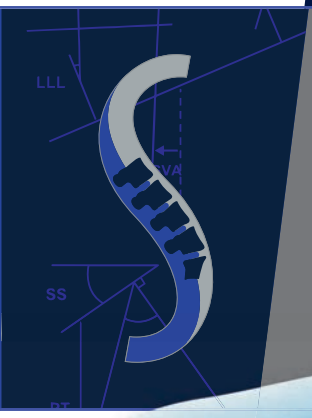
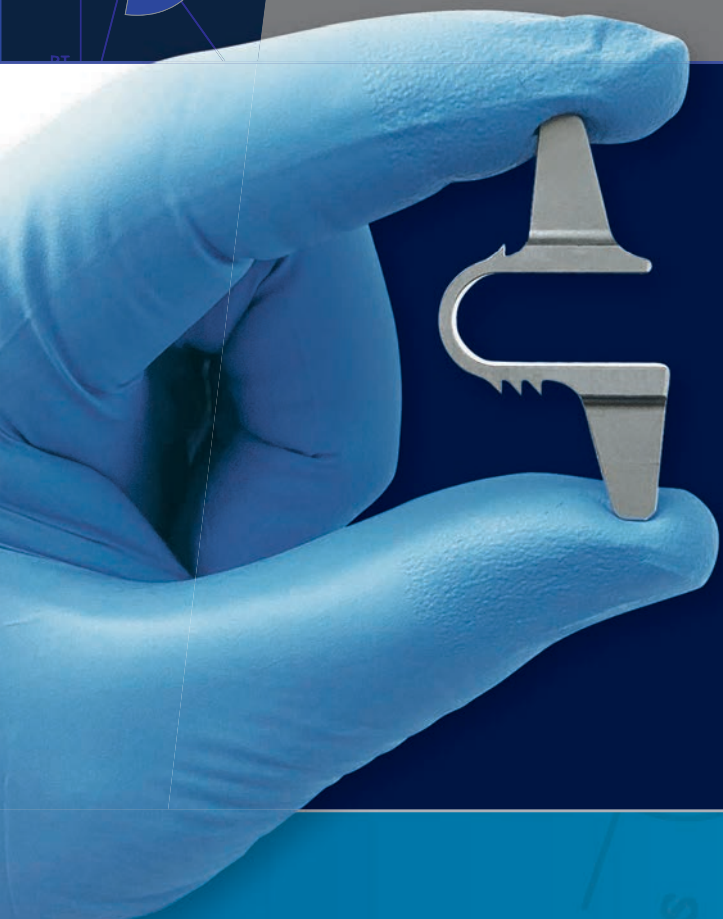
Surgalign™
SPINE TECHNOLOGIES



coflex® Interlaminar Stabilization®

2020 Reimbursement Resource Guide



Prepared by MCRA, LLC

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① coflex® Technology Overview

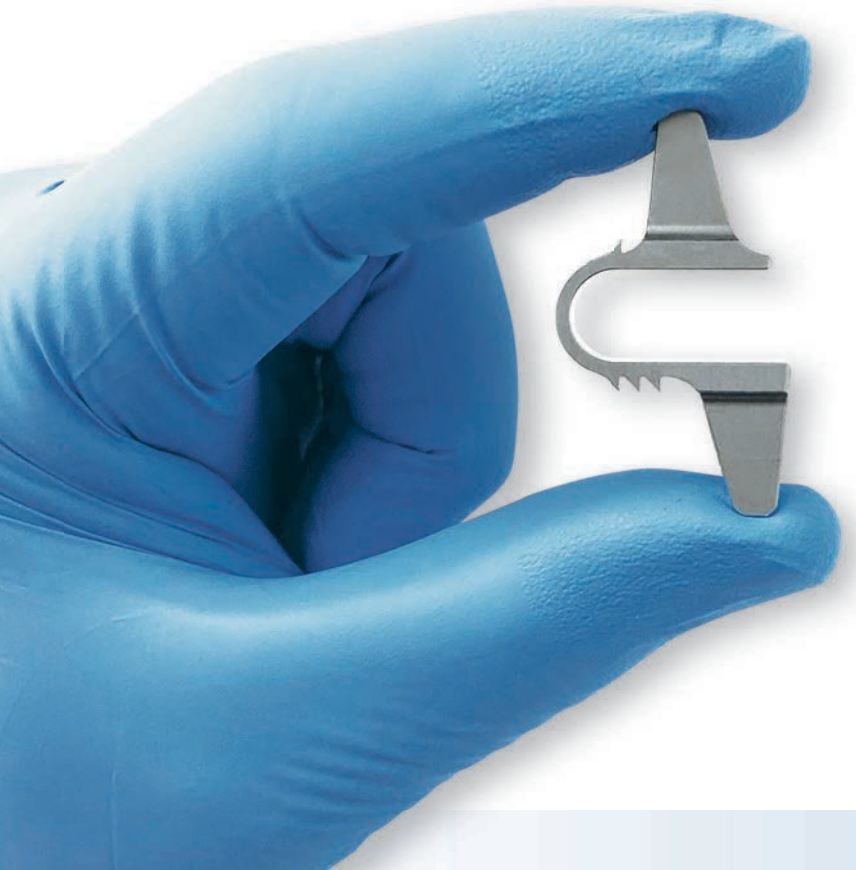
TECHNOLOGY DESCRIPTION

The coflex® Interlaminar Technology is an Interlaminar Stabilization® device indicated for use in one or two level lumbar stenosis from L1-L5 in skeletally mature patients with at least moderate impairment in function, who experience relief in flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least 6 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). Please see Instructions for Use for a complete list of warnings, precautions and contraindications.

The use and reporting of Surgalign's coflex® technology and products are supported by this Reimbursement Resource Guide.

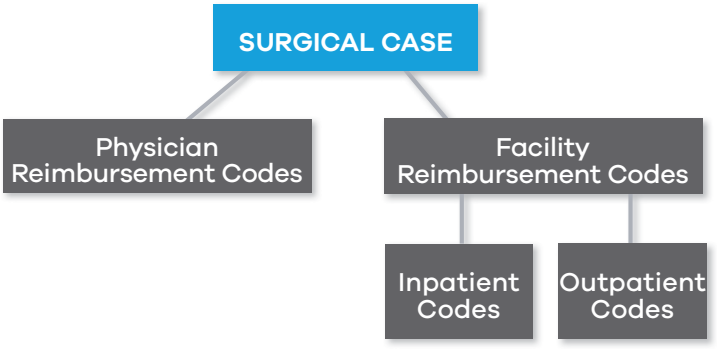
This information is for educational/informational purposes only and should not be construed as authoritative. The information presented here is current as of December 2019 and is based upon publicly available source information.



② Coding Basics

A general overview of the different coding and reimbursement pathways and types of code sets available has been provided below. Distinct code sets are used to report various aspects of procedures and technologies for reimbursement depending on the entity billing the case.

Reimbursement pathways and appropriate code sets take two directions resulting in two separate reimbursements for a single patient encounter when performed in a facility. Physicians report their work separately from the facility where the procedure is performed. This in turn creates unique coding pathways for each side of the equation that results in appropriate reimbursement from third party payers (such as Medicare or private payers).



