June 22, 2017

David Zieve, MD, MHA
Medical Director
Hayes, Inc.
157 S. Broad St.
Lansdale, PA 19446

RE: Hayes Brief -- "iFuse Implant System (SI-BONE, Inc.) for Sacroiliac Joint Fusion for Treatment of Low Back Pain" – December 29, 2016

Dear Dr. Zieve:

I am writing on behalf of the International Society for Advancement of Spine Surgery (ISASS), to request the opportunity to discuss the Hayes Brief, "iFuse Implant System (SI-BONE, Inc.) for Sacroiliac Joint Fusion for Treatment of Low Back Pain," released December 29, 2016.

ISASS 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. ISASS and its sister organization International Advocates for Spine Patients (IASP), advocate for high quality, widely accessible, and cost effective spine care for patients around the world.

ISASS performed a thorough review of all available data and literature on CPT 27279,® "Arthrodesis, sacroiliac joint, minimally invasive (indirect visualization), with image guidance, includes obtaining bone

graft when performed and placement of transfixing device." In March 2014, ISASS issued a comprehensive policy statement on minimally invasive sacroiliac joint fusion (MIS SIJ fusion) and updated that policy in March 2015, December 2015, and July 2016.[1] Please note, the ISASS Policy does not endorse any specific MIS SIJ fusion system. There are numerous devices available that have received FDA 510(k) clearance for use in MIS SIJ fusion surgery. ISASS maintains that the instrumentation utilized in a MIS SIJ fusion procedure is the purview of surgeon preference. Acceptable bone growth and fusion rates (bridging bone) have been demonstrated by triangular iFuse implants (SI-Bone Inc., San Jose, CA) and screw-based technology SImmetry (Zyga, Minnetonka, MN), 87%[2] and 88%[3] respectively.

Since Hayes' last review, additional evidence has been published, including a two-year randomized control trial (RCT) and a six-year, two control group study. These studies are consistent with the body of evidence on MIS SIJ fusion and show:

1. **Effectiveness:** average 50-point pain reduction *vs.* ~12 point non-surgical management (NSM)
2. **Safety:** Revision rates ~1/3 lumbar fusion and low complication rates
3. **Durability:** 2-year RCT, 2-year prospective, 3.7-year, 4.5-year, 5-year, 6-year two-control-group studies
4. **Cost & Cost-effectiveness:** five studies
5. **Reduction in Opioid Use**
    - 30% MIS SIJ fusion patients were no longer taking opioids at two-years; opioid use increased with NSM [INSITE RCT]
    - Six-year: 11x reduction: 7% opioid users in MIS SIJ fusion group *vs*. >80% NSM groups[4]

Of particular note is a RCT published in the ISASS sponsored peer-reviewed scientific medical journal the *International Journal of Spine Surgery*. The study, "Two-Year Outcomes from a Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion vs. Non-Surgical Management for Sacroiliac Joint Dysfunction"[5] concluded:

> *In this Level 1 multicenter prospective randomized controlled trial, minimally invasive SIJF with triangular titanium implants provided larger improvements in pain, disability and quality of life compared to NSM. Improvements after SIJF persisted to 24 months.*

Moreover, a pooled analysis[6] recently published in *Spine* concludes:

> *Results support the view that SIJF leads to better treatment outcomes than conservative management of SIJ pain.*

Lastly, a six-year study[4] published in *Neurosurgery* concludes:

In patients with SIJ pain unresponsive to CM [conservative management], SIJF resulted in excellent long-term clinical responses, with low opioid use and better work status compared to other treatments.

Additionally, NICE and ECRI have also issued positive clinical evidence reviews:

- The National Institute for Health and Care Excellence (NICE) reviewed MIS SIJ fusion and concluded, "Current evidence on the safety and efficacy of minimally invasive sacroiliac (SI) joint fusion surgery for chronic SI pain is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit." (https://www.nice.org.uk/guidance/IPG578/chapter/1-Recommendations)

- ECRI:
  - MIS SIJ fusion "significantly improves SIJ pain, disability scores and quality of life measures compared to nonsurgical conservative management."
  - Gives a grade of 4 out of 5 to the evidence
  - Includes 19 clinical publications versus eight in the last review

I am requesting the opportunity to discuss this Hayes Brief and the most up-to-date literature on MIS SIJ fusion with you by phone or in person as many of our members and their patients have experienced denials by insurers based on this Hayes Brief and its "C" rating.

Thank you for reviewing this request.

Sincerely,

Morgan P. Lorio, MD, FACS

Chair, ISASS Coding & Reimbursement Task Force

References

1. Lorio, M.P. ISASS Policy Statement – Minimally Invasive Sacroiliac Joint Fusion – July 2016. http://www.isass.org/public-policy/isass-policy-statement-minimally-invasive-sacroiliac-joint-fusion-july-2016/
2. Rudolf L., Capobianco R. Five-Year Clinical and Radiographic Outcomes After Minimally Invasive Sacroiliac Joint Fusion Using Triangular Implants. *Open Orthop. J*. 2014; 8: 375-383.
3. Kube, R.A. & Muir J.M. Sacroiliac Joint Fusion: One Year Clinical and Radiographic Results Following Minimally Invasive Sacroiliac Joint Fusion Surgery. *Open Orthop J*. 10, 679-689 (2016). Doi: 10.2174/1874325001610010679.
4. Vanaclocha, V., Herrera, J. M., Sáiz-Sapena, N., Rivera-Paz, M. & Verdú-López, F. Minimally Invasive Sacroiliac Joint Fusion, Radiofrequency Denervation, and Conservative Management for Sacroiliac Joint Pain: 6-Year Comparative Case Series. *Neurosurgery* (2017). doi:10.1093/neuros/nyx185
5. Polly D.W. et al., "Two-Year Outcomes from a Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion vs. Non-Surgical Management for Sacroiliac Joint Dysfunction," *International Journal of Spine Surgery*, 2016;10: Article 28. doi: 10.14444/3028. http://ijssurgery.com/10.14444/3028
6. Dengler J, Duhon B, Whang P, et al. Predictors of Outcome in Conservative and Minimally Invasive Surgical Management of Pain Originating from the Sacroiliac Joint: A Pooled Analysis. *Spine* (2017). doi:10.1097/BRS.0000000000002169