

Cohere Medicare Advantage Policy - Sacroiliac Joint Fusion

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Guideline Information:

Specialty Area: Disorders of the Musculoskeletal System

Policy Name: Cohere Medicare Advantage Policy - Sacroiliac Joint Fusion

Type: $[\underline{X}]$ Adult (18+ yo) | $[\underline{X}]$ Pediatric (0-17 yo)

Table of Contents

Important Notices	2
Medical Necessity Criteria	4
Service: Sacroiliac Joint Fusion	4
Related CMS Documents	4
Description	5
Medical Necessity Criteria	5
Indications	5
Non-Indications	6
Level of Care Criteria	7
Procedure Codes (CPT/HCPCS)	7
Evaluation of Clinical Harms and Benefits	7
Medical Evidence	10
References	11
Clinical Guideline Revision History/Information	16

Medical Necessity Criteria

Service: Sacroiliac Joint Fusion

Related CMS Documents

Please refer to the <u>CMS Medicare Coverage Database</u> for the most current applicable CMS National Coverage.¹⁻¹²

- Local Coverage Determination (LCD). Percutaneous minimally invasive fusion/stabilization of the sacroiliac joint for the treatment of back pain (L36000)
 - Billing and Coding: Percutaneous minimally invasive fusion/stabilization of the sacroiliac joint for the treatment of back pain (A57596)
- Local Coverage Determination (LCD). Minimally-invasive surgical (MIS)
 fusion of the sacroiliac (SI) joint (L36406)
 - Billing and Coding: Minimally-invasive surgical (MIS) fusion of the sacroiliac (SI) joint (A57431)
- <u>Local Coverage Determination (LCD)</u>. <u>Minimally invasive arthrodesis of the sacroiliac joint (SIJ) (L39797)</u>
 - Billing and Coding: Minimally invasive arthrodesis of the sacroiliac joint (SIJ) (A59672)
- Local Coverage Determination (LCD). Minimally invasive arthrodesis of the sacroiliac joint (SIJ) (L39802)
 - Billing and Coding: Minimally invasive arthrodesis of the sacroiliac joint (SIJ) (A59682)
- <u>Local Coverage Determination (LCD)</u>. <u>Minimally invasive arthrodesis of the sacroiliac joint (SIJ) (L39810)</u>
 - Billing and Coding: Minimally invasive arthrodesis of the sacroiliac joint (SIJ) (A59695)
- Local Coverage Determination (LCD). Minimally invasive arthrodesis of the sacroiliac joint (SIJ) (L39812)
 - Billing and Coding: Minimally invasive arthrodesis of the sacroiliac joint (SIJ) (A59697)

Description

Sacroiliac joint fusion is a surgical procedure in which the iliac bone is fused to the sacrum for stabilization. It may be performed for a variety of conditions, including chronic pain, trauma, infection, cancer, and spinal instability. The initial treatment for sacroiliac joint pain is usually nonsurgical in nature; however, surgical options may be explored when the symptoms are refractory or when the individual is unable to tolerate more conservative interventions. Implants – often made of titanium – are used to permanently fuse the sacroiliac joint and therefore limit its movement and provide long-term stabilization, reducing pain and improving function for many patients. 13.5.7.9.11

Medical Necessity Criteria

Indications

Sacroiliac joint fusion is considered appropriate if **ALL** of the following are **TRUE**^{1,3,5,7,9,11}:

- **ANY** of the following 13-15:
 - Current nicotine user with no product use for 6 weeks, and ANY of the following:
 - Negative urine (cotinine) lab test within 30 days; OR
 - Surgery is urgently required due to documented reason; OR
 - No history of nicotine product use within the last 12 months; OR
 - o No lifetime history of nicotine product use; AND
- Placement of transfixation device; AND
- Moderate to severe persistent pain with functional impairment; AND
- The patient reports non-radiating, unilateral pain that is caudal to the lumbar spine (L5 vertebrae), localized over the posterior SI joint, and consistent with SI joint pain; AND
- There is an absence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders (e.g., fibromyalgia);
- The patient has a positive response to **3 or more** provocative tests, including **ANY** of the following:
 - Distraction test; OR
 - Compression test; OR
 - Thigh thrust test; OR
 - Gaenslen's test; OR

- o FABER maneuver/Patrick's sign; OR
- Posterior provocation test; AND
- A thorough physical examination has revealed localized tenderness with palpation of the posterior SI joint in the absence of tenderness of similar severity elsewhere, such as the greater trochanter, lumbar spine, or coccyx, and there are no other obvious sources of pain; AND
- Failure of conservative management for greater than 6 months, including
 ALL of the following:
 - Oral steroid or anti-inflammatory medication; AND
 - Physical therapy; AND
 - At least one image-guided diagnostic SI joint block resulting in ALL of the following:
 - At least 75% reduction of pain for the expected duration of the anesthetic; AND
 - Ability to perform previously painful maneuvers; AND
 - A trial of at least one therapeutic intra-articular SIJ injection (i.e., corticosteroid injection) that results in at least 50% reduction of pain for the expected duration of the injected agent; AND
 - Patient should be part of an ongoing care plan, and be actively participating in a rehabilitation program, home exercise program, or functional restoration program; AND
- Diagnostic imaging that includes ALL the following:
 - Imaging of the pelvis (anteroposterior (AP) plain radiograph) documents no concomitant hip pathology; AND
 - Imaging of the lumbar spine (CT or MRI) documents no neural compression or other degenerative conditions that may be causing low back or buttock pain; AND
 - Imaging (plain radiographs and a CT or MRI) with image report and radiologic interpretation of the SIJ that excludes the presence of destructive lesions (e.g., tumor, infection), fracture, traumatic SIJ instability, or inflammatory arthropathy that would not be properly addressed by percutaneous SIJ fusion (SIJF).

