



Overview

As the clinical proficiencies within a particular specialty advance and technology evolves, the reimbursement landscape for these services must also change to accommodate for the reporting and coverage of these new services. This Coding and Reimbursement Guide has been developed to provide guidance for reference when determining the applicable physician and facility coding for the Aurora Spine ZIP Ultra™, Zip LP™, and Zip 51™ MIS Interspinous Fusion Systems. Additionally, pre-authorization/appeals guidance and Medicare National Average reimbursement rates are also provided for reference. Please note actual reimbursement rates will vary dependent upon the negotiated provider contracts and the payer should be contacted directly to determine specific payment rates.

Indications for Use

The Aurora Spine Zip Ultra[™], LP[™], and 51[™] MIS Interspinous Fusion Systems are posterior, non-pedicle supplemental fixation devices, intended for use in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to the spinous process for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), and Lumbar Spinal Stenosis. The Aurora Spine Zip MIS Interspinous Fusion System is intended for use with bone graft material and is not intended for stand-alone use.

Zip MIS Interspinous Fusion Systems Ultra™, LP™, and 51™ Product Description

The Aurora Spine Zip Ultra[™], LP[™], and 51[™] MIS Interspinous Fusion Systems are intended to provide immobilization of spinal segments as an adjunct to fusion at a single level of the thoracic, lumbar and/or sacral spine. Unlike dynamic stabilization and interspinous process spacer devices, the Zip MIS Interspinous Fusion Systems are minimally invasive fixation devices utilized to help facilitate fusion specifically for the treatment of degenerative disc disease, spondylolisthesis, trauma and Lumbar Spinal Stenosis.

Understanding the application of the Zip MIS Interspinous Fusion Systems as an adjunct to fusion is not only important clinically it is also an important point to remember when applying the appropriate coding and medical policy coverage criteria for the procedure. The Zip MIS Interspinous Fusion Systems are not reported using the CPT® Codes for interspinous process distraction as the intent of the services reported using these codes vary significantly. While both product types are placed between the interspinous processes only the Zip MIS Interspinous Fusion Systems are placed to help facilitate fusion as an alternative to traditional posterior spinal fixation.

Spinal decompression and spinal fusion have long been the standard of care for the treatment of instability and deformity of the lumbar spine. Based on the established coding mechanisms for reporting spinal fusion procedures, the following guidelines have been developed for reference and consideration when utilizing the Zip UltraTM, LPTM, and 51^{TM} MIS Interspinous Fusion Systems.



Physician Coding Recommendation

AMA CPT® Codes are utilized by physicians to report the services they provide to their patients in all settings of care. Physicians are separately reimbursed from the facility services. The rate of reimbursement is provider specific and will be dependent upon the region, negotiated contracted rate and the payer among other things. Outlined below are the applicable codes for the fusion procedures commonly performed with the use of the Zip Ultra $^{\text{TM}}$, LP $^{\text{TM}}$, and 51^{TM} MIS Interspinous Fusion Systems. The complete procedure will include codes from the arthrodesis, instrumentation, and bone grafting sections of the physician coding recommendations.

Zip Ultra™, LP™, and 51™ MIS Interspinous Fusion Systems

Outlined below are CPT® Codes that may be applicable when utilizing Zip Ultra™, LP™, and 51™ in conjunction with the applicable arthrodesis procedure.

CPT® CODE	DESCRIPTION	ASC	MEDICARE NATIONAL AVERAGE PROFES- SIONAL FEE 2024
22612	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)	\$14,715.82 / J8	\$1,565

Bone Graft - ZIP™ Graft

ZIP™ Graft is a custom cancellous allograft designed specifically for Zip Ultra™, LP™, and 51™ MIS Interspinous Fusion Systems. Outlined below is the CPT® code for reference when reporting the application of this product.

CPT® CODE	DESCRIPTION	MEDICARE NATIONAL AVERAGE FACILITY 2024 PAYMENT
20930	Allograft, morselized, or placement of osteopromo- tive material, for spine surgery only (List separately in addition to code for primary procedure)	N/A



AMA CPT® Modifiers

The following Modifiers may be used in conjunction with the CPT® codes for reporting the use of the Zip UltraTM, LPTM, and 51TM MIS Interspinous Fusion Systems and the associated procedures. Please reference the current year AMA CPT® Coding Manual for a full listing of the available Modifiers.

MODIFIER	DESCRIPTION	
-51	Multiple Procedures	
-59	Distinct Procedural Service	
-62	Two Surgeons	

Diagnosis Codes

ICD-10-CM Diagnosis codes are used to report the patient's actual diagnosis supporting the medical necessity for providing the surgical services. Outlined below are some of the commonly reported diagnosis codes associated with the Zip UltraTM, LPTM, and 51TM MIS Interspinous Fusion Systems for reference.