SURGEON CODES

Physician services and surgical procedures are reported using Common Procedural Terminology (CPT) codes. These codes are created by the American Medical Association (AMA). The creation and adoption of CPT codes involves a process controlled by the AMA/CPT Editorial Panel that approves new codes and code descriptions per a set of defined standards and review process criteria.[1] New technologies and procedures are evaluated and assigned codes depending on the opinions of this panel, relevant society input and clinical literature establishing efficacy of the procedure. This is in addition to FDA approval, which must be obtained prior to consideration for a new code.

Following adoption of a new CPT code (either a Permanent CPT code or a Temporary (Category III) CPT code) the process of evaluating the code begins. The Centers for Medicare and Medicaid Services (CMS) works alongside the AMA/CPT process and commonly (but not always) adopts CPT codes created by the AMA Editorial Panel. Through its Relative Value Scale Update Committee (RUC) the AMA then begins the valuation of the code by establishing Relative Value Units (RVUs) based on a complex system that incorporates surgeon experience reports, work involved, time elements, skill measurements and a host of other factors on which to base Medicare reimbursement.[2] Although CMS adopts the RVU value, this is also often used by private payers to create their physician fee schedules and payments.

Permanent (Category I) CPT Codes both existing and newly created, for physician procedures and services, have met the qualifications outlined by the AMA/CPT Editorial Panel and typically have established RVU values that can be directly used to determine reimbursement. These RVU values are multiplied by a conversion factor (published yearly by CMS or established per contract by private payers) to provide payment for surgeon services within coverage guidelines. Just because a permanent CPT code exists does not mean that it will be paid. All reimbursement is subject to coverage guidelines and payer policies.

1. American Medical Association Website. CPT-Current Procedural Terminology. Available at: http://www.ama- assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt.page. (Accessed December 2019).
2. American Medical Association Website. The RVS Update Committee. Available at: http://www.ama- assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/medicare/the-resource-based- relative-value-scale/the-rvs-update-committee.page. (Accessed December 2019).

Temporary (Category III) CPT "T" Codes for physician procedures and services, have met the qualifications outlined by the AMA/CPT Editorial Panel for temporary code status. New technologies that do not qualify for a new permanent CPT code are often assigned these "T" codes to provide a means of tracking procedures and collecting data essential to becoming a permanent CPT code. "T" codes are not assigned RVU values, do not have established national Medicare reimbursement rates and are set to "sunset" or retire in 5 years unless there is a change requested to extend usage or transition to permanent CPT codes. Reporting temporary codes for reimbursement requires that additional information to be submitted to the payer following its guidelines.

Unlisted CPT Codes Unlisted permanent CPT codes are used to report procedures that do not precisely fall into the description of a current CPT code per CPT/AMA guidelines. CPT coding guidelines require that CPT codes be assigned to procedures that exactly match the current use and description of a published code. Unlisted codes are often used for new technologies as they come to market and require that surgeons reporting these codes provide the payer with an explanation of the procedure as performed and a request for reimbursement based on the detail and medical necessity of the case.

Facility Codes: Surgical procedures are performed in either the outpatient or inpatient setting of care, as determined by the physician. Each setting utilizes a different code set to report its services to the payer for reimbursement. This is in addition to the surgeon, who reports his services separately with CPT codes.

Outpatient APC Codes are based on the same CPT codes reported by physicians but these are typically mapped to or placed into a second code set called APC Codes. Ambulatory Payment Classification (APC) codes combine CPT procedure services into like groupings that utilize similar resources in the outpatient setting and are paid an established rate for the APC. These APC code sets can be reported and reimbursed singularly or in inclusive groupings, as determined by payer guidelines. Government payers and some private payers use this system but reimbursement guidelines can differ considerably depending on the payer and contracted agreements. Medicare reimbursement rates are determined by the Outpatient Prospective Payment System (OPPS) and are published semi-annually.[3]

HCPCS Level II Codes Outpatient reporting also requires that implantable devices and biologics used in procedures be coded separately using the Healthcare Common Procedure Coding System (HCPCS) Level II Codes. This code set allows line item reporting of products used in procedures that are not already included within the reimbursement rate for the reported APC. This system differs for government payers where a pass-through payment code must be adopted and valued by CMS, and private payers, who use the HCPCS code to determine contracted rates with more generalized codes.

Inpatient ICD-10-PCS Codes International Classifications of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS) code set reporting inpatient procedures performed on the patient during the hospital stay, was implemented on October 1, 2015. These hospital procedure codes are more specific in reporting the procedure performed as to approach used and anatomic level than the previous ICD-9 code set. Specific diagnoses and detailed procedure coding is important to ensure correct assignment of the MS-DRG code that determines the total inpatient reimbursement. It is important that all ICD-10-PCS procedure codes be reported to capture the use of a device and map to the appropriate MS-DRG reported.

3. Centers for Medicare & Medicaid Services Medicare Learning Network. Hospital Outpatient Prospective Payment System. Available at: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network- MLN/MLNProducts/downloads/HospitalOutpaysysfctsht.pdf. (Accessed December 2019).

MS-DRG Codes Medicare Severity, Diagnosis Related Grouping (MS-DRG) codes are used to report hospital inpatient stays for reimbursement. These codes are groupings that represent the entire patient stay at the inpatient facility, inclusive of all services, costs and devices utilized during the episode of care. There are typically no line item reimbursements for devices as in the outpatient setting of care.

CPT Code Modifiers In specific cases it is sometimes necessary to submit a CPT code with a modifier. Modifiers indicate that a reported service has been altered by a specific circumstance but that the CPT code description has not changed. Modifiers enable healthcare professionals to report services more accurately and to provide detail and clarity to the third party payer per required guidelines and policies. The following table provides a list of some common CPT code modifiers. Complete lists are available in the AMA/CPT book and online on the Medicare website.

SAMPLE CPT/HCPCS MODIFIERS

Modifier	Description
-AS	Physician assistant, nurse practitioner, or clinical nurse specialist services for assistant at surgery.
-26	**Professional Component.** Some procedures have both a professional and technical component. When the modifier -26 is appended to the professional service the components may be paid separately per payer guidelines.
-50	**Bilateral Procedure.** When CPT codes are not identified as bilateral in the code description or parenthetical a modifier -50 may be appended when the procedure is performed bilaterally.
-51	**Multiple Procedures.** When more than one procedure is performed at the same session a modifier -51 is appended to additional procedures. It is not appended to codes listed as "add-on" codes.
-59	**Distinct Procedural Service.** Modifier -59 is used to report separate services that are distinct or independent and not normally reported together. Documentation must support the distinct service (Example; separate area of injury in extensive injuries)
-80	**Assistant Surgeon:** Surgical assistant services may be identified by adding the modifier 80 to the usual procedure numbers. This modifier should be reported to identify surgical assistant services performed in a non-teaching setting or in a teaching setting when a resident was available, but the surgeon opted not to use the resident. In the latter case, the service is generally not covered by Medicare.

Effective January, 1 2015 CMS established four new modifiers to define specific subsets of the -59 modifier. Modifier -59 is still recognized but should not be used when a more descriptive modifier is available.– X {EPSU} modifiers are below.[4]

Modifier	Description
-XE	**Separate Encounter,** a service that is distinct because it occurred during a separate encounter.
-XS	**Separate Structure,** a service that is distinct because it was performed on a separate organ/structure.
-XP	**Separate Practitioner,** a service that is distinct because it was performed by a different practitioner.
-XU	**Unusual Non-Overlapping Service,** the use of a service that is distinct because it does not overlap usual components of the main service.

