32 patients, heterotopic ossification was detected in the interspinous space but had not bridged the space, while in 2 (6.3%) patients there was interspinous fusion. In the 9 patients followed for more than 3 years, class II (interspinous space but not bridging) and class III (bridging) heterotopic ossification were detected in all 9. Lee et al (2016) reported erosion around the spinous process and reductions in disc height and range of motion in patients treated with a coflex device plus spinal decompression and had at least 24 months of follow-up.58, Erosion around the coflex device,

which was observed in 47% of patients, has the potential to result in spinous process fracture or device malposition. Continued follow-up is needed.

Subsection Summary: Coflex Device Plus Decompression Versus Decompression Alone

One RCT, conducted in a patient population who had moderate-to-severe lumbar spinal stenosis with or without spondylolisthesis, showed that a greater proportion of patients who received coflex plus decompression achieved the primary endpoint of composite clinical success compared with decompression alone. This composite endpoint was primarily driven by a greater proportion of patients who received a secondary rescue epidural steroid injection in the control arm while there was no difference in the proportion of patients who achieved a meaningful reduction of 15 points in Oswestry Disability Index score in the treatment and the control arms. However, the decision to use rescue epidural steroid injection introduced possible bias given that the trial was open-label. No attempts were made to mitigate this potential bias using protocol-mandated standard objective clinical criteria to guide decisions about the use of secondary interventions and subsequent adjudication of these events by an independent blinded committee. Given these critical shortcomings, trial results might have been biased.

Greater certainty about the net health outcome of adding coflex to decompression surgery might be demonstrated when results of 5-year follow-up of this trial and an ongoing RCT, A 2 and 5 Year Comparative Evaluation of Clinical Outcomes in the Treatment of Degenerative Spinal Stenosis With Concomitant Low Back Pain by Decompression With and Without Additional Stabilization Using the Coflex® (NCT02555280) on decompression with and without the coflex implant in the U.S. are published. Consideration of existing studies as indirect evidence regarding the outcomes of using spacers in this subgroup is limited by substantial uncertainty regarding the balance of potential benefits and harms. Limitations of the published evidence preclude determining the effects of the technology on the net health outcome.

Interlaminar Stabilization Devices Used With Spinal Decompression Surgery in Individuals With No Spondylolisthesis or Instability

Clinical Context and Therapy Purpose

The purpose of placement of an interlaminar spacer in individuals with spinal stenosis and no spondylolisthesis or spinal instability is to provide a treatment option that is less invasive than lumbar spinal decompression surgery with fusion and more effective for back pain than lumbar spinal decompression surgery alone. Lumbar spinal stenosis has a broad clinical spectrum. Features that may affect the choice of the surgical procedure include the severity of leg pain, back pain, and instability; the presence of facet hypertrophy, diminished disc height, or deformity; the risk of general anesthesia, and the individual's preferences.10, The clinical feature that best distinguishes the target population for coflex is the severity of back pain, specifically, back pain that is worse than leg pain. The hypothesis underlying this use of coflex is that decompression alone, while effective for claudication and other symptoms of spinal stenosis, may be less effective for severe back pain than decompression plus a stabilizing procedure.

The following PICO was used to select literature to inform this review.

Populations

Individuals with spinal stenosis and no spondylolisthesis or instability who have not responded to conservative treatment.

Interventions
The treatment being considered is the placement of an interlaminar spacer as an adjunct to spinal decompression.

Comparators
The comparators are lumbar spinal decompression alone.

Outcomes
The main outcomes of interest are (1) improvements in symptoms of spinal stenosis (e.g., claudication, leg pain), (2) reductions in back pain, and (3) reductions in limitations on activities related to symptoms. Symptoms can be measured by scores of validated instruments such as the Oswestry Disability Index and the Zurich Claudication Questionnaire as well as a visual analog scale for back and leg pain. Other measures such as the SF-36 to assess the quality of life are relevant. Other key outcome measures are reoperations, including fusion procedures, and adverse events. The window to judge treatment success is a minimum of 2 years post procedure.

