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February 20, 2017

Trent Haywood, MD, JD  
Chief Medical Officer  
Blue Cross Blue Shield Association  
225 North Michigan Avenue  
Chicago, IL 60601

**RE: Blue Cross Blue Shield Association – Evidence Street –  
Diagnosis and Treatment of Sacroiliac Joint Pain**

Dear Dr. Haywood:

On behalf of the International Society for the Advancement of Spine Surgery (ISASS), I am writing to submit comments regarding the Blue Cross Blue Shield Association (BCBSA) Evidence Street review on the Diagnosis and Treatment of Sacroiliac Joint Pain, specifically related to minimally invasive sacroiliac joint fusion (MIS SIJ fusion) surgery.

ISASS is one of the largest global, scientific and educational societies organized to advance spinal care and spine surgery. ISASS joined BCBSA's Evidence Street program in September 2016.

In 2008, the U.S. Food and Drug Administration approved the first minimally invasive device for sacroiliac joint 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<sup>1-7</sup> and comparative series<sup>8-10</sup>, published results from two prospective, multi-center, randomized controlled trials of MIS SIJ fusion vs. non-surgical management (NSM)<sup>11, 12</sup> and a prospective multi-center single arm trial<sup>13</sup> have substantiated high rates of pain relief, improvement in functional measures (Oswestry Disability Index

(ODI), SF-36, and EQ-5D) and a low rate of both revisions and serious adverse events.

In both prospective, multi-center, randomized controlled trials of MIS SIJ fusion vs. NSM<sup>11, 12</sup>, pain relief, disability reduction and improvement in quality of life were markedly higher in MIS SIJ fusion subjects compared to NSM subjects. Polly et al.<sup>11</sup> found in the MIS SIJ fusion group, mean SIJ pain improved rapidly and was sustained (mean improvement of 55.4 points, 0-100 scale) at month 24. The 6-month mean change in the NSM group (12.2 points on the 0-100 scale) was substantially smaller than that in the MIS SIJ fusion group (by 38.3 points,  $p < .0001$  for superiority). By month 24, 83.1% and 82.0% received either clinical improvement or substantial clinical benefit in VAS SIJ pain score. Similarly, 68.2% and 65.9% had received clinical improvement or substantial clinical benefit in ODI score at month 24. In the NSM group, these proportions were  $< 10\%$  with non-surgical treatment only. Parallel changes were seen for EQ-5D and SF-36, with larger changes in the surgery group at 6 months compared to NSM. The rate of adverse events related to MIS SIJ fusion was low and only 3 subjects assigned to MIS SIJ fusion underwent revision surgery within the 24-month follow-up period. In the other randomized trial, Stuesson et al.<sup>12</sup> found mean self-rated low back pain improved by 43.3 points (0-100 scale) in the MIS SIJ fusion group and 5.7 points in the NSM group (difference of 38.1 points,  $p < 0.0001$ ) at 6 months. Mean ODI improved by 26 points in the MIS SIJ fusion group and 6 points in the NSM group ( $p < 0.0001$ ). Active straight leg raise test, EQ-5D-3L, walking distance and satisfaction were statistically superior in the MIS SIJ fusion group. The frequency of adverse events did not differ between groups.

Other relevant peer-reviewed published papers adding to the evidence base on MIS SIJ fusion include safety analyses<sup>14, 15</sup>, economic analyses<sup>16-18</sup>, cost analyses<sup>19, 20</sup>, a validation study<sup>21</sup>, burden of disease analyses<sup>22, 23</sup> and a systematic review<sup>24</sup>. Taken together, these studies represent a substantial amount of evidence supporting MIS SIJ fusion as a safe and effective treatment option. After performing a thorough 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, December 2015 and July 2016. The 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. 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.