4. MLN Matters® Number MM8863 http://cms.gov/Outreach-and-Education/Medicare-Learning-Network- MLN/MLNMattersArticles/Downloads/MM8863.pdf

③ Coding Pathway Options by Place of Service

DIAGNOSIS CODING PATHWAY OPTIONS

Diagnosis codes are assigned by the physician to accurately report the patient's condition as it relates to the procedure. Below is a list of diagnosis codes and definitions that may apply to patients indicated for a coflex® procedure. This is only a list of possible codes that represent a typical diagnosis associated with the procedure and is not intended to be a complete list. No actual patient condition is represented by the examples provided.

ICD-10-CM DIAGNOSIS CODE	
ICD-10-CM Code[5]	Diagnosis Description
M48.061	Spinal stenosis, lumbar region without neurogenic claudication
M48.062	Spinal stenosis, lumbar region with neurogenic claudication
M99.23	Subluxation stenosis of neural canal of lumbar region
M99.33	Osseous stenosis of neural canal of lumbar region
M99.43	Connective tissue stenosis of neural canal of lumbar region
M99.53	Intervertebral disc stenosis of neural canal of lumbar region
M99.63	Osseous and subluxation stenosis of intervertebral foramina of lumbar region
M99.73	Connective tissue and disc stenosis of intervertebral foramina of lumbar region

5. 2020 ICD-10-CM, 2020, www.cms.gov
6. CPT 2020 Professional Edition, 2019 American Medical Association (AMA); CPT is a trademark of the AMA

POTENTIAL PHYSICIAN CODING PATHWAYS

Information for Use of coflex® Interlaminar Stabilization® Procedure

Physicians bill Medicare and other payers separately for services performed, regardless of whether the service takes place in the physician's office, a hospital or other outpatient facility. Procedure codes identify the specific treatment that is performed on the patient. It is possible to report more than one procedure code on a claim form, and the type of payer and setting of care often dictate whether the services are paid independently or as a single bundled payment.

Physicians report their surgical work, with CPT codes, separately to payers. CPT codes are assigned to report the actual procedure performed and documented in the medical record. The code options below may or may not represent the actual procedure performed and are presented here as options only.

The choice of codes must be made by the surgeon as documented in the medical record. We strongly advise that the provider review specific payer guidelines for reporting of procedures when making coding decisions. We encourage you to seek input from the AMA, relevant medical societies, CMS, your local Medicare Administrative Contractor and other health plans to which you submit claims.

While these options are intended to provide context for procedure and related coding, providers should select the procedure, diagnosis, and technology coding that best represents each patient's medical condition and treatment.

The coflex® device is indicated for use in one or two level lumbar stenosis from L1-L5 in skeletally mature patients with at least moderate impairment in function, who experience relief in flexion from their symptoms of leg/buttocks/groin pain, with or without pain, and who have undergone at least 6 months of non-operative treatment.

The coflex® procedure involves 1) a separate surgical decompression and 2) the implantation of the coflex® device between adjacent lamina of 1 or 2 contiguous lumbar motion segments, for treatment of lumbar spinal stenosis.

Primary coflex procedure (L1-L5), single level

CPT® 22867 – Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level

If a second adjacent lumbar level coflex procedure is performed at the same operative session the following add-on code is reported in addition to the primary procedure code CPT 22867;

CPT +22868 (Do not add modifier -51 when using this code)

The following parenthetical information about the code set is published in the CPT 2020 Code Book.

(Do not report 22867, 22868 in conjunction with 22532, 22533, 22534, 22558, 22612, 22614, 22630, 22632, 22633, 22634, 22800, 22802, 22804, 22840, 22841, 22842, 22869, 22870, 63005, 63012, 63017, 63030, 63035, 63042, 63044, 63047, 63048, 77003 for the same level)

(For insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, see 22869, 22870)

PHYSICIAN CODING PATHWAY			
CPT Code	CPT Description	RVUs	Medicare National Average Payment
22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level	28.28	$1,020.63
+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)	7.08	$255.52

This information is for educational/informational purposes only and should not be construed as authoritative. The information presented here is current as of December 2019 and is based upon publicly available source information. Codes and values are subject to frequent change without notice. The entity billing Medicare and/or third-party payers is solely responsible for the accuracy of the codes assigned to the services or items in the medical record. Items and services that are billed to payers must be medically necessary and supported by appropriate documentation. Surgalign does not promote the off-label use of its products. It is important to remember that while a code may exist describing certain procedures and/or technologies, it does not guarantee payment by payers.

HOSPITAL OUTPATIENT AND AMBULATORY SURGICAL CENTER CODING PATHWAYS

Below is a list of diagnosis codes and definitions that may apply to patients indicated for a coflex® procedure. This is only a list of possible codes that represent a typical diagnosis associated with the procedure and is not intended to be a complete list.

ICD-10-CM DIAGNOSIS CODE	
ICD-10-CM Code[7]	Diagnosis Description
M48.061	Spinal stenosis, lumbar region without neurogenic claudication
M48.062	Spinal stenosis, lumbar region with neurogenic claudication
M99.23	Subluxation stenosis of neural canal of lumbar region
M99.33	Osseous stenosis of neural canal of lumbar region
M99.43	Connective tissue stenosis of neural canal of lumbar region
M99.53	Intervertebral disc stenosis of neural canal of lumbar region
M99.63	Osseous and subluxation stenosis of intervertebral foramina of lumbar region
M99.73	Connective tissue and disc stenosis of intervertebral foramina of lumbar region

7. 2020 ICD-10-CMwww.cms.gov

Procedures performed in the hospital outpatient or ASC setting of care are reported to third party payers utilizing a system of CPT code, ambulatory payment classification (APC) codes and comprehensive ambulatory payment classification (C-APC) codes. Payment methodologies differ with payer guidelines including Medicare, government payers and private commercial insurers. Specific payer guidelines should be followed for each case when the physician selects codes for the documented procedure.

The following table provides the details pertaining to CPT 22867 and CPT +22868 and the assigned comprehensive APC (C-APC) that is reported for the coflex procedure in 2020. The C-APC assignment is applicable to both the OPPS and ASC setting of care.

CPT CODE	CPT DESCRIPTION	APC	APC DESCRIPTION	SI/PI	SI DESCRIPTION	MEDICARE NATIONAL AVERAGE PAYMENT APC	MEDICARE NATIONAL AVERAGE PAYMENT ASC
22867	Insertion of interlaminar/ interspinous process stabilization/ distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level	5116	Level 6 Musculo-skeletal Procedures	J1/J8	Comprehensive APC (C-APC). All covered services on the claim are packaged with the primary "J1/ J8" service.	$16,138.63	$12,262.47
+22868	Insertion of interlaminar/ interspinous process stabilization/ distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level	—	—	N/N1	Service packaged into C-APC. Includes additional level procedure.	—	—

Note that second level procedures are inclusive to the primary procedure C-APC 5116, per Medicare guidelines.

Status/Payment Indicators:
J1=Paid through Comprehensive APC
J8=Device-intensive procedure; paid at adjusted rate
N, N1 = Included in C-APC

Private commercial carriers often use this same APC system as well as reporting procedures using CPT codes and HCPCS Level II codes for line item reimbursement for devices and other supplies. While there is no consistent method with which these codes are established or reimbursed, several codes commonly used by leading national payers are provided below.

HCPCS Level II codes identify specific products and services that can be provided in a variety of settings and are utilized to report these products to third party payers for line item reimbursement. Some code sets are used only by specific payer types, while other sets are used only in certain settings. The following HCPCS codes can be used to denote the use of various fixation devices in the outpatient setting of care.

