

### UnitedHealthcare® Medicare Advantage Coverage Summary

## **Spine Procedures**

Policy Number: MCS089.08 Approval Date: November 8, 2023

☐ Instructions for Use

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#### **Related Medicare Advantage Policy Guidelines**

- Category III CPT Codes
- Percutaneous or Minimally Invasive Surgical Fusion of the Sacroiliac Joint

## **Coverage Guidelines**

Spine procedures may be covered when Medicare criteria are met.

**Note**: The guidelines in this Coverage Summary are for specific procedures only. For procedures not addressed in this Coverage Summary, refer to the <u>Medicare Coverage Database</u> to search for applicable coverage policies (National Coverage Determinations, Local Coverage Determinations and Local Coverage Articles).

#### **Lumbar Spinal Fusion**

Medicare does not have a National Coverage Determination (NCD) for lumbar spinal fusion. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for <u>Lumbar Spinal Fusion</u>.

For coverage guidelines for states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled Spinal Fusion and Decompression.

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**Note**: After checking the <u>Lumbar Spinal Fusion</u> table and searching the <u>Medicare Coverage Database</u>, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

When coflex-F° implant system is used as part of spinal fusion, refer to Interlaminar Lumbar Instrumented Fusion (ILIF).

#### **Cervical Spinal Fusion**

Medicare does not have a National Coverage Determination (NCD) for cervical spinal fusion. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist at this time.

For coverage guidelines, refer to the UnitedHealthcare Commercial Medical Policy title Spinal Fusion and Decompression.

**Note**: After searching the <u>Medicare Coverage Database</u>, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

For lumbar spinal fusion, refer to **Lumber Spinal Fusion** above.

# Thoracic Spinal Procedures (CPT Codes 63003, 63016, 63046, 63055 63064, 63077, 63085, 63087, 63090, and 63101)

Medicare does not have a National Coverage Determination (NCD) for thoracic spinal procedures. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist at this time.

For coverage guidelines, refer to the UnitedHealthcare Commercial Medical Policy title Spinal Fusion and Decompression.

**Note**: After searching the <u>Medicare Coverage Database</u>, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

# Allograft or Synthetic Bone Graft Materials (CPT Codes 20930, 20931, 20932, 20933, 20934, 20939, and 22899)

Medicare does not have a National Coverage Determination (NCD) for bone healing and fusion enhancement products. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist.

**For coverage guidelines**, refer to the UnitedHealthcare Commercial Medical Policy titled <u>Spinal Fusion and Bone Healing</u> <u>Enhancement Products</u>.

**Note**: After searching the <u>Medicare Coverage Database</u>, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

# Spinal Decompression and Interspinous Process Decompression Systems for the Treatment of Lumbar Spinal Stenosis [e.g., Interspinus Process Decompression (IPD)] (CPT Codes 22853, 22859 22867, 22868, 22869, and 22870)

Medicare does not have a National Coverage Determination (NCD) for spinal decompression and interspinous process decompression systems. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist at this time.

**For coverage guidelines**, refer to the UnitedHealthcare Commercial Medical Policy titled <u>Interspinous Fusion and Decompression Devices</u>.

Note: After searching the Medicare Coverage Database, if no LCD/LCA is found, then use the above referenced policy.

#### Examples of IPD devices include but are not limited to:

X STOP® Interspinous Process Decompression System (CPT codes 22869 and 22870)
 The X-STOP is a titanium implant that fits between the spinous processes yard of the lower (lumbar) spine. It is made from titanium alloy and consists of two components: a spacer assembly and a wing assembly. FDA Information for X STOP®

Interspinous Process Decompression System; available at <a href="https://www.accessdata.fda.gov/cdrh">https://www.accessdata.fda.gov/cdrh</a> docs/pdf4/P040001b.pdf.

Coflex<sup>®</sup> Interlaminar Technology (CPT codes 22867 and 22868)

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). FDA Information for coflex® Interlaminar Technology; available at <a href="https://www.accessdata.fda.gov/cdrh.docs/pdf11/P110008b.pdf">https://www.accessdata.fda.gov/cdrh.docs/pdf11/P110008b.pdf</a>.

Vertiflex<sup>™</sup> Indirect Decompression System (CPT codes 22869 and 22870)

The Vertiflex™ (Superion®) device is a one-piece implant that requires no assembly in situ. It consists of an implant body, within which resides the actuation mechanism, and two Cam Lobes, or "wings" which – when deployed – rotate away from the axis of the implant body to encompass the lateral aspects of the superior and inferior spinous processes. FDA information for Vertiflex™ (Superion®) available at <a href="https://www.accessdata.fda.gov/cdrh\_docs/pdf14/P140004b.pdf">https://www.accessdata.fda.gov/cdrh\_docs/pdf14/P140004b.pdf</a>. (Accessed September 25, 2023)

Interlaminar Lumbar Instrumented Fusion (ILIF) Utilizing an interspinous Process Fusion Device (e.g., coflex-F° Implant System) (CPT Code 22899)

Medicare does not have a National Coverage Determination (NCD) for interlaminar lumbar instrumented fusion (ILIF), e.g., Coflex-F° implant system. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist at this time.

