KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Sacroiliac Joint Fusion (SIJ Fusion)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Sacroiliac Joint Injections and procedures (L39464)
Local Coverage Article	Billing and Coding: Sacroiliac Joint Injections and Procedures A59246
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance for ***Open or Percutaneous (minimally invasive) SIJ Fusion,*** Kaiser Permanente has chosen to use their own Clinical Review Criteria for medical necessity determinations. Please refer to the Non-Medicare criteria below. ***Please Note:** Noridian currently does not cover RFA ablation of the SIJ joint. Potential candidates for SIJ fusion must be evaluated on a case-by-case basis regarding this issue referenced in above LCD.

For Non-Medicare Members

A. Open sacroiliac joint fusion is medically necessary when **ALL of the following** are met:
   1. Appropriate imaging studies demonstrate localized sacroiliac joint pathology
   2. The individual is a nonsmoker, or in the absence of progressive neurological compromise will refrain from use of tobacco products for at least 6 weeks prior to the planned surgery
   3. And **ONE of the following**:
      a. Post-traumatic injury of the SI joint (e.g., following pelvic ring fracture)
      b. As an adjunctive treatment for sacroiliac joint infection or sepsis
      c. Management of sacral tumor (e.g., partial sacrectomy)
      d. When performed as part of multisegmental long fusions for the correction of spinal deformity (e.g., idiopathic scoliosis, neuromuscular scoliosis)

B. Open sacroiliac joint fusion is not covered for **ANY** other indication, including the following, because it is considered experimental, investigational or unproven:
   1. Mechanical low back pain
   2. Sacroiliac joint syndrome
   3. Degenerative sacroiliac joint
   4. Radicular pain syndromes

C. Percutaneous or Minimally Invasive sacroiliac joint fusion, using an FDA-approved implant, placed across the SI joint and intended to promote bone fusion, is considered medically necessary for the treatment of low back/buttock pain resulting from degenerative sacroiliitis or sacroiliac joint disruption when **ALL of the following** criteria are met:

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1. Adults 18 years of age or older with sacroiliac joint pain for greater than 6 months (or greater than 18 months for pregnancy induced pelvic girdle pain)

2. Significant pain originating from sacroiliac joint (e.g., pain rating of at least 5 on a 0 to 10 numeric scale)

3. Pain is located at or close to the posterior superior iliac spine (PSIS) with possible radiation into buttocks, posterior thigh, or groin and can point to the location of pain (Fortin Finger Test)

4. Sacroiliac joint diagnosed as etiology of pain by response (pain) to 3 or more provocative examination maneuvers that stress the sacroiliac joint (e.g., FABER test*, thigh thrust*, pelvic gapping test*, pelvic compression*, Gaenslen's test*) *see below for definitions*

5. Clinical documentation that pain limits activities of daily living (ADL).
    a. ADLs are defined as feeding, bathing, dressing, grooming, meal preparation, household chores, and occupational tasks that are required for daily functioning

6. Failure to respond to at least **6** months of alternative treatments consisting of **ALL of the following**
    a. Anti-inflammatory medication, one or more of the following:
        - Non-steroidal anti-inflammatory drugs (oral or topical), unless contraindicated
        - Acetaminophen
    b. A trial of Physical Therapy in the last 12 months, which should include some of the following features:
        - Supervised Physical therapy, attendance at >75% of sessions, minimum of 3 visits

        *If conservative therapy is not appropriate, the medical record must clearly document why such approach is not reasonable.

7. Trials of the following interventions:
    a. At least 2 (two) intraarticular SI joint *steroid* injections (location confirmed by either contrast spread or both A/P and lateral views). If patient fails to get 80% or greater pain relief as measured by a standard pain questionnaire, should have a second steroid injection at least one month later. *If this is unsuccessful in long-term relief, proceed to b.*
    b. Trial of at least 2 (two) *anesthetic* injections in the lateral branch (location confirmed by either contrast spread or both A/P and lateral views), with at least 80% reduction in pain as measured by a standard pain scale, for the expected duration of the anesthetic used. 2 week minimum between the 2 injections.
    c. If anesthetic injection is successful, patient should have an RFA ablation* (*RFA ablation not covered and therefore not required for Medicare patients)*. If the anesthetic injection is not successful, or if post ablation, the pain is not reduced by less than 80% after 1 month, patient should consult with an SI joint surgeon regarding other options.

