Washington State Health Care Authority

Sacroiliac Joint Fusion

Peer review and public comment on draft evidence report

December 3, 2018

Health Technology Assessment Program (HTA)

Washington State Health Care Authority

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This document was created in response to peer review and public comments on a Draft Health Technology Assessment (HTA) report prepared by the RTI-UNC Evidence-based Practice Center through a contract to RTI International from the State of Washington Health Care Authority (HCA). The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of the State of Washington HCA and no statement in this document should be construed as an official position of the State of Washington HCA.

The information in the document is intended to help the State of Washington's independent Health Technology Clinical Committee make well-informed coverage determinations. This document and its associated Evidence Report are not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this document and the associated Evidence Report in the same way as any medical reference and in conjunction with all other pertinent information (i.e., in the context of available resources and circumstances presented by individual patients).

Acknowledgments

The following individuals contributed to this report:

Lead Investigator:	Leila Kahwati, MD, MPH
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Peer Review Comments and Responses

Seven independent, external peer reviewers were invited to provide comments on the Draft Evidence Report, but we only received comments from one individual. This individual did not receive any compensation in exchange for their review. The peer reviewer's name, affiliations, and conflicts of interest are reported in ***Table 1***.

Table 1. External Peer Reviewer of the Draft Evidence Report

Name	Title/ Affiliation	Conflicts of Interest Reported
David W. Polly, Jr., MD, FACS, FAAOS, FAOA	Professor and Chief of Spine Surgery, Department of Orthopaedic Surgery and Department of Neurosurgery, University of Minnesota	Financial conflicts: None. Non-financial conflicts: Primary clinical specialty is orthopaedic spine surgery. Regularly treats patients clinically with SI joint pain. Author of industry-sponsored RCT cited in this report, and lead author for 1 year and 2 year follow-up papers for that RCT (also cited in report). Additionally, author of multiple peer reviewed articles, book chapters, presentations, and participant in debates on this topic. Member of both the North American Spine Society, but not involved in formulating its position statement on this topic. As a member of the International Society for the Advancement of Spine Surgery, provided information to the person responsible for formulating that group's position statement. Reviewer's institution has also received funding for various biomechanical projects related to this topic on reviewer's behalf, but reviewer does not receive any of those funds.

The peer reviewer did not identify any missing studies and did not identify any studies that should have been excluded from the report. The reviewer offered a suggestion for an additional article regarding diagnosis. We addressed many of the comments submitted by the reviewer in the Final Evidence Report; though some comments or suggestions were outside the scope of the HTA. We considered most revisions made based on peer review comments as minor revisions. Specific peer review comments and responses are provided in ***Table 2***.

Table 2. Peer Reviewer Comments on Draft Evidence Report and Response

Item	Comment	Response
Introduction		
Are there any additional issues you think we should cover in the introduction?	The introduction outlines the goal of assessing the evidence for SI fusion. What it neglects is the counterfactual of what is the health care state outcome for patients with the condition not treated by fusion (and the level of evidence for alternative treatment strategies). As this document is intended to guide decision makers for Washington state about making a coverage determination assessing the surgical treatment in isolation does not fully inform policy makers about choosing the best treatment strategy for patients with the condition of interest.	The HTA includes both controlled and uncontrolled studies of SI Joint Fusion. With a few exceptions where alternative surgical procedures are compared, most of the controlled studies compare SI joint fusion to either no treatment or to conservative treatment. The outcomes expressed from these comparison are the incremental benefit (or harms) of surgery relative to the control group (i.e., the counterfactual). A comprehensive review of all non-surgical treatment strategies for SI joint fusion was outside the scope of this HTA.
Do you see anything inaccurate, superfluous, or unclear?	In the discussion under burden of disease, the only discussion is about the prevalence. There is no discussion about the disability associated with the condition. There is one article in the references that addresses this. Cher D, Polly D, Berven S. Sacroiliac joint pain: burden of disease. Med Devices (Auckl). 2014 Apr 12;7:73-81. It turns out that this is a very disabling condition.	We have added some data and information about the impact on quality of life from the cited study.
Any additional comments?	No.	Thank you.
Methods		
Do you see any problems with our methods?	The methodology appropriately looks at the data for fusion, but there is no examination of the efficacy of non-operative management.	An evidence synthesis on non-operative management was outside the scope of this HTA.
Any additional comments about the Methods section?	No.	Thank you.

