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

Last Approval: 6/8/2022
Next Review Due By: June 2023

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 possible 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 generally 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 (ISASS, 2015).

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 generally 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 (Lorio, 2016).

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 sacroiliac joint pain and meet **ALL** of 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** of 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); **AND**
   b. Significant limitations in activities of daily living; **AND**
   c. Presence of localized tenderness with palpation over the sacral sulcus; **AND**
   d. Absence of localized tenderness over the greater trochanter, lumbar spine, coccyx.

AND

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); **AND**

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

AND

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; **AND**

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** of the following:
   a. Non-steroidal anti-inflammatory drugs, muscle relaxants and/or opioids (if not contraindicated); **AND**
   b. An adequate period of rest; **AND**
   c. An adequate course of physical therapy wherein the physical therapist specifically documents lack of response to treatment; **AND**
   d. SI joint 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.

AND

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

7. All other diagnoses that could be causing Member's pain have been ruled out, including but not limited to:
   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; **AND**
   b. Imaging of the pelvis (e.g., plain radiograph) completed and excludes the presence of hip pathology; **AND**
   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 low risk of complications or need for revision.

Whang et al. (2015) conducted a prospective multicenter randomized controlled trial of 148 subjects with SI joint dysfunction due to degenerative sacroiliitis or sacroiliac joint disruptions who were assigned to either minimally invasive SI joint fusion with triangular titanium implants (N=102) or non-surgical management (NSM, n=46). Subjects (mean

age 51, 70% women) were highly debilitated at baseline (mean SI joint VAS pain score 82, mean ODI score 62). Six-month follow-up was obtained in 97.3%. By 6 months, success rates were 81.4% in the surgical group vs. 23.9% in the NSM group (difference of 56.6%, 95% posterior credible interval 41.4-70.0%, posterior probability of superiority >0.999). Clinically important (≥15 point) ODI improvement at 6 months occurred in 75% of surgery subjects vs. 27.3% of NSM subjects. At six months, quality of life improved more in the surgery group and satisfaction rates were high. The mean number of adverse events in the first six months was slightly higher in the surgical group compared to the non-surgical group (1.3 vs. 1.0 events per subject, p=0.1857). Six-month follow-up from this level 1 study showed that minimally invasive SI joint fusion using triangular titanium implants was more effective than non-surgical management in relieving pain, improving function and improving quality of life in patients with SI joint dysfunction due to degenerative sacroiliitis or SI joint disruptions. Polly and associates conducted a study on the 12-month (Polly et al., 2015) and two-year (Polly et al. 2016) outcomes following the trial. These studies showed that improvements in pain, disability, and quality of life persisted to 24 months.

Duhon et al. (2013) conducted a multicenter prospective single-arm cohort study of 94 patients with SI joint degeneration or disruption who underwent minimally invasive fusion using the iFuse Implant System. Mean subject age was 51 years (n=94, safety cohort) and 66% of patients were women. Subjects were highly debilitated at baseline (mean VAS pain score 78, mean ODI score 54). Three implants were used in 80% of patients; two patients underwent staged bilateral implants. Twenty-three adverse events occurred within 1 month of surgery and 29 additional events occurred between 30 days and latest follow-up. Six adverse events were severe, but none were device-related. Complete 6-month postoperative follow-up was available in 26 subjects. In the effectiveness cohort, mean (± standard deviation) SI joint pain improved from a baseline score of 76 (±16.2) to a 6-month score of 29.3 (±23.3, an improvement of 49 points, P<0.0001), mean ODI improved from 55.3 (±10.7) to 38.9 (±18.5, an improvement of 15.8 points, P<0.0001) and SF-36 PCS improved from 30.7 (±4.3) to 37.0 (±10.7, an improvement of 6.7 points, P=0.003). Ninety percent of subjects who were ambulatory at baseline regained full ambulation by month 6; median time to full ambulation was 30 days. Satisfaction with the procedure was high at 85%.