8. Alternative or contributing diagnoses MUST be absent (e.g., hip osteoarthritis, L5-S1 spine degeneration, tumor, infection, fracture). Diagnostic imaging of the SI Joint should exhibit DJD or disruption but can be read as "normal" as long as the following imaging findings are met:
    a. Imaging (CT or MRI) of the sacroiliac joint excludes the presence of destructive lesions (e.g., tumor, infection) or inflammatory arthropathy of the sacroiliac joint and rules out concomitant hip pathology;
    b. Imaging of the ipsilateral hip (plan radiographs, CT or MRI) that excludes the presence of osteoarthritis
    c. Imaging of the lumbar spine (CT or MRI) that excludes neural compression or other degenerative conditions that can be causing low back or buttock pain

9. There is an absence of generalized pain behavior
    a. (e.g., somatoform disorder)
    b. or generalized pain disorders (e.g., fibromyalgia)

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NOTE: Any operative candidate should be nicotine-free for at least 6 weeks prior to elective surgery. For persons with recent nicotine use (unless there is evidence of cord compression, or other indications for urgent intervention, noted below), documentation of nicotine cessation should include a lab report (not surgeon summary) showing blood or urine nicotine level of 0, drawn within 6 weeks prior to surgery)

NOTE: BMI > 40 is a relative contraindication to SI joint fusion

* Provocative examination maneuvers definitions:

- **Faber (Patrick's) Test:** Applies tensile force on the anterior aspect of the SI joint on the side tested
  Flexion, Abduction and External Rotation (FABER). The patient is supine with one leg extended and the other flexed at the knee. The lateral malleolus of the flexed leg lies across the other leg superior to the patella. The test may also be performed so that the foot of the flexed leg is in contact with the medial aspect of the knee of the contralateral leg. The flexed leg is then allowed to fall into abduction, and from this position the examiner increases the external rotation by increasingly pressing the patient's knee down toward the examining table with one hand. The examiner must immobilize the pelvis on the extended contralateral side to prevent it from moving during the test.

- **Thigh Thrust Test (Posterior Shear Test):** *Applies anteroposterior shear stress on the SI joint*
  Patient lies in supine position with 90 degrees of flexion in the hip and knee on the side being tested. The examiner stabilized the contralateral side of the pelvis over the anterior superior iliac spine ASIS and applied a light manual pressure to the participant's flexed knee along the longitudinal axis of the femur.

- **Pelvic Gapping Test (SIJ distraction test):** Applies tensile forces on the anterior aspect of the SI joints
  Patient lies supine, and the examiner applies a vertically orientated, posteriorly directed force to both the anterior superior iliac spines (ASIS). The presumed effect is a DISTRACTION of the anterior aspect of the SIJ. A test is positive if it reproduces the patient's symptoms. This indicates SIJ dysfunction or a sprain of the anterior sacroiliac ligaments.

- **Pelvic Compression:** Applies compression force across the SI joints
  Patient is placed in a side-lying position, with the affected side up, facing away from the examiner, with a pillow between the knees. The examiner places a steady downward pressure through the anterior aspect of the lateral ilium, between the greater trochanter and ilia crest.

- **Gaenslen's test:** Applies torsional stress on the SI joints
  The patient lies supine with the affected side leg near the edge of the table. For safety, the patient's shoulders are positioned toward the middle of the table. The patient then draws the non-affected side leg into full flexion and holds the flexed knee. The examiner stabilizes the let with their hand placed over the patient's hand. This action keeps the ilium on the non-tested side in a slightly posterior and stable position during the maneuver.