Study Selection Criteria

- Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Coflex Device Plus Decompression Versus Decompression Plus Posterolateral Fusion Abjornson et al (2018) reported outcomes from the subgroup of patients without spondylolisthesis who received an interlaminar device with decompression in the pivotal investigational device exemption trial, but comparison with decompression alone in this population has not been reported.47, The major weakness in this trial was its use of lumbar
spinal fusion as a comparator for patients with no spondylolisthesis. The underlying premise that patients with back pain and spinal stenosis do not respond well to decompression (alone or followed by nonsurgical treatments for back pain) has been challenged. For example, the Oswestry Disability Index success rate for decompression alone in the European Study of Coflex And Decompression Alone trial46, was comparable to the Oswestry Disability Index success rate for decompression plus fusion in the pivotal trial. +

Gilbert et al (2022) retrospectively evaluated interlaminar stabilization with coflex following decompressive laminectomy in 20 patients with lumbar stenosis without instability or spondylolisthesis.59, The average visual analog scale score for low back pain preoperatively was 8.8, which improved postoperatively to 4.0, 3.7, and 3.9 at 2 months, 6 months, and 1 year, respectively ($p<.001$). The average visual analog scale score for lower extremity pain preoperatively

was 9.0, which improved postoperatively to 2.7, 2.5, and 2.5 at 2 months, 6 months, and 1 year, respectively (p<.001). Furthermore, the average Oswestry Disability Index scores significantly improved from 66.6 preoperatively to 23.8, 23.3, and 24.5 at 2 months, 6 months, and 1 year postoperatively, respectively (p<.001). The difference in visual analog scale or Oswestry Disability Index scores between 2 months, 6 months, and 1 year did not reach statistical significance. The retrospective nature of the study and short follow-up period after surgery limit conclusions on the role of coflex interlaminar stabilization.

Section Summary: Interlaminar Stabilization Devices Used With Spinal Decompression Surgery in Individuals With No Spondylolisthesis or Instability

The pivotal RCT, conducted in a patient population with spondylolisthesis no greater than grade 1 and significant back pain, showed that stabilization of decompression with the coflex implant was noninferior to decompression with spinal fusion for the composite clinical success measure. However, there is uncertainty about the net benefit of routinely adding spinal fusion to decompression in patients with no spondylolisthesis. Fusion after open decompression laminectomy is a more invasive procedure that requires a longer operative time and has a potential for higher procedural and postsurgical complications. When the trial was conceived, decompression plus fusion was viewed as the standard of care for patients with spinal stenosis with up to grade 1 spondylolisthesis and back pain; thus demonstrating noninferiority with a less invasive procedure such as coflex would be adequate to result in a net benefit in health outcomes. However, the role of fusion in the population of patients represented in the pivotal trial is uncertain, especially since the publication of the Swedish Spinal Stenosis Study and SLIP, 2 RCTs comparing decompression alone with decompression plus spinal fusion that were published in 2016. As a consequence, results generated from a noninferiority trial using a comparator whose net benefit on health outcome is uncertain confounds meaningful interpretation of trial results. Therefore, demonstrating the noninferiority of coflex plus spinal decompression versus spinal decompression plus fusion, a comparator whose benefit on health outcomes is uncertain, makes it difficult to apply the results of the study. Outcomes from the subgroup of patients without spondylolisthesis who received an interlaminar device with decompression in the pivotal investigational device exemption trial have been published, but comparison with decompression alone in this population has not been reported. Limitations of the published evidence preclude determining the effects of the technology on the net health outcome.

Summary of Evidence

For individuals who have spinal stenosis and no spondylolisthesis or grade 1 spondylolisthesis who receive an interspinous or interlaminar spacer as a stand-alone procedure, the evidence includes 1 systematic review of randomized controlled trials (RCTs) of X-STOP spacer devices (which is no longer marketed) or other devices not approved in the US, observational retrospective claims data analyses, and 2 RCTs of 2 spacers compared to each other (Superion Indirect Decompression System, coflex interlaminar implant). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Overall, the use of interspinous or interlaminar distraction devices (spacers) as an alternative to spinal decompression has shown high failure and complication rates. A systematic review of RCTs comparing interspinous spacer devices (ISDs) and decompression surgery in patients with lumbar spinal stenosis found that ISD resulted in an increased rate of reoperation compared to decompression, as well as no statistically significant differences in pain, functional, and quality of life outcomes. Additional longitudinal retrospective

