Sacroiliac Joint Fusion

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

The sacroiliac (SI) joint is a strong weight bearing joint with a self-locking mechanism that provides stability with movement on the left and right side of the sacrum. Similar to other structures in the spine, it is assumed that the SI joint may be a source of low back pain but there are currently no reference standards for diagnosis. If conservative therapies fail to adequately treat symptoms, SI joint fusion may be used to stabilize the SI joint including open, percutaneous, and minimally invasive techniques.

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*	None

National Coverage Determinations (NCDs)*	None
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*	None It has since been retired, but Noridian (the Medicare Administrative Contractor [MAC] for the health plan's service area) noted within the LCA A54302 that they " removed this service from the Non-covered services LCD, but is concerned that this procedure has limited usefulness and may develop an LCD…"[1] While they do have an LCA providing *documentation* requirements for spinal fusion services published, it does not provide specific *coverage* requirements[2] and to date, Noridian continues to not have an applicable LCD or LCA for sacroiliac joint fusion with specific criteria published. Several other MACs have applicable coverage policies with criteria that are consistent with our *Medical Policy Manual* criteria.
Medical Policy Manual	*Medicare coverage guidance for the health plan's service area is not available for sacroiliac joint fusion or injection. Therefore, the health plan's medical policy is applicable.* Sacroiliac Joint Fusion, Surgery, Policy No. 193 *(see "NOTE" below)*

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 A*). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- History and Physical/Chart Notes;
- Current Symptomology including indication for procedure (diagnostic or treatment of specific condition) and whether procedure will be open or minimally invasive;
- Documentation of specific conservative pain management including length of time utilized including rheumatologic evaluation when indicated;
- Documentation of diagnostic blocks including agents used, duration of action and if completed under imaging guidance;

- If request is for minimally invasive fusion/stabilization with a titanium triangular implant provide the following; documentation of specifically how pain limits ADLs, failure of minimum of six months of specific nonoperative therapy attempted, percentage of pain reduction achieved using the specific image guided injections listed above on two separate occasions, trial of injection has been performed at least once, absence of generalized pain behavior/disorders, documentation of location of pain on spine/joint, documentation per physical exam of location of pain including tenderness, positive response to at least three provocative tests and diagnostic imaging studies/reports completed;
- Documentation of specific device being utilized if applicable;
- Any other documentation requested to support medical necessity criteria are met.

REGULATORY STATUS

Several percutaneous or minimally invasive fixation/fusion devices have received marketing clearance by the Food and Drug Administration. These include the Rialto™ SI Joint Fusion System (Medtronic), SIJ-Fuse (Spine Frontier), IFUSE® Implant Systems which include the iFuse-3D, iFuse TORQ, and iFuse INTRA (SI Bone), SImmetry® Sacroiliac Joint Fusion System (Zyga Technologies), Silex™ Sacroiliac Joint Fusion System (XTANT Medical), SambaScrew® (Orthofix), and the SI-LOK® Sacroiliac Joint Fixation System (Globus Medical). FDA Product Code: OUR.

Note, the fact a new service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, Medicare or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services, Medicine, Policy No. M-149

REFERENCES

1. Retired Noridian LCA for *Article for Response to Comments: Non-Covered Services Policy, L24473* (A54302) *(To access, see the MCD Archive Site)*
2. Noridian LCA for *Spinal Fusion Services: Documentation Requirements* (A53975) *(This reference can be found on the Medicare Coverage Database website)*

CODING

Codes	Number	Description
CPT	~~0775T~~	~~Arthrodesis, sacroiliac joint, percutaneous, with image guidance, includes placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s])~~ (Deleted 01/01/2024)
	~~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)~~ (Deleted 01/01/2024)
	22899	Unlisted procedure, spine
	27096	Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography when performed
	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, including obtaining bone graft, including instrumentation, when performed
	27299	Unlisted procedure, pelvis or hip joint
HCPCS	None	

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*