There is no Medicare value associated with these HCPCS codes. Implants, pins and screws are typically included in Medicare APC and are not reimbursed separately; however, the HCPCS code may be reported for tracking and cost purposes. Private health plans may reimburse separately for implants and devices based on individual carrier guidelines. Separate or additional payment for these items is based upon the individual contract between a commercial health plan and an individual facility.

HCPCS CODING PATHWAYS	
HCPCS[8]	HCPCS Description
C1713	Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)
C1821	Interspinous process distraction device (implantable)
C1889	Implantable/insertable device for device intensive procedure, not otherwise classified

8. 2020 HCPCS, www.cms.gov

HOSPITAL INPATIENT CODING PATHWAY OPTIONS

Medicare reimburses hospital inpatient stays based on the Medicare Severity Diagnosis Related Group (MS-DRG) system. MS-DRGs represent a consolidated prospective payment for all services provided by the hospital during the patient's hospitalization, based on submitted claims data. With limited exceptions, the MS-DRG payment is inclusive of all services, products, and resources, regardless of the final cost to the hospital. Medicare and many private payers use the MS-DRG based system to reimburse facilities for inpatient services.

Medicare establishes MS-DRG groupings depending on the procedures performed, the individual's diagnosis, and the patient's condition in order to provide a single reimbursement value for the entire inpatient stay. Certain MS-DRGs account for the possibility of complications and comorbidities present on arrival to the facility or arising during the case, which complicate the case and increase the hospital payment.

While this advice is intended to provide context for inpatient procedure coding, providers should select the procedure, diagnosis, and technology coding that best represents each patient's medical condition and treatment as documented in the medical record.

The FDA approved use of the coflex® device and procedure includes the indication of lumbar spinal stenosis. Diagnoses for any procedure are derived from the surgeon's documentation. The ICD-10-CM available diagnosis coding options for lumbar spinal stenosis are as follows:

ICD-10-CM DIAGNOSIS CODES	
ICD-10-CM Code[10]	Diagnosis Description
M48.061	Spinal stenosis, lumbar region without neurogenic claudication
M48.062	Spinal stenosis, lumbar region with neurogenic claudication
M99.23	Subluxation stenosis of neural canal of lumbar region
M99.33	Osseous stenosis of neural canal of lumbar region
M99.43	Connective tissue stenosis of neural canal of lumbar region
M99.53	Intervertebral disc stenosis of neural canal of lumbar region
M99.63	Osseous and subluxation stenosis of intervertebral foramina of lumbar region
M99.73	Connective tissue and disc stenosis of intervertebral foramina of lumbar region
Z98.1	Arthrodesis Status

10. 2020 ICD-10-CM www.cms.gov1

Hospital inpatient ICD-10-PCS procedure coding is derived from the surgeon's operational report and may include the following ICD-10-PCS procedure codes when the documentation reports a spinal decompression procedure and the insertion of a spinal device.

ICD-10-PCS INPATIENT PROCEDURE CODE	
ICD-10-PCS Code[12]	Procedure Description
0SB00ZZ	Excision of Lumbar Vertebral Joint, Open Approach
00NY0ZZ	Release Lumbar Spinal Cord, Open Approach
0SB20ZZ	Excision of Lumbar Vertebral Disc, Open Approach
0SH00BZ	Insertion of Interspinous Process Spinal Stabilization Device into Lumbar Vertebral Joint, Open Approach

Specifically for the coflex® procedure, the exact codes to assign are also based on the documentation contained in the surgeon's operational report. Typically the procedure consists of (1) decompression of spinal canal; and (2) insertion of the coflex® device. ICD-10-PCS code options include:

MS-DRG[13]	MS-DRG Description	Medicare National Average Payment
518	Back and Neck Procedures except Spinal Fusion with MCC or Disc Device/Neurostimulator	$21,350.58

ICD-10-PCS codes for the coflex® procedure and device support MS-DRG 518 beginning on October 1, 2014.

12. 2020 ICD-10-PCS www.cms.gov
13. 2020 MS-DRG relative weight multiplied by 2020 rate per IPPS Final Rule, as calculated by MCRA, payment rates will vary by facility. Calculation includes labor related, non-labor related and capital payment rates.

④ Documentation Support

Documentation of a patient's history, conservative therapies and reason for any service or procedure is the key to a positive reimbursement scenario. When a procedure is indicated by the physician, the patient's medical record should clearly state the reason for the procedure as well as the outcomes and recommended therapies to follow. This documentation will support claim review and pre-authorization alike. Follow-up or staged procedures will depend on the initial documentation to support medical necessity. The following general documentation guidelines should be followed for all payers.

Clinical notes should contain the following details:

- Reason for the procedure based on physical exam
- All conservative therapies previously used in the treatment of the current disease
- Specific reason why this treatment is indicated for this patient
- Anticipated outcomes

Recommended therapies or treatments Operational notes might include the following:

- History of patient encounters including conservative therapies
- Current diagnosis or history of disease state
- Details of findings on exam
- Reason for procedure relevant to condition
- Usual details of procedure
- Explanation of technology specific to products or devices utilized
- Findings and any anticipated further treatments

A letter of medical necessity (LMN) may be required for pre-authorization of any procedure or for supporting documentation following a request for a claim review. Details of the LMN should include the items on the checklist above. An example LMN is provided in the following section of this guide.

⑤ Pre-Authorization Overview

In order to facilitate coverage access for a proposed procedure, the physician may request a pre-authorization from the patient's private insurance carrier. Some health plans require pre-authorization for all surgical procedures. Requesting pre-authorization may only involve a simple contact by the physician's office to verify benefits and acquire an approval number to submit with the claim. Alternatively, pre-authorization may require that the physician provide more substantive information about the case.

To prepare a pre-authorization request that requires additional information beyond basic coding, the physician's staff must provide technical information about the procedure and the unique technology involved. The treating physician must also establish the medical necessity for the procedure, as it applies to the specific patient.

Typically the pre-authorization process and/or appeal process may require submitting some or all of the following documentation:

- Patient clinical notes, including documentation of prior conservative care;
- Supporting technical information in the form of the FDA approval letter, peer-reviewed clinical literature and other available technical resources;
- Description of the technology and its use in this patient's case; and
- Description of medical necessity of the procedure for the specific patient.

STAGES OF THE PRE-AUTHORIZATION PROCESS:

Initiate Pre-Authorization
Verify benefits and submit clinical information and literature on device.
Peer to Peer
Opportunity for the treating physician to discuss the medical neccessity of the case with a Medical Director at the Health Plan.
1st Level Appeal
Expeditited/Standard - Opportunity to request a Medical Director that did not review the initial submission. There may be one or two levels of internal appeals.
2nd Level Appeal
Expeditited/Standard - Opportunity to request a Medical Director that did not review the initial submission as well as the peer to peer.
External Appeal
Following appeal denial at all available internal levels, the patient should pursue an External Appeal with the applicable State Department of Insurance.