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ICD-10-CM DIAG- NOSIS ^V CODE	DESCRIPTION	
D16.6	Benign neoplasm of vertebral column	
M51.34	Other intervertebral disc degeneration, thoracic region	
M51.35	Other intervertebral disc degeneration, thoracolumbar region	
M51.36	Other intervertebral disc degeneration, lumbar region	
M51.37	Other intervertebral disc degeneration, lumbasacral region	
M43.14	Spondylolisthesis, thoracic region	
M43.15	Spondylolisthesis, thoracolumbar region	
M43.16	Spondylolisthesis, lumbar region	
M43.17	Spondylolisthesis, lumbosacral region	
\$22.00-\$22.06	Fracture thoracic vertebra	
\$32.00-\$32.05	Fracture of lumbar vertebra	
\$33.10-\$33.2	Dislocation vertebra	



Facility Coding Recommendation

Medicare's Medical Severity-Diagnosis Related Group (MS-DRG) is an all-inclusive payment methodology that provides a single reimbursement that is inclusive of the services provided to the patient as well as the products and supplies utilized during the surgical service. Private and Commercial Reimbursement rates for hospital inpatient services will vary depending on their negotiated contracts. The fusion MS-DRG's outlined below reflect the larger spinal fusion procedures performed in conjunction with the use of the Zip UltraTM, LPTM, and 51TM MIS Interspinous Fusion Systems.

MS-DRG CODE	DESCRIPTION	2024 MEDICAL NATIONAL AVERAGE PAYMENT ^{vi}	
028	Spinal Procedures with MCC	\$40,317	
029	Spinal Procedures with CC or Spinal Neurostimulator	\$23,443	
030	Spinal Procedures without CC/MCC	\$16,059	
453	Combined Anterior/Posterior Spinal Fusion with MCC	\$62,797	
454	Combined Anterior/Posterior Spinal Fusion with CC	\$41,781	
455	Combined Anterior/Posterior Spinal Fusion without CC/ MCC	\$32,843	
456	Spinal Fusion Except Cervical with Spinal Curvature/Ma- lignancy/Infection or Extensive Fusions with MCC	\$57,957	
457	Spinal Fusion Except Cervical with Spinal Curvature/Ma- lignancy/Infection or Extensive Fusions with CC	\$41,409	
458	Spinal Fusion Except Cervical with Spinal Curvature/Malignancy/Infection or Extensive Fusions without CC/MCC	\$33,015	
459	Spinal Fusion Except Cervical with MCC	\$45,499	
460	Spinal Fusion Except Cervical without MCC	\$25,833	

CC=Complications and Comorbidities, MCC=Major complications and Comorbidities



Hospital Outpatient/Ambulatory Surgery Center

Most of the corresponding CPT® Codes for thoracic and lumbar fusion are considered by Medicare to be inpatient only procedures and are not reimbursable in the hospital outpatient or ambulatory surgery center settings. Outlined below are the associated Medicare National Average payment rates for those that are approved for the outpatient settings of care. Private and commercial coverage and payer reimbursement will vary widely. Please contact the payer directly for coverage and reimbursement rate information.

Spine Arthrodesis Procedures

CPT® CODE	DESCRIPTION	Medicare National Average Payment-	Status/ Payment Indicators
22556	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic	Inpatient Only Procedure	С
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	Inpatient Only Procedure	С
22610	Arthrodesis, posterior or posterolateral technique, single level; thoracic (with lateral transverse technique, when performed)	Inpatient Only Procedure	С
22612	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)	APC 5116 \$17,775 ASC-\$14,715.82	18
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar	APC 5116 - \$21,898	JI
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar	APC 5116 - \$21,898 Surgical procedures that are excluded from payment in ASCs	Jl

Bone Graft - ZIP™ Graft

CPT® CODE	DESCRIPTION	Medicare National Average Payment	Status/ Payment Indicators
20930	Allograft, morselized, or placement of osteopro- motive material, for spine surgery only (List sepa- rately in addition to code for primary procedure)	Packaged into APC payment Packaged service/item; no separate payment made in ASC	N N1

APC Status Indicator J1 Hospital Part B services paid through a comprehensive APC. T-Significant Procedure, Multiple Procedure Reduction Applies. C-Inpatients only procedure. N-Items and services Packaged into APC Rate.

ASC Status Indicator J8-Device Intensive procedure; paid at adjusted rate. N1-Packaged service/item; no separate payment made.



Insurance Pre-Authorization Process

Pre-Authorization and Medical Necessity

Most insurance companies will require pre-authorization of surgical services prior to rendering the service. The use of the Zip UltraTM, LPTM, and 51TM MIS Interspinous Fusion Systems are considered to be a surgical service and as such a pre-authorization request should be submitted to the applicable insurance company for consideration and approval. Pre-authorization requests can be submitted verbally or in writing. Both types of submission should result in a case specific pre-authorization number or written approval.