comparative claims analyses found that there was a significantly lower rate of reoperation in patients with lumbar spinal stenosis who received ISD compared to open surgery. However, there are many limitations inherent to claims analyses, including the possibility of coding or data entry errors and the omission of clinical details not needed to justify payment. For example, diagnosis codes identified in claims data lack clinical context, such as the severity of lumbar spinal stenosis or postoperative complications, as well as other prior therapies. Claims data also does not capture patient-reported outcomes, such as visual analog scale scores or Zurich Claudication Questionnaire scores, limiting the ability to determine true efficacy. It is unknown if authors were able to see when a patient was lost to follow-up due to death or end of Medicare coverage, as these rates were not reported. Additionally, in 1 of the studies, since the baseline characteristics of patients receiving ISD indicated that these patients may be inherently sicker than those receiving open surgery, we need clinical context to infer if the reason they did not receive additional surgical procedures post initial ISD placement is because they truly didn't require intervention, or they were too sick to tolerate the procedure. While claims data gives us some information related to re-operation rates, direct or indirect comparative studies using clinical data and validated outcomes measures are required to draw conclusions on the utility of ISDs compared to open surgery. A pivotal trial compared the Superion Interspinous Spacer with the X-STOP Interspinous Process Decompression System (which is no longer marketed), without conservative care or standard surgery comparators. The trial reported significantly better outcomes with the Superion Interspinous Spacer on some measures. For example, the trial reported more than 80% of patients experienced improvements in certain quality of life outcome domains. Interpretation of this trial is limited by questions about the number of patients used to calculate success rates, the lack of efficacy of the comparator, and the lack of an appropriate control group treated by surgical decompression. The coflex interlaminar implant (formerly called the interspinous U) was compared with decompression in the multicenter, double-blind FELIX trial. Functional outcomes and pain levels were similar in the 2 groups at 1 year follow-up, but reoperation rates due to the absence of recovery were substantially higher with the coflex implant (29%) than with bony decompression (8%). For patients with 2-level surgery, the reoperation rate was 38% for coflex and 6% for bony decompression. At 2 years, reoperations due to the absence of recovery had been performed in 33% of the coflex group and 8% of the bony decompression group. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have severe spinal stenosis and grade 1 spondylolisthesis or instability who have failed conservative therapy who receive an interlaminar spacer with spinal decompression surgery, the evidence includes 2 RCTs with a mixed population of patients. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Use of the coflex interlaminar implant as a stabilizer after surgical decompression has been studied in 2 situations-as an adjunct to decompression compared with decompression alone (superiority) and as an alternative to spinal fusion after decompression (noninferiority). For decompression with coflex versus decompression with lumbar spinal fusion, the pivotal RCT, conducted in a patient population with spondylolisthesis no greater than grade 1 and significant back pain, showed that stabilization of decompression with the coflex implant was noninferior to decompression with spinal fusion for the composite clinical success measure. A secondary (unplanned) analysis of patients with grade 1 spondylolisthesis (99 coflex patients and 51 fusion patients) showed a decrease in operative time (104 vs. 157 minutes; $p<.001$) and blood loss (106 vs. 336 mL; $p<.001$). There were no statistically significant differences between the coflex and fusion groups in Oswestry Disability Index, visual

analog scale, and Zurich Claudication Questionnaire scores after 2 years. In that analysis, 62.8% of coflex patients and 62.5% of fusion patients met the criteria for operative success. The efficacy of the comparator in this trial is uncertain because successful fusion was obtained in only 71% of the control group, leaving nearly a third of patients with pseudoarthrosis. The report indicated no significant differences in Oswestry Disability Index or visual analog scale between the patients with pseudoarthrosis or solid fusion but Zurich Claudication Questionnaire scores were not reported. There were 18 (18%) spinous process fractures in the coflex group, of which 7 had healed by the 2-year follow-up. Reoperation rates were 6% in the fusion group and 14% in the coflex group (p=.18), including 8 (8%) coflex cases that required conversion to fusion. This secondary analysis is considered hypothesis-generating, and a prospective trial in patients with grade 1 spondylolisthesis is needed. In an RCT conducted in a patient population with moderate-to-severe lumbar spinal stenosis with significant back pain and up to grade 1 spondylolisthesis, there was no difference in the primary outcome measure, the Oswestry Disability Index, between the patients treated with coflex plus decompression versus decompression alone.