**For coverage guidelines**, refer to the UnitedHealthcare Commercial Medical Policy titled <u>Interspinous Fusion and</u> Decompression Devices.

**Note**: After searching the <u>Medicare Coverage Database</u>, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

#### Note: Coflex-F° Implant System (CPT Code 22899)

A spinous process fixation device that stabilizes the spinous processes and spine to act as an adjunct to fusion. It consists of a single, U-shaped component, fabricated from medical grade titanium alloy (Ti6Al4V). A set of two wings extends vertically from the superior long arm of the device, with a second set of wings extending below the inferior long arm. A screw and sleeve are inserted through a prepared hole and fixes the crimped wings to the superior and inferior spinous processes. FDA information for coflex-F° implant system; available at <a href="https://www.accessdata.fda.gov/cdrh\_docs/pdf11/K112595.pdf">https://www.accessdata.fda.gov/cdrh\_docs/pdf11/K112595.pdf</a>. (Accessed September 25, 2023)

#### Intra-facet Implants (CPT Codes 0219T, 0220T, 0221T, and 0222T)

Medicare does not have a National Coverage Determination (NCD) for intra-facet implants. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) **exist for all states/territories** and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for <u>Intra-facet Implants</u>.

#### Percutaneous Image-Guided Lumbar Decompression (PILD)

PILD is a posterior decompression of the lumbar spine performed under indirect image guidance without any direct visualization of the surgical area. This is a procedure proposed as a treatment for symptomatic lumbar spinal stenosis (LSS) unresponsive to conservative therapy. This procedure is generally described as a non-invasive procedure using specially designed instruments to percutaneously remove a portion of the lamina and debulk the ligamentum flavum. The procedure is performed under x-ray guidance (e.g., fluoroscopic, CT) with the assistance of contrast media to identify and monitor the compressed area via epidurogram.

#### **Covered Indications**

I. Effective for services performed on or after January 9, 2014, the Centers for Medicare and Medicaid Services (CMS) has determined that PILD will be covered by Medicare when provided in a clinical study under section 1862(a)(1)(E) through

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- coverage with evidence development (CED) for beneficiaries with LSS who are enrolled in an approved clinical study that meets the criteria outlined in the NCD.
- II. Effective for services performed on or after December 7, 2016, CMS will cover through a prospective, longitudinal study PILD procedures using an FDA-approved/cleared device that completed a CMS-approved randomized control trial (RCT) that met the criteria that are listed in section I.

#### Non-Covered Indications

Effective for services performed on or after January 9, 2014, CMS has determined that PILD for LSS may only be covered under the context of a clinical trial as described in the above section according to section 1862(a)(1)(E) of the Social Security Act. CMS has determined that PILD for LSS is not reasonable and necessary under section 1862(a)(1)(A) of the Act.

#### Refer to the:

- NCD for Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis (150.13).
- Medicare Managed Care Manual, Chapter 4, Section 10.7.3 Payment for Clinical Studies Approved Under Coverage with Evidence Development (CED).
- The list of Medicare approved clinical trials is available at <a href="http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/PILD.html">http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/PILD.html</a>.

(Accessed September 25, 2023)

# Percutaneous Vertebroplasty and Percutaneous Vertebral Augmentation (also known as Balloon-Assisted Percutaneous Vertebroplasty, Kyphoplasty) (CPT Codes 22510, 22511, 22512, 22513, 22514, and 22515)

Medicare does not have a National Coverage Determination (NCD) for percutaneous vertebroplasty and percutaneous vertebral augmentation. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) **exist** and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for <u>Percutaneous Vertebroplasty and Percutaneous Vertebral Augmentation</u>.

For coverage guidelines for states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Medical Policy titled Percutaneous Vertebroplasty and Kyphoplasty.

**Note**: After checking the <u>Percutaneous Vertebroplasty and Percutaneous Vertebral Augmentation</u> table and searching the <u>Medicare Coverage Database</u>, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

#### Percutaneous Sacral Augmentation (Sacroplasty) (CPT Codes 0200T and 0201T)

Medicare does not have a National Coverage Determination (NCD) for sacroplasty. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist.

