Subject: iFuse Implant System (SI-BONE Inc.) for Sacroiliac Joint Fusion for Treatment of Low Back Pain	Original Effective Date: 1/13/16
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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.[1]

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL [21-22 26]

There are two types of implants, the first is called the **iFuse Implant System** (SI-BONE Inc.) which is intended for performing sacroiliac joint fusion (arthrodesis) in patients with disabling low back pain due to sacroiliitis or to degeneration or disruption of the sacroiliac joint (SIJ) that has not responded to conservative medical therapy. This minimally invasive surgery is designed to fuse and stabilize this joint to relieve pain and other symptoms. The iFuse system consists of titanium rods coated with pure titanium porous plasma spray and associated surgical instruments and accessories. The length of the implant ranges from 30 to 90 millimeters. This procedure is performed by an orthopedic surgeon or a neurosurgeon and involves the fluoroscopically guided insertion of the titanium implants across the sacroiliac joint. With the patient under general anesthesia, the surgeon creates a small incision for the percutaneous cannulated delivery system to insert the titanium rods into the proper position. Most patients receive 3 implants to stabilize the joint. Patients are discharged on the same or next day followed by physical therapy with the goal of full ambulation and return to normal activities about 6 weeks post-operatively. An alternative to the minimally invasive approach is open fusion of the SIJ which can provide pain relief but recovery times are long and the complication rate is high. Patients can experience significant intraoperative bleeding and require prolonged postoperative rehabilitation. Therefore, open fusion of the SIJ is best performed on patients who are not candidates for minimally invasive SIJ fusion.

The second is called the **iFuse 3D Implant** (SI-BONE Inc.) that uses a proprietary 3D printing technology to develop its titanium implant for SIJ fusions. According to the manufacturer, the iFuse 3D implant features a

porous surface that resembles the trabecular structure of cancellous bone with a fenestrated design that is intended to promote osteointegration and intra-articular fusion. The implant can be prepacked with allograft or autograft. The implant is deployed through the ilium into the sacrum and articular surfaces of the SIJ by an orthopedic surgeon or neurosugeon during a minimally invasive surgical (MIS) procedure under general anesthesia. The iFuse 3D received 510(k) clearance (K162733) on March 10, 2017 and is intended for sacroiliac fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. [26]

Conservative methods for treating sacroiliac joint pain include rest, muscle relaxants, nonsteroidal anti-inflammatory drugs, physical therapy, exercise or activity modification, bracing (sacroiliac belt), therapeutic intra-articular steroid or anesthetic injections, and radiofrequency neurotomy. If conservative therapies are not effective, surgical treatments such as sacroiliac fusion may be indicated.

RECOMMENDATION [24-29 32]

The **iFuse Implant System** (SI-BONE Inc.) for sacroiliac joint fusion may be considered medically necessary on a case by case basis in select adult skeletally mature patients who have chronic severely debilitating sacroiliac joint pain and meet all of the following criteria: [ALL]

- ❑ Performed by an orthopedic or neurosurgeon trained in the procedure; and
- ❑ Diagnosis of post-traumatic injury of the SI joint (e.g., following pelvic ring fracture); **OR**
- ❑ A complete history and physical documenting the existence of significant SIJ pain (nonradicular low back pain and lower extremity pain below the level of L5 vertebra) by all of the following:
  - pain rating greater than 6 a scale of 0-10 (where 0 represents no pain and 10 represents worst imaginable pain); and
  - significant limitations in activities of daily living; and
  - presence of localized tenderness with palpation over the sacral sulcus [25]; and
  - absence of localized tenderness over the greater trochanter, lumbar spine, coccyx [25]
- ❑ 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
- ❑ SIJ pain confirmed with at least 3 physical examination maneuvers that stress the SIJ and cause the patients typical pain including any three of the following: [21]
  - Thigh thrust test
  - Compression test
  - Gaenslen's test
  - Distraction test
  - Patrick's sign
  - Posterior provocation test; and
- ❑ Confirmation of the SIJ as a pain generator with ≥ 80% acute decrease in pain upon fluoroscopically guided diagnostic intra-articular SIJ block using local anesthetic and patients had recurrence of symptoms after the initial positive response; and

- ❑ Failure to respond (i.e. 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: [ALL]
    - o non-steroidal anti-inflammatory drugs, muscle relaxants and/or opioids (if not contraindicated); and
    - o an adequate period of rest; and
    - o an adequate course of physical therapy wherein the physical therapist specifically documents lack of response to treatment; and
    - o *SI joint steroid injections into the affected joint with inadequate response or return of pain after 6 weeks

  Please see MCP-033 Sacroiliac Injections and Radiofrequency Ablation for Sacroiliac Joint Pain for additional information and criteria for SIJ injections

- ❑ All other diagnoses that could be causing the patient's pain have been ruled out that include but are not limited to:
    - o L5/S1 compression; or
    - o hip osteoarthritis
    - o infection, tumor or fracture of the hip
    - o acute instability of the sacroiliac joint
    - o generalized pain disorder such as fibromyalgia or somatoform disorder
    - o systemic arthropathy such as ankylosing spondylitis or rheumatoid arthritis

The **iFuse 3D implant system** is considered experimental, investigational and unproven due to insufficient peer reviewed published literature.