Pre-Authorization/Letter of Medical Necessity Example Letter

Providers, please note: *Coverage requirements will typically vary by payer. Therefore, facilities and physicians should seek pre-authorization for the procedure, during which time health plans will determine whether the procedure is covered as described in the pre-authorization submission. When initiating a pre-authorization request, it is important to remember that payers may require all elements of a procedure to be pre-authorized per their payer guidelines. This sample letter includes technical information regarding the FDA on-label, approved use of the coflex® Interlaminar Stabilization® device per the product instructions for use.*

This template and the information provided herein are intended to provide context for the procedure and related coding. Providers should select the procedure, diagnosis, and technology coding that best represents each patient's medical condition and treatment and should reflect the services and products that are medically necessary for the treatment of that patient. Providers must ensure that all statements made to insurance carriers are true and correct.

[SURGEON LETTERHEAD & SIGNATURE]

[DATE]

[NAME OF INSURANCE COMPANY] [ATTN:]
[FAX #: AND/OR ADDRESS]

RE: [PATIENT NAME]
[INSURANCE IDENTIFICATION NUMBER] [REFERENCE #:]
[PRIMARY CPT CODE:] [PRIMARY DX:]

Dear Utilization Manager:

On behalf of my patient, [PATIENT NAME], this letter serves as a pre-authorization request and provides clinical information on this patient's condition. It also serves as a formal request for coverage from [INSURANCE] for medically necessary health care services set forth above. This letter and its supporting documents will provide you with this patient's clinical history and need for coflex® Interlaminar Stabilization®. It is my sincere hope that this additional information will inform your decision to approve this procedure.

During your review, I ask you to consider the following key items:

1. **Positive Coverage Guidelines Published in Support of coflex® Interlaminar Stabilization® including:**
    - The North American Spine Society (NASS) has a positive coverage recommendation for Interlaminar Stabilization® published on May 2, 2018.
    - ISASS's (International Society of Spine Surgery) recent policy statement on Decompression with Interlaminar Stabilization® published on November 10, 2016.
    - Highmark Blue Cross Blue Shield's positive coverage policy for coflex® Interlaminar Stabilization® published on November 6, 2017.
    - Blue Cross Blue Shield of Michigan's published positive coverage policy for the coflex® Interlaminar Stabilization® device issued on September 1, 2017.
2. **Recently published Level 1 Study demonstrating statistical superiority of coflex®. (Schmidt 2018)**

PUBLISHED CLINICAL EVIDENCE FOR COFLEX®

To further assist you in your coverage determination, several peer-reviewed, published articles pertaining to coflex® Interlaminar Stabilization® technology are summarized below for your review.

NASS Guidelines of Lumbar Interspinous Device without Fusion & with Decompression (May 2018)

- The North American Spine Society (NASS) published coverage recommendations for "Lumbar Interspinous Device without Fusion and with Decompression." coflex® Interlaminar Stabilization® is the only device to meet the coverage criteria of the guideline.

European Study of coflex® and decompression alone (ESCADA Study) (Schmidt 2018)

- Prospective, randomized, controlled, multi-center study with 230 patients enrolled at six sites.
- There were no severe device-related complications involving device failure or device migration.
- Statistical Superiority in Time for No Lumbar Injections (p=0.0065)
- 38% Fewer Patients Taking Opioid Pain Killers at 24 Months
- Statistical Superiority for Foraminal and Disc Height Maintenance (p<0.001)
- Statistical Superiority in Walking Distance: 5 Times Improvement from Baseline (p=0.06)

Five-Year Follow-Up of IDE Study (Musacchio et al. 2016)

- Results of the Level I prospective, randomized, multi-center coflex® IDE study demonstrates the long-term sustainability, durability, and efficacy of coflex® Interlaminar Stabilization® for the treatment of lumbar spinal stenosis.
- coflex® patients presented a statistically significant improvement from pre-operative scores that were similar or superior to fusion.

Five-year follow-up study comparing coflex® stabilization following decompression and posterior lumbar interbody fusion (Yuan 2016)

- Five-year analysis comparing clinical and radiological outcomes between coflex® Interlaminar Stabilization® with posterior lumbar interbody fusion (PLIF).
- coflex® patients experienced less blood loss, shorter hospital stays and shorter operative times than PLIF patients demonstrating that coflex® is able to reduce the consumption of clinical resources, and therefore decreases the cost of treatment.
- coflex® patients had significantly better clinical outcomes during early follow-up than PLIF patients and that success continued until the final follow-up at five years.
- The authors concluded that coflex® Interlaminar Stabilization® after decompression is safe and effective to treat lumbar degenerative disease.

A systematic review and meta-analysis of decompression and coflex® Interlaminar Stabilization® compared with conventional surgical procedures for lumbar stenosis (Li 2017)

- A systematic review and meta-analysis on eight studies that compared coflex® with decompression versus decompression and fusion surgery for the treatment of lumbar spinal stenosis patients.
- coflex® demonstrated non inferiority when compared with conventional decompression plus fusion procedure in terms of functional clinical outcomes, including ODI, and VAS pain scores.
- coflex® use also revealed less blood loss, shorter length of stay and similar device-related complications than decompression plus fusion surgery.

PATIENT'S CLINICAL NEED

[PATIENT NAME] presented to me with symptoms of stenosis that include: [DESCRIBE]. [MR/MS]'s symptoms are exacerbated by: [DESCRIBE]. [INSERT PATIENT'S NAME]'s debilitating pain has limited [HIS/HER] daily functions which include: [DESCRIBE]. The neurogenic claudication as defined by leg/buttock/groin pain is alleviated by: [DESCRIBE]. Furthermore, [PATIENT'S NAME] has exhausted all forms of conservative treatments which include: [LIST].

[INSERT PATIENT'S NAME] has radiographic evidence of lumbar spinal stenosis [with Grade 1 spondylolisthesis] at [INSERT LEVEL]. The degree of stenosis is [MODERATE TO SEVERE OR SEVERE] based on the extent of back and leg pain, and pain-related disability.

A significant portion of patients who receive a well-done microsurgical decompression alone develop recurrent stenosis in the foramina as well as lateral recesses due to the presence of worsening spondylotic disease as they age. Ultimately, they will require revision surgery and may experience higher complication rates. Simple decompression undertreats high VAS Back Pain and Facet Pathology. Decompression and fusion over treats the segment and is expensive and irreversible and leads to adjacent level disease and multiple additional surgeries. The addition of coflex® Interlaminar Stabilization® device instrumentation offers the ability to improve procedural effectiveness and sustainability of the surgical decompression by providing immediate and ongoing stability.

Should you have further questions or concerns, please do not hesitate to call me at [INSERT PHYSICIAN TELEPHONE NUMBER]. Thank you for your immediate attention and anticipated authorization of these services for your insured.

