Via email

July 23, 2020

Washington Health Care Authority
Health Technology Clinical Committee
shtap@hca.wa.gov

Re: Sacroiliac joint fusion

Dear Washington HCA Director and Clinical Leadership,

On behalf of the International Society for the Advancement of Spine Surgery (ISASS), we would like to comment publicly on the topic of **sacroiliac joint fusion**. We understand the re-review request for this topic has been denied by the Health Care Authority (HCA). **We encourage the Washington HCA to reconsider its denial of re-review for this topic of minimally invasive sacroiliac joint fusion, which would be of significant benefit to Washington Medicaid members, or falling under workers compensation or other benefits plans controlled by the HCA's decisions.** We believe there is ample rationale for the HCA and the HTCC to revise its current policy and position on this topic, and to adopt coverage criteria that includes SI joint pain and dysfunction due to degenerative conditions not limited to patients with a history of direct trauma or injury to the pelvic girdle. With Level I and II evidence showing the immediate as well as long-term impact this important treatment option has had on a mostly degenerative sacroiliitis population, including more than 80 papers published in peer-reviewed journals with follow-up of 5 years prospectively, we believe there is sufficient rationale for Washington HCA's coverage with adequate pre-operative criteria.

During the last HTCC meeting convened on this topic in January 2019, there were two issues seeming to confound the data and Final Evidence Report's conclusions, in the opinion of the clinical committee members:

1. Complication types, rates and incidence, and the revisability of the SIJ Fusion procedure; and

2. Sponsor bias and why a sham study was not advisable or possible in key studies; and, whether the level of evidence is sufficient to support broader coverage of this topic

Within this letter, we address these two items and hope to continue the discussion in support of Washington HCA's ongoing review of this topic.

1. Complications and Revisions for MIS-SIJ Fusion

In 2018, the Washington HCA conducted a comprehensive review of the literature on this topic. The report finalized in December 2018 following this review was favorable for SI joint fusion, yet when the Washington HCA HTCC meeting was convened on this topic on January 18, 2019, the committee decided against its broader application for conditions other than trauma. Certain committee members questioned the complications resulting from this procedure, characterizing them as significant, and occurring with significant frequency. No references were provided in support of these statements, certainly none as strong as those supporting the broader population of mostly degenerative sacroiliitis patients. Also, they argued the procedure was not easily revisable.

The safety of any product and procedure is of critical importance. There are numerous FDA-cleared devices indicated for SI joint fusion that are available on the U.S. market. Speaking to relevant and available safety data, unfortunately data on this procedure is not available, other than for those using iFuse. The safety of the iFuse Implant System [Miller 2013[65], Cher 2015[66]] [Cher 2018[67]] has been demonstrated with low complication and revision rates. Notably, the complication and revision rates for iFuse-3D are the same as for iFuse Implants [Cher 2018[67]]. The revision rate for iFuse has been shown to be better than a majority of spine and orthopedic procedures. The safety profile for iFuse implants and the procedure is supported by multiple publications[1–3,5,6,8,60,65–67,87,88,96] as summarized in the table below; ISASS does not endorse any specific MIS SIJ System. There are numerous devices available that have received FDA 510(k) clearance for use in minimally invasive/percutaneous sacroiliac joint fusion stabilization.

Safety & Revision Rate Profile

Article	*Description*	*Adverse Events (AEs)*	*Revision Rate*
Cher 2018[67]	Postmarket surveillance of complaints for iFuse-3D Implants, and comparison to iFuse Implants (n=14,210) 11,070 cases using iFuse Implants 3,140 cases using iFuse-3D Implants	~1.3% overall complaint rate. <0.5% pain-related complaints for both iFuse and iFuse-3D. No implant breakages or migrations	One-year cumulative probability of revision: 1.5% iFuse Implants 1.0% iFuse-3D Implants
Darr 2018b[5]	Prospective, multicenter (n=93) 4-year results	No new device- or procedure-related AEs during follow-up year 4. *(AEs for year 3 reported in Darr 2018a, and through 2 years were reported in SIFI and INSITE publications.)*	<1% (1 subject underwent revision at year 3.8)
Darr 2018a[6]	Prospective, multicenter (n=103) 3-year results	No new device- or procedure-related AEs during follow-up year 3.	<1% (1 subject underwent revision at year 3.8)

