Medicare Medical Policy

Back: Sacroiliac Joint Fusion or Stabilization

MEDICARE MEDICAL POLICY NUMBER: 379

Effective Date: 7/1/2023

Last Review Date: 5/2023

Next Annual Review: 2/2024

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, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

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
Open, Percutaneous or Minimally Invasive Sacroiliac Joint Fusion	Company medical policy for Back: Sacroiliac Joint Fusion or Stabilization I. These services may be considered **medically necessary** for Medicare when the Company medical policy criteria are met. II. These services are considered **not 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 Company medical policy 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
    - 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)*.

The Company 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. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.) which addresses the medical necessity of a given medical service, Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. *(Medicare Managed Care Manual, Ch. 4, §90.5)*

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	Indications for Use	Contraindications for Use	Marketed Surgical Technique (CPT stated by Manufacturer)
iFuse Implant System® (SI-Bone)	Intended for sacroiliac joint fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac 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.	• Deformities or anatomic variations that prevent or 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.	Minimally invasive technique only (27279)
SImmetry® SIJ Fusion System (Zyga Technology Inc.)	Intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.	Not reported on FDA or manufacturer website.	Minimally invasive technique only (27279)
Silex™ SIJ Fusion System (X-Spine System Inc./Xtant Medical)	Intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.	Not reported on FDA or manufacturer website.	Open technique (27280) **or** Minimally invasive technique (27279)
Entasis™ Dual-Lead SI Implant (Corelink Inc.)	Intended for sacroiliac joint fusion for conditions including degenerative sacroiliitis and sacroiliac joint disruptions.	Not reported on FDA or manufacturer website.	Not reported on manufacture website.
SIMPACT® Sacroiliac Joint Compression Screw System (Life Spine Inc.)	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	Not reported on FDA or manufacturer website.	Not reported on manufacture website.

	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.		
Sicage System (Sicage LLC)	Intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.	Not reported on FDA or manufacturer website.	Not reported on manufacture website.
RIALTO™ SI Fusion System (Medtronic Sofamor Danek)	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.	Minimally invasive technique only (27279)
Siconus™ Si Joint Fixation System (Camber Spine Technologies)	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.	Not reported on manufacture website.
Firebird SI Fusion System (Orthofix Inc.)	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	• Open wounds, infection, presence of tumor, pregnancy, osteoporosis, certain metabolic disorders affecting osteogenesis, certain inflammatory /	Not reported on manufacture website.

	sacropelvic fixation as part of a lumbar or thoracolumbar fusion and Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint	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.	

BILLING GUIDELINES AND CODING

GENERAL

iFuse Implant System's coding guide, the correct codes to report for the iFuse implant system is 27279 or 27280.[1]

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 0775T.
- For percutaneous arthrodesis of the sacroiliac joint using **both a transfixation device and intra-articular implant(s)**, use 0809T as of July 1, 2023 (*prior to* July 1, 2023, CPT instructed providers to use 27299).

CODES*		
CPT	0775T	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, includes placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s])
	0809T	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, placement of transfixing device(s) and intraarticular implant(s), including allograft or synthetic device(s)
	22899	Unlisted procedure, spine

	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	None	

***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 **not** 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 Medical Policy, Reimbursement Policy, Pharmacy 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

1. CODING GUIDE – iFuse Implant System®. 2022. https://assets.si-bone.com/doc/2022-Deformity-Long-Construct-Coding-Guide_10443-122021.pdf. Accessed 1/4/2023

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
5/2023	New Medicare Advantage medical policy
7/2023	Q3 2023 Code Updates