



Via email

March 2, 2020

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Dear Mr. LaPaglia:

On behalf of the International Society for the Advancement of Spine Surgery (ISASS), a leading professional society for orthopedic and neurosurgeons for over 20 years, we appreciate the opportunity to provide the latest updates on the evidence for sacroiliac joint (SIJ) fusion, as we understand that MCG is actively reviewing its own ODG recommendations via its editorial process. We have undertaken a comprehensive review of the evidence, and have maintained professional guidelines for spine surgeons on this topic since 2015. To the extent we can be a help to your organization, ISASS would appreciate the opportunity to provide input and feedback on the current ODG conditional recommendations.

Currently, ISASS understands that ODG recommends the SIJ fusion procedure...

...on a case-by-case basis as a last line of therapy (including either open or minimally invasive [percutaneous] procedures) as treatment for sacroiliac (SI) joint infection, tumor involving the sacrum, disabling pain due to sacroiliitis due to spondyloarthropathy, or sacroiliac pain due to severe traumatic injury. The procedure may be required for multisegmental spinal constructs (i.e., scoliosis or kyphosis surgery). Not recommended for mechanical low back pain, non-specific low back pain, SI joint disruption (in the absence of major pelvic fracture), degenerative sacroiliitis, SI joint osteoarthritis, or "SI joint-mediated pain" (other than pain due to etiologies noted above). The procedure is considered investigational for these diagnoses.

ISASS does not believe the ODG conditional recommendations to be in line with the published Level I and II evidence on this topic; nor does it follow a majority of other commercial and government payers' review of the evidence, including numerous guidelines development organizations that recommend SIJ fusion procedures for over 280 million Americans.

ISASS developed and maintains a Policy Statement for Minimally Invasive Sacroiliac Joint Fusion (July 5, 2016 update)¹, and recommends the minimally invasive SIJ fusion procedure for patients who have all of the following criteria:

- 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.

¹ ISASS Policy Statement – Minimally Invasive Sacroiliac Joint Fusion (July 2016). Coverage, Indications, Limitations and/or Medical Necessity Guidelines
<https://www.isass.org/public-policy/isass-policy-statement-minimally-invasive-sacroiliac-joint-fusion-july-2016/> Updated July 5, 2016 (This supplements the ISASS Policy Statement – Minimally Invasive Sacroiliac Joint Fusion in IJSS), Author: ISASS Task Force (Coding & Reimbursement) Chair; Morgan P. Lorio, MD, FACS.



- Significant SIJ pain that impacts quality of life or significant limitations in activities of daily living.
- SIJ pain confirmed with at least 3 physical examination maneuvers that stress the SIJ and reproduce the patient's typical pain.
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- Confirmation of the SIJ as a pain generator in $\geq 50\%$ acute decrease in pain upon fluoroscopically guided diagnostic intra- articular SIJ block using local anesthetic.
- 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.

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.

Since the publication of ISASS' recommendations in 2015 (and updated recommendations in 2016), the evidence base for minimally invasive SIJ fusion has continued to evolve. The evidence now includes over 83 peer-reviewed papers, including Level I and II evidence extending out to 5 years of follow-up for the iFuse SIJ fusion device (Whang et al 2019). This 5-year study (LOIS) represents improvement in a mostly degenerative sacroiliitis or SIJ disruption patient population's long-term follow-up with iFuse. After 5 years, the patients in the iFuse treatment group had reduced VAS pain and disability scores from pre-op levels; there was an absence of device-related serious adverse events, as well as an absence of surgical revision. Particularly impactful from the perspective of ODG, there was a high proportion of patients who returned to work and who also saw reduced reliance on opioids.

There are more than 100 government and commercial payers in the U.S. that cover SIJ fusion as a standard of care, when conservative therapies have failed. Numerous payers, such as United Healthcare, rely on the current edition of MCG (GRG, SG-MS) clinical coverage criteria for SIJ fusion within the Musculoskeletal Surgery or Procedure General Recovery Guideline (GRG), which ISASS guidelines support.

We encourage the editorial review team at MCG to adopt ODG recommendations that allow for access among the majority of SIJ pain patients, as opposed to restricting the procedure.

If you have additional questions or need additional follow-up information, I may be reached directly at (423) 340-1795 or via email at mloriomd@gmail.com. Thank you for your efforts to provide evidence-based recommendations for important therapies such as SIJ fusion.

Sincerely,



Morgan P. Lorio MD

Morgan Lorio, MD
Chair, ISASS Coding and Reimbursement Task Force