SUMMARY OF MEDICAL EVIDENCE [2-24]

The iFuse Implant System

The current medical evidence consists of a prospective randomized controlled trial (n=148), a multicenter prospective uncontrolled study (n=94 in safety cohort and n=32 in effectiveness cohort), 3 retrospective comparative studies (n=63 to 263), a systematic review (n=430) and retrospective cohort studies (n=10 to 144) that evaluated the efficacy and safety of the iFuse for minimally invasive fusion of the sacroiliac joint. Follow-up times ranged from 6 months to 5 years. All of the studies included patients with refractory pain due to sacroiliac joint pathology confirmed by image-guided injection of anesthetic. Most studies included several patients with previous lumbar spine surgery, a risk factor for subsequent sacroiliac joint pathology and symptoms.

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. [2 17]

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%. [3]

Three retrospective comparative studies (Smith et al., 2013; Ledonio et al., 2014a; Ledonio et al., 2014b) evaluated outcomes in patients with sacroiliac joint pain treated by the iFuse or by open surgical fusion. The larger multicenter study comparing iFuse with open surgery in 263 patients with sacroiliac joint disorders (Smith et al., 2013) found that patients in the iFuse 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 iFuse 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 iFuse 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 iFuse group experienced SCB at 1 year (86% versus 58%) and at 2 years (82% versus 47%). Mean operative time was significantly shorter in the iFuse 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 iFuse 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 iFuse-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 (iFuse) 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 (MIS) iFuse 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. [4-6]

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. However, 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. [7]

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. [16]

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 iFuse therapy. A majority of patients were satisfied with treatment results (> 80%). [8-15]

The iFuse 3D Implant System

At the current time there are no published peer reviewed literature reporting on human clinical studies using the iFuse 3D implant system. There are no professional society evidence based guidelines found.

CODING INFORMATION THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

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	Description
	N/A

ICD-10	Description: [For dates of service on or after 10/01/2015]
M46.1	Sacroilitis not elsewhere classified
M47.28	Other spondylosis with radiculopathy, sacral and sacrococcygeal region
M47.818	Spondylosis without myelopathy or radiculopathy, sacral and sacrococcygeal region
M47.898	Other spondylosis, sacral and sacrococcygeal region
M53.3	Sacrococcygeal disorders nec
M53.88	Other specified dorsopathies, sacral and sacrococcygeal region
M99.04	Segmental and somatic dysfunction of sacral region
S33.6	Sprain sacroiliac joint

REFERENCES

Government Agency

1. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. National coverage determination (NCD) Search. Accessed at: http://www.cms.gov/medicare-coverage-database/

Peer Reviewed Publications

2. Whang P, Cher D, Polly D, et al. Sacroiliac Joint Fusion Using Triangular Titanium Implants vs. Non-Surgical Management: Six-Month Outcomes from a Prospective Randomized Controlled Trial. International Journal of Spine Surgery, March, 2015. Accessed at: http://ijssurgery.com/10.14444/2006
3. 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.
4. Smith AG, Capobianco R, Cher D, et al. Open versus minimally invasive sacroiliac joint fusion: a multi-center comparison of perioperative measures and clinical outcomes. Ann Surg Innov Res. 2013 Oct 30;7(1):14.
5. Ledonio CG, Polly DW Jr, Swiontkowski MF. Minimally invasive versus open sacroiliac joint fusion: are they similarly safe and effective? Clin Orthop Relat Res. 2014 Jun;472(6):1831-8.
6. Ledonio CG, Polly DW Jr, Swiontkowski MF. Comparative effectiveness of open versus minimally invasive sacroiliac joint fusion. Med Devices (Auckl). 2014b Jun 5;7:187-93
7. Zaidi HA1, Montoure AJ, Dickman CA. Surgical and clinical efficacy of sacroiliac joint fusion: a systematic review of the literature. J Neurosurg Spine. 2015 Apr 3:1-8.
8. Rudolf L. MIS fusion of the SI joint: does prior lumbar spinal fusion affect patient outcomes? Open Orthop J. 2013;7:163-168.

