Medicare Medical Policy

Sacroiliac Joint Fusion or Stabilization

Effective Date: 3/1/2025

MEDICARE MEDICAL POLICY NUMBER: 379

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INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as "Company" and collectively as "Companies").

PRODUCT AND BENEFIT APPLICATION



MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
As of 2/16/2025	Local Coverage Determination (LCD): Minimally Invasive Arthrodesis of
4/17/2025: Minimally	the Sacroiliac Joint (SIJ) (<u>L39812</u>)
Invasive Arthrodesis of	
the Sacroiliac Joint (SIJ)	
(CPT codes 27278, 27279)	

Medicare Coverage Criteria: "MA organizations may create publicly accessible internal coverage criteria... when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs." (§ 422.101(b)(6) – see Policy Guidelines below)

- **Medicare Coverage Manuals:** Medicare does not have criteria for open or percutaneous minimally invasive fusion/stabilization of the sacroiliac joint (SIJ) in a coverage manual.
- National Coverage Determination (NCD): Medicare does not have an NCD for open or percutaneous minimally invasive fusion/stabilization of the SIJ.
- Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA): As of the
 most recent policy review, no Medicare Administrative Contractors (MACs) have LCDs for
 open sacroiliac joint fusion.
- Therefore, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance, Company criteria below are applied for medical necessity decisionmaking.

Open Arthrodesis of SIJ
(Code 27280)

I. These services may be considered medically necessary for Medicare when the Company medical policy criteria are met.

4/17/2025) Percutaneous or Minimally Invasive SIJ Fusion (27278, 27279)

Company medical policy for Sacroiliac Joint Fusion or Stabilization

I. These services may be considered medically necessary for Medicare when the Company medical policy criteria are not met.

See Policy Guidelines below.

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization

determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. (Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)

POLICY CROSS REFERENCES

None

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

In order to review for medical necessity, the following documentation **must** be provided. If any of these items are not submitted, the review may be delayed and the decision outcome could be affected:

- Indication for the requested surgery
- Clinical notes documenting that the individual has been evaluated at least once by the requesting surgeon before submitting a request for surgery.
- Medical records must document that a detailed examination has been performed by, or reviewed by the operating surgeon, within 3 months prior to surgery.
- Clinical documentation of extent and response to conservative care (see <u>Company medical policy</u> for all requirements), as applicable to the policy criteria, including outcomes of any procedural interventions, medication use and physical therapy notes.
- Evaluation and documentation of the extent and specifics of one or more of the functional impairments or disabilities.
- Evaluation and appropriate management of associated cognitive, behavioral or addiction issues
 if and when present.
- Copy of radiologist's report(s) for diagnostic imaging (MRIs, CTs, etc.) completed within the past 12 months or at the time of onset of symptoms
 - o Imaging must be performed and read by an independent radiologist
 - If discrepancies should arise in the interpretation of the imaging, the radiologist report will supersede

MEDICARE AND MEDICAL NECESSITY

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, the member's unique personal medical history (e.g., diagnoses, conditions, functional status, co-morbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. (§ 422.101(c)(1))

"MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage

criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question." (§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5)

The Plan's Medicare policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development.

Since there are not fully established Medicare coverage criteria for **open** arthrodesis of the SIJ available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria will be applied.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

There are several devices that have been approved by the U.S. Federal Drug & Administration (FDA) for sacroiliac joint fixation under the 510(k) premarket approval process, whose approval, safety, and effectiveness are all based off predicate devices. The FDA 510(k) approvals do not indicate the appropriate type of surgical technique (open or minimally invasive/percutaneous) which should be used in conjunction with each device. Therefore, indications for use, as outlined in the table below, are based on the device manufacturer website, including manufacturer reported billing for procedure (if available). The list below is not all-inclusive.

Product code: OUR

Table 1. Examples of FDA-Approved Sacroiliac Joint Fusion/Stabilization Implants

Device & Manufacturer (CPT)	Indications for Use	Contraindications for Use	Implant Type & Surgical Technique
iFuse Implant System® (SI-Bone)¹ 27279	Intended for sacroiliac joint fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac	Deformities or anatomic variations that prevent or	Titanium triangular rod, transfixing device

	joint disruptions and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.	 interfere with iFuse placement. Tumor of sacral or ilial bone. Active infection at treatment site. Unstable fracture of sacrum and or ilium involving the sacroiliac joint. Allergy to metal components. 	
iFuse Bedrock Granite® Implant System (SI-Bone) ²	 Intended for sacroiliac joint fusion for the following conditions: Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months. To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion. Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint 	Not reported on FDA or manufacturer website.	
SImmetry® SIJ Fusion System (Zyga Technology Inc.)³	Intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.	Not reported on FDA or manufacturer website.	Cannulated screw, transfixing device
Silex™ SIJ Fusion System (X-Spine System Inc./Xtant Medical)⁴ Open technique (27280) or Minimally invasive technique (27279)	Intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.	Not reported on FDA or manufacturer website.	Cannulated screw, transfixing device

