HEALTH PLANS
UNIVERSITY OF UTAH

Medical Policy

Sacroiliac Joint (SI) Joint Fusion

Policy MP-049

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Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial, CHIP and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
4. This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.

Description:

Sacroiliac Joint Fusion (SIJF) is a surgical procedure, which fuses the iliac bone (pelvis) to the spine (sacrum) for stabilization. It is performed for a variety of conditions including trauma, infection, cancer, and spinal instability. SIJF may be performed as a minimally invasive procedure or as an open surgical procedure requiring a larger incision and subsequent increased recovery time.

Sacroiliac joint dysfunction/pain is usually managed by conservative therapy which includes cold application, anti-inflammatory medication, and relative rest in the acute stages. Physical therapy is also employed to restore normal mechanics, including manual medicine techniques; pelvic stabilization exercises to allow dynamic postural control, and muscle balancing of the trunk and lower extremities. If conservative treatment fails, sacroiliac joint (SIJ) intra-articular injections are often performed not only as a therapeutic intervention but also to confirm the diagnosis. Reproduction of symptoms upon distension of the joint capsule and/or mitigation of symptoms by analgesic block is the most reliable and reproducible means by which a pain-generator can be identified. In these cases, SIJ injection may affirm the diagnosis, avoid unnecessary surgery, reduce pain, and facilitate rehabilitation.

As a last resort, open sacral fusion surgery is infrequently considered. This surgery has significant morbidity and has significant risk for complications and suboptimal outcomes. Open surgical techniques involve direct visualization of the sacroiliac joint and may include anterior

and posterior approaches that can be performed with and without screws or plates, and a posterior midline fascial splitting approach.

More recently, several minimally invasive implant systems have been developed for SIJF. The most prominent is the iFuse Implant System® (SI-Bone, Inc., San Jose, CA); also, notable is the SImmetry® Sacroiliac Joint Fusion System (Zyga Technology®, Minnetonka, MN). With regards to the iFuse Implant System®, this minimally invasive surgical procedure is typically performed under general anesthesia with the patient in the prone position. A small incision is made in the lateral buttock through which the procedure is performed. The procedure is a typical orthopedic pin-based technique (pin, drill, broach, and implant). The entire procedure takes approximately 1-hour and instrument/implant position is confirmed with intraoperative fluoroscopy. Related to the iFuse Implant System, the manufacturer of the iFuse implant describes it as follows: "The iFuse Implant System is comprised of a titanium implant coated with a porous, titanium plasma spray (TPS) and an instrument system. Typically, 3 implants are placed across the SIJ using a lateral transarticular approach during a minimally invasive surgical (MIS) procedure. The implant's unique triangular shape, large surface area, and interference fit are designed to minimize micromotion and rotation to provide immediate joint stability and to allow for biological fixation to support long-term fusion.

The SImmetry® Sacroiliac Joint Fusion System® is a MIS procedure for patients with SIJ dysfunction who have not gained relief from conservative care. The SImmetry System utilizes the proprietary SImmetry Decorticator, allowing surgeons to prepare the articular region of the SIJ and insert bone graft into the joint to help facilitate a true SIJF. The muscles and ligaments surrounding the SIJ are maintained. The SImmetry System is cleared by the FDA for commercial distribution.

Policy Statement and Criteria

1. Commercial Plans/CHIP

U of U Health Plans covers minimally invasive fusion of the sacroiliac joint ONLY using the iFuse Implant System® (transiliac approach) as a proven technology in limited circumstances where coverage criteria are met.

Criteria for Coverage of iFuse minimally invasive SI joint Fusion (ALL Must be Met):

A. Back Pain present for $\geq$ 6 months of moderate-to-severe despite conservative therapy (baseline score of 30 or greater on the Oswestry Disability Index (ODI) and/or numeric pain score in the last week of 5 or higher on a 10-point VAS scale)

B. Alternative Diagnosis for low back/sacral pain excluded including but not limited to:
    i. Recent major pelvic trauma
    ii. Metabolic Bone Disease

C. History and physical exam supportive of Sacroiliac (SI) Joint mediated pain including positive Fortin's finger sign and at least 3 of the 5 provocative maneuvers that stress the SI joint (e.g., distraction test, compression test, thigh thrust, FABER (Patrick's) test, Gaenslen's maneuver), causing the patient's typical pain.

D. Advanced imaging studies of the joint such as CT, MRI exclude other diagnoses (e.g., L5/S1 compression, hip osteoarthritis, sacroiliitis, ankylosing spondylitis, etc.)

E. Failure to respond* to at least 6 months of non-surgical treatment (if not contraindicated), including ALL the following:
    i. Non-steroidal anti-inflammatory drugs;
    ii. Formal Physical Therapy ;
    iii. Activity modification; and
    iv. CT or Fluoroscopic guided SIJ steroid injection.