Item	Comment	Response
Results		
Are there any studies you believe we may have missed?	No.	Thank you.
Are there studies that you believe we should have excluded?	No.	Thank you.
Do you believe we have inaccurately described any studies?	No.	Thank you.
Any additional comments about the Results?	No.	Thank you.
Discussion		
Do you think we missed any important points?	In terms of contextual question on diagnostic accuracy the following study should be added Petersen T, Laslett M, Juhl C. Clinical classification in low back pain: best-evidence diagnostic rules based on systematic reviews. BMC Musculoskelet Disord. 2017 May 12;18(1):188. This indicates that the reliability of the mulittest survey is as good or better than any other condition in the low back.	We have reviewed the suggested article (a narrative review) and do not think it provides any additional or new information to address the contextual question.
Do you disagree with any of the discussion items?	N/A	N/A
Any additional comments about the Discussion?	N/A	N/A
Other Sections		
Any comments on the structured abstract, conclusion,	For insurance coverage it appears that you only discuss payers in Washington state as there are certainly many other payers that cover the procedure (such as the brief comment about other BCBS). It may also be	The focus of the payor coverage section is primarily on Washington state payors. We have added information about TRICARE coverage to the report. We were unable to

Item	Comment	Response
figures, tables and appendices?	appropriate to note that it is covered by DoD and TRICARE as there are many military health care system beneficiaries in Washington state as well.	locate any specific DOD policy regarding coverage of this procedure.
General Comments		
Is the report clearly written, adequately detailed and of an appropriate length?	Yes. You have appropriately analyzed the data according to your pre-specified criteria. Your criteria sets a high bar for level of evidence, generally RCT's and CCS. I believe that there is greater emphasis emerging on real world data as opposed to only RCT's and CCS, but that is probably beyond the scope of this report.	Thank you.
Please make any additional comments you feel would help us improve the report.	No additional comments.	Thank you.

Abbreviations: BCBS = Blue Cross Blue Shield; CCS = controlled cohort studies; DoD = Department of Defense; HTA = health technology assessment; N/A = not applicable; RCT = randomized controlled trial; SI = sacroiliac;

Public Comments and Responses

The Draft Evidence Report was posted for public comment from October 10, 2018 to November 9, 2018. Three public comments were submitted. The names and affiliations of those submitting comments are summarized in ***Table 3.***

Table 3. Individuals or Organizations Submitting Public Comments on the Draft Evidence Report

Name	Title/Affiliation
J. Michael Schweitzer, DC	President, Washington State Chiropractic Association
Robert H. Quinn, MD; Ganesh Rao, MD, FAANS; Shelly D. Timmons, MD, PhD, FAANS; Michael Y. Wang, MD, FAANS; Jeffrey C. Wang, MD; Jean-Christophe Leveque, MD	Chairman, American Academy of Orthopaedic Surgeons, Council on Research and Quality; President, Congress of Neurological Surgeons; President, American Association of Neurological Surgeons; Chair, AANS/CNS Disorders of the Spine and Peripheral Nerves; President, North American Spine Society; President, Washington State Association of Neurological Surgeons
Morgan Lorio, MD	Chair, ISASS Coding and Reimbursement Task Force

Public comments and responses to comments are detailed in ***Table 4***. Complete copies of the comments submitted by individuals follow the table.

Table 4. Public Comments on Draft Evidence Report and Specific Responses

Name (#)	Public Comment	Response
Schweitzer (1)	I congratulate the Health Technology Assessment Committee (HTAC) in their continued effort to assess and recommend safe and effective devices and procedures for the citizens of the State of Washington. Upon review of the recent recommendation concerning Sacroiliac Joint Fusion I have some concerns. The conclusion, noted on page A-1 (pg47) stated that upon "meeting *diagnostic criteria* for SI joint pain or dysfunction, minimally invasive SI joint fusion surgery with the IFuse Implant System is more effective than conservative management". This statement is inaccurate since no study compared conservative care until after 6 months of conservative care. Perhaps amending the conclusion to have "….is more effective than conservative management after 6 months" would be more reflective of the evidence.	We thank the reviewer for this observation and have made slight revisions to the text to reflect this concern.
Schweitzer (2)	It is mentioned in 1.3 Technology Description, that "SI joint fusion procedures are typically reserved for persons who fail less invasive treatments" where manipulative therapy is mentioned. The Conclusion lacks a discussion on requirements for conservative care prior to the authorization of this surgery. While there is very little literature documenting appropriate conservative care avenues, there is a review that was not discussed in the committee's review that recommends 6 months of exercise and manipulation [1]. Similarly, the SI joint is commonly placed in a broad "Low Back Pain" category in the literature and there is demonstration of the benefits of chiropractic management of low back condition reducing disability in the working population with low back pain [2].	The evidence synthesized in this HTA is focused solely on the effectiveness and safety of surgery; we are unable to draw conclusions about the effectiveness, safety, or costs of non-surgical treatment and cannot draw conclusions about what should be required as part of conservative care prior to surgery. The cited review (1) is a narrative review and is not eligible for inclusion in this HTA.

