




Coflex® Interlaminar Stabilization 2024 Reimbursement Resource Guide

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Disclaimer: This information is for educational/informational purposes only and should not be construed as authoritative. The information presented here is current as of January 1st 2024 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. 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. Items and services that are billed to payers must be medically necessary and supported by appropriate documentation. Xtant Medical 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.

Coflex® Technology Overview

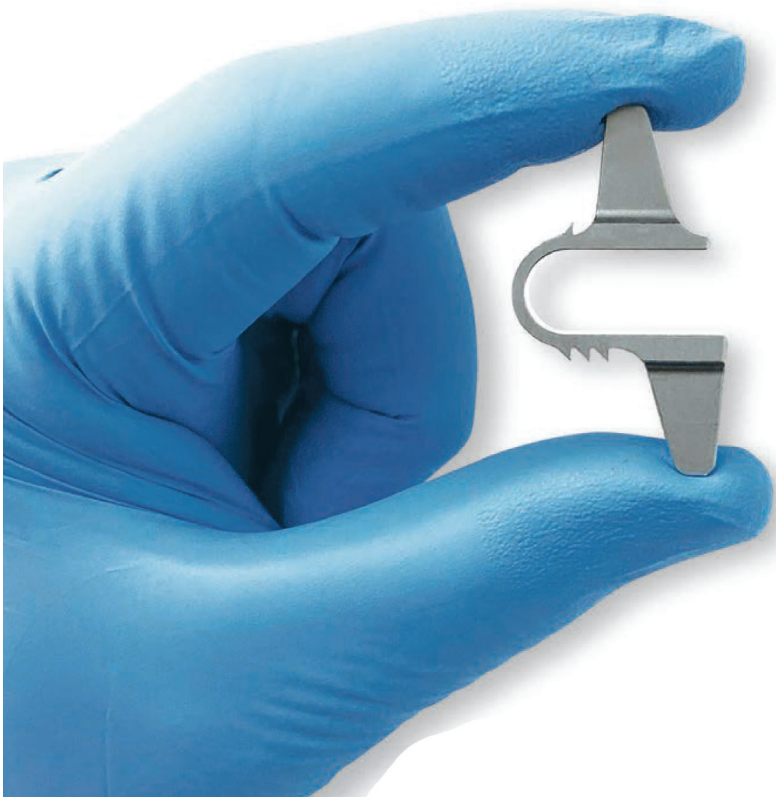
TECHNOLOGY DESCRIPTION

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. 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 Xtant Medical's Coflex technology and products are supported by this Reimbursement Resource Guide.

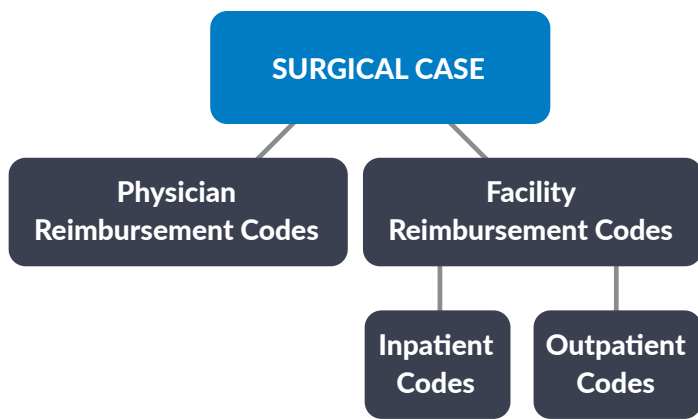
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Coding Basics

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 January 1st 2024).

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 January 1st 2024).

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.

SIMPLE 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. |
| -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. |

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/HospitalOutpaysysfctshst.pdf>. Accessed January 1st 2024

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.

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. 2024 ICD-10-CM, 2024, www.cms.gov

6. CPT 2024 Professional Edition, 2024 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 procedure (L1-L5), single level

CPT⁶ 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 | 32.470 | \$1,063.20 |
| +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) | 7.250 | \$237.40 |

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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 |

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.

| CPT Code | CPT Description | APC | APC Description | SI/PI | SI Description | Medicare National Average Payment | |
|--|--|------|-------------------------------------|-------|---|-----------------------------------|-------------|
| 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 OPSS and ASC setting of care. | | | | | | Hospital Outpatient | 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. | \$17,774.75 | \$14,082.47 |
| +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. | — | — |

7. 2024 ICD-10-CM, www.cms.gov

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 |

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It is important to remember that while a code may exist describing certain procedures and/or technologies, it does not guarantee payment by payers.

8. 2024 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. 2024 ICD-10-CM, www.cms.gov

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 Or Neurostimulator | \$25,568 |

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

The coding pathways presented here are for example only. They do not represent any actual procedures or services. Xtant Medical and its reimbursement consultants assume no responsibility for coding. Appropriate codes can only be determined by the provider at the time the actual procedure is performed and documented. This information should not be construed as authoritative. This information is for educational/informational purposes only and should not be construed as authoritative. The information presented here is current as of January 1st 2024 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. Therefore, health care providers must use great care and validate coding requirements ascribed by payers with whom they work. MCRA assumes no responsibility for coding and cannot recommend codes for specific cases. 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. Items and services that are billed to payers must be medically necessary and supported by appropriate documentation. Xtant Medical does not promote the off-label use of its devices. It is important to remember that while a code may exist describing certain procedures and/or technologies, it does not guarantee payment by payers.

12. 2024 ICD-10-PCS, www.cms.gov

13. 2024 MS DRG relative weight multiplied by 2024 rate per IPPS Final Rule, as calculated by Xtant, payment rates will vary by facility. Calculation includes labor related, non-labor related and capital payment rates.

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

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.

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

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 PREAUTHORIZATION 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 necessity of the case with a Medical Director at the Health Plan. |
| 1st Level Appeal |
| Expedited/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 |
| Expedited/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. |

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.

**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/Distracton Devices (Spacers) Available at: *BCBS MI Positive Medical Policy*

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

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), 174184. 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/>

IDE Study Five-Year Follow-Up

- Musacchio, M., Lauryssen, C., Davis, R., Bae, H., Pelozo, 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>



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