# Molina Clinical Policy
# Minimally Invasive Sacroiliac Joint Fusion: Policy No. 266

**Last Approval: 6/12/2024**
**Next Review Due By: June 2025**

## DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

## OVERVIEW

The sacroiliac joint (SIJ) has been proposed as one source of chronic lower back pain. Pain related to SIJ dysfunction typically presents in the buttock(s) with radiation to the groin or upper legs, which may lead to substantial functional impairment. Physical examination techniques that can assist in predicting the presence of SIJ dysfunction include the compression test, FABER test, Gaenslen's maneuver, thigh thrust and distraction test. Imaging tests do not reveal the presence of SIJ dysfunction, rather they are used to rule out other diagnoses which may have similar presentation (e.g., lesions, fracture, inflammatory arthropathy, hip pathology, lower back conditions, etc.). If SIJ dysfunction is suspected as the cause of disabling pain based on physical examination and diagnostic tests have ruled out other potential sources, the diagnosis of SIJ pain is confirmed by performing a fluoroscopy guided percutaneous SIJ block with local anesthetic (e.g., lidocaine). A reduction in pain following the injection is indicative of a positive test, suggesting that the injected joint is a pain generator (CMS 2022; NASS 2021).

Medical treatment options for SIJ dysfunction include pain medications (e.g., non-steroid anti-inflammatory agents), physical therapy, and steroid injections. Surgical intervention is proposed to be an option for long-term pain relief when non-operative treatment fails. Minimally invasive SIJ fusion is a procedure performed under general anesthesia in which one to three implants are inserted under fluoroscopic guidance to fuse the sacrum and ilium together, thus stabilizing the joint with the intent of relieving pain and other symptoms. The procedure can be performed on an outpatient basis in most cases and patients usually return to full activity within 6 weeks following the procedure. The percutaneous procedure is preferred to open SIJ fusion when the patient is a candidate, since intraoperative times, hospital length of stay, and recovery times associated with open SIJ fusion are longer (CMS 2022; NASS 2021).

Regulatory Status
Several types of implants are used to perform minimally invasive SIJ fusion, including triangular, titanium coated implants (e.g., iFuse Implant System, SI-BONE Inc.); hollow modular screws, titanium cages, and threaded allograft dowels (e.g., Rialto SI Fusion System, Medtronic). A list of SIJ fusion devices with United States Food & Drug Administration (FDA) clearance can be found by searching the FDA 510(k) Premarket Notification Database using the Product Code "OUR."

## COVERAGE POLICY

Minimally invasive sacroiliac joint (SIJ) fusion **may be considered medically necessary** in select adult skeletally mature patients who have chronic severely debilitating SIJ pain and meet **ALL** the following criteria:

1. A complete history and physical documenting the existence of significant SIJ pain (e.g., non-radicular low back pain below the L5 level of vertebra and/or lower extremity pain) including **ALL** the following:
   a. Pain rating greater than 6 on a scale of 0-10 (where 0 represents no pain and 10 represents worst imaginable pain)
   b. Significant limitations in activities of daily living
   c. Presence of localized tenderness with palpation over the sacral sulcus
   d. Absence of localized tenderness over the greater trochanter, lumbar spine, coccyx

2. A comprehensive pain evaluation and treatment plan has been performed by a qualified practitioner with pain management expertise in conjunction with a comprehensive treatment plan (e.g., medications, rehabilitation and psychological evaluation and intervention)

3. SIJ pain confirmed with at least 3 physical examination maneuvers that stress the SIJ including **ANY** of the following:
   a. Thigh thrust test
   b. Compression test
   c. Gaenslen's test
   d. Distraction test
   e. FABER (Patrick's) test
   f. Posterior provocation test

4. Confirmation of the SIJ as a pain generator with ≥ 75% reduction in pain following fluoroscopically guided diagnostic intra-articular SIJ block using local anesthetic with recurrence of symptoms after the initial positive response

5. Failure to respond (e.g., continued pain that interferes with activities of daily living and/or results in functional disability) to at least 6 months of non-surgical treatment including **ALL** the following:
   a. Non-steroidal anti-inflammatory drugs, muscle relaxants and/or opioids (if not contraindicated)
   b. An adequate period of rest
   c. An adequate course of physical therapy wherein the physical therapist specifically documents lack of response to treatment
   d. SIJ steroid injections into the affected joint with return of pain after 6 weeks*
      *See *MCP-033 Sacroiliac Injections and Radiofrequency Ablation for Sacroiliac Joint Pain* for additional information for SIJ injections.