The November 2016 BCBSA Evidence Street review on the Diagnosis and Treatment of Sacroiliac Joint Pain notes, “both non blinded RCTs reported superior short-term results for fusion, but there is potential for bias because of unblinded controls and the trials used self-reported outcomes.” The assessment also notes that the data raises “uncertainty about net health outcomes achievable in clinical practice” in regard to adverse event reporting. The assessment concludes that “the evidence is insufficient to determine the effects of the technology on health outcomes” for individuals with sacroiliac joint pain treated with MIS SIJ fusion. We disagree with this conclusion and would like to highlight the following issues with the evidence review:

### Blinded vs. Non-Blinded Randomized Controlled Trials

- The evidence base for MIS SIJ fusion includes two open-label surgery vs. non-surgery randomized trials. The design of these studies (open label trials with patient-reported outcomes) is very similar to unblinded trials of other technologies BCBSA has found acceptable as evidence to support those technologies. It is disingenuous to suggest that subjects could be blinded between surgical and non-surgical treatments and then use this flawed hypothesis to downgrade surgical evidence.
- A blinded clinical trial with an FDA-cleared/approved medical device is virtually impossible for several reasons:
  - Because the device is available outside of the study, most patients would elect to undergo the procedure in the standard setting, outside of the trial.
  - Blinding requires a sham surgery including a 2-inch incision with dissection down to the ilium. This would be considered by most to be unethical and Institutional Review Boards would likely reject this as would surgeons and patients.
  - The patients who would participate in such trials would almost certainly be different from those in standard practice, limiting the generalizability of the trial.
  - We note that trials such as SPORT<sup>25-27</sup> which BCBSA has found acceptable in some of its reviews, were open label. There was a substantial early crossover in SPORT, requiring an “as-treated” analysis; in contrast, the MIS SIJ fusion studies had no early crossover.

### Self-Reported Outcomes

- The instruments used in the MIS SIJ fusion trials to measure the impact of sacroiliac joint pain and its treatment on health (pain measured using a visual analog scale, disability measured with ODI, and quality of life measured with SF-36 and EQ-5D) are accepted, validated and standard instruments. The use of these tools allows comparison to other trials of accepted treatments; treatment effect sizes after MIS SIJ fusion are in the same range as other treatments that BCBSA deems acceptable.
- The assessment suggests that the treatment effect is related entirely to placebo. With a large treatment effect (38 points on 0-100 VAS score and 18 points for ODI) – effects as large as shown with other accepted surgical treatments – it is inappropriate to dismiss the entire observed MIS SIJ fusion effect as placebo.
- It is our understanding that electronic means (i.e., an iPad) were used to administer pain, disability and quality of life instruments in the US prospective clinical trial. The outcome measures were completed by patients and iPads were managed by unconflicted study coordinators and participating surgeons did not routinely review results. Use of “blinded assessors” for patient-reported outcomes is not, to our knowledge, a concept espoused by any clinical trialists. To imply that outcome data completed by patients independent of the treating physician is questionable would essentially invalidate outcomes of almost all surgical trials.

### Adverse Event Reporting

- Adverse event rates from the U.S. Food and Drug Administration's MAUDE database are uninterpretable in the absence of a denominator. The article of Schoell et al.<sup>28</sup> reporting high adverse event rates uses an unvalidated database<sup>29</sup> and is inconsistent with results from reported clinical trials and a published safety analysis.<sup>30</sup>

### Literature Review

- Duhon et al.<sup>13</sup> is labeled as a case series but it is better characterized as a prospective multicenter clinical trial. Its design and execution is similar to other trials BCBSA has found acceptable.
- The literature review appears to be incomplete, with missing comparative studies<sup>8-10</sup>, missing case series<sup>3, 5, 7, 31, 32, 33</sup> and missing systematic reviews.<sup>24, 34, 35</sup>
- The review includes policy statements from other societies that predate the most current literature.

Patients with chronic SIJ pain are highly burdened by their disease. The evidence base is clear that MIS SIJ fusion provides substantial improvements in pain, disability and quality of life. We welcome the opportunity to further discuss this assessment with you prior to your next review. Please contact Kristy Radcliffe, ISASS Executive Director by email at [kristy@isass.org](mailto:kristy@isass.org) or by phone at (630) 375-1432 with questions or requests for additional information. Thank you for your time and consideration of our comments.