Sincerely,

[PHYSICIAN NAME]
[FACILITY NAME]

PLEASE CONSIDER THE FOLLOWING REFERENCES IN SUPPORT OF COFLEX® INTERLAMINAR STABILIZATION®:

NASS Coverage Policy Recommendations. Lumbar Interspinous Device without Fusion & with Decompression: *Direct link for payers to request NASS coverage documents: https://www.spine.org/PolicyPractice/CoverageRecommendations/PayerAccess*

Schmidt, S. (2018). Prospective, randomized, multicenter study with 2-year follow-up to compare the performance of decompression with and without interlaminar stabilization. Journal Neurosurgery. Doi: 10.3171/2017.11.SPINE17643. *Available at: https://thejns.org/doi/abs/10.3171/2017.11.SPINE17643*

Musacchio, M.. (2016). Evaluation of decompression and Interlaminar Stabilization compared with decompression and fusion for the treatment of lumbar spinal stenosis: 5 year follow-up of a prospective, randomized, controlled trial. International Journal of Spine Surgery. *Available at: http://dx.doi.org/10.14444/3006*

Yuan W. (2016). Evaluation of coflex interspinous stabilization following decompression compared with decompression and posterior lumbar interbody fusion for the treatment of lumbar degenerative disease: A minimum 5-year follow-up study. Journal of Clinical Neuroscience. *Available at: http://dx.doi.org/10.1016/j.jocn.2016.09.030*

Li AM. (2017). Decompression and coflex interlaminar stabilization compared with conventional surgical procedures for lumbar spinal stenosis: A systematic review and meta-analysis. International Journal of Surgery. *Available at: https://www.ncbi.nlm.nih.gov/pubmed/28254421*

ISASS Policy Statement – Decompression with Interlaminar Stabilization *Available at: ISASS Policy Statement*

Röder, C. (2015) Superior outcomes of decompression with an interlaminar dynamic device versus decompression alone in patients with lumbar spinal stenosis and back pain: a cross registry study. European spine journal 24.10 (2015): 2228-2235. *Available at: https://www.ncbi.nlm.nih.gov/pubmed/26187621*

Kumar, N. (2014). Role of coflex as an adjunct to decompression for symptomatic lumbar spinal stenosis." Asian spine journal 8.2 (2014): 161- 169. *Available at: https://www.ncbi.nlm.nih.gov/pubmed/24761198*

BCBS Michigan – Medical Policy for Interspinous/Interlaminar Stabilization/Distraction Devices (Spacers) *Available at: BCBS MI Positive Medical Policy*

Highmark BCBS – Medical Policy for Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers) *Available at: Highmark BCBS Positive Medical Policy*

⑥ Health Plan Denial Appeal Process Overview

When a third party health plan denies a procedure in accordance with its medical policy guidelines, there is a process available to appeal that decision. Insurance carriers provide this check and balance to allow for reconsideration of the decision per its plan provisions and applicable state regulations. The process will vary depending on the plan and regulatory requirements; however, there are basic steps that can assist the provider in appealing the initial denial.

To present an effective appeal, follow these steps:

1. Carefully review the denial reason and understand the specific health plan's policy;
2. Write an appeal letter clearly addressing the specific denial reasons;
3. Provide supporting information including product details and FDA approval; and
4. Submit the appeal on time.

The following additional considerations may be helpful:

5. If the health plan is self-funded (employer based), patients can contact their Human Resources (HR) department to assist in the patient's appeal of the decision. HR departments may have contacts within the health plan that can provide helpful support.
6. The patient can contact the health plan directly and is the policy-holder with an influence on the decision.
7. There are multiple steps in the appeal process, and providers and patients may exercise these rights according to their third party payer and state guidelines.

WRITING AN APPEAL LETTER

When appealing a denial, the first step is often composing a letter to the health plan that initially reviewed the case. This letter is submitted by the provider on behalf of the patient, with the patient's approval, and should outline the reasons the denial should be overturned.

Detailed information regarding the denial reason should be prepared utilizing the case specific information in the denial, as well as the more general technology specific information and supporting clinical literature.

First, collect all the information required to support the appeal:

- Denial letter
- Health plan contracts and provider agreements
- Applicable medical policy guidelines from the health plan (website access is often a good resource for general policy)
- Literature supporting the technology
- FDA approval letter
- Safety and effectiveness documentation
- Peer-reviewed literature references (when available)

In drafting an appeal letter, consider the following:

- Did the reviewer miss information about the technology?
- Did the reviewer overlook a case specific detail?
- Does the health plan clearly understand the procedure?
- Was the information provided about the case correctly submitted?
- Review the plan's official policy online for more detailed understanding of the denial reason

Be mindful of details, including:

- Patient's name
- Subscriber's name
- Policy number
- Description of exact service denied
- Date denied

Health Plan Denial Appeal
Example Letter

Providers, please note: *Despite the filing of a pre-authorization request, certain commercial health plans may still elect not to cover or grant pre-authorization for this procedure without further information and clinical evidence supporting its use. Should pre-authorization be denied, the physician requesting coverage should immediately file a written appeal with the health plan and request reconsideration of the coverage decision. When requesting a pre-authorization appeal it is important to remember that payers may require all elements of a procedure to be pre-authorized per their payer guidelines. This sample letter includes technical information regarding the FDA on-label use of the coflex® Interlaminar Stabilization® device, per the product instructions for use. To assist you, the following example is offered as a starting point for your pre-authorization denial appeal and reconsideration request.*

[SURGEON LETTERHEAD & SIGNATURE]

[DATE]

[NAME OF INSURANCE COMPANY] [ATTN:]
[FAX #: AND/OR ADDRESS]

RE: [PATIENT NAME]
[INSURANCE IDENTIFICATION NUMBER] [REFERENCE #:]
[PRIMARY CPT CODE:] [PRIMARY DX:]

Dear Utilization Review Manager:

Please accept this letter as an appeal of [HEALTH PLAN]'s decision to deny coverage for the recommended [PROCEDURE] and the application of coflex® Interlaminar Stabilization® on behalf of [PATIENT NAME]. It is my understanding, per [HEALTH PLAN]'s denial letter dated [INSERT DENIAL LETTER DATE], that this procedure has been denied and deemed to be [REASON FOR DENIAL]. Within this letter is additional, pertinent clinical information regarding [MR/MS] from which you can form a more knowledgeable decision about the services I strongly believe are medically necessary and appropriate.

I respectfully request that [HEALTH PLAN] reconsider its denial decision and provide authorization and payment for this treatment option. [PATIENT'S NAME]'s symptoms include, [LIST SYMPTOMS]. [MR/MS] has attempted to relieve [HIS/HER] symptoms by, [LIST TREATMENT(S)]. Unfortunately, these treatment options have not alleviated the symptoms. At this time, I believe this procedure and the application of coflex® Interlaminar Stabilization® would be the best option for my patient.

During your review, I ask you to consider the following key items:

1. **Positive Coverage Guidelines Published in Support of coflex® Interlaminar Stabilization® including:**
    - The North American Spine Society (NASS) has a positive coverage recommendation for Interlaminar Stabilization® published on May 2, 2018.
    - ISASS's (International Society of Spine Surgery) recent policy statement on Decompression with Interlaminar Stabilization® published on November 10, 2016.
    - Highmark Blue Cross Blue Shield's positive coverage policy for coflex® Interlaminar Stabilization® published on November 6, 2017.
    - Blue Cross Blue Shield of Michigan's positive coverage policy for the coflex® Interlaminar Stabilization® device issued on September 1, 2017.
2. **Recently published Level 1 Study demonstrating statistical superiority of coflex®. (Schmidt 2018) Published Clinical Evidence for coflex®**

PUBLISHED CLINICAL EVIDENCE FOR COFLEX®

To further assist you in your coverage determination, several peer-reviewed, published articles pertaining to coflex® Interlaminar Stabilization® technology are summarized below for your review.

NASS Guidelines of Lumbar Interspinous Device without Fusion & with Decompression (May 2018)

The North American Spine Society published coverage recommendations for "Lumbar Interspinous Device without Fusion and with Decompression." coflex® Interlaminar Stabilization is the only device to meet the coverage criteria of the guideline.