Composite clinical success defined as a minimum 15-point improvement in Oswestry Disability Index score, no reoperations, no device-related complications, no epidural steroid injections in the lumbar spine, and no persistent new or worsening sensory or motor deficit was used to assess superiority. A greater proportion of patients who received coflex plus decompression instead of decompression alone achieved the composite endpoint. However, the superiority of coflex plus decompression is uncertain because the difference in the composite clinical success was primarily driven by a greater proportion of patients in the control arm who received a secondary rescue epidural steroid injection. Because the trial was open-label, surgeons' decision to use epidural steroid injection could have been affected by their knowledge of the patient's treatment. Consequently, including this component in the composite clinical success measure might have overestimated the potential benefit of treatment. Analysis was not reported separately for the group of patients who had grade 1 spondylolisthesis, leaving the question open about whether the implant would improve outcomes in this population.

Consideration of existing studies as indirect evidence regarding the outcomes of using spacers in this subgroup is limited by substantial uncertainty regarding the balance of potential benefits and harms. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have spinal stenosis and no spondylolisthesis or instability who receive an interlaminar spacer with spinal decompression surgery, the evidence includes an RCT and a retrospective study. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The pivotal RCT, conducted in a patient population with spondylolisthesis no greater than grade 1 and significant back pain, showed that stabilization of decompression with the coflex implant was noninferior to decompression with spinal fusion for the composite clinical success measure. However, in addition to concerns about the efficacy of fusion in this study, there is uncertainty about the net benefit of routinely adding spinal fusion to decompression in patients with no spondylolisthesis. Fusion after open decompression laminectomy is a more invasive procedure that requires longer operative time and has a potential for higher procedural and postsurgical complications. When the trial was conceived, decompression plus fusion was viewed as the standard of care for patients with spinal stenosis with up to grade 1

spondylolisthesis and back pain; thus demonstrating noninferiority with a less invasive procedure such as coflex would be adequate to result in a net benefit in health outcomes. However, the role of fusion in the population of patients represented in the pivotal trial is uncertain, especially since the publication of the Swedish Spinal Stenosis Study, and the Spinal Laminectomy versus Instrumented Pedicle Screw study, 2 RCTs comparing decompression alone with decompression plus spinal fusion that were published in 2016. As a consequence, results generated from a noninferiority trial using a comparator whose net benefit on health outcome is uncertain confounds meaningful interpretation of trial results. Therefore, demonstrating the noninferiority of coflex plus spinal decompression versus spinal decompression plus fusion, a comparator whose benefit on health outcomes is uncertain, makes it difficult to apply the results of the study. Outcomes from the subgroup of patients without spondylolisthesis who received an interlaminar device with decompression in the pivotal Investigational Device Exemption trial have been published, but comparison with decompression alone in this population has not been reported. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.+

Supplemental Information
The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2018 Input
Clinical input was sought to help determine whether the use of interlaminar spacer with spinal decompression surgery for individuals with spinal stenosis, predominant back pain, and no or grade 1 spondylolisthesis who failed conservative treatment would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 6 respondents, including 2 specialty society-level responses and 4 physician-level responses, including 2 identified through a specialty society and 2 through an academic medical center.
For individuals who have severe spinal stenosis and grade 1 spondylolisthesis or instability who have failed conservative therapy who receive an interlaminar spacer with spinal decompression surgery, clinical input is not universally supportive of a clinically meaningful improvement in net health outcome. While some respondents considered the shorter recovery time and lower complication rate to be an advantage compared to fusion, others noted an increase in complications and the need for additional surgery with the device.

For individuals who have spinal stenosis and no spondylolisthesis or instability who receive an interlaminar spacer with spinal decompression surgery, clinical input is not universally supportive of a clinically meaningful improvement in net health outcomes, with clinical experts noting an increase in complications and need for additional surgery compared to laminectomy alone.

Further details from clinical input are included in the Appendix.

2011 Input
In response to requests, input was received from 2 physician specialty societies and 2 academic medical centers while this policy was under review in 2011. Two of those providing input agreed this technology is investigational due to the limited high-quality data on long-term outcomes (including durability). Two reviewers did not consider this technology investigational, stating that it has a role in the treatment of selected patients with neurogenic intermittent claudication.

