Prior Authorization Information for Coflex® Interlaminar Stabilization® with Decompression Current as of March 1, 2025



Information to Document

History & Physical Information

- Physical symptoms of pain and location (radicular symptoms inclusive of buttock/leg pain and/or back pain). If you have determined that your patient suffers from moderate to severe spinal stenosis, consider documenting the presence of neurogenic claudication.
- Degree of pain (persistent, disabling, duration of pain). Are narcotics required? Is pain modifiable with position or medication?
- Degree of functional impairment: If you have determined your patient suffers from moderate to severe functional impairment, consider documenting the impact on ADLs, presence of distance limited gait, leg weakness or numbness, inability to walk upright, and/or need for gait support. If possible, describe activities patient is no longer able to perform due to function impairment.
- Conservative treatment failure (what treatments and length of treatments)?
 Conservative treatment to include patient education, modification of activities, NSAIDS, oral or injectable steroids, braces, physical therapy or other treatments. Consider documenting start and end dates along with response, or lack of response, to the attempted conservative treatment.
- Is there a spondylolisthesis present? Consider documenting degree/Grade
 of spondylolisthesis and stability with flexion and extension films.

Imaging

(MRI, CT, X-ray) Consider documenting the presence/degree of stenosis, number of levels, and comments about the integrity of the facet joints at the index level of planned surgery.

Plan

What the physician is planning to do: Consider documenting steps and details of surgical plan inclusive of any anticipated physician concerns regarding post decompression iatrogenic instability and/or facet joint integrity. Additionally, elaborate as much as possible, on why Coflex is the best treatment option for said patient.

Helpful Hints

- You want your submission to be detailed, concise, and supported by clinical documentation
- The insurance company is likely to require only the last imaging reports, unless patient has had prior lumbar surgery
- Double check and assure documentation is complete in its entirety to prevent delay with review.
- CPT 2025 Professional Edition, 2025 American Medical Association (AMA); CPT is a trademark of the AMA.
- ICD-10-CM Diagnosis Coding System, 2025 Tables and Index, Medicare/Coding/ICD-10/2025-ICD-10-CM, www.cms.gov
- ICD-10-PCS Procedure Coding System, 2025 Tables and Index, Medicare/Coding/ICD-10/2025-ICD-10- PCS, www.cms.gov
- Medicare Severity Diagnosis Related Group (MS-DRG) Grouper and Medicare Code Editor (MCE) Version 34 ICD-10 Software, FY 2025 IPPS Final Rule, CMS-1655-F, Medicare/AcuteInpatientPPS/ FY2025-IPPS. www.cms.gov
- CMS-1656-FC Hospital Outpatient Prospective Payment Final Rule with Comment and Final CY2025 Payment Rates - Addendum C, www.cms.gov

*Note: this is not intended to be a complete listing of options and other ICD-10-PCS codes may reflect the actual lumbar decompression procedure as documented in the operational note.

It is the responsibility of the healthcare provider to determine the best treatment for each patient based on each patient's condition and diagnosis. The codes denoted within are suggestions only. This information should not be construed as authoritative. Codes and values are subject to frequent change without notice. The entity billing Medicare and/or third party payors is solely responsible for the accuracy of the codes assigned to the services and items in the medical record. Therefore healthcare providers must use great care and validate billing and coding requirements ascribed by payors with whom they work. 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. All data referenced herein are based on publicly available information.