European Study of coflex® and Decompression Alone (ESCADA Study) (Schmidt 2018)

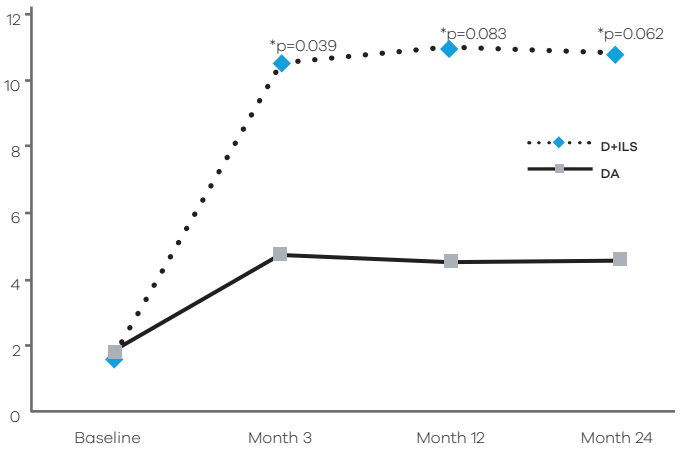
This was a Level 1, prospective, randomized, controlled, multi-center study comparing decompression with coflex® Interlaminar Stabilization® versus decompression alone with 230 patients enrolled at six sites. The coflex® group demonstrated statistical superiority in the Composite Clinical Success (p=0.017). There were no severe device-related complications involving device failure or device migration.

The coflex® group also demonstrated statistical superiority in:

- Time for No Lumbar Injections (p=0.0065)
- Statistical Superiority for Foraminal and Disc Height Maintenance (p<0.001)
- Statistical Superiority in Walking Distance: 5 Times Improvement from Baseline (p=0.06)
- 38% Fewer Patients Taking Opioid Pain Killers at 24 Months

The figure below demonstrates that foraminal height and disc height were largely maintained in patients who underwent D+ILS, whereas patients treated with DA showed a significant decrease at 24 months.

Baseline and Change in Walking over Time (min)



Five-Year Follow-Up of IDE Study (Musacchio et al. 2016)

Results of the Level I prospective, randomized, multi-center coflex® IDE study demonstrates the long-term sustainability, durability, and efficacy of coflex® Interlaminar Stabilization® for the treatment of lumbar spinal stenosis. coflex® patients presented a statistically significant improvement from pre-operative scores that were similar or superior to fusion. Five-year results for the coflex® and fusion groups are shown in the Table below and demonstrate the long-term sustainability and durability of decompression with Interlaminar Stabilization® using the coflex® device.

PRIMARY ENDPOINTS AT MONTH 60	COFLEX®	FUSION	P-VALUE
Achieved Composite Clinical Success (CCS)	50.3%	44.0%	>0.30
15+ Point Improvement in ODI	80.6%	74.5%	>0.40
Secondary Surgical Procedures	16.3%	17.8%	>0.90
Major Device-Related Complications	1.4%	4.7%	>0.10
No Lumbar Epidural Injections at Any Level in Lumbar Spine	80.5%	76.6%	>0.40

As shown above, 50.3% of coflex® patients met the success criteria for CCS endpoint, compared to 44.0% of fusion patients through Month 60. This difference was not statistically significant; however, at all time points, the CCS percentage was higher for the coflex® group.

Five-year follow-up study comparing coflex® stabilization following decompression and posterior lumbar interbody fusion (Yuan 2016)

The objective of this study was to compare at least 5-year follow-up clinical and radiological outcomes of coflex implantation following decompression versus traditional posterior lumbar interbody fusion in the treatment of lumbar spinal stenosis. The coflex® cohort had significantly better clinical outcomes during early follow-up than PLIF patients and that success continued through the final follow-up at five years. Additionally, coflex® patients experienced less blood loss, shorter hospital stays and shorter operative times than PLIF patients demonstrating that coflex® is able to reduce the consumption of clinical resources, and therefore decreases the cost of treatment. The authors concluded that coflex® Interlaminar Stabilization® after decompression is safe and effective to treat lumbar degenerative disease.

A systematic review and meta-analysis of decompression and coflex® Interlaminar Stabilization® compared with conventional surgical procedures for lumbar stenosis (Li 2017)

A meta-analysis was conducted to investigate whether decompression and coflex results in better performance for lumbar spinal stenosis patients when compared with decompression and fusion surgery. coflex® demonstrated non inferiority when compared with conventional decompression plus fusion procedure in terms of functional clinical outcomes, including ODI, and VAS pain scores. The use of coflex® also revealed less blood loss, shorter length of stay and similar device-related complications than decompression plus fusion surgery. The authors concluded that the coflex® device is safe for use in lumbar spinal stenosis.

Cross-Registry Study of coflex® vs. Decompression (Roder 2015)

This study conducted by Roder et al. examined patients in the SWISS spine registry (decompressions plus coflex®) versus patients in the Spine Tango registry (decompression only) compared with decompression controls (Spine Tango registry). Outcome measures included back and leg pain relief, COMI score improvement, patient satisfaction, complication, and revision rates. In total, 50 matched pairs without residual significant differences but age were created. At 7-9 months follow-up, the coflex® group had higher back and leg pain relief and COMI score improvement than the decompression group. No revision was documented in the coflex® group and one in the decompression group. The authors concluded that in the short-term, lumbar decompression with coflex® compared to decompression alone in patients with lumbar spinal stenosis and pronounced low back pain at baseline is a safe and effective treatment option.

Prospective Cohort Study of coflex® vs. Decompression (Kumar et al. 2014)

This prospective study evaluated 46 patients with symptomatic lumbar stenosis, 22 of whom were placed in the coflex® implantation group, while the remaining 24 were treated with decompression alone. Standard clinical outcomes were assessed pre-operatively and at six months, one year, and two years using ODI, VAS for back and leg pain, and SF-36 measures. Radiological indices such as disc height, foraminal height, and sagittal angle were also recorded.

Post-operatively, both groups showed statistically significant improvement in all clinical outcome measures at each time point as compared with baseline. Clinical improvement in the coflex® group was found to be significantly greater than in the group treated with decompression alone. Radiographic findings demonstrated increases in mean disc and foraminal heights at all three time points in the coflex® cohort, and these increases were significantly greater than the decompression alone group. They attributed these findings to the coflex® function of unloading the facet joints and stabilizing the spinal segment post decompression. A longer follow-up study is currently underway.

PATIENT'S CLINICAL NEED FOR THE COFLEX® PROCEDURE

[INSERT PATIENT'S NAME] presented to me with symptoms of stenosis that include: [DESCRIBE]. [MR/MS]'s symptoms are exacerbated by: [DESCRIBE]. [INSERT PATIENT'S NAME] debilitating pain has limited [HIS/HER] daily functions which include: [DESCRIBE]. The neurogenic claudication as defined by leg/buttock/groin pain is alleviated by: [DESCRIBE]. Furthermore, [PATIENT'S NAME] has exhausted all forms of conservative treatments which include: [LIST].

Two large Blue Cross Blue Shield Health Plans (Blue Cross Blue Shield of Michigan and Highmark Blue Cross Blue Shield) reviewed the available peer-reviewed literature and ISASS coverage guidelines and adopted a positive coverage decision for Interlaminar Stabilization®. With two, Level 1 studies, countless peer-reviewed articles, positive coverage policies from health plans and medical societies, I implore [INSERT HEALTH PLAN] to provide a favorable coverage decision for my patient.

To assist in your reconsideration of this patient's clinical need for the intended procedure, a copy of the relevant clinical notes that support the use of coflex® is enclosed to support your decision to overturn your initial denial of coverage for these services. Should you have further questions or concerns, please do not hesitate to call me at XXX-XXX-XXXX. Thank you for your immediate attention and reconsideration.