Sincerely,

Morgan P. Lorio, MD, FACS  
Chair, Coding and Reimbursement Task Force  
International Society for the Advancement of  
Spine Surgery

cc: Suzanne Belinson, PhD, MPH  
Executive Director, Clinical Markets  
Office of Clinical Affairs  
Blue Cross Blue Shield Association

## References

1. Bornemann R, Roessler PP, Strauss A, et al. 2-year clinical results of patients with sacroiliac joint syndrome treated by arthrodesis using a triangular implant system. *Technol. Health Care Off. J. Eur. Soc. Eng. Med.* 2016 Nov 7;1-7.
2. Sachs D, Capobianco R, Cher D, et al. One-year outcomes after minimally invasive sacroiliac joint fusion with a series of triangular implants: a multicenter, patient-level analysis. *Med. Devices Evid. Res.* 2014;7:299–304.
3. Gaetani P, Miotti D, Risso A, et al. Percutaneous arthrodesis of sacroiliac joint: a pilot study. *J. Neurosurg. Sci.* 2013; 57:297–301.
4. 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.
5. Sachs D, & Capobianco, R. Minimally invasive sacroiliac joint fusion: one-year outcomes in 40 patients. *Adv. Orthop.* 2013;536128.
6. Sachs D, Kovalsky D, Redmond A, et al. Durable intermediate-to long-term outcomes after minimally invasive transiliac sacroiliac joint fusion using triangular titanium implants. *Med. Devices Auckl.* 2016 Jul 13;9:213–222.
7. Vanaclocha-Vanaclocha V, Verdu-Lopez F, Sancehz-Pardo M, et al. Minimally Invasive Sacroiliac Joint Arthrodesis: Experience in a Prospective Series with 24 Patients. *J. Spine.* 2014;3:5.
8. Graham Smith A, Capobianco R, Cher D, et al. Open versus minimally invasive sacroiliac joint fusion: a multi-center comparison of perioperative measures and clinical outcomes. *Ann. Surg. Innov. Res.* 2013;7(1):14.
9. Ledonio CGT, Polly DW, Swiontkowski, MF. Minimally invasive versus open sacroiliac joint fusion: are they similarly safe and effective? *Clin. Orthop.* 2014;472:1831–1838.
10. Ledonio C, Polly D, Swiontkowski MF, et al. Comparative effectiveness of open versus minimally invasive sacroiliac joint fusion. *Med. Devices Evid. Res.* 2014;187–193.
11. Polly DW, Swofford J, Whang PG, et al. Two-Year Outcomes from a Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion vs. Non-Surgical Management for Sacroiliac Joint Dysfunction. *Int. J. Spine Surg.* 2016;10:28.
12. Sturesson B, Kools D, Plugmacher R, et al. Six-Month Outcomes from a Randomized Controlled Trial of Minimally Invasive SI Joint Fusion with Triangular Titanium Implants vs. Conservative Management. *Eur. Spine J.* 2016 May 14.