Non-Indications

Sacroiliac joint fusion is not considered appropriate if **ANY** of the following is **TRUE**^{1,3,5,7,9,11}:

• Infection at the surgical site; OR

- Systemic inflammatory arthropathy (e.g., ankylosing spondylitis or rheumatoid arthritis); **OR**
- Acute, traumatic instability of the SI joint; OR
- Presence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorder (e.g., fibromyalgia); OR
- Tumor; OR
- Fracture; OR
- SI fusion with use of a device that does not transfix the SI joint (PainTEQ's LinQ SI Joint Stabilization procedure). 16

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description	
20999	Unlisted procedure, musculoskeletal system, general	
27278	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, including placement of intra-articular implant(s) (e.g. bone allograft[s], synthetic device[s]), without placement of transfixing 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 and placement of transfixing device	

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established," Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for **sacroiliac joint fusion** may include:

 Adverse effects from delayed or denied treatment in order to comply with the requirement for current smokers to abstain from nicotine for at least 6 weeks and provide a urine sample that is negative for cotinine (unless surgery is urgently required for documented reasons). Social determinants of health (SDOH) remain an important area of ongoing orthopaedic surgery research, with recent literature raising questions regarding the healthcare disparities that may be potentiated by care limitations based on smoking status/nicotine dependence. These disparities include inequitable access to effective cessation resources, as well as systemic sociodemographic, racial, and ethnic differences that contribute to an individual's ability to achieve and sustain smoking cessation. The American Academy of Orthopaedic Surgeons (AAOS) has issued Information Statement 1047, published in 2016, which states that patients who are active smokers are at increased risk for complications, and that patients may reduce serious surgical risk (including risk of death) through cessation of smoking prior to elective orthopaedic surgery; the AAOS also notes the special role orthopaedic surgeons play in counseling patients on the benefits of reduced or eliminated tobacco use prior to surgery. Importantly, unconfirmed cessation is not endorsed as a hard stop to elective orthopaedic surgery; rather, the surgeon's unique role as an advocate for preoperative smoking cessation is emphasized. 15.17 - 24

The clinical benefits of using these criteria for **sacroiliac joint fusion** may include:

- Improved patient selection, resulting in better long-term outcomes. Ideal surgical candidates are lifetime nonsmokers, have not smoked for a period of 12 months, or are current smokers who have abstained from nicotine use for at least 6 weeks prior to surgery and can provide a negative urine test for cotinine (unless surgery is urgently required for documented reasons). According to the American Academy of Orthopaedic Surgeons (AAOS), there are increased patient safety risks conferred by tobacco use, including pneumonia, impeded healing, surgical site infection, postoperative cardiopulmonary events, and death. Among spinal fusion patients, smoking has been associated with an increased overall perioperative complication rate, increased risk of nonunion, and increased postoperative pain and disability. Smoking cessation, conversely, may mitigate these risks. In addition, among spinal fusion patients, preoperative smoking cessation is associated with lower postoperative pain scores, reduced opioid intake, reduced risk of chronic pain, improved quality of life, and improved patient satisfaction. Smoking status is a profoundly powerful modifiable risk factor for short-term and long-term health.²⁵⁻³¹
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

Shamrock et al. (2019) performed a systematic review of the safety profile of percutaneous minimally invasive sacroiliac (SI) joint fusion. Of 720 patients, 99 (13.75%) underwent bilateral SI joint arthrodesis, including 819 fused SI joints. Surgical wound infection and drainage occurred in 11% of patients, and the revision rate was low (2.56%). Similarly, Polly et al. (2016) reported the two-year outcomes from a randomized controlled trial (RCT) of 148 patients who received minimally invasive SI joint fusion or non-surgical management for SI joint dysfunction. At two-year follow-up, those assigned to the fusion group reported clinical improvement (83%) or substantial improvement (82.0%) in pain scores. Conversely, these percentages were lower among non-surgical treatment patients (68.2% and 65.9%, respectively). Adverse events were minimal; three patients in the fusion group required revision surgery before a two-year follow-up.

Zaidi et al. (2015) reviewed the surgical and clinical efficacy of SI joint fusion. A total of 430 patients were identified in five consecutive case series, eight retrospective studies, and three prospective cohort studies. Open surgery was performed in 131 patients, and 299 required minimally invasive surgery (MIS) for SI joint fusion. Follow-up was 60 months for open surgery and 21 months for MIS. The most common indication for 257 patients who underwent surgical treatment was SI joint degeneration/arthrosis (59.8%), SI joint dysfunction (18.4%), postpartum instability (7.2%), post-traumatic (6.5%), idiopathic (5.8%), pathological fractures (1.4%), and HLA-B27+/ rheumatoid arthritis (0.9%). Satisfaction was excellent, with noted improvements in pain, function, and quality of life.³⁴ The authors felt this reflected the efficacy of SI joint fusion in appropriately selected patients.

The North American Spine Society (NASS) published a coverage policy recommendation for *Minimally Invasive Sacroiliac Joint Fusion*, which supports coverage for treating SI joint pain. NASS noted that the procedure is relatively safe – estimated blood loss is low, as are infection rates, complications, and the need for revision surgery.³⁵

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Clinical Guideline Revision History/Information

Original Date: May 24, 2024			
Review History			
Version 2	6/10/2024	422.101 Disclaimer added	
Version 3	5/22/2025	Annual policy review and restructure.	
		Incorporated newly published CMS guidance (L39797, L39810, L39812)	
		Removed code 0809T - temporary code has been deleted.	
		Literature review - medical evidence updated (including references).	
		Addition of medically necessary patient selection criteria regarding smoking status as a modifiable and critical driver in creating optimal surgical outcomes	