2009 Input
In response to requests, input was received from 1 physician specialty society and 3 academic medical centers while this policy was under review in 2009. Differing input was received; several reviewers indicated data were sufficient to demonstrate improved outcomes.

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Society of Pain and Neuroscience
In 2022, the American Society of Pain and Neuroscience (ASPN) published a consensus guideline outlining best practices for minimally invasive lumbar spinal stenosis treatment.60, The following recommendation was provided with regard to the use of interspinous spacers:

- "Interspinous spacers should be considered for treatment of symptomatic spinal stenosis at the index level with mild-to-moderate spinal stenosis, with less than or equal to grade 1 spondylolistheses, in the absence of dynamic instability or micro-instability represented as fluid in the facets on advanced imaging. Grade A; Level of certainty high; Quality of Evidence 1-A"

In 2022, ASPN also published evidence-based clinical guidelines informed by a systematic review of randomized controlled trials on interventional treatments for low back pain.61, The following recommendation was provided with regard to the use of interspinous spacers:

- "Stand-alone interspinous spacers for indirect decompression are safe and effective for the treatment of mild to moderate lumbar spinal stenosis if no contraindications exits. Grade A; Level of certainty high; Quality of Evidence: I-A."

Department of Health & Human Services
In 2019, a Department of Health & Human Services inter-agency task force released a report on pain management best practices.62, The report provides best practices for development of effective pain management plans using a patient-centered approach in the diagnosis and treatment of acute and chronic pain. All of their statements are on generalized pain and their recommendations relate to gaps in comprehensive pain plan development. In their report, regarding interspinous process spacer devices, they state: "research has shown that interspinous process spacer devices can provide relief for patients with lumbar spinal stenosis with neuroclaudication." The guidelines do not compare therapies to each other and is not informed by

a systematic review, it only offers various options to consider when building a pain management plan for a patient.

International Society for the Advancement of Spine Surgery
In 2016, the International Society for the Advancement of Spine Surgery published recommendations and coverage criteria for decompression with interlaminar stabilization.63, The Society concluded that an interlaminar spacer in combination with decompression can provide stabilization in patients who do not present with greater than grade 1 instability. Criteria included:

1. Radiographic confirmation of at least moderate lumbar stenosis.
2. Radiographic confirmation of the absence of gross angular or translatory instability of the spine at index or adjacent levels.
3. Patients who experience relief in flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least 12 weeks of non-operative treatment.

The document did not address interspinous and interlaminar distraction devices without decompression.

North American Spine Society
In 2018, the North American Spine Society (NASS) published specific coverage policy recommendations on the lumbar interspinous device without fusion and with decompression.64, The NASS recommended that: "Stabilization with an interspinous device without fusion in conjunction with laminectomy may be indicated as an alternative to lumbar fusion for degenerative lumbar stenosis with or without low-grade spondylolisthesis (less than or equal to 3 mm of anterolisthesis on a lateral radiograph) with qualifying criteria when appropriate:

1. Significant mechanical back pain is present (in addition to those symptoms associated with neural compression) that is felt unlikely to improve with decompression alone. Documentation should indicate that this type of back pain is present at rest and/or with movement while standing and does not have characteristics consistent with neurogenic claudication.
2. A lumbar fusion is indicated post-decompression for a diagnosis of lumbar stenosis with a Grade 1 degenerative spondylolisthesis as recommended in the NASS Coverage Recommendations for Lumbar Fusion.
3. A lumbar laminectomy is indicated as recommended in the NASS Coverage Recommendations for Lumbar Laminectomy.
4. Previous lumbar fusion has not been performed at an adjacent segment.
5. Previous decompression has been performed at the intended operative segment.

Interspinous devices are NOT indicated in cases that do not fall within the above parameters. In particular, they are not indicated in the following scenarios and conditions:

- Degenerative spondylolisthesis of Grade 2 or higher.
- Degenerative scoliosis or other signs of coronal instability.
- Dynamic instability as detected on flexion-extension views demonstrating at least 3 mm of change in translation.
- Iatrogenic instability or destabilization of the motion segment.

- A fusion is otherwise not indicated for a Grade 1 degenerative spondylolisthesis and stenosis as per the NASS Coverage Recommendations for Lumbar Fusion.
- A laminectomy for spinal stenosis is otherwise not indicated as per the NASS Coverage Recommendations for Lumbar Laminectomy."