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of imaging reports (if applicable)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

The sacroiliac joint (SIJ) connects the sacrum to the pelvis (iliac bone) on each side of the lower spine and transmits the load of the body to the lower extremities. The joint is reinforced by strong ligaments that secure the fit of the joint, and help the sacrum support the weight of the spine and head. The SIJ has a unique anatomy as it is classified as one type of joint anteriorly, and as another posteriorly. In the front, it is synovial and classified as a diarthrodial joint (a freely movable type of joint), while in the back it is fibrous or ligamentous and classified as synarthrodial (an immobile or nearly immobile joint) (Vleeming 2012, Polly 2017, Thawrani 2019).

The unique anatomic and physiologic characteristics of the SIJ makes it vulnerable to unusual mechanical stress or strain. Too much motion (hypermobility), or too little motion (hypomobility) of the joint, may lead to sacroiliac joint pain or dysfunction. This may be caused by a specific traumatic event (disruption) such as a motor vehicle accident, fall, lifting, pregnancy and childbirth; or can develop over time (degeneration) because of osteoarthritis, anatomical abnormalities such as scoliosis, leg length difference as, well as a complication of lumbar or lumbosacral fixation procedures. SIJ pain may be localized to the lower buttocks or radiates into the groin, lower back and lower extremity. It is believed that the SIJ may be the source of up to 15-30% of chronic low back pain (Rashbaum 2017, Polly, 2015, 2016.2017, Dengler 2017. Thawrani 2019).

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The clinical evaluation and diagnosis of SIJ pain is challenging due to the wide variability in its clinical presentation and the overlap with the lumbar spine and hip pains. Back strain from lifting, facet syndrome, disc herniation, inflamed spinal cord roots, and sciatica can be confused with SI joint dysfunction. The joint is not easily palpated or manipulated, and there are no reliable pathognomonic or specific clinical history or physical examination findings. Imaging alone cannot accurately diagnose SJI dysfunction or differentiate between spine. hip, and SIJ pain. Assessing the pain location, patient posture/movement, and provocative manual testing are useful in making a probable diagnosis of SIJ disfunction. The most definitive evaluation is image-guided injection of anesthetic solutions into the joint which is diagnostic if there is at least 75% symptom relief (Polly 2017, Thawrani 2019).

Conservative non-surgical measures including oral analgesics, physical therapy, osteopathic and chiropractic manipulation are typically the first line therapies used for SIJ pain. Periarticular or intraarticular SIJ steroid injection and radiofrequency neurotomy of the sacral never are sometime used as last options of nonoperative management to provide short-term pain relief in some patients, but with variable success and insufficient data on the long-term effectiveness. SIJ fusion has been proposed as a potential option when the nonoperative measure have failed. Surgical fusion of the joint immobilizes the joint and eliminates its motion, which is believed to cause the inflammation and pain (Dangler 2017, Polly 2017 Tran 2019).

Traditional sacroiliac joint fusion is an open surgery that involves an incision to access the joint, removal of cartilaginous material from the joint, and use of bone grafts and screws to help the fusion. Open surgical fusion of SIJ was first reported in the early 1900s. However, it is not routinely used because of the challenges and risks associated with the procedure including the bone harvesting, potential damage to surrounding anatomic structures, intraoperative blood loss, wound size, extended hospital stays, and limits on postoperative weightbearing. Minimally invasive surgical (MIS) methods have thus been introduced over the years to provide the potential benefit of permanent stabilization of the SIJ with smaller surgical incision; less operative time, blood loss, and perioperative morbidity; and potentially faster healing (Heiney 2015.Polly 2016, Dengler 2017).