Three retrospective comparative studies evaluated outcomes in patients with sacroiliac joint pain treated by the iFuse or by open surgical fusion. The larger multicenter study comparing minimally invasive SIJ fusion with open surgery in 263 patients with sacroiliac joint disorders (Smith et al., 2013) found that patients in the minimally invasive group were more likely to have undergone previous lumbar spinal surgery (P<0.0001) and had higher mean baseline VAS pain scores (P<0.0001). After matching for age and gender and controlling for a history of previous lumbar spinal fusion, mean postoperative pain scores in the minimally invasive group were 3.02 points lower than those of the open surgery group on a 10-point VAS (P<0.0001). More patients in the minimally invasive group demonstrated the prespecified MCID at 1 year (86.0% versus 61.1%) and at 2 years (81.6% versus 50.0%), and more patients in the minimally invasive group experienced SCB at 1 year (86% versus 58%) and at 2 years (82% versus 47%). Mean operative time was significantly shorter in the minimally invasive group (70 versus 163 minutes; P<0.0001) and mean EBL was lower (33 versus 288 mL; P<0.0001). The mean HLOS was significantly shorter in the minimally invasive group (1.3 versus 5.1 days; P<0.0001). The smaller retrospective comparative study (Ledonio et al., 2014a) also found that intraoperative blood loss, operative time, and HLOS were lower in the minimally invasive -treated patients than in the open surgical fusion group. However, in this study, mean disability scores improved significantly in both groups at the mean follow up of 15 months (minimally invasive) and 13 months (open surgical fusion) (P<0.001) with no significant difference between the groups (P=0.272). The additional retrospective comparative study (Ledonio et al, 2014b) found that surgical time and hospital stay were significantly shorter in the minimally invasive group than in the open group. Preoperative ODI was significantly greater in the open group than in the MIS group. Postoperative improvement in ODI was statistically significant within and between groups, with MIS resulting in greater improvement.

A systematic review by Zaidi et al. (2015) reported on a total of 16 peer-reviewed journal articles: 5 consecutive case series, 8 retrospective studies, and 3 prospective cohort studies. A total of 430 patients were included, of whom 131 underwent open surgery and 299 underwent minimally invasive surgery (MIS) for SIJ fusion. The mean duration of follow-up was 60 months for open surgery and 21 months for MIS. SIJ degeneration/arthrosis was the most common pathology among patients undergoing surgical intervention (present in 257 patients [59.8%]), followed by SIJ dysfunction (79 [18.4%]), postpartum instability (31 [7.2%]), posttraumatic (28 [6.5%]), idiopathic (25 [5.8%]), pathological fractures (6 [1.4%]), and HLA-B27+/rheumatoid arthritis (4 [0.9%]). Radiographically confirmed fusion rates were 20%-90% for open surgery and 13%-100% for MIS. Rates of excellent satisfaction, determined by pain reduction, function, and quality of life, ranged from 18% to 100% with a mean of 54% in open surgical cases. For MIS patients, excellent outcome, judged by patients' stated satisfaction with the surgery, ranged from 56% to 100% (mean 84%). The reoperation rate after open surgery ranged from 0% to 65% (mean 15%). Reoperation rate after MIS ranged

from 0% to 17% (mean 6%). Major complication rates ranged from 5% to 20%, with 1 study that addressed safety reporting a 56% adverse event rate. The review concluded that surgical intervention for SIJ pain is beneficial in a subset of patients. With the difficulty in accurate diagnosis and evidence for the efficacy of SIJ fusion itself lacking, serious consideration of the cause of pain and alternative treatments should be given before performing the operation.

Another systematic review by Heiney et al. (2015) reported operative and clinical outcomes after MIS SI joint fusion using a lateral transarticular approach for SI joint dysfunction. A total of 18 articles were identified. The study design and number of these are as follows: 10 retrospective single-center case series, 2 prospective single center case series, 1 multi-center retrospective case series, 1 single center, and 2 multi-center comparative cohort studies, one prospective single-arm study, and one prospective multi-center randomized controlled trial that included 430 participants. ODI decreased by 31 points at 12 months (baseline score of 56.2 [51.0-61.5], 6-month score of 30.7 [21.8-39.6], and 12-month score of 25.1 [12.3-37.9]). Some estimates showed significant variation across studies and between the types of implants used. Other reported outcomes were supportive of the positive effects of SI joint fusion. The review concluded that published studies of MIS SI joint fusion using a lateral transarticular approach confirm its minimally invasive characteristics with minimal blood loss and short operating room times, and show consistent, rapid, sustained and clinically important improvements in patient reported SI joint pain, disability and quality of life scores.

Additional single-arm, retrospective studies with follow-up times up to 5 years in patients (n=10 to 144) with confirmed sacroiliac joint disruption or degeneration found that the majority of patients experienced significant relief of pain and symptoms and improvements in disability after SIJ fusion. A majority of patients were satisfied with treatment results (> 80%) (Rudolf, 2013; Rudolf, 2012; Sachs & Capobianco, 2013; Rudolph & Capobianco, 2014; Sachs et al., 2014; Miller et al., 2013; Cummings & Capobianco, 2013; Gaetani et al., 2015).

National and Specialty Organizations

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

- 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 mainly 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 (NASS, 2021).

The **International Society for Advancement of Spine Surgery (ISASS)** (2016) has released a policy statement on minimally invasive SIJ fusion with similar recommended indications, including:

- Significant SIJ pain that impacts quality of life or limits activities daily living
- Pain confirmed with at least 3 physical examination maneuvers.
- An image-guided intra-articular SIJ injection of anesthetic provides at least 50% decrease in pain
- Failure to respond to at least 6 months of non-surgical treatment including NSAIDs and therapy
- Additional or alternative diagnosis that could be the cause of pain have been considered

For additional peer-reviewed and evidence-based sources used in the creation and revision of this policy, please see the references section.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT	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

HCPCS Codes – N/A

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

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.
03/08/2018	Policy reviewed, no changes.
06/22/2017	Policy reviewed, no changes.
01/13/2016	New policy.