13. Duhon BS, Bitan F, Lockstadt H, et al. Triangular Titanium Implants for Minimally Invasive Sacroiliac Joint Fusion: 2-Year Follow-Up from a Prospective Multicenter Trial. *Int. J. Spine Surg.* 2016 Apr 20;10:13.
14. Miller L, Reckling WC, Block JE. Analysis of postmarket complaints database for the iFuse SI Joint Fusion System: a minimally invasive treatment for degenerative sacroiliitis and sacroiliac joint disruption. *Med. Devices Evid. Res.* 2013;6:77–84.
15. Cher DJ, Reckling WC, Capobianco RA. Implant survivorship analysis after minimally invasive sacroiliac joint fusion using the iFuse Implant System. *Med. Devices Evid. Res.* 2015;8:485–492.
16. Ackerman S, Polly DW, Knight T, et al. Comparison of the costs of nonoperative care to minimally invasive surgery for sacroiliac joint disruption and degenerative sacroiliitis in a United States commercial payer population: potential economic implications of a new minimally invasive technology. *Clin. Outcomes Res.* 2014;6:283–296.
17. Ackerman S, Polly DW, Holt T, et al. Management of sacroiliac joint disruption and degenerative sacroiliitis with nonoperative care is medical resource-intensive and costly in a United States commercial payer population. *Clin. Outcomes Res.* 2014;6:3–74.
18. Ackerman S, Polly DW, Knight T, et al. Comparison of the costs of nonoperative care to minimally invasive surgery for sacroiliac joint disruption and degenerative sacroiliitis in a United States Medicare population: potential economic implications of a new minimally-invasive technology. *Clin. Outcomes Res.* 2013;5:575–587.
19. Cher DJ, Frasco MA, Arnold RJ, et al. Cost-effectiveness of minimally invasive sacroiliac joint fusion. *Clin. Outcomes Res.* 2016;8:1–14.
20. Polly D, Cher D. Ignoring the sacroiliac joint in chronic low back pain is costly. *Clin. Outcomes Res.* 2016;8:23–31.
21. Copay AG, Cher DJ. Is the Oswestry Disability Index a valid measure of response to sacroiliac joint treatment? *Qual. Life Res. Int. J. Qual. Life Asp. Treat. Care Rehabil.* 2016;25:283–292.
22. Cher D, Polly D, Berven S. Sacroiliac Joint pain: burden of disease. *Med. Devices Evid. Res.* 2014;7:73–81.
23. Cher DJ, Polly DW. Improvement in Health State Utility after Sacroiliac Joint Fusion: Comparison to Normal Populations. *Glob. Spine J.* 2016;6:100–107.
24. Heiney J, Capobianco R, Cher D. A systematic review of minimally invasive sacroiliac joint fusion utilizing a lateral transarticular technique. *Int. J. Spine Surg.* 2015;9:40.

25. Weinstein JN, Lurie JD, Tosteson TD, et al. Surgical vs Nonoperative Treatment for Lumbar Disk Herniation: The Spine Patient Outcomes Research Trial (SPORT) Observational Cohort. *JAMA*. 2006 Nov 22;296(20):2451.
26. Weinstein JN, Lurie JD, Tosteson TD, et al. Surgical versus Nonsurgical Treatment for Lumbar Degenerative Spondylolisthesis. *N Engl J Med*. 2007 May 31;356(22):2257–70.
27. Weinstein JN, Tosteson TD, Lurie JD, et al. Surgical versus Nonsurgical Therapy for Lumbar Spinal Stenosis. *N Engl J Med*. 2008 Feb 21;358(8):794–810.
28. Schoell K, Buser Z, Jakoi A, et al. Postoperative complications in patients undergoing minimally invasive sacroiliac fusion. *Spine J Off J North Am Spine Soc*. 2016 Jun 24.
29. Cher D. Rates reported by Schoell et al. are of questionable validity. *Spine J* [Internet]. 2016 Nov 9 [cited 2016 Nov 10];0(0). Available from: [http://www.thespinejournalonline.com/article/S1529-9430\(16\)30948-2/fulltext](http://www.thespinejournalonline.com/article/S1529-9430(16)30948-2/fulltext)
30. Cher DJ, Reckling WC, Capobianco RA. Implant survivorship analysis after minimally invasive sacroiliac joint fusion using the iFuse Implant System. *Med Devices Evid Res*. 2015 Nov 23;8:485–92.
31. Sachs D, Capobianco R. One year successful outcomes for novel sacroiliac joint arthrodesis system. *Ann Surg Innov Res*. 2012;6(1):13.
32. Cummings J Jr, Capobianco RA. Minimally invasive sacroiliac joint fusion: one-year outcomes in 18 patients. *Ann Surg Innov Res*. 2013 Sep 16;7(1):12.
33. Schroeder JE, Cunningham ME, Ross T, et al. Early Results of Sacroiliac Joint Fixation Following Long Fusion to the Sacrum in Adult Spine Deformity. *Hosp Spec Surg J*. 2013 Dec 11;10(1):30–5.
34. Lingutla KK, Pollock R, Ahuja S. Sacroiliac joint fusion for low back pain: a systematic review and meta-analysis. *Eur Spine J*. 2016;25(6):1924–31.
35. Zaidi HA, Montoure AJ, Dickman CA. Surgical and clinical efficacy of sacroiliac joint fusion: a systematic review of the literature. *J Neurosurg Spine*. 2015 Jul;23(1):59–66.