**For coverage guidelines**, refer to the UnitedHealthcare Commercial Medical Policy titled <u>Minimally Invasive Spine Surgery Procedures</u>.

**Note**: After searching the <u>Medicare Coverage Database</u>, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

#### Stereotactic Computer Assisted Volumetric and/or Navigational Procedure

Refer to the Coverage Summary titled Radiation and Oncologic Procedures.

# Percutaneous Minimally Invasive Fusion/Stabilization of the Sacroiliac Joint for the Treatment of Back Pain (CPT Codes 0775T, 27279, and 27280)

Medicare does not have a National Coverage Determination (NCD) for percutaneous minimally invasive fusion/stabilization of the sacroiliac joint for the treatment of back pain. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for <a href="Percutaneous Minimally Invasive Fusion/Stabilization">Percutaneous Minimally Invasive Fusion/Stabilization of the Sacroiliac Joint for the Treatment of Back Pain</a>.

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For coverage guidelines for states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled Sacroiliac Joint Interventions.

**Note**: After checking the <u>Percutaneous Minimally Invasive Fusion/Stabilization of the Sacroiliac Joint for the Treatment of Back Pain</u> table and searching the <u>Medicare Coverage Database</u>, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

#### **Lumbar Artificial Disc**

#### For Members Over 60 Years of Age

Lumbar artificial disc replacement (LADR) for the members over 60 years of age is not covered. Refer to the NCD for Lumbar Artificial Disc Replacement (LADR) (150.10). (Accessed September 26, 2023)

#### For Members Age 60 and Younger (CPT Codes 22857, 22860, 22862, and 0165T)

Medicare does not have a National Coverage Determination (NCD) for members 60 years of age and younger; coverage determination is to be made by the local contractor. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for <u>Lumbar Artificial Disc</u>.

For **coverage guidelines**, refer to the UnitedHealthcare Commercial Medical Policy titled <u>Total Artificial Disc Replacement for</u> the Spine.

**Note**: After checking the <u>Lumbar Artificial Disc</u> table and searching the <u>Medicare Coverage Database</u>, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

#### Cervical Artificial Disc (CPT Codes 22856, 22858, 22861, and 0098T)

Medicare does not have a National Coverage Determination (NCD) for cervical artificial disc replacement. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCD/LCA, refer to the table for <u>Cervical Artificial Disc</u>.

For **coverage guidelines**, refer to the UnitedHealthcare Commercial Medical Policy titled <u>Total Artificial Disc Replacement for</u> the Spine.

**Note**: After checking the <u>Cervical Artificial Disc</u> table and searching the <u>Medicare Coverage Database</u>, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

## **Supporting Information**

	Intra-facet Implants Accessed September 25, 2023			
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
L38773 (A58364)	Facet Joint Interventions for Pain Management	Part A and B MAC	CGS Administrators, LLC	KY, OH
L33930 (A57787)	Facet Joint Interventions for Pain Management	Part A and B MAC	First Coast Service Options, Inc.	FL, PR, VI
L35936 (A57826)	Facet Joint Interventions for Pain Management	Part A and B MAC	National Government Services, Inc	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
L38801 (A58403)	Facet Joint Interventions for Pain Management	Part A and B MAC	Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY

	Intra-facet Implants Accessed September 25, 2023			
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
L38803 (A58405)	Facet Joint Interventions for Pain Management	Part A and B MAC	Noridian Healthcare Solutions, LLC	AS, CA, GU, HI, MP, NV
L34892 (A56670)	Facet Joint Interventions for Pain Management	Part A and B MAC	Novitas Solutions, Inc.	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
L38765 (A58350)	Facet Joint Interventions for Pain Management	Part A and B MAC	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV
L38841 (A58477)	Facet Joint Interventions for Pain Management	Part B MAC	Wisconsin Physicians Service Insurance Corporation	IA, IN, KS, MI, MO, NE
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	Percutaneous Vertebroplasty and Percutaneous Vertebral Augmentation (Also Known as Balloon-Assisted Percutaneous Vertebroplasty, Kyphoplasty)				
	Accessed September 25, 2023				
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories	
L38201 (A57282)	Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture	Part A and B MAC	CGS Administrators, LLC	KY, OH	
L34976 (A55960)	Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF)	Part A and B MAC	First Coast Service Options, Inc.	FL, PR, VI	
L33569 (A56178)	Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)	Part A and B MAC	National Government Services, Inc	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	
L34106 (A57695)	Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)	Part A and B MAC	Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	
L34228 (A57694)	Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)	Part A and B MAC	Noridian Healthcare Solutions, LLC	AS, CA, GU, HI, MP, NV	
L35130 (A57752)	Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF)	Part A and B MAC	Novitas Solutions, Inc.	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX	
L38213 (A57630)	Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF)	Part B MAC	Wisconsin Physicians Service Insurance Corporation	IA, IN, KS, MI, MO, NE	

