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MEDICAL POLICY – 7.01.107

Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

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Effective Date:	Jul. 1, 2026
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RELATED MEDICAL POLICIES:

7.01.120	Facet Arthroplasty
7.01.591	Interspinous Fixation (Fusion) Devices
7.01.551	Lumbar Spine Decompression Surgery: Discectomy, Foraminotomy, Laminotomy, Laminectomy in Adults

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POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Back pain is a common symptom and can cause disability in some people. Despite extensive knowledge of the bones, nerves, muscles, tendons and structures of the spine, it can still be very difficult to identify a specific cause of pain for many people. Scientists and physicians have felt that one cause may be pressure put on the nerves by the vertebrae (bones in the spine). Devices known as spacers have been designed to be positioned between the vertebrae. Spacers are intended to reduce pain. Generally speaking, a surgeon places the device and then expands it. This expansion lifts the part of the bone that's pressing on the nerve. Some devices are used after surgery to take pressure off of nerves and some devices are used as a stand-alone treatment. These devices are considered unproven for all uses. Published scientific studies show high failure and complications rates.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Note: **(see Appendix for a list of examples of devices not addressed in the Regulatory Status).**

Device	Investigational
Interspinous or interlaminar distraction device	**Interspinous or interlaminar distraction devices as a stand-alone procedure are considered investigational as a treatment of spinal stenosis.**
Interlaminar stabilization device	**Use of an interlaminar stabilization device following decompression surgery is considered investigational.**

Coding

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

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

N/A

Evidence Review

Description

Interspinous and interlaminar implants (spacers) stabilize or distract the adjacent lamina and/or spinous processes and restrict extension to reduce pain in individuals with lumbar spinal stenosis and neurogenic claudication. Interspinous spacers are small devices implanted between the vertebral spinous processes. After implantation, the device is opened or expanded to distract (open) the neural foramen and decompress the nerves. Interlaminar spacers are implanted midline between the adjacent lamina and spinous processes to provide dynamic stabilization either following decompression surgery or as an alternative to decompression surgery.

Background

Spinal Stenosis

Lumbar spinal stenosis (LSS), which affects over 200,000 people in the United States (US), 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 US, spondylosis (degenerative arthritis affecting the spine) is the most common cause. The primary symptom of LSS 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 LSS 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 individuals remain stable, some improve, and some deteriorate.[1,2]

The lack of a valid classification for LSS contributes to wide practice variation and uncertainty about who should be treated surgically and which surgical procedure is best for each individual.[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 individuals with spinal stenosis is minimally symptomatic individuals with mild back pain and no spinal instability. These individuals are typically treated nonsurgically. At the other end of the spectrum are individuals 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 individuals 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 individuals with spinal deformity or moderate grade spondylolisthesis.

Conservative treatments for spinal stenosis may include physical therapy, pharmacotherapy, and 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 LSS should be considered only after an individual 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 individuals 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 individuals 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, individuals 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 trial by Delitto et al (2015) compared surgical decompression with a specific therapy program emphasizing physical therapy and exercise.[9] Individuals with lumbar spinal stenosis and from 0 to 5 mm of slippage (spondylolisthesis) who were willing to be randomized to decompression 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 individuals 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 individuals 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 individuals 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 individuals who do not have spondylolisthesis, because nearly all individuals with spondylolisthesis underwent fusion whereas nearly all those who did not have spondylolisthesis underwent decompression alone. In general, individuals 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 individuals as for the unfused spinal stenosis individuals at 2 years, the SPORT investigators concluded that it was unlikely that fusion led to the better surgical outcomes in individuals 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 two randomized trials of decompression alone vs decompression plus fusion were published. The Swedish Spinal Stenosis Study (SSSS) found no benefit of fusion plus decompression compared with decompression alone in individuals 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 individuals who had spinal stenosis with grade 1 spondylolisthesis (3-14 mm).[18] The individuals in SLIP who had laminectomy alone had higher reoperation rates than those in SSSS, and the individuals who underwent fusion had better outcomes in SLIP than in SSSS. While some interpret the studies to reflect differences in individual factors-in particular, SSSS but not SLIP included individuals 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 individual-reported outcome data on the individuals before and after reoperation, to see whether the threshold for reoperation differed in the two settings.[25] A small trial conducted in Japan, Inose et al (2018) found no difference in individual-reported outcomes between laminectomy alone and laminectomy plus posterolateral fusion in individuals with 1-level spinal stenosis and grade 1 spondylolisthesis; about 40% of the individuals 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 individuals with LSS 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 (4-8 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 adjacent lamina and spinous processes to provide dynamic stabilization either following decompression surgery or as an alternative to decompression surgery. Interlaminar spacers have two 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 individuals with spinal stenosis and neurogenic claudication.