F. $\geq$ 80% relief of typical pain on CT or fluoroscopic confirmed diagnostic or therapeutic injection

**Failure to respond is defined as continued pain interfering in activities of daily living or resulting in functional disability.*

U of U Health Plans does NOT cover the SImmetry Sacroiliac Joint Fusion System or the use of other minimally invasive fusion products (posterior approach) as current evidence related to alternative systems are inadequate to determine efficacy and safety of these products. Use of these technologies are considered experimental/ investigational or unproven.

U of U Health Plans considers open sacroiliac joint fusion medically necessary in the following circumstances:

A. As an adjunct to sacrectomy or partial sacrectomy related to tumors involving the sacrum

B. As an adjunct to the medical treatment of sacroiliac joint infection (e.g., osteomyelitis, pyogenic sacroiliitis)/sepsis

C. As a treatment for severe traumatic injuries associated with pelvic ring fracture.

U of U Health Plans considers sacroiliac joint fusions experimental/investigational for all other indications as their effectiveness, for indications other than the ones listed above, have not been established.

2. **Medicaid Plans**

   Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: https://medicaid.utah.gov/utah-medicaid-official-publications/ or the Utah Medicaid code Look-Up tool

   CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.

Clinical Rationale

Two systematic reviews and 27 primary studies were identified which met inclusion criteria for this review. The primary literature included outcomes from 7,589 patients who underwent sacroiliac joint fusion (SIJF). With the exclusion of the Miller et al. paper, an analysis of post-market complaints, outcomes from 2,231 unique SIJ fusion patients have been reported.

The 2 systematic reviews included 34 studies: 18 reported on outcomes from minimally invasive surgical (MIS) and 16 compared open to MIS surgeries. Pertaining to improvements in length of stay (LoS), blood loss, surgical time, and patient-reported pain improvements and revision surgeries at follow-up, MIS surgery outperformed open procedures. Of the 27 primary studies, all used only the iFuse implant. Limitations to the identified literature include the low quality of the studies with most of the studies were cohort studies with only 3 of the 26 (12%) primary literature articles comparing minimally invasive SIJ fusion to open surgery.

Notably, none of the long-term studies were comparative to open SIJ fusion. However, both papers that followed patients past 48 months illustrated comparatively low Oswestry disability Index (ODI) scores at follow-up, a meaningful primary endpoint (Cher et al. and Rudolf et al.). Notably there is a lack of a sham control in any of the studies. That said, Polly et al. and Sturesson et al. both compared MIS SIJ fusion to conservative therapy, and both illustrated substantial improvements of the former to the latter.

As related to cylindrical threaded implants no systematic reviews identified for SIJ Fusion/Fixation with a Cylindrical Threaded Implant. Rappoport et al. in 2017 reported on an industry-sponsored prospective study of SIJ fusion with a cylindrical threaded implant (SI-LOK). The study included 32 patients with a diagnosis of SIJ dysfunction who had failed nonoperative treatment, including medication, physical therapy, and therapeutic injections. A diagnostic injection was performed to confirm the source of pain to the SIJ. The procedure included drilling to prepare for screw insertion and implantation of three screws, at least one of which was slotted. The slotted screws were packed with autogenous bone graft from the drill reamings. Pain and disability scores were reduced following device implantation, and revisions within the first 12 months of the study were low (n=2). In a follow up published in 2021 related to the 2-year follow up data was collected on 32 consecutive patients who underwent minimally invasive SIJ fusion with a novel HA-coated screw. Clinical assessments and radiographs were collected and evaluated at 24 months postoperatively. Outcomes from the study included mean preoperative visual analog scale (VAS) back, left, and right leg pain scores decreased significantly to 20.0 (±18.4), 5.8 (±8.1), and 11.5 (±20.1) at 24-month follow-up, respectively. Oswestry Disability Index (ODI) scores significantly decreased to 27.5 (±18.8) points at 24 months ($P<0.01$). Two patients who required revision surgery reported improvement of their symptoms within 3 weeks and did not require subsequent surgery to be performed. Limitations to these studies included the fact they were manufacturer

sponsored and the small study size. The studies also lack randomization and a comparative arm to either open or triangular titanium implants (iFuse).

In conclusion, the literature regarding MIS SIJF illustrates clinically relevant patient improvements compared to conservative therapies or open SIJF. There is substantial evidence from both short-term and long-term, cohort and randomized controlled studies, to know the effects of iFuse on patient outcomes. Studies also demonstrate minimally invasive implant surgery using the iFuse system appears to have lower morbidity and complication issues than open SI joint fusion. However, current evidence is insufficient to demonstrate safety and efficacy for alternative minimally invasive approaches.

Applicable Coding

CPT Codes

Possibly covered (if criteria are met)

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

27280 Arthrodesis, sacroiliac joint, open, includes obtaining bone graft, including instrumentation, when performed

27299 Unlisted procedure, pelvic or hip joint

HCPCS Codes

L8699 Prosthetic implant, not otherwise specified

C1713 Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)

C1776 Joint device (implantable)

Not covered

27278 Arthrodesis, sacroiliac joint, percutaneous, with image guidance, including placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s]), without placement of transfixation device

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