Sincerely,

[PHYSICIAN] [FACILITY]

PLEASE CONSIDER THE FOLLOWING REFERENCES IN SUPPORT OF COFLEX® INTERLAMINAR STABILIZATION®:

NASS Coverage Policy Recommendations. Lumbar Interspinous Device without Fusion & with Decompression: *Direct link for payers to request NASS coverage documents: https://www.spine.org/PolicyPractice/CoverageRecommendations/PayerAccess*

Schmidt, S. (2018). Prospective, randomized, multicenter study with 2-year follow-up to compare the performance of decompression with and without interlaminar stabilization. Journal Neurosurgery. Doi: 10.3171/2017.11.SPINE17643. *Available at: https://thejns.org/doi/abs/10.3171/2017.11.SPINE17643*

Musacchio, M.. (2016). Evaluation of decompression and Interlaminar Stabilization compared with decompression and fusion for the treatment of lumbar spinal stenosis: 5 year follow-up of a prospective, randomized, controlled trial. International Journal of Spine Surgery. *Available at: http://dx.doi.org/10.14444/3006*

Yuan W. (2016). Evaluation of coflex interspinous stabilization following decompression compared with decompression and posterior lumbar interbody fusion for the treatment of lumbar degenerative disease: A minimum 5-year follow-up study. Journal of Clinical Neuroscience. *Available at: http://dx.doi.org/10.1016/j.jocn.2016.09.030*

Li AM. (2017). Decompression and coflex interlaminar stabilization compared with conventional surgical procedures for lumbar spinal stenosis: A systematic review and meta-analysis. International Journal of Surgery. *Available at: https://www.ncbi.nlm.nih.gov/pubmed/28254421*

ISASS Policy Statement – Decompression with Interlaminar Stabilization *Available at: ISASS Policy Statement*

Röder, C. (2015) Superior outcomes of decompression with an interlaminar dynamic device versus decompression alone in patients with lumbar spinal stenosis and back pain: a cross registry study. European spine journal 24.10 (2015): 2228-2235. *Available at: https://www.ncbi.nlm.nih.gov/pubmed/26187621*

Kumar, N. (2014). Role of coflex as an adjunct to decompression for symptomatic lumbar spinal stenosis." Asian spine journal 8.2 (2014): 161- 169. *Available at: https://www.ncbi.nlm.nih.gov/pubmed/24761198*

BCBS Michigan – Medical Policy for Interspinous/Interlaminar Stabilization/Distraction Devices (Spacers) *Available at: BCBS MI Positive Medical Policy*

Highmark BCBS – Medical Policy for Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers) *Available at: Highmark BCBS Positive Medical Policy*

⑦ Resources for Technology Support

The following resources can provide support when coding and preparing a pre-authorization for coflex® procedures performed in the inpatient or outpatient settings of care.

Complete understanding of the product and procedure, FDA approval and directions for use can provide a payer with the information they need to review and approve a procedure.

These resources have been referenced in this Reimbursement Resource Guide and can be utilized when required. They can be accessed in the accompanying Reimbursement Tool Kit (sent electronically).

- FDA Product Approval Letter
- coflex® Brochures
- Instructions for Use (IFU)

The following hyperlinks can also provide information to assist providers when procedures and technologies are considered for reimbursement.

- Medicare Claims Manual
- AMA CPT Code Search Tool
- Medicare Physician Fee Schedule Look-up Tool
- AAOS Homepage
- NASS Homepage
- AANS Homepage
- National Association of Insurance Commissioners (NAIC) Homepage
- OMHA ALJ Appeal Status Information System (AASIS)

⑧ Supportive Literature Links

COFLEX® INTERLAMINAR STABILIZATION®

The following citations and links to published literature may be useful in demonstrating the safety and efficacy of decompression with coflex® Interlaminar Stabilization®.

IDE Study Comparing coflex® to Pedicle Screw Fusion

- Davis, R. J., Errico, T. J., Bae, H., & Auerbach, J. D. (2013). "Decompression and coflex® interlaminar stabilization compared with decompression and instrumented spinal fusion for spinal stenosis and low-grade degenerative spondylolisthesis: Two-year results from the prospective, randomized, multicenter, food and drug administration investigational device exemption trial." Spine, 38(18), 1529-1539. *Available at: http://www.ncbi.nlm.nih.gov/pubmed/23680830*

IDE Study Spondylolisthesis Cohort

- Davis, R., Auerbach, J. D., Bae, H., & Errico, T. J. (2013). "Can low-grade spondylolisthesis be effectively treated by either coflex® interlaminar stabilization or laminectomy and posterior spinal fusion? Two-year clinical and radiographic results from the randomized, prospective, multicenter US investigational device exemption trial: clinical article." Journal of Neurosurgery: Spine, 19(2), 174-184. *Available at: http://www.ncbi.nlm.nih.gov/pubmed/23725394*

IDE Study Four-Year Follow-Up

- Bae, H. W., Lauryssen, C., Maislin, G., Leary, S., & Musacchio Jr, M. J. (2015). "Therapeutic sustainability and durability of coflex® interlaminar stabilization after decompression for lumbar spinal stenosis: a four year assessment." International journal of spine surgery, 9. *Available at: http://www.ncbi.nlm.nih.gov/pubmed/26056630*

IDE Study Five-Year Follow-Up

- Musacchio, M., Lauryssen, C., Davis, R., Bae, H., Peloza, J., Guyer, R., Zigler, J., Ohnmeiss, DD., Leary, S. (2016). "Evaluation of decompression and Interlaminar Stabilization compared with decompression and fusion for the treatment of lumbar spinal stenosis: 5 year follow-up of a prospective, randomized, controlled trial." International Journal of Spine Surgery. *Available at: http://www.ncbi.nlm.nih.gov/pubmed/26913226*

Comparative Cost Effectiveness Study Comparing coflex® to Fusion

- Schmier, J., Halevi, M., Maislin, G., Ong, K. (2014). "Comparative cost effectiveness of coflex® interlaminar stabilization versus instrumented posterolateral lumbar fusion for the treatment of lumbar spinal stenosis and spondylolisthesis." ClinicoEconomics and Outcomes Research 2014:6 125-131. *Available at: http://dx.doi.org/10.2147/CEOR.S59194*

Comparative Study of Decompression With coflex® vs. Decompression Alone

- Kumar, N., Shah, S. M., Ng, Y. H., Pannierselvam, V. K., DasDe, S., & Shen, L. (2014). "Role of coflex® as an adjunct to decompression for symptomatic lumbar spinal stenosis." Asian spine journal, 8(2), 161-169. *Available at: http://www.ncbi.nlm.nih.gov/pubmed/24761198*

Comparative Study of Decompression with and without Interlaminar Stabilization

- Schmidt, S. (2018). Prospective, randomized, multicenter study with 2-year follow-up to compare the performance of decompression with and without interlaminar stabilization. Journal Neurosurgery. Doi: 10.3171/2017.11.SPINE17643. *Available at: https://thejns.org/doi/abs/10.3171/2017.11.SPINE17643*

NASS Coverage Policy Recommendations. Lumbar Interspinous Device without Fusion & with Decompression. ***Direct link for payers to request NASS coverage documents: https://www.spine.org/PolicyPractice/CoverageRecommendations/PayerAccess***