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 one 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, an RCT of interspinous spacer device (ISD) versus surgical decompression, observational retrospective claims data analyses, and two RCTs of two 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 a high failure and complication rates. A systematic review of RCTs comparing interspinous spacer devices (ISDs) and decompression surgery in individuals 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. A small RCT of ISD versus decompression surgery found no differences in clinical outcomes between groups. Additional longitudinal retrospective comparative claims analyses found that there was a significantly lower rate of reoperation in individuals with lumbar spinal stenosis who received ISD compared to open surgery. However, there are many limitations inherent to claims analysis, 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 individual-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 an individual 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 individuals receiving ISD indicated that these individuals 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 did not 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 individuals experienced improvements in certain quality of life outcome domains. Interpretation of this trial is limited by questions about the number of individuals 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 Foraminal Enlargement Lumber Interspinous distraXion trail (FELIX). Functional outcomes and pain were similar in the two groups at one year follow-up, but reoperation rates due to absence of recovery were substantially higher with the coflex implant (29%) than with bony decompression (8%). For individuals with 2-level surgery, the reoperation rate was 38% for coflex and 6% for bony decompression. At two years, reoperations due to absence of recovery had been performed in 33% of the coflex group and in 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 who have failed conservative therapy who receive an interlaminar spacer with spinal decompression surgery, the evidence includes two RCTs with a mixed population of individuals. Relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Use of the coflex interlaminar implant as a stabilizer after surgical decompression has been studied in two 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 an individual 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 individuals with grade 1 spondylolisthesis (99 coflex individuals and 51 fusion individuals) 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 two years. In that analysis, 62.8% of coflex individuals and 62.5% of fusion individuals 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 individuals with pseudoarthrosis. The report indicated no significant differences in Oswestry Disability Index or visual analog scale between the individuals 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 seven had healed by the two-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 individuals with grade 1 spondylolisthesis is needed. In an RCT conducted in an individual population with moderate-to-severe LSS 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 individuals treated with coflex plus decompression vs. 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 individuals 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 individuals 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 individual'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 individuals 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 individuals 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 individuals 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 individuals represented in the pivotal trial is uncertain, especially since the publication of the SSSS, and the SLIP study, two 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 individuals 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in **Table 1**.

Table 1. 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	300	Nov 2027

NCT No.	Trial Name	Planned Enrollment	Completion Date
	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)		
NCT04192591[a]	A 5-year Superion IDS Clinical Outcomes Post-Approval Evaluation (SCOPE)	166	Feb 2041
Unpublished			
NCT04087811[a]	Postmarket Registry for Evaluation of the Superion Spacer	1674	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.

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 in 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 six respondents, including two specialty society-level responses and four physician-level responses, including two identified through a specialty society and two 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 generally 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.

2011 Input

In response to requests, input was received from two physician specialty societies and two 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 the technology has a role in the treatment of selected individuals with neurogenic intermittent claudication.

2009 Input

In response to requests, input was received from one physician specialty society and three 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

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

Guidelines or position statements will be considered for inclusion 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.[63] 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.[64] 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, the Department of Health & Human Services inter-agency task force released a report on pain management best practices.[65] 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 individuals with lumbar spinal stenosis with neuroclaudication." The guidelines do not compare therapies to each other and are not informed by a systematic review, it only offers various options to consider when building a pain management plan for an individual.

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.[66] The Society concluded that an interlaminar spacer in combination with decompression can provide stabilization in individuals who do not present with greater than grade I 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. Individuals 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 lumbar interspinous device without fusion and with decompression.[67] 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."

Both of these policy recommendations were updated in March 2025; however, the documents are no longer freely available to the public without a paid subscription.

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 individuals in the short and medium term, although failure may occur and further surgery may be needed."[68] The evidence reviewed consisted mainly of reports on X-STOP Interspinous Process Decompression System.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Three interspinous and interlaminar stabilization and distraction devices have been approved by the US Food Drug Administration (FDA) through the premarket approval (FDA product code: NQO) and are summarized in **Table 2**.

Table 2. 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 individuals suffering from pain, numbness, and/or cramping in the legs secondary to a diagnosis of moderate degenerative LSS, with or without Grade 1 spondylolisthesis, confirmed by x-ray, magnetic resonance imaging (MRI) and/or have computed tomography (CT) evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing. It is intended for individuals with 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 individuals 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 non-operative treatment. The coflex "is intended to be implanted midline between adjacent lamina of 1 or 2 contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s)."

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 BMI > 40
- Active or chronic infection- systemic or local
- Known allergy to titanium alloys or magnetic resonance (MR) 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, FDA requested additional postmarketing studies to provide longer-term device performance and device performance under general conditions of use. The first was the five-year follow-up of the pivotal investigational device exemption trial. The second was a multicenter trial with 230 individuals in Germany who were followed for five years, comparing decompression alone with decompression plus coflex. The third, a multicenter trial with 345 individuals in the US who were followed for five years, compared decompression alone with decompression plus coflex.[27] FDA product code: NQO.

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Appendix

Examples of other interspinous and interlaminar distraction devices that are under investigation and do not have premarket approval status by the US Food and Drug Administration (FDA), this list may not be all-inclusive.