Quick Reference

Physician CPT Codes

CPT 228671

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

CPT + 228681

Second level (list separately in addition to code for primary procedure)

ICD-10-CM2 Diagnosis Codes

M48.061

Spinal Stenosis, Lumbar Region

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

ICD-10-PCS3 Inpatient Procedure

Codes*0SB00ZZ

Excision / Lumbar Vertebral Joint, Open Approach

00NY0ZZ

Release Lumbar Spinal Cord, Open Approach

0SH00BZ

Insertion of Interspinous Process Spinal Stabilization Device into Lumbar Vertebral Joint, Open Approach

MS-DRG 5184

Back and Neck Procedures Except Spinal Fusion with MCC or Disc Device / Neurostimulator

Hospital Outpatient

C-APC 51165

Level 6 Musculoskeletal Procedures NOTE: Please Stipulate Hospital Outpatient

Ambulatory Surgical Center (ASC) Codes

CPT 22867¹ 1 or 2 Level (+CPT 22868¹)

Appeal Considerations for Coflex® Interlaminar Stabilization® with Decompression

Coverage Access Process Stages of the prior authorization process:

Initiate Prior Authorization (15-30 Days)

Verify benefits and submit clinical information and literature on device

Peer-to-Peer (1-3 Days)

Opportunity for the treating physician to discuss the medical necessity of the case with a Medical Director at the health plan

1st Level Appeal (15-30 Days)

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 (15-45 Days)

Expedited/Standard: Opportunity to request a Medical Director that did not review the initial submission as well as the peer-to-peer

External Appeal (45-60 Days)

Following appeal denial at all available internal levels, the patient may pursue an External Appeal with the applicable state Department of Insurance

Post Claim Denial Appeal (45-60 Days)

Following a claim denial the patient, provider or facility may pursue an appeal with the health plan

Helpful Information

Note the following:

- Prior authorization and appeals assistance is available to providers/patients
- Case must be initiated by the provider or provider's staff
- Contact the Patient Access Support Center at the hotline number: 1-888-813-1790
- Available Monday Friday, 8:30am-5:00pm MST
- Most commercial plans and Medicare Advantage plans require prior authorization. Coflex does not require prior authorization with Medicare
- Remember to leave sufficient time for prior authorization process and appeals
- Coordinate with facility

Why should providers consider contacting the Support Center?

Experienced professionals are available to help patients and practices through the prior authorization process and appeals

The information contained in this document has been prepared by reimbursement and coding professionals at Xtant Medical, to assist you in understanding the reimbursement process. It is not intended to increase or maximize reimbursement by any payor. We strongly suggest that you consult your payor organization with regard to local reimbursement policies. The information contained in this document is provided for information purposes only, and represents no statement, promise or guarantee by Xtant Medical concerning levels of reimbursement, payment, charge, or that third-party reimbursement will be made.

Indications: See Package Insert for a more complete listing of indications, contraindications, warnings, precautions, and other important information

Limited Warranty and Disclaimer: Xtant Medical products have a limited warranty against defects and workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are disclaimed.

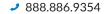
1-888-813-1790

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

Caution: USA Law restricts these devices to sale by or on the order of a physician.

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Best practices for individual case coverage:

Coverage Access Hints

- Set expectations with the patient and provider— the approval may come quickly or may require appeals.
- Fully describe the clinical justification. Consider that every reviewer is different, they may have never heard about Coflex or treatment options before. Education on Coflex and treatment options can be beneficial.
- Exhaust all appeals when possible-some cases may be approved at external review, but most patient give up before this step

Examples of common problems encountered:

- A provider seeks assistance with an off-label case or government plans.
 - The Coverage Access Support Center cannot provide assistance for these cases.
 - If the issue is discovered after initial intake, the Coverage Access Support Center must cease assistance.
- A provider seeks assistance within the seven days prior to scheduled surgery.
 - Initial prior authorization submission can take seven days or more AFTER submission.
 - The initial prior authorization answer may not even be received by the surgery date.
 - This is a common frustration for providers when the appeal process is unclear.
- A provider expects the Coverage Access Support Center to contact the office to initiate he appeal process.
- The provider office must contact the Coverage Access Support Center.
- The Coverage Access Support Center staff cannot call offices to initiate discussion under any circumstances.

For coverage access support, contact:

coflexreimbursement@xtantmedical.com

Available Monday-Friday, 8:30am-5:00pm MST