When submitting the pre-authorization request it is important to include all of the applicable CPT® codes. This should include the applicable arthrodesis, instrumentation and bone graft codes. In addition, the diagnosis code should support the medical necessity for providing the service. The payer specific medical necessity criteria should be referenced in order to avoid any denials due to not having met the published criteria. This information is most often available by referencing the payer specific medical coverage policy. For assistance with locating a policy please feel free to call the AuroraTM Spine Coding and Reimbursement Hotline at 800-390-3092.

Appeals

In the event the procedure is denied, the provider or member appeals rights may be utilized. The appeals process allows the provider and member several opportunities to appeal for coverage of the denied services. Through this process, the provider and/or member will provide the insurance company with documentation supporting their reasoning for providing the service as well as any supporting evidence. Outlined below is a summary of each step of the appeals process.

First Level Appeal - The first level appeal can be submitted by the provider or patient directly to the insurance company. Once received it is sent to an internal medical director or medical reviewer of any specialty at the insurance company for reconsideration of the denial. The reviewer will take into consideration all supporting documentation and clinical notes submitted with the request as well as any existing medical policies that may be in place for the procedure.

Second Level Appeal - The second level appeal can also be submitted by the provider or patient directly to the insurance company. The second level appeal is also sent to an internal insurance company medical director or reviewer of any specialty for reconsideration of the denial. All previously submitted documentation and clinical notes will be reviewed in addition to any newly submitted literature or notes.

Third Level Appeal/External Review - The third level appeal is an external review performed by a provider within the same or similar specialty contracted by an Independent Review Organization (IRO) not associated with the insurance company. The external review performed by the IRO provides an opportunity for an unbiased review of the previously submitted supporting documentation, clinical notes and any new documentation. The IRO reviewer is not bound by any previous determinations and has the authority to overturn the denial.

Timeline - Insurance companies can take up to thirty days or longer to review each pre-authorization or appeals request; therefore, it is important to allow for completion of the review when scheduling a potential procedure.



Interspinous Fixation - Literature References for use with Payers

- Davis RJ, Errico TJ, Bae H, Auerbach JD.. 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. 2013; 38(18), 1529-1539.
- Kaibara T, Karahalios DG, Porter RW, Kakarla UK, Reyes PM, Choi SK, Yagoobi AS, Crawford NR: Biomechanics of a Lumbar Interspinous Anchor With Transforaminal Lumbar Interbody Fixation. World Neurosurg 2010 May;73(5):572-7
- 3. Karahalios DG, Kaibara E, Porter RW, et al. Biomechanics of a lumbar interspinous anchor with anterior lumbar interbody fusion. J Neurosurg Spine. 2010; 12: 372 380.
- 4. Richter A, Schütz C, Hauck M, Halm H. Does an interspinous device (Coflex™) improve the outcome of decompressive surgery in lumbar spinal stenosis? One-year follow up of a prospective case control study of 60 patients. European Spine Journal. 2010; 19(2), 283-289.
- 5. Tatsum RL, Meek RD. Single Level Posterior Lumbar Fusion and Decompression for Degenerative Spondylolisthesis- Comparison Between Pedicle Screws and Spinous Process Fixation. Poster Presentation. National Spine Research Foundation. 2013
- 6. Vokshoor A, Esmaili A, Khurana S, Filsinger P, Wilson D. Evaluation of Radiographic Evidence of Interspinous Fusion in Various Constructs of Minimally Invasive Lumbar Surgery. 2012 Poster Presentation.
- 7. Wang JC, Haid RW, Miller JS, Robinson JC. Comparison of CD HORIZON SPIRE spinous process plate stabilization and pedicle screw fixation after anterior lumbar interbody fusion. J Neurosurg Spine. 2006;4: 132-136.
- 8. Wang JC, Spenciner, D, Robinson JC. SPIRE spinous process stabilization plate: biomechanical evaluation of a novel technology. J Neurosurg Spine. 2006;4: 160-164.
- 9. Wang JC, Haid RW Jr, Miller JS, Robinson JC: Comparison of CD HORIZON SPIRE spinous process plate stabilization and pedicle screw fixation after anterior lumbar interbody fusion. Invited submission from the Joint Section Meeting on Disorders of the Spine and Peripheral Nerves. J Neurosurg Spine 2005: 4: 132-136, 2006.

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ⁱⁱ Instructions for Use – Aurora Spine Zip™ MIS Interspinous Fusion System

iii 510K Summary K141317

¹ 2024 Medicare Physician Fee Schedule www.cms.gov

VICD-10-CM Diagnosis Code List www.cms.gov

vi ICD-10-PCS List www.cms.gov

vii 2024 IPPS Final Rule.

viii 2024 OPPS Final Rule.