# Percutaneous Vertebroplasty and Percutaneous Vertebral Augmentation (Also Known as Balloon-Assisted Percutaneous Vertebroplasty, Kyphoplasty)

Accessed September 25, 2023

LCD/LCA ID	LCD/LCA Title	<b>Contractor Type</b>	Contractor Name	Applicable States/Territories
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	Lumbar Spinal Fusion Accessed September 25, 2023			
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
L33382 (A57654)	Lumbar Spinal Fusion for Instability and Degenerative Disc Conditions	Part A and B MAC	First Coast Service Options, Inc.	FL, PR, VI
L37848 (A56396)	Lumbar Spinal Fusion	Part A and B MAC	Palmetto GBA	AL, GA, SC, TN, VA, WV, NC
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Percuta	Percutaneous Minimally Invasive Fusion/Stabilization of the Sacroiliac Joint for the Treatment of Back Pain  Accessed September 25, 2023			
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
L36494 (A56535)	Minimally-Invasive Surgical (MIS) Fusion of the Sacroiliac (SI) Joint	Part A and B MAC	CGS Administrators, LLC	KY, OH
L36406 (A57431)	Minimally-invasive Surgical (MIS) Fusion of the Sacroiliac (SI) Joint	Part A and B MAC	National Government Services, Inc.	IL, MN, WI, CT, NY, ME, MA, NH, RI, VT
L39025 (A58739)	Minimally Invasive Surgical (MIS) Fusion of the Sacroiliac Joint (SIJ)	Part A and B MAC	Palmetto GBA	AL, GA, SC, TN, VA, WV, NC
L36000 (A57596)	Percutaneous minimally invasive fusion/stabilization of the sacroiliac joint for the treatment of back pain	Part B MAC	Wisconsin Physicians Service Insurance Corp.	IA, IN, KS, MI, MO, NE
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		Lumbar Artifici Accessed September		
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
L37826 (A56390)	<u>Lumbar Artificial Disc</u> <u>Replacement</u>	Part A and B MAC	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV
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	Cervical Artificial Disc  Accessed September 25, 2023			
LCD/LCA ID LCD/LCA Title Contractor Type Contractor Name				
L38033 (A57021)	Cervical Disc Replacement	A and B MAC	Palmetto GBA	States/Territories AL, GA, NC, SC, TN, VA, WV
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## **Policy History/Revision Information**

Date	Summary of Changes
11/08/2023	Coverage Guidelines  Thoracic Spinal Procedures (CPT Codes 63003, 63016, 63046, 63055 63064, 63077, 63085, 63087, 63090, and 63101) (new to policy)  Added language to indicate:  Medicare does not have a National Coverage Determination (NCD) for thoracic spinal procedures  Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist at this time  Tor coverage guidelines, refer to the UnitedHealthcare Commercial Medical Policy titled Spinal Fusion and Decompression
	<ul><li>Supporting Information</li><li>Archived previous policy version MCS089.07</li></ul>

### **Instructions for Use**

This information is being distributed to you for personal reference. The information belongs to UnitedHealthcare and unauthorized copying, use, and distribution are prohibited. This information is intended to serve only as a general reference resource and is not intended to address every aspect of a clinical situation. Physicians and patients should not rely on this information in making health care decisions. Physicians and patients must exercise their independent clinical discretion and judgment in determining care. Each benefit plan contains its own specific provisions for coverage, limitations, and exclusions as stated in the Member's Evidence of Coverage (EOC)/Summary of Benefits (SB). If there is a discrepancy between this policy and the member's EOC/SB, the member's EOC/SB provision will govern. The information contained in this document is believed to be current as of the date noted.

The benefit information in this Coverage Summary is based on existing national coverage policy; however, Local Coverage Determinations (LCDs) may exist and compliance with these policies are required where applicable.

UnitedHealthcare follows Medicare coverage guidelines found in statutes, regulations, NCDs, and LCDs to determine coverage. The clinical coverage criteria governing the items or services in this coverage summary have not been fully established in applicable Medicare guidelines because there is an absence of any applicable Medicare statutes, regulations, NCDs, or LCDs setting forth coverage criteria and/or the applicable NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD. As a result, UnitedHealthcare applies internal coverage criteria in the UnitedHealthcare commercial policies referenced in this coverage summary. The coverage criteria in these commercial policies was developed through an evaluation of the current relevant clinical evidence in acceptable clinical literature and/or widely used treatment guidelines. UnitedHealthcare evaluated the evidence to determine whether it was of sufficient quality to support a finding that the items or services discussed in the policy might, under certain circumstances, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

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