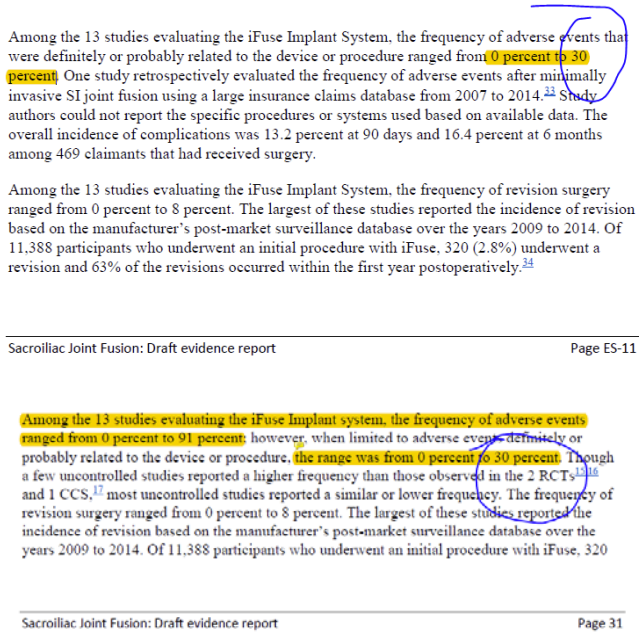
Name (#)	Public Comment	Response
Schweitzer (3)	The few studies HTA includes around conservative care show that after a point around 6 months, conservative care doesn't seem to offer a lot of benefit and only at that point would it be appropriate to consider a fusion. Even after 6mo, 1yr and 2yr follow-ups, the conservative group only has very small improvements. At that point, they should have responded to conservative care and consideration of surgery could be appropriate for some patients [3,4,5]. This 6mo conservative care trial that all studies have used is not reflected in the HTA's conclusion. It is important to keep in mind that these are patients with chronic (in pain >3 months). Most of the recommendations by other insurers cited in the HTA report (pg. 45 of the draft document) only approve this procedure after 6 months of conservative care failure. My experience with surgeons that do this procedure is that they usually refer out for conservative care for a number of months before they book the pre-surgical evaluation. Perhaps our recommendation could be that the conclusions of the HTA should be similar to those of other major carriers like Regence and United that require an initial conservative management for up to 6 months (Regence guidelines Pg. 45 of draft) prior to authorization of this procedure.	We describe the conservative care study arms in detail in the evidence tables in the appendix and briefly in the text. We have modified text in the discussion and conclusion to reinforce the applicability of findings to persons who do not adequately respond to conservative management.
Quinn/Rao/ Timmons/Wang/ Wang/Leveque (1)	On behalf of the American Academy of Orthopaedic Surgeons (AAOS), American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS), AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves (DSPN), North American Spine Society (NASS) and Washington State Association of Neurological Surgeons (WSANS), we appreciate the opportunity to submit comments regarding the Washington State Health Care Authority (HCA) Draft Evidence Report on Sacroiliac (SI) Joint Fusion Surgery, which was prepared by RTI International–University of North Carolina Evidence-based Practice Center.	Thank you.