Of note, clinical guidelines from NASS are no longer freely available.

National Institute for Health and Care Excellence
In 2010, NICE published guidance that indicated "Current evidence on interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication shows that these procedures are efficacious for carefully selected patients in the short and medium-term, although failure may occur and further surgery may be needed."65, The evidence reviewed consisted mainly of reports on X-STOP® Interspinous Process Decompression System.

U.S. Preventive Services Task Force Recommendations
Not applicable

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 19.

Table 19. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02555280[a]	A 2 and 5 Year Comparative Evaluation of Clinical Outcomes in the Treatment of Degenerative Spinal Stenosis With Concomitant Low Back Pain by Decompression With and Without Additional Stabilization Using the Coflex® Interlaminar Technology for FDA Real Conditions of Use Study (Post-Approval 'Real Conditions of Use' Study)	300	Nov 2027
NCT04192591[a]	A 5-year Superion® IDS Clinical Outcomes Post-Approval Evaluation (SCOPE)	214	May 2032
Unpublished			
NCT02457468[a]	The Coflex® COMMUNITY Study: An Observational Study of Coflex® Interlaminar Technology	325	Dec 2019
NCT04087811[a]	Postmarket Registry for Evaluation of the Superion® Spacer	1625	Mar 2021
NCT04563793[a]	Postmarket Outcomes Study for Evaluation of the Superion Spacer	129	Mar 2023

NCT: national clinical trial. [a] Denotes industry-sponsored or cosponsored trial.

Essential Health Benefits

The Affordable Care Act (ACA) requires fully insured non-grandfathered individual and small group benefit plans to provide coverage for ten categories of Essential Health Benefits ("EHBs"), whether the benefit plans are offered through an Exchange or not. States can define EHBs for their respective state.
States vary on how they define the term small group. In Idaho, a small group employer is defined as an employer with at least two but no more than fifty eligible employees on the first day of the plan or contract year, the majority of whom are employed in Idaho. Large group employers, whether they are self-funded or fully insured, are not required to offer EHBs, but may voluntarily offer them.

The ACA requires any benefit plan offering EHBs to remove all dollar limits for EHBs.

Applicable Coding
CPT Category III Codes - Not Covered

CPT Codes	Number	Description
	22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level
	22868	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	second level (List separately in addition to code for primary procedure)
HCPCS	**C1821**	Interspinous process distraction device (implantable)
ICD-10-CM		Investigational for all codes
	M48.00-M48.08	Spinal stenosis code range

	ICD-10-PCS		ICD-10-PCS codes are only used for inpatient services	
		0RH008Z, 0RH038Z, 0RH048Z, 0RH108Z, 0RH138Z, 0RH148Z, 0RH408Z, 0RH438Z, 0RH448Z, 0RH608Z, 0RH638Z, 0RH648Z, 0RHA08Z, 0RHA38Z, 0RHA48Z	Surgical, upper joints, insertion, spacer, interspinous process, code by body part and approach (open, percutaneous, percutaneous endoscopic)	
		0SH008Z, 0SH038Z, 0SH048Z, 0SH308Z, 0SH338Z, 0SH348Z	Surgical, lower joints, insertion, spacer, interspinous process, code by body part and approach (open, percutaneous, percutaneous endoscopic)	
		0RP008Z, 0RP038Z, 0RP048Z, 0RP108Z, 0RP138Z, 0RP148Z, 0RP408Z, 0RP438Z, 0RP448Z, 0RP608Z, 0RP638Z, 0RP648Z, 0RPA08Z, 0RPA38Z, 0RPA48Z	Surgical, upper joints, removal, spacer, interspinous process, code by body part and approach (open, percutaneous, percutaneous endoscopic)	
		0SP008Z, 0SP038Z, 0SP048Z, 0SP308Z, 0SP338Z, 0SP348Z	Surgical, lower joints, removal, spacer, interspinous process, code by body part and approach (open, percutaneous, percutaneous endoscopic)	

Type of Service	**Surgical**	
Place of Service	**Outpatient /Inpatient**	

Vendors

- **Personify**
- **HPS**

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Review/Revision/Approval History	
Date	Description
07/01/2024	**New**

05/04/2026	Reviewed and Approved by Mountain Health CO-OP Policy Committee

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