9. Rudolf L. Sacroiliac joint arthrodesis-MIS technique with titanium implants: report of the first 50 patients and outcomes. Open Orthop J. 2012;6:495-502.
10. Sachs D, Capobianco R. Minimally invasive sacroiliac joint fusion: one-year outcomes in 40 patients. Adv Orthop. 2013;2013:536128.
11. 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.
12. 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.
13. Miller LE, Reckling WC, Block JE. Analysis of postmarket complaints database for the iFuse SI Joint Fusion System®: a minimally invasive treatment for degenerative sacroiliitis and sacroiliac joint disruption. Med Devices (Auckl). 2013;6:77-84.
14. 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.
15. Gaetani P1, Miotti D, Risso A et al. Percutaneous arthrodesis of sacro-iliac joint: a pilot study. J Neurosurg Sci. 2013 Dec;57(4):297-301.
16. 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
17. 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.
18. Polly DW, Swofford J, Whang PG, et al.; INSITE Study Group. 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;10:28.
19. Sturesson B, Kools D, Pflugmacher R, Gasbarrini A, Prestamburgo D, Dengler J. Six-month outcomes from a randomized controlled trial of minimally invasive SI joint fusion with triangular titanium implants vs conservative management. Eur Spine J. 2016. Epub ahead of print. May 15, 2016. Available at: http://link.springer.com/article/10.1007%2Fs00586-016-4599-9.
20. Cher D, Wroe K, Reckling WC, Yerby S. Postmarket surveillance of 3D-printed implants for sacroiliac joint fusion. Med Devices. 2018;11:337-343.
21. Darr E, Cher D. Four-year outcomes after minimally invasive transiliac sacroiliac joint fusion with triangular titanium implants. Med Devices. 2018;11:287-289.
22. 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.
23. Vanaclocha V, Herrera JM, Saiz-Sapena N, Rivera-Paz M, Verdu-Lopez F. Minimally invasive sacroiliac joint fusion, radiofrequency denervation, and conservative management for sacroiliac joint pain: 6-year comparative case series. Neurosurgery. 2018;82(1):48-55.
24. 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.

Professional Society Guidelines

25. International Society for the Advancement of Spine Surgery (ISASS) Advocacy: ISASS Proposed Recommendations / Coverage Criteria for Minimally Invasive Sacroiliac Joint Fusion. March, 2015. Updated July 5, 2016. Available at: http://www.isass.org/
26. North American Spine Society (NASS) coverage recommendation for percutaneous or minimally invasive surgical (MIS) sacroiliac (SI) joint fusion. June, 2015. Accessed at: https://www.spine.org
27. Manchikanti, L. et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: Guidance and recommendations. Pain Physician 16, S49-S283 (2013). Available at: http://www.painphysicianjournal.com/2013/april/2013;16;S49-S283.pdf.
28. National Institute for Health and Care Excellence (NICE). Ifuse for treating chronic sacroiliac joint pain. London, UK: National Institute for Health and Care Excellence; 2018. NICE Medical Technologies Guidance No. 39. Available at: https://www.nice.org.uk/guidance/mtg39.

Other Resources

29. Hayes Health Technology Brief. iFuse Implant System (SI-Bone Inc.) for Sacroiliac Joint Fusion for Treatment of Sacroiliac Joint Dysfunction. Winifred Hayes Inc. Lansdale, Pa. Dec, 2018.
30. Hayes Health Technology Brief. Open Sacroiliac Joint Fusion for Unspecified Sacroiliac Joint Dysfunction. Winifred Hayes Inc. Lansdale, Pa. June, 2017.
31. Official Disability Guidelines (ODG) for SI joint fusion – Treatment Integrated Treatment/Disability Duration Guidelines/Hip & Pelvis (Acute & Chronic), SI Joint fusion and percutaneous SI joint fusion. 2016.
32. Advanced Medical Review (AMR): Policy reviewed by a practicing physician board certified in Orthopaedic Surgery, 1/16 & 3/26/19.
33. Hayes Clinical Research Response. iFuse 3-D Implant System (SI-Bone Inc.) for Sacroiliac Joint Fusion. Winifred Hayes Inc. Lansdale, Pa. Aug, 2017.

Revision/Review History:

3/8/18: Policy reviewed, clinical criteria has not changed.
6/19/19: Policy reviewed, clinical criteria for the iFuse implant has not changed. Revisions include the addition of the iFuse 3D implant which was cleared by the FDA in 2017. This implant system is considered experimental, investigational and unproven based on a lack of peer reviewed literature. Updated professional society guidelines, references.