REFERENCES

Government Agency

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database: Local coverage determination (LCD) L36494 – Minimally-Invasive Surgical (MIS) fusion of the sacroiliac (SI) joint. Available from CMS. Effective February 1, 2016. Updated January 6, 2022.

Peer Reviewed Publications

1. Cher D, Wroe K, Reckling WC, Yerby S. Postmarket surveillance of 3D-printed implants for sacroiliac joint fusion. Med Devices. 2018;11:337-343.
2. Cummings J Jr, Capobianco RA. Minimally invasive sacroiliac joint fusion: One-year outcomes in 18 patients. Ann Surg Innov Res. 2013 Sep 16;7(1):12.
3. Darr E, Cher D. Four-year outcomes after minimally invasive transiliac sacroiliac joint fusion with triangular titanium implants. Med Devices. 2018;11:287-289.
4. Darr E, Meyer SC, Whang PG, et al. Long-term prospective outcomes after minimally invasive trans-iliac sacroiliac joint fusion using triangular titanium implants. Med Devices. 2018;11:113-121.
5. Dengler J, Kools D, Pflugmacher R, et al. Randomized trial of sacroiliac joint arthrodesis compared with conservative management for chronic low back pain attributed to the sacroiliac joint. J Bone Joint Surg Am. 2019 Mar 6;101(5):400-411. doi: 10.2106/JBJS.18.00022.
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8. Duhon BS, Cher DJ, Wine KD, et al. Safety and 6-month effectiveness of minimally invasive sacroiliac joint fusion: a prospective study. Med Devices (Auckl). 2013 Dec 13;6:219-29.
9. Duhon BS, Cher DJ, Wine KD, Kovalsky DA, Lockstadt H, Group SS. Triangular titanium implants for minimally invasive sacroiliac joint fusion: A prospective study. Global Spine J. 2016;6(3):257-269.
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11. Heiney J. Capobianco R, Cher D. A systematic review of minimally invasive sacroiliac joint fusion utilizing a lateral transarticular technique. IJSS, Volume 9, Article 40, July, 2015.
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16. Polly DW, Cher DJ, Wine KD, et al. Randomized controlled trial of minimally invasive sacroiliac joint fusion using triangular titanium implants vs nonsurgical management for sacroiliac joint dysfunction: 12-month outcomes. Neurosurgery. 2015.
17. Polly DW, Swofford J, Whang PG, et al. Two-year outcomes from a randomized controlled trial of sacroiliac joint fusion vs. non-surgical management for sacroiliac joint dysfunction. Int J Spine Surg. 2016 Aug 23;10:28. doi: 10.14444/3028. eCollection 2016.
18. Rudolf L, Capobianco R. Five-year clinical and radiographic outcomes after minimally invasive sacroiliac joint fusion using triangular implants. Open Orthop J. 2014 Oct 17;8:375-83.
19. Rudolf L. MIS fusion of the SI joint: Does prior lumbar spinal fusion affect patient outcomes? Open Orthop J. 2013;7:163-168.
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21. Sachs D, Capobianco R, Cher D et al. One-year outcomes after minimally invasive sacroiliac joint fusion with a series of triangular implants: a multicenter, patient-level analysis. Med Devices (Auckl). 2014 Aug 28;7:299-304.
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National and Specialty Organizations

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2. Lorio MP. ISASS policy 2016 update: Minimally Invasive Sacroiliac Joint Fusion. International Journal of Spine Surgery. 2016 ;10:26. doi: 10.14444/3026.
3. North American Spine Society (NASS). NASS coverage recommendation for percutaneous on minimally invasive sacroiliac joint fusion. September 2022. Available from NASS. Registration and login required.
4. National Institute for Health and Care Excellence (NICE). NICE medical technologies guidance no. 39: ifuse for treating chronic sacroiliac joint pain. Available from NICE. Published 2018.
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Other Evidence Based Reviews and Publications

1. AMR Peer Review. Policy reviewed on March 26, 2019 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the area of Orthopedic Surgery.
2. Hayes. Registration and login required.
   - Health technology assessment: Minimally invasive sacroiliac joint fusion using triangular titanium implants (iFuse Implant System, SI-Bone Inc.). Available from Hayes. Published September 2020. Reviewed October 2021.
   - Health technology assessment: Minimally invasive sacroiliac joint fusion using cylindrical threaded implants. Available from Hayes. Published September 2020.

APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*