Name (#)	Public Comment	Response
Quinn/Rao/ Timmons/Wang/ Wang/Leveque (2)	We agree with the authors of the Washington State HCA Draft Evidence Report who conclude that minimally invasive SI joint fusion procedures provide significant benefit to carefully selected patients. We recognize that there is a relative paucity of high quality randomized controlled studies at the current time and the best available studies focus on one particular product from one manufacturer. These studies show clear evidence of benefit for the procedure in terms of pain control and functional improvement compared to conservative management.	Thank you.
Quinn/Rao/ Timmons/Wang/ Wang/Leveque (2)	In addition, we also agree with the finding that comparative studies between minimally invasive SI joint fusion and open joint fusion procedures show a preference for the minimally invasive option regarding improved postoperative pain and shorter length of hospital stay.	Thank you.
Quinn/Rao/ Timmons/Wang/ Wang/Leveque (3)	Equally important is the fact that current evidence supports minimally invasive SI joint fusion procedures as safe and cost-effective for pain management and improved quality of life for patients with chronic SI joint dysfunction.	Thank you.
Quinn/Rao/ Timmons/Wang/ Wang/Leveque (4)	Furthermore, we found the literature search and data extraction in the report to be up to date and comprehensive.	Thank you.
Quinn/Rao/ Timmons/Wang/ Wang/Leveque (5)	We recognize the limitations of the currently existing evidence, which makes it difficult to generalize the findings to all minimally invasive SI joint fusion products and procedures. However, the concept of creating an arthrodesis across the SI joint has been demonstrated to be clinically efficacious, and it would be difficult to dismiss other products that accomplish that same task. The summary of evidence clearly shows a need for continued development of well-designed controlled studies to explore several aspects of SI joint fusion. The draft evidence report justifies continued research into SI joint fusion products and procedures based on the promising results from one manufacturer to evaluate whether other products can provide equal benefit to patients when compared to either conservative management or the currently tested system itself.	Thank you.
Quinn/Rao/ Timmons/Wang/ Wang/Leveque (6)	Additional and continuing studies will be important to examine the long-term effects of these procedures to determine both the durability of pain relief and functional improvement compared to long-term conservative management.	We agree.

Name (#)	Public Comment	Response
Quinn/Rao/ Timmons/Wang/ Wang/Leveque (7)	We also recognize that further evaluation of the diagnostic criteria used for patient selection will both validate these criteria and hopefully provide additional guidance for appropriate patient selection for SI joint fusion procedures.	We agree.
Quinn/Rao/ Timmons/Wang/ Wang/Leveque (8)	Overall, we support the findings of this evidence report and welcome it as justification for continued research and study of minimally invasive SI joint fusion procedures.	Thank you.
Lorio (1)	We are in general agreement with the authors of the Washington State HCA Draft Evidence Report who conclude that Minimally Invasive Surgery Sacroiliac Joint (MIS SIJ) Fusion procedures provide significant benefit to carefully selected patients.	Thank you.
Lorio (2)	Although we recognize the best available studies utilize one particular device from one manufacturer, ISASS policy does not endorse any specific MIS SIJ System. There are numerous devices available that have received FDA 510(k) clearance for use in minimally invasive joint fusion (MIS SIJ) stabilization. The clinical concept of creating a true arthrodesis (either anatomic or extra-anatomic) across the SI joint have been reported with favorable outcomes at one year[1] which are sustained long term (up to 5 years)[2 3]. Of importance is the clinically documented opioid reduction for low back pain patients as a result of this procedure, agnostic to the specific MIS SIJ system [4 5]. ISASS recommends that WSHCA revise the wording in the draft "conclusions and summary of evidence" sections to refer to MIS SIJ Fusion "procedurally" where it currently refers specifically to the "i-Fuse technology."	All of the comparative evidence that we synthesized is from studies evaluating the iFuse Implant System. It would not be appropriate for the evidence report to generalize the summary of evidence and conclusions to other procedures and devices. However, it may be in the purview of the HTCC to consider whether the findings from the evidence report are applicable to other procedures and devices in order to formulate their policy decision.
Lorio (3)	We found the literature search and data extraction that was the basis of this report to be comprehensive; however, we would recommend updated wording in the summary of evidence section and the addition of specific citations within that section (E1.4) as suggested below.	We thank the commenter for offering alternative language. • Regarding the suggestion to

