Via email

April 22, 2020

TO Evan London, MS, MPH
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CC John Whitney, MD
Vice President Medical Policy and Clinical Pharmacy Policy
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Dear Anthem Medical Policy Team:

On behalf of the International Society for the Advancement of Spine Surgery (ISASS), a leading professional society for orthopedic and neurosurgeons for more than 20 years, we appreciate the opportunity to provide the latest updates on the evidence for **sacroiliac joint (SIJ) fusion**, as we understand that Anthem has recently reviewed its policy **SURG.00127** on this topic numerous times over the past 12 months. We respectfully request a reconsideration or a re-review of this topic area by the OMPTA and MPTAC at Anthem in light of the Level I evidence supporting use of this surgery for well-selected patients. The broader, more common patient population suffers from chronic SIJ pain that may or may not be a result of pelvic girdle trauma, specifically. Rather, patients may experience chronic SIJ pain from degenerative sacroiliitis and other conditions that do not include trauma. In fact, there are only case series data to support Anthem's current position, which allows for coverage of the minimally invasive SIJ fusion procedure subsequent to pelvic girdle trauma only. This is not in keeping with the current evidence on this topic; nor is it in keeping with the current medical practice, which includes a thorough differential diagnosis to identify the SIJ as the pain generator, which does not necessarily require an injury.

We have undertaken a comprehensive review of the evidence, primarily consisting of degenerative sacroiliitis populations, and have maintained professional guidelines for spine surgeons on this topic since 2015. To the extent we can be of help to your organization, ISASS would appreciate the opportunity to provide input and feedback on the current Anthem conditional coverage policy.

Currently, ISASS understands that Anthem does not cover SIJ fusion procedures for degenerative sacroiliitis patients. ISASS does not believe this 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 more than 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.
- 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.
- 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.
- 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 that 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.

For ease of reference, the key differences between ISASS' policy statement on MIS SIJ fusion, and Anthem's policy SURG.00127 (updated on 12/18/19 and on 4/15/20) are summarized and highlighted as follows:

	Anthem SURG.00127 (4/15/20)	**ISASS MIS SIJF Policy Statement**
Indications	Chronic sacroiliac joint pain or functional impairment subsequent to pelvic girdle trauma	SIJ pain impacting QOL or ADLs
ICD-10 codes	All diagnoses	M46.1, M53.2×8, M53.3, S33.2xxA, S33.6xxA, 099.8, 094
Duration	12 months old injury or greater	6 months or greater duration of SIJ pain and/or functional impairment
Pre-op work-up	A. The original injury (that is, fracture, subluxation or	• 3 physical examination maneuvers.

[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.

	dislocation) is documented radiographically; and B. At least 12 months have elapsed since the pelvic girdle trauma; and C. Physical examination includes reproduction of typical sacroiliac joint pain with at least three of five established provocative tests; and D. There has been at least a 50% reduction in sacroiliac joint pain after image-guided arthrography and sacroiliac injection with a local anesthetic agent.	• ≥50% acute decrease in pain upon fluoroscopically guided diagnostic intra-articular SIJ block using local anesthetic. • 6 months of non-surgical treatment. • Additional or alternative diagnoses that could be responsible for the patient's ongoing pain or disability have been considered.

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 more than 80 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 ACOEM, 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. We encourage the OMPTA and MPTAC at Anthem to adopt policies that allow for access to this important surgical option for more typical SIJ pain patients, as opposed to restricting the procedure to those having suffered a pelvic girdle trauma only.

Given the availability of robust Level I and II data for chronic SIJ pain patients, it is unclear why Anthem characterizes the data as follows:

> ***"Although the evidence published to date is largely limited to case series, current specialty society recommendations from both the ISASS (2016) and NASS (2015) along with surveyed expert opinions support the use of percutaneous sacroiliac joint fusion procedures in the treatment of individuals with a history of traumatic injury that has resulted in chronic sacroiliac joint pain or functional impairment."***

While it is true the evidence for the SIJ fusion procedure to treat pelvic girdle trauma is, in fact, limited to case series data, this statement in the Anthem SURG.00127 policy ignores Level I data available for populations that include degenerative sacroiliitis patients. We therefore request and encourage additional review by the Anthem team, so that the right patients may receive this surgical option. 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 coverage policies for important therapies such as SIJ fusion.

Sincerely,

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