The minimally invasive SIJ fusion approach and technique differ according to the device used, but in general the steps for performing the procedure are similar. The surgery is generally performed under general anesthesia and fluoroscopy monitoring. With the patient lying face down on the operating table, a 2-3 cm incision is made in the side of the buttock and the gluteal muscles are dissected to access the ilium. A small guide pin is then inserted through the side of the ilium to create a small hole and an opening is then broached or drilled through the ilium to provide passage for the implants to reach the sacrum. If a bone graft is necessary, the SIJ is cleared of cartilage and soft tissues, and a bone graft is packed into the joint space (the bone graft is typically collected from a different area of the ilium or from shavings left behind from broaching the ilium). The implant instruments are guided through the passage in the ilium, and are put into place using screws, pins, or a mallet. For the triangular shaped titanium implants, a second and third device are implanted in the same procedure. The incision site is then irrigated, and the wound closed. Patients requiring treatment in both joints could undergo staged procedures (Rudolf 2012).

Reported adverse events associated with the procedure include neuropathic pain, neural impingement, postoperative hematoma, urinary retention, nausea, vomiting, SIJ pain, trochanteric bursitis, iliac bone fracture, malpositioning of the implant, wound problems, and the need for reoperations. A major risk of SIJ fusion is its failure to alleviate pain. It is also reported that because the SIJ is a key energy transfer mechanism, its fusion may possibly displace the pressure typically absorbed in the pelvis to the lower spine, creating pain and pressure in the lower back (adjacent segment disease). The latter complication was reported in about 5% of sacroiliac joint fusion patients within 6 months of surgery (Schell 2016).

Medical Technology Assessment Committee (MTAC)

Sacroiliac Fusion (SI Fusion) for Sacroiliac Joint Dysfunction

12/08/2014: MTAC REVIEW

Evidence Conclusion: Lower back pain is extremely common and the sacroiliac (SI) joint has been implicated as one of the potential sources dating all the way back to the early 1900s (Goldthwait and Osgood 1905). Formed by the connection of the sacrum and the right and left iliac bones, the SI joint lies at the junction of the spine and the pelvis. Held together by a collection of strong ligaments the SI joint only allows for limited rotation and translation. The SI joint plays a primary role in supporting the weight of the upper body. Pregnancy, gout, rheumatoid arthritis, psoriasis, ankylosing spondylitis, and other conditions that cause abnormal wear may aggravate the joints by placing an increased amount of stress on the SI joints. There are many different terms for SI joint problems,

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including SI joint dysfunction, SI joint syndrome, SI joint strain, and SI joint inflammation. With the most common symptoms being pain, stiffness and burning the diagnosis of SI joint conditions can prove difficult for a multitude of reasons. For starters, there are no widely accepted guidelines for diagnosis and treatment nor has any imaging modality established definitive symptoms that correlate with a visible pathology. These issues are further complicated by the large spectrum of different etiologic factors and variability that contribute to the pain. As a result, diagnosis of SI joint dysfunction relies on thorough history and physical examination. Conventional treatments for SI joint dysfunction typically consist of non-operative interventions such as injections and anti-inflammatory oral medications. However, oral steroids and physical therapy can also be helpful (Ashman, Norvell et al. 2010). In the event that conservative interventions fail, SI joint fusion has been proposed as an additional treatment option. A variety of techniques have been described over the years without the wide acceptance of a single technique. Generally speaking, the surgery entails removal of the cartilage in the SI joints followed by an implant of plates or screws to hold the bones together. The technique may even employ the use of bone grafts to promote fusion. Ultimately, the surgery is designed to eliminate SI joint motion with the overall goal to relieve pain. Several implants have received 501(k) approval from the Food and Drug Administration (FDA) and are detailed in table 1. Minimally invasive (MIS) SI joint fusions have not previously been reviewed by the Medical Technology and Assessment Committee (MTAC) and are currently being reviewed due to increased requests for coverage.
Articles: The literature search revealed just under 200 articles. No randomized control trials (RCTs) comparing MIS SI joint fusion with non-surgical treatment for the treatment of chronic low back pain due to sacroiliac joint dysfunction were identified. The only comparison studies were cohorts investigating MIS SI joint fusion versus open surgical techniques or SI joint denervation and were not selected because they did not include a nonsurgical group. Currently, there are numerous trials registered with the NIHCT set to compare MIS SI joint fusion with conservative management. The majority of the literature base was small and retrospective. The best available publications were two prospective cohorts with no comparison groups and a retrospective medical chart review of 18 patients who underwent MIS SI joint fusion surgery. The following publications were selected for critical appraisal: Wise, CL and Dall, B. Minimally invasive sacroiliac arthrodesis outcomes of a new technique. *J Spinal Disord Tech* 2008;**21**(8):579-584. **[Evidence Table 1]**. Cumming, J and Capobianco, RA. Minimally invasive sacroiliac joint fusion: one-year outcomes in 18 patients. *Annals of Surgical Innovation and Research* 2013;**7**(1):12-18. **[Evidence Table 2]**. Duhon BS, Cher DJ, Wine KD, et al. Safety and 6-month effectiveness of minimally invasive sacroiliac joint fusion: a prospective study. *Medical Devices: Evidence and Research* 2013;**6:**219-229. **[Evidence Table 3]**