		(AEs through 2 years were reported in SIFI and INSITE.)	
Dengler 2017b[2]	Prospective, multicenter, RCT (n=52 iFuse, n=51 CM) 1-year results	Within first 200 days, 17 AEs in each group. By 6 months, mean number of AEs per patient was 0.33 in both groups (p=0.9549 for rate diff).	3.8% (2 of 52 iFuse patients within 1 year)
Polly 2016[1]	Prospective, multicenter, RCT (n=102 iFuse, n=46 NSM) 2-year results	Within first 180 days: 1.5 per iFuse subject 1.3 per NSM subject (p=0.2253)	3% (3 of 102 iFuse patients within 2 years)
Sachs 2016[60]	Retrospective, multicenter (n=107) 3.7-year follow-up	3 (2.8%) procedure-related complications	4.7% (5 of 107 patients)
Duhon 2016[3]	Prospective, multicenter, single-arm, clinical trial (n=172) 2-year results	2.9% probably/definitely device-related 12.2% probably/definitely procedure-related	4.7% (8 of 172 patients)
Cher 2015[66]	4-year survivorship analysis (free from revision surgery) n=11,388	-NA-	3.5% cumulative rate (96.5% survivorship, free from revision, adjusted 4-year rate) *NOTES:* • *Likelihood of revision has decreased annually since 2009* • *Rate did not differ by age (< or > 65 years old) or sex*
Miller 2013[65]	Retrospective complaints database analysis (n=5319)	3.8% overall complaint rate	1.8%

Specifically looking at 4-year cumulative revision rates, the 3.5% iFuse Procedure revision rate [Cher 2015[66]] is favorable when compared with revision rates of other accepted and common lumbar surgeries: decompression (10-12%) and fusion (12-14%) [Martin 2007[123], Deyo 2011[124], Basques 2015[125]]. Most manufacturers provide revision kits in the event a revision is necessary, however as previously mentioned the relative rate of revision procedures is exceedingly low.

The Washington HCA committee members also expressed some concern about study bias issues with the iFuse procedure, and the decision by investigators not to compare the procedure to a sham surgery. More on this is discussed in the following section.

3. Sponsor Bias, Sham Study Design and Level of Evidence

The effectiveness of SI joint fusion is well established in numerous prospective trials, producing Level I and II evidence on this topic from research conducted ethically and with adequate controls:

1 **INSITE** is a prospective multicenter randomized controlled trial conducted at 19 centers in the US. Two-year results showed that SIJ Fusion surgery provided markedly superior pain and disability relief compared to state-of-the art non-surgical treatment.
2 **iMIA** is a prospective multicenter randomized controlled trial conducted at 9 centers in Europe. The design of iMIA was very similar to INSITE, but control treatment focused on intensive physical therapy. This study also showed marked superiority of surgical vs. non-surgical treatment. Two-year data were just published in Journal of Bone and Joint Surgery.
3 **SIFI** is a prospective multicenter single-arm clinical trial in the same patient population. SIFI results confirmed the above two randomized trials.
4 **LOIS** is a 5-year follow-up study of patients prospectively enrolled in INSITE and SIFI.

The prospective and RCT study of iFuse patients has yielded more than 80 papers published in peer-reviewed, scientific journals, including Level I and II evidence. As a result, many U.S. payers and health technology assessment organizations cover or recommend the procedure. An additional 15 to 20 papers have been published on other FDA/510k cleared MIS-SIJ Fusion systems as well.

Below are direct responses to some of the objections about the study design, and the industry sponsor bias relating to the study of SIJ Fusion:

- **Sham surgery as control.** In 2012, when INSITE was designed, investigators refused to do sham surgery as unethical. It is unclear whether IRBs would have approved such a study. Moreover, it is unclear whether patients participating in such a study would be representative of all patients in general. Notably, sham is not necessarily a requirement for evaluation; no other spine surgical procedure has been subjected to a sham-control trial. A meta-analysis of numerous orthopedic sham trials found these studies have significant methodologic deficiencies that may invalidate their conclusions.[137] The favorable method for studying spine and orthopedic therapies is the randomized, controlled trials with valid control groups to study the experimental arms – of which there are numerous on this topic, all supporting the use of SI joint fusion for well selected patients.

- **Placebo effect.** Large effect sizes were seen in INSITE. While some placebo effect might be present, the sheer size of the effect speaks against any of the observed effect being due to placebo. From a payer perspective, it may not be necessary to determine the proportion of the observed effect that is directly attributable to the device as opposed to placebo. Treated patients feel and perform better.