Name (#)	Public Comment	Response
	ES 4.1 Summary of the Evidence. Compared to conservative management, minimally invasive SI joint fusion surgery improves pain, physical function and quality of life. The quality of evidence for these findings is moderate for outcomes at 6 months[1,2] and very low for outcomes between 6 months and 6 years[3]. Findings are mixed with respect to opioid use (modest reductions in use with low to very low quality of evidence). From both randomized trials, no differences in the rate of serious adverse events exist between surgery and conservative management (low to very low quality of evidence). Blinded randomized trials were not done, but blinding subjects would be challenging as all implant systems are highly radiopaque and obvious on any radiographic study. The incidence of revision surgery is likely no higher than 3.4 percent at 2 years[4,5] (moderate quality of evidence). Minimally invasive surgery costs $13,313 per additional quality of life-adjusted year gained compared to conservative management[6]; an amount that most would consider cost-effective. No differences exist between open fusion and conservative management with respect to pain, function, and quality of life, but this conclusion is based on one low quality evidence study[7]. Minimally invasive SI joint fusion improves pain over 2 years[8,9] or longer[3,10,11] and is associated with a shorter length of hospital stay compared to open fusion[12]. The incidence of adverse events was similar for open fusion and Minimally Invasive SI Joint Fusion,[12] but findings were mixed for the comparative incidence of revision surgery. All findings related to this comparison are based on very low quality of evidence. We limited the evidence from uncontrolled studies to safety outcomes. The heterogeneity in the reporting of adverse events across the 8 uncontrolled studies evaluating open fusion limits our ability to draw definitive conclusions from this body of evidence. Similarly, the incidence of adverse events and revision surgery reported in the 24 uncontrolled studies of minimally invasive surgery is heterogenous, likely reflecting differences in outcome definitions and ascertainment, but is generally low. The incidence of complications from minimally invasive fusion reported from an analysis of insurance claims is higher than the incidence reported in controlled studies;[14] issues regarding the identified patient population in this analysis[15] make interpretation of this result challenging. The incidence of revision surgery after fusion observed in trials is similar to the incidence reported in post-market surveillance.[4,5]	remove references to iFuse in several places, for the same reasons we cite in comment "Lorio (2)", we will keep the reference to the iFuse Implant System intact, as that is the intervention reflected by the evidence. • Regarding the insertion of the sentence about blinding, the issue of blinding is discussed in section ES 4.2 and it is not necessary to include it in section ES 4.1. • Regarding the edits to the sentence describing results from open fusion compared to conservative management, the proposed edits conflate risk of bias assessment and strength of evidence, we retain our original language which reflects the strength of evidence assessment for this comparison.

Name (#)	Public Comment	Response
		• Regarding the suggestion to remove the wording describing inconsistent findings for physical function comparing MIS to open fusion, we will retain these findings as they are part of the evidence synthesis. • Regarding the suggestion to add "and is generally low" when describing the incidence of adverse events, we will retain our original wording which is accurate. • Regarding the suggestion to modify language around the interpretation of the incidence of complications from the study using insurance claims, we retain our original language which we believe is accurate.
Lorio (4)	We also noted that the WA State Health Authority document cites a rate of adverse events after MIS SIJF of up to 30% in two locations; however, we are not aware of where the 30% figure comes from and believe the figure mischaracterizes the safety of most MIS procedures. Please see the abstracted sections with highlights. We recommend the Health Authority	The 13 uncontrolled studies for which we synthesized adverse event data are cited in Table 16. The specific adverse

Name (#)	Public Comment	Response
	review these statements to ensure they are accurate and provide direct citations in order to allow for proper verification and documentation.  Among the 13 studies evaluating the iFuse Implant System, the frequency of adverse events that were definitely or probably related to the device or procedure ranged from 0 percent to 30 percent. One study retrospectively evaluated the frequency of adverse events after minimally invasive SI joint fusion using a large insurance claims database from 2007 to 2014.[33] Study authors could not report the specific procedures or systems used based on available data. The overall incidence of complications was 13.2 percent at 90 days and 16.4 percent at 6 months among 469 claimants that had received surgery. Among the 13 studies evaluating the iFuse Implant System, the frequency of revision surgery ranged from 0 percent to 8 percent. The largest of these studies reported the incidence of revision based on the manufacturer's post-market surveillance database over the years 2009 to 2014. Of 11,388 participants who underwent an initial procedure with iFuse, 320 (2.8%) underwent a revision and 63% of the revisions occurred within the first year postoperatively.[34] Sacroiliac Joint Fusion: Draft evidence report Page ES-11 Among the 13 studies evaluating the iFuse Implant system, the frequency of adverse events ranged from 0 percent to 91 percent; however, when limited to adverse events definitely or probably related to the device or procedure, the range was from 0 percent to 30 percent. Though a few uncontrolled studies reported a higher frequency than those observed in the 2 RCTs[12,16] and 1 CCS,[17] most uncontrolled studies reported a similar or lower frequency. The frequency of revision surgery ranged from 0 percent to 8 percent. The largest of these studies reported