6. Absence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders such as fibromyalgia

7. All other diagnoses that could be causing Member's pain have been ruled out by **ALL** the following studies:
   a. Imaging (e.g., plain radiograph, computed tomography [CT], or magnetic resonance imaging [MRI]) of the SIJ joint completed and excludes the presence of tumor, infection, inflammatory arthropathy, or other pathology not amenable to correction with SIJ fusion
   b. Imaging of the pelvis (e.g., plain radiograph) completed and excludes the presence of hip pathology
   c. Imaging of the lumbar spine (CT or MRI) completed and excludes the presence of neural compression or other degenerative condition that could be the cause of symptoms

**DOCUMENTATION REQUIREMENTS.** Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

## SUMMARY OF MEDICAL EVIDENCE

There is at least moderate quality evidence that minimally invasive SIJ fusion is an acceptable treatment for adults with chronic SIJ dysfunction unresponsive to non-surgical treatments. Studies have consistently shown both short- and long-term improved pain and disability scores with minimal risk of complications or need for revision.

Hermans et al. (2022) completed a systematic review and meta-analysis that included 4 studies comparing minimally invasive SIJ fusion to conservative management. The analysis included a total of 388 patients with 207 managed using conservative management and 181 undergoing minimally invasive SIJ fusion. The primary outcomes observed were pain using the Visual Analog Scale (VAS) and disability using the Oswestry Disability Index (ODI). Secondary outcomes included adverse events, serious adverse events, and costs. SIJ dysfunction was confirmed in both groups using image-guided intraarticular injection of a local anesthetic. Patient characteristics were similar among both groups. VAS and ODI were significantly improved with the minimally invasive SIJ fusion group in all studies. There was a mean

difference of -33.40 to -40.20 for VAS scores at 6 months and a mean difference of -20.00 to -23.10 for ODI at 6 months. A total of 81 adverse or serious adverse events were reported among 341 patients. There were 50 events reported for the minimally invasive SIJ fusion group with 10 of those considered serious. The serious adverse events consisted of 5 surgical wound problems and 5 implant malposition. The remaining adverse events were related to hypertensive crises, herpes infection, depression, carpal tunnel syndrome, stress incontinence, medication overdose, worsening ulcerative colitis, and brain metastases. There were 31 adverse events reported in the conservative management group related to new pain in the pelvic or lower back areas, SIJ or back pain related to physical therapy, and pain or shortness of breath related to steroid injections. Upfront costs were noted to be higher for the minimally invasive SIJ fusion group. However, minimally invasive SIJ was shown to be more cost effective in the long-term.

Kucharzyk et al. (2022) published a 1-year follow-up on the EVoluSIon (EVSI) clinical study. The EVSI study was a prospective, multicenter study using the SImmetry SIJ Fusion System. Inclusion criteria for the study included patient age ≥ 18 years, at least 6 months of nonoperative management of SIJ pain, 3 positive provocative tests, at least 1 positive diagnostic SIJ injection with at least 50% reduction in pain, a VAS ≥ 60, and an ODI ≥ 40. The study included 250 patients. Median age at baseline was 60.5 years with 70.8% of patients being female. Approximately 56% of patients had a SIJ-related pain duration ≥ 2 years. The primary outcomes measured including VAS, ODI, quality of life, and opioid use. The mean VAS at baseline was 76.4, mean ODI 54.4, and mean quality of life 60.9. Patients were asked to rank their quality of life using a scale of 0-100 with 100 being the best quality of life. A total of 80.4% of patients were available for follow-up at the 1-year mark. The mean VAS at the 1-year follow-up was 33.0, mean ODI 30.5, and mean quality of life 72.8. Opioid use was reported as use of opioids, non-opioid pain medications, non-steroidal anti-inflammatory drugs (NSAIDs), and steroids. At baseline, 62.7% were using opioids, 51.7% were using NSAIDs, 37.3% were using non-opioid analgesics, and 9.0% were using steroids. At the 1-year follow-up, 26.9% of patients were continuing to use opioids, 14.4% using NSAIDs, 9.0% using non-opioid analgesics, and no patients were using steroids.

Tran et al. (2019) completed a systematic review and meta-analysis of 20 studies comparing minimally invasive SIJ fusion surgery using the iFuse system to screw-type surgeries. Of the 20 studies, 14 used an iFuse implant group and 6 used a screw-type group. A total of 1370 patients were included in the meta-analysis. The primary outcomes were limited to pain, disability and physical function, and quality of life measures. The standardized mean difference (SMD) was used to evaluate pooled outcome data for all studies. Pain outcomes across all studies favored the iFuse group with a SMD of 2.05 compared to a SMD of 1.28 for the screw-type group. Disability and physical function outcomes significantly favored the iFuse group with a SMD of 1.68 versus 0.26 for the screw-type group. Quality of life outcomes also favored the iFuse group with a SMD of 0.99 compared to 0.60 for the screw-type group. Overall SMD for the iFuse group was 2.05 compared to 1.28 for the screw-type group.