SILO TFX MIS Sacroiliac Joint Fixation System (Aurora Spine) Minimally invasive technique: 27279	Intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. Intended for sacroiliac joint	Not reported on FDA or manufacturer website.	Cannulated screw, transfixing device
Entasis [™] Dual- Lead SI Implant (Corelink Inc.) ⁵	fusion for conditions including degenerative sacroilitis and sacroiliac joint disruptions.	Not reported on FDA or manufacturer website.	Cannulated screw, transfixing device
SIMPACT® Sacroiliac Joint Compression Screw System (Life Spine Inc.)6	Intended for sacroiliac fusion for the following conditions: • Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months. • To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion. • Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.	Not reported on FDA or manufacturer website.	Cannulated screw, transfixing device
Sicage System (Sicage LLC) ⁷	Intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.	Not reported on FDA or manufacturer website.	Cannulated screw, transfixing device
RIALTO™ SI Fusion System (Medtronic Sofamor Danek) ⁸ CPT 27279	Intended for Sacroiliac Joint fusion for conditions including Sacroiliac Joint disruptions and degenerative sacroiliitis.	 Deformities. Tumor resection. Infection local to the operative site and/or signs of local inflammation. Suspected or documented allergy or intolerance to the component materials. 	Cannulated screw, transfixing device

Siconus [™] Si Joint Fixation System (Camber Spine Technologies) ⁹	Intended to provide fixation and stabilization of large bones, including the sacrum and ilium. It is intended for use in skeletally mature patients as an adjunct to sacroiliac joint fusion in the treatment of degenerative sacroiliitis, or sacroiliac joint disruptions.	Not reported on FDA or manufacturer website.	Cannulated screw, transfixing device
Firebird SI Fusion System (Orthofix Inc.) ¹⁰	Intended for fixation of sacroiliac joint disruptions, and intended for sacroiliac joint fusion for conditions including; • sacroiliac joint disruptions, • degenerative sacroiliitis, • to augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion and • Acute, non-acute, and nontraumatic fractures involving the sacroiliac joint	 Open wounds, infection, presence of tumor, pregnancy, osteoporosis, certain metabolic disorders affecting osteogenesis, certain inflammatory / neuromuscular conditions, and certain neuromuscular deficits which would place an unusually heavy load on the device during the healing period. The implant is made from Ti-6Al-4V ELI (medical-grade titanium alloy). The fixation implant is contraindicated in any individual with a known or suspected allergy, sensitivity or intolerance to metal. 	Cannulated screw, transfixing device

BILLING GUIDELINES AND CODING

GENERAL

See associated local coverage articles (LCAs) for related billing and coding guidance, as well as additional coverage and non-coverage scenarios and frequency utilization allowances and limitations:

LCA: Billing and Coding: Minimally Invasive Arthrodesis of the Sacroiliac Joint (SIJ) (A59697)

According to CPT guidelines:

- For percutaneous arthrodesis of the sacroiliac joint with transfixation device, use 27279.
- For percutaneous arthrodesis of the sacroiliac joint by intra-articular implant(s), use 27278.
 Code 27278 describes the percutaneous placement of an intra-articular stabilization device into the sacroiliac joint using a minimally invasive technique that does not transfix the sacroiliac joint. Note that this service is considered not medically necessary by Medicare according to LCD L39812 and LCA A59697.

CODES*		
СРТ	22899	Unlisted procedure, spine
	27278	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, including placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s]), without placement of transfixation device
	27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device
	27280	Arthrodesis, sacroiliac joint, open, includes obtaining bone graft, including instrumentation, when performed
	27299	Unlisted procedure, pelvis or hip joint
HCPCS	C1737	Joint fusion and fixation device(s), sacroiliac and pelvis, including all system components (implantable)

*Coding Notes:

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does <u>not</u> make a procedure medically reasonable or necessary or a covered benefit by Medicare. (Medicare Claims Processing Manual, Chapter 23 Fee Schedule Administration and Coding Requirements, §30 Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be denied as not covered. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, prior authorization is recommended.
- See the non-covered and prior authorization lists on the Company <u>Medical Policy, Reimbursement Policy, Pharmacy</u> Policy and Provider Information website for additional information.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling
 edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and
 Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website
 for coding guidelines and applicable code combinations.

REFERENCES

 U.S. Food & Drug Administration (FDA). 510(k) Premarket Notification - iFuse Implant System® - iFuse-3D implant (K162733). 3/10/2017. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K162733. Accessed 1/20/2025.

- 2. U.S. Food & Drug Administration. 510(k) Premarket Notification. iFuse Bedrock Granite® Implant System. Decision date, 12/22/2022. https://www.accessdata.fda.gov/cdrh_docs/pdf22/K222774.pdf. Accessed 1/20/2025.
- U.S. Food & Drug Administration. 510(k) Premarket Notification. K151818. SImmetry® Sacroiliac Joint Fusion System. (Zyga Technology, Inc.). Approved 08/05/2015. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K151818. Accessed 1/20/2025.
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- U.S. Food & Drug Administration. 510(k) Premarket Notification. SIMPACT Sacroiliac Joint Fixation System. Approved 12/15/2021. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K212903. Accessed 1/20/2025.
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- 9. U.S. Food & Drug Administration. 510(k) Premarket Notification. K162121. Siconus™ SI Joint Fixation System. (Camber Spine Technologies). Approved 01/18/2017. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K162121. Accessed 1/20/2025.
- U.S. Food & Drug Administration. 510(k) Premarket Notification. Firebird SI Fusion System. Decision date, 11/18/2020. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K203138. Accessed 1/20/2025.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
5/2023	New Medicare Advantage medical policy
7/2023	Q3 2023 code updates
1/2024	Q1 2024 code updates
3/2024	Annual review, no change to criteria, update title
1/2025	Q1 2025 code updates
2/2025	Interim update, add new LCD for minimally invasive arthrodesis of the SIJ (Noridian changed the effective date from 2/16/2025 to 4/17/2025)
3/2025	Annual review, no change to criteria