- **Cross-over to surgery.** Additionally, investigators were still able to draw conclusions after 6 months due to high crossover. While it is true that INSITE has high crossover, the crossover rate in iMIA was substantially lower. Analyses published at 1 year[11] and 2 years[12] in the *Journal of Bone and Joint Surgery* show that the superiority of SI joint fusion persists at 2 years. Moreover, there is very little evidence that chronic SIJ pain resolves on its own. Thus, the expectation in the control group is continued pain and disability.

- **Industry sponsorship and bias.** The vast majority of high-quality trials of spine surgery-related devices are industry sponsored.[40]

We respectfully propose the HCA reconsider the recent decision to deny a re-review of this important topic, and potentially a very helpful and effacicous treatment option for Washington patients. As appendices to this letter, enclosed is a listing of references as well as a summary of ISASS and NASS recommendations and guidelines on this topic. Please do not hesitate to contact us if we may provide any additional information (mloriomd@gmail.com) or be of help in your review process.

Sincerely,

Morgan Lorio, MD, FACS
Chair, ISASS Task Force Coding & Reimbursement

Appendix – References

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Appendix– Comparison of ISASS and NASS Coverage Criteria for Minimally Invasive SI Joint Fusion

Criteria	International Society for the Advancement of Spine Surgery (ISASS)	North American Spine Society (NASS)
GUIDELINES	**ISASS Policy 2016 Update – Minimally Invasive Sacroiliac Joint Fusion: Coverage Indications, Limitations, and/or Medical Necessity (Updated July 5, 2016)**[1] (This supplements the ISASS Policy Statement – Minimally Invasive Sacroiliac Joint Fusion published in *Int J Spine Surg* in 2014) Patients who have all of the following criteria may be eligible for minimally invasive SIJ fusion:	**NASS Coverage Policy Recommendations: Percutaneous Sacroiliac Joint Fusion (June 9, 2015)**[2] **Percutaneous (also referred to as minimally invasive) SIJ fusion** (*e.g.*, insertion of a metallic device across the SIJ that is intended to fuse to the bone or lead to fusion of the joint itself, in distinction from insertion of screws without bone graft across the SIJ which are intended to stabilize but not fuse the joint) is indicated for the treatment of SIJ pain for patients with low back/buttock pain who meet ALL of the following criteria:
TREATMENT PRIOR TO SURGERY	Failure to respond to at least 6 months of non-surgical treatment consisting of non-steroidal anti-inflammatory drugs and physical therapy. Failure to respond means continued pain that interferes with activities of daily living and/or results in functional disability; *Note: Additional ISASS Documentation Requirements are outlined on page 4 of this document.*	Have undergone and failed a minimum six months of intensive nonoperative treatment that must include medication optimization, activity modification, bracing, and active therapeutic exercise targeted at the lumbar spine, pelvis, SIJ, and hip including a home exercise program. A trial of at least one therapeutic intra-articular SIJ injection (i.e. corticosteroid injection). *Note: Traditional care for the treatment of pain arising from the sacroiliac joint not due to an infectious or neoplastic process begins with physical therapy and activity modification. Analgesic medication including NSAIDS, acetaminophen, or opioids could be considered depending on each patient's medical history and symptom severity. Alternative treatments such as sacroiliac support belts and manual medicine may be considered as well. It is important to note that while these treatments are utilized routinely, no comparative*
SI JOINT PAIN	Significant SIJ pain (*e.g.*, pain rating at least 5 on the 0-10 numeric rating scale where 0 represents no pain and 10 represents worst imaginable pain) that impacts quality of life or significantly limits activities of daily living. *(Patients with SI joint pain typically report pain in the buttocks, with possible radiation into the groin or upper legs.)*	Patient's report of typically unilateral pain that is caudal to the lumbar spine (L5 vertebrae), localized over the posterior SIJ, and consistent with SIJ pain.