Minimally invasive sacroiliac joint fusion, with or without bone grafts and other metal implant devices and does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Sacroiliac Fusion (SI Fusion) for Sacroiliac Joint Dysfunction

04/08/2019: MTAC REVIEW

Evidence Conclusion:

- Moderate quality evidence from two open-label short-term, industry sponsored RCTs with subjective outcomes, suggest that sacroiliac joint fusion using triangular titanium implants may be more effective than conservative measures in reducing pain and improving function at 6 months among selected patients with a confirmed diagnosis of SIJ chronic disabling pain or dysfunction.
- An ideal RCT would be a sham-controlled trial or blinded assessment of the outcomes.
- The SIJ fusion procedure was associated with a low rate of adverse events, but some were severe and required re-operation. Reported adverse events include neuropathic pain, neural impingement, respiratory failure, trochanteric bursitis, iliac bone fracture, wound problems, recurrent SIJ pain, malposition or loosening of the implant, recurrent SIJ pain due to implant malposition, and the need for revision surgeries.
- There is insufficient to determine the net health outcome of the SI fusion procedure.
- There is insufficient evidence from RCTs to determine the long-term comparative efficacy and safety of minimally invasive SIJ fusion versus nonsurgical management of patients with SIJ dysfunction.

Articles: The literature search for studies published after the last MTAC review identified 6 systematic reviews (three with quantitative meta-analyses), two randomized control trials (published in multiple articles) comparing minimally invasive SIJ joint fusion with non-surgical treatment for the treatment of chronic low back pain due to sacroiliac joint dysfunction, one observational study with 4 years follow-up, and a retrospective study with six-years follow-up data. One meta-analysis pooled the results of the two published RCTs together with an observational study to identify the patient characteristics that may predict clinical outcome after surgical or nonsurgical treatment. The two RCT were selected for critical appraisal, and the outcome of the meta-analysis was summarized. See Evidence Table.

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Sacroiliac Joint Fusion (SIJ Fusion) for Sacroiliac Joint Pain/Dysfunction does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Minimally Invasive Sacroiliac Joint Fusion (MIS SIJF) for Sacroiliac Joint Pain/Dysfunction
07/12/2021: MTAC REVIEW
Evidence Conclusion:

- Moderate strength evidence from two open-label, industry sponsored RCTs with subjective outcomes, and high crossover rate after 6 months, suggest that minimally invasive sacroiliac joint fusion using the iFuse TTI system may be more effective (for up to six months) than conservative measures in reducing pain and improving function among selected patients with a confirmed diagnosis of SIJ chronic disabling pain or dysfunction.
- There is insufficient evidence from RCTs with long -term follow-up of patients in their initial randomization group, to determine the long-term comparative efficacy and safety of minimally invasive SIJF versus nonsurgical management of patients with SIJ dysfunction. The crossover of participants from the conservative treatment arm to the SIJF limits the long-term comparative assessment.
- Low-to moderate strength evidence from industry sponsored observational studies suggest that the benefits observed with SIJF using iFuse implanted via the lateral transiliac approach may be sustained for the 24 months follow-up duration.
- There is insufficient evidence to determine the safety and efficacy of the SIJF to patients with other sources of back pain who were excluded from the trials. Also, it is unclear if the procedure may be safe and effective in patients with other chronic disease and comorbidities e.g., osteoporosis, diabetes. cardiovascular diseases and others.
- The publishes studies indicate that SIJF procedure was associated with a low rate of adverse events, but some were severe and required re-operation. Reported adverse events include neuropathic pain, neural impingement, respiratory failure, trochanteric bursitis, iliac bone fracture, wound problems, recurrent SIJ pain, malposition or loosening of the implant, recurrent SIJ pain due to implant malposition, and the need for revision surgeries.
- The comparative studies of minimally invasive procedures evaluated lateral transiliac SIJF using iFuse triangular titanium implants, and the result may not be generalized to other devices or implantation approaches used for SIJF.

Articles: The literature search for studies published after the last MTAC review did not identify any more recent meta-analyses or RCTs on the effectiveness and safety of SIJF compared to nonsurgical therapies. The search however, revealed a report on the two-year follow-up of the iMIA randomized controlled trial reviewed earlier (Dengler, et al, 2019); one observational study assessing the long-term outcomes for patients enrolled in the INSITE randomized controlled trial and the SIFI single-arm prospective multicenter study (LOIS study, Whang et al, 2019); a small observational single-arm study assessing the safety and effectiveness of SIJF using a 3D-printed TTI (Patel et al 2020); a systematic review on the safety profile on minimally invasive SIJF (Shamrock, et al, 2019) a cost utility analysis of MIS SIJF from a National Health Service (NHS) England perspective; and a protocol for a meta-analysis on SIJF versus conservative management for low back pain attributed to the SIJ (Chen et al 2020). See evidence tables.

The two long-term observational follow-up of patients participating in the iMIA and INSITE studies were selected for critical appraisal; and the results of the systematic review on the safety of the procedure was summarized.

Minimally Invasive Sacroiliac Joint Fusion (MIS SIJF) for Sacroiliac Joint Pain/Dysfunction
does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
27280	Arthrodesis, sacroiliac joint, open, includes obtaining bone graft, including instrumentation, when performed
0775T	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, includes placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s])
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device

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***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
08/27/2014	09/02/2014[MPC], 11/03/2015 [MPC], 09/06/2016[MPC], 07/11/2017[MPC], 05/01/2018[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	04/27/2023

[MPC] Medical Policy Committee

Revision History	Description
06/23/2016	Added NCD/LCD Medical Director review language
09/08/2015	Revised LCD L35008
09/06/2016	Added GH policy for Medicare members and new criteria for non-Medicare members
05/07/2019	MPC approved to adopt policy of non-coverage for SIJ Fusion for Sacroiliac Joint Pain/Dysfunction
05/05/2020	Added Medicare LCD L36000 and LCA A57596 for percutaneous/minimally invasive SIJ fusion Added clarification that policy addresses open and percutaneous/minimally invasive SIJ fusion. Added CPT code 27280.
05/21/2020	Removed Medicare LCD L36000 and LCA A57596 for percutaneous/minimally invasive SIJ fusion as it is from Wisconsin Physicians Service instead of Noridian
09/07/2021	MPC approved to adopt MTAC's recommendation of non-coverage, maintaining a non-coverage policy for Minimally Invasive Sacroiliac Joint Fusion (SIJF). Added MTAC's review from 7/12/2021.
01/10/2023	MPC approved to adopt revised changes to the SI Joint Fusion criteria to allow coverage in certain situations. Requires 60-day notice; effective June 01, 2023.
03/06/2023	Updated applicable CPT code 0775T effective 1/1/23.
04/27/2023	Clarified indications for Medicare due to new LCD not covering RFA ablation of SI Joint.

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