September 22, 2015

Dear Medical Director,

ISASS, the International Society for the Advancement of Spine Surgery, is a global, scientific and educational society organized to provide an independent venue to discuss and address the issues involved with all aspects of basic and clinical science of motion preservation, stabilization, innovative technologies, MIS procedures, biologics and other fundamental topics to restore and improve motion and function of the spine.

I am writing to follow-up on our letter regarding coding changes for minimally invasive sacroiliac joint fusion (MIS SIJ fusion) dated March 31, 2014. Today, I am writing to inquire about the status of your company's coverage policy for MIS SIJ fusion. ISASS supports decision-making at the physician-patient level based on medical necessity and achieving the best outcomes to address the patient's medical condition and therefore supports patient access to and coverage of MIS SIJ fusion. ISASS respectfully requests an update on whether your company covers MIS SIJ fusion and the criteria for coverage so that we can provide an update to our members.

In 2008, the U.S. Food and Drug Administration approved the first MIS device for SIJ fusion and MIS SIJ fusion surgery obtained a Category I CPT® code effective January 1, 2015. The body of literature on MIS SIJ fusion has grown substantially and continues to show positive outcomes for patients who receive the surgery. In addition to outcomes published of multiple retrospective case series[1], published results from a prospective multi-center randomized controlled trial of minimally invasive SIJ fusion vs. non-surgical management (NSM)[2] and a multi-center prospective single arm trial[3] have substantiated high rates of pain relief, improvement

[1] (Sachs & Capobianco, 2013); (Rudolf 2013); (Gaetani et al. 2013); (Sachs et al. 2014); (Sachs & Capoblanco 2012); and (Rudolf 2013)
[2] (Whang et al. 2015)
[3] (Duhon et al. 2013)

in functional measures (SF-36, ODI and EQ-5D) and a low rate of both revisions (<5%) and serious adverse events. Furthermore, these improvements are significantly greater in patients treated with MIS SIJ fusion compared to NSM---VAS scores improved by 53-points in the fusion group compared to 12-points for NSM; ODI improved 30 points in the surgery group vs. 4.9 points in NSM patients; EQ-5D scores improved by 0.29 in the fusion group ($p<.0001$) vs. 0.05 points in the NSM group; mean scores for all SF-36 domains improved significantly in the surgery group while no improvement was seen for any domain in the NSM group; and mean SF-36 Physical Component Summary improved by 12.7 points in the surgery group vs. 1.2 points in the NSM group.

Additionally, in a multi-center retrospective review of 263 patients undergoing either open or MIS SIJ fusion, MIS SIJ fusion was associated with statistically significant and clinically marked decreases in operating room time (mean 163 minutes for open vs. 70 minutes for minimally invasive), decreased blood loss (mean 288 cc vs. 33 cc), and decreased length of stay (5.1 vs. 1.3 days) as well as improved relief of pain at 1 (-2.7 points on 0-10 scale vs. -6.2 points) and 2-year follow-up (-2.0 vs. -5.6 points).[4] Two published studies report that favorable outcomes achieved at one year are sustained long term (up to 5-years).[5] The complication rate for MIS SIJ fusion is low and importantly, the rate of removal or revision is less than 2%.[6]

Based on information we have gathered over the past several years from surgeons performing MIS SIJ fusion and from a systematic review of all available data and literature on the procedure, in March 2014, ISASS issued a comprehensive policy statement on MIS SIJ fusion and updated that policy in March 2015. The ISASS policy statement includes a discussion on the SIJ as a pain generator, information on diagnosing the SIJ as the primary source of pain, a discussion of non-surgical and surgical treatment options and recommended coverage criteria for MIS SIJ fusion.

ISASS developed and supports the following criteria for coverage:

Indications for coverage include:

- Significant SI joint 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) or significant limitations in activities of daily living because of pain from the SI joint(s);

- SI joint pain confirmed with typical pain reproduction on at least 3 positive physical provocative examination maneuvers that stress the SI joint;

- Confirmation of the SI joint as a pain generator with ≥ 75% acute decrease in pain immediately following fluoroscopically guided diagnostic intra-articular SI joint block using local anesthetic. This improvement is specifically accomplished in the immediate post-injection period when the anesthetic agent is active (i.e., 4 hours dependent on the agent, dose level, and concentration;

[4] (Graham-Smith, Capobianco & Cher 2013)
[5] (Vanaclocha et al. 2014) and (Rudolf & Capobianco 2014)
[6] (Duhon et al. 2013); (Whang et al. 2015) and (Miller, Reckling & Block 2013)

- Failure to respond to at least 6 months of non-surgical treatment consisting of non-steroidal anti- inflammatory drugs and/or opioids (if not contraindicated) and one or more of the following: rest, physical therapy, SI joint steroid injection or rhizotomy. Failure to respond means continued pain that interferes with activities of daily living and/or results in functional disability; and

- Additional or alternative diagnoses that could be responsible for the patient's ongoing pain or disability have been clearly considered, investigated and ruled out.

Limitations to coverage include:

- Less than 6 months of back pain;

- Failure to pursue conservative treatment of the SIJ (unless contra-indicated);

- Pain not confirmed with a diagnostic SIJ block; and

- Existence of other pathology that could explain the patient's pain.

Based upon the wide acceptance and utilization of the procedure by our surgeons[7] and the growing body of positive literature supporting the use of the procedure, ISASS supports coverage of MIS SIJ fusion. For your reference, I have included our MIS SIJ fusion policy statement, the March 2015 update to our policy statement and our MIS SIJ fusion utilization paper as attachments to this letter.

Thank you for your time and consideration of our comments and policy statement. Please feel free to reach out Liz Vogt, ISASS Director of Health Policy and Advocacy at liz@isass.org with any questions or requests for additional information. We look forward to hearing back from you soon with information on your company's coverage policy for MIS SIJ fusion.

Sincerely,

Morgan P. Lorio MD

Morgan P. Lorio, MD, FACS
Chair, ISASS Coding and Reimbursement Task Force

Enclosures:
1. "ISASS Policy Statement – MIS SIJ Fusion"
2. March 2015 Update to ISASS MIS SIJ Fusion Policy Statement – "ISASS Proposed Recommendations/Coverage Criteria for Minimally Invasive Sacroiliac Joint Fusion 2015 Coverage Indications, Limitations, and/or Medical Necessity"
3. "Utilization of Minimally Invasive Surgical Approach for Sacroiliac Joint Fusion in Surgeon Population of ISASS and SMISS Membership"

[7] (Lorio et al. 2014)

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