Criteria	International Society for the Advancement of Spine Surgery (ISASS)	North American Spine Society (NASS)
DIAGNOSTIC INJECTIONS	Confirmation of the SIJ as a pain generator in ≥ 50% acute decrease in pain upon fluoroscopically guided diagnostic intra-articular SIJ block using local anesthetic.	At least 75 percent reduction of pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular SIJ injection on two separate occasions.
PHYSICAL EXAM	SIJ pain confirmed with at least 3 physical examination maneuvers that stress the SIJ (*e.g.*, distraction test, compression test, thigh thrust, FABER (Patrick's test), Gaenslen's maneuver, sacral sulcus tenderness) and reproduce the patient's typical pain.	Positive response to a cluster of 3 provocative tests (*e.g.*, thigh thrust test, compression test, Gaenslen's test, distraction test, Patrick's sign, posterior provocation test). *(Note that the thrust test is not recommended in pregnant patients or those with connective tissue disorders.)* A thorough physical examination demonstrating localized tenderness with palpation over the sacral sulcus (Fortin's point, *i.e.*, at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine or PSIS) in the absence of tenderness of similar severity elsewhere (*e.g.*, greater trochanter, lumbar spine, coccyx) and that other obvious sources for their pain do not exist
DIAGNOSTIC IMAGING	Imaging of the SIJ typically does not provide valuable diagnostic information. Rather imaging is used to ensure that the patient does not have alternative diagnoses that could mimic SIJ pain (*e.g.*, hip osteoarthritis, occasionally L5/S1 spine degeneration).	Diagnostic imaging studies have not been shown to reliably predict pain arising from the SI joint, but are sometimes necessary to identify other pathologic conditions that may be the source of the patient's back pain. **Diagnostic imaging studies that include ALL of the following:** Imaging (plain radiographs and a CT or MRI) of the SI joint that excludes the presence of destructive lesions (*e.g.*, tumor, infection) or inflammatory arthropathy that would not be properly addressed by percutaneous SIJ fusion Imaging of the pelvis (AP plain radiograph) to rule out concomitant hip pathology. Imaging of the lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that can be causing low back or buttock pain. Imaging of the SI joint that indicates evidence of injury and/or degeneration. Note: NASS guidance - Diagnostic imaging studies have not been shown to reliably predict SI joint pain.

Criteria	International Society for the Advancement of Spine Surgery (ISASS)	North American Spine Society (NASS)
OTHER DIAGNOSES CONSIDERED	Additional or alternative diagnoses that could be responsible for the patient's ongoing pain or disability have been considered. Physicians should take into account that patients can have multiple pain generators and addressing just one pain generator may not adequately relieve disability or all back pain.	Absence of generalized pain behavior (somatoform disorder) or generalized pain disorders (*e.g.*, fibromyalgia).
Not indicated for patients with the following scenarios:	Minimally invasive SIJ fusion is NOT indicated for patients with the following: • Less than 6 months of SIJ pain and/or functional impairment; • Failure to pursue conservative treatment of the SIJ (unless contra-indicated); • Pain not confirmed with a diagnostic SIJ block; • Presence of other pathology that would substantially prevent the patient from deriving benefit from SIJ fusion.	Percutaneous SIJ fusion for SIJ pain is NOT indicated in ANY of the following scenarios: • Any case that does not fulfill ALL of the above criteria • Presence of systematic arthropathy such as ankylosing spondylitis or rheumatoid arthritis • Presence of generalized pain behavior (*e.g.*, somatoform disorder) or generalized pain disorder (e.g., fibromyalgia) • Presence of infection, tumor, or fracture • Presence of acute, traumatic instability of the SIJ • Presence of neural compression as seen on an MRI or CT that correlates with the patient's symptoms or other more likely source for the pain.

ISASS Documentation Requirements:

- A complete history and physical documenting the likely existence of SIJ pain;
- Performance of a fluoroscopically-guided SIJ block on the affected side (or both sides, see discussion above) which shows at least a 50% acute reduction in pain;
- A course of conservative treatment to include use of non-steroidal anti-inflammatory drugs and one of the following:
  1. an adequate period of rest,
  2. an adequate course of physical therapy wherein the physical therapist specifically documents lack of response to treatment;
- SIJ pain has continued for a minimum of six months; and

All other diagnoses that could be causing the patient's pain have been considered and the physician believes that SIJ fusion is clinically required.

REFERENCES

1. ISASS Policy Statement – Minimally Invasive Sacroiliac Joint Fusion (July 2016): Coverage Indications, Limitations, and/or Medical Necessity
   Updated July 5, 2016
   http://www.isass.org/public-policy/isass-policy-statement-minimally-invasive-sacroiliac-joint-fusion-july-2016/

PDF version click here
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[This supplements the ISASS Policy Statement – Minimally Invasive Sacroiliac Joint Fusion in IJSS (Lorio MP, Rashbaum R. *Int J Spine Surg*. 2014;8:Article 25. doi: 10.14444/1025.2014)]

2. NASS Coverage Policy Recommendations: Percutaneous Sacroiliac Joint Fusion (June 9, 2015). https://www.spine.org/Documents/PolicyPractice/CoverageRecommendations/PercutaneousSacroiliacJointFusion.pdf