- Aperius PercLID System (Kyphon/ Medtronic Spine)
- DIAM Spinal Stabilization System (Medtronic Sofamor Danek)
- Falena Interspinous Decompression Device (Mikai Spine)
- FLEXUS Interspinous Spacer (Globus Medical)
- Helifix Interspinous Spacer System (Alphatec Spine)
- In-Space (Synthes)
- NL-Prow Interspinous Spacer (Non-Linear Technologies)
- Stenofix (Synthes)
- Wallis System (Abbott Spine/ Zimmer Spine)

History

Date	Comments
03/13/07	New Policy – Add to Surgery section.
08/23/07	Codes updated; no other changes.
11/11/08	Codes updated; 84.58 removed from policy.
07/14/09	Replace policy – Policy updated with literature search; no change to the policy statement. References added.
09/14/10	Related Policies updated.
06/13/11	Replace policy – Policy updated with literature review, reference numbers 10-17 added, clinical input reviewed, policy statement unchanged.
02/27/12	Related policies updated; 7.01.130 added.
08/22/12	Update Related Policies – Change title to 7.01.116.
12/19/12	Replace policy. References 18, 19, 20 added. No change to policy statement.
07/24/13	Replace policy. Interlaminar stabilization added to title. New policy statement added "Use of an interlaminar stabilization device following decompressive surgery is considered investigational". New, approved device, added to regulatory status section. Rationale updated with literature review through April 4, 2013; references 7, 19, 20 added; others renumbered/removed. Policy statement changed as noted.
09/30/13	Update Related Policies. Change title to 7.01.120.
12/06/13	Update Related Policies. Add 7.01.138.
01/21/14	Update Related Policies. Add 7.01.551
05/20/14	Update Related Policies. Remove 7.01.116 as it was deleted, and replace with 7.01.555.
11/20/14	Annual Review. Policy updated with literature review through April 22, 2014. References 20-22,28 added; others renumbered/removed. Policy statements unchanged.
11/10/15	Annual Review. In the Regulatory Status section under Coflex contraindications for degenerative lumbar scoliosis, the Cobb angle was corrected to greater than 25°. Clinical trials reformatted into a table. Policy updated with literature review through March 11, 2015; references 1-2, 7, 9-12, 27 added. HCPCS code C1821 removed from policy as not used for adjudication. Policy statements unchanged.
07/01/16	Annual Review, approved June 14, 2016. Policy updated with literature review through February 22, 2016; references 21, 26-27, and 29 added. Rationale section revised; policy statements unchanged.
10/11/16	Policy moved into new format; no change to policy statements.

Date	Comments
01/01/17	Coding update, added new CPT codes 22867-22870 effective 1/1/17.
07/01/17	Annual Review, approved June 6, 2017. Policy updated with literature review through February 23, 2017; references 7-8 and 14-16 added. Removed CPT code 22899. Policy statements edited for clarification; the intent of the policy is unchanged.
01/01/18	Coding update; removed CPT codes 0171T and 0172T as they terminated 1/1/17.
10/01/18	Annual Review, approved September 20, 2018. Reviewed literature through August 2018. No references added. Policy statement unchanged.
07/01/19	Annual Review, approved June 20, 2019. Policy updated with literature review through March 2019, references added. Policy statements unchanged.
12/01/19	Interim Review, approved November 6, 2019. Policy updated with literature review through July 2019. Policy statements unchanged.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.
06/10/20	Interim Review, approved June 9, 2020, effective June 10, 2020. This policy is reinstated immediately and will no longer be deleted or replaced with InterQual criteria on July 2, 2020.
08/01/20	Annual Review, approved July 23, 2020. Policy updated with literature review through February, 2020; reference added. Policy statements unchanged.
11/01/20	Coding update. Added HCPCS code C1821.
07/01/21	Annual Review, approved June 1, 2021. Policy updated with literature review through February 23, 2021; references added. Policy statements unchanged.
07/01/22	Annual Review, approved June 13, 2022. Policy updated with literature review through March 2, 2022; references added. Policy statements unchanged.
11/01/22	Interim Review, approved October 10, 2022. Appendix added for examples of other interspinous and interlaminar distraction devices that are considered investigational and not addressed in the Regulatory Status. Changed the wording from "patient" to "individual" throughout the policy for standardization.
07/01/23	Annual Review, approved June 12, 2023. Policy updated with literature review through February 15, 2023; references added. Policy statements unchanged.
07/01/24	Annual Review, approved June 10, 2024. Policy updated with literature review through February 28, 2024; references added. Policy statements unchanged. Updated Related Policies section, 7.01.138 was deleted and replaced with 7.01.591 Interspinous Fixation (Fusion) Devices.
07/01/25	Annual Review, approved June 9, 2025. Policy updated with literature review through March 10, 2025; references added. Policy statements unchanged.
07/01/26	Annual Review, approved June 22, 2026. Policy updated with literature review through February 17, 2026; references added. Policy statements unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2026 Premera All Rights Reserved.

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