Dengler et al. (2019) completed a prospective, multicenter randomized controlled trial comparing SIJ fusion to conservative management. The study included 103 participants randomly assigned to either conservative management (n=51) or surgical SIJ fusion (n=52). Participants were followed for 2 years. The primary outcomes measured were VAS, ODI, and quality of life. Participants undergoing SIJ fusion either underwent staged bilateral fusion for bilateral pain (n=7), unilateral fusion for bilateral pain (n=11), bilateral fusion for unilateral pain (n=6), or unilateral fusion for unilateral pain (n=28). Those randomized to the conservative group underwent 25 physical therapy sessions over the first 6 months. Deviations in the conservative group included 2 participants who received corticosteroid injections and 1 participant that received corticosteroid injections with radiofrequency ablation. The mean baseline VAS for lower back pain was 77.7 for the SIJ fusion group compared to 73.0 for the conservative management group. Mean VAS improvement at 6 months was 43.3 for the SIJ group and 5.7 for the conservative management group. Mean VAS improvement at 24 months was 45.3 for SIJ fusion compared to 11.3 for conservative management. VAS scores for leg pain were similar to those for lower back pain. ODI scores were notably lower for the SIJ group with an overall decrease by 26 points from baseline at the 24-month follow-up. ODI scores decreased by 8.0 points from baseline at the 24-month follow-up. There was no change noted in opioid usage noted from baseline to the 24-month follow-up for the conservative management group while the SIJ fusion group noted a decrease to 33% from a baseline of 56%.

**National and Specialty Organizations**

The **National Association of Spinal Specialists (NASS)** published coverage policy recommendations for minimally invasive SIJ fusion stating it may be appropriate for carefully selected patients who meet the following criteria (NASS 2021):

- The individual has tried and failed a minimum of 6 months of intensive nonoperative treatment (medication,

activity modification, physical therapy, and home exercise program).
- Pain is consistent with SIJ pain (nonradicular, typically unilateral pain below the L5 vertebrae, localized over the posterior SIJ).
- Positive response to at least three provocative tests is present.
- Generalized pain behavior or disorders are absent.
- An image-guided intra-articular SIJ injection of anesthetic provides at least 75% pain relief on 2 separate occasions.
- Diagnostic imaging includes all of the following:
  - Plain radiographs, CT, or MRI of the SIJ excludes the presence of destructive lesions (e.g., tumor, infection) or autoimmune arthropathy that would not be addressed properly by the procedure.
  - Pelvic radiographs rule out hip pathology that would better explain patient's symptoms.
  - CT or MRI of the lumbar spine excludes neural compression or other degenerative condition that is more likely to be the source of pain.

The **National Institute for Health and Care Excellence (NICE)** published recommendations supporting the use of minimally invasive SIJ fusion surgery for chronic SIJ pain. The recommendations state patients "should have a confirmed diagnosis of unilateral or bilateral SIJ dysfunction due to degenerative sacroiliitis or SIJ disruption" (NICE 2017).

## CODING & BILLING INFORMATION

**CPT (Current Procedural Terminology) Codes**

| Code | Description |
|---|---|
| **27279** | Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device |
| **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 transfixation device |

**CODING DISCLAIMER.** Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

## APPROVAL HISTORY

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| **06/12/2024** | Policy reviewed, no changes to criteria. |
| **02/14/2024** | Coding and billing updated. |
| **06/14/2023** | Policy reviewed, no changes to criteria. Grammatical edits to Disclaimer section and Documentation Requirements disclaimer. Overview, Summary of Medical Evidence, and References updated. Added code 0775T. IRO Peer Review on June 3, 2023, by a practicing, board-certified physician with a specialty in orthopedic surgery. |
| **06/08/2022** | Policy updated to pertain to minimally invasive sacroiliac joint fusion rather than the iFuse implant system specifically. |
| **06/09/2021** | Policy reviewed, no changes. |
| **06/17/2020** | Policy reviewed, no changes. |
| **06/19/2019** | Policy reviewed, no changes to criteria for iFuse implant. Revisions made to the addition of the iFuse 3D implant (FDA approved in 2017). Implant system is considered experimental, investigational. Updated professional guidelines. IRO Peer Review on March 26, 2019, by a practicing, board-certified physician in the area of Orthopedic Surgery. |
| **03/08/2018** | Policy reviewed, no changes. |
| **06/22/2017** | Policy reviewed, no changes. |
| **01/13/2016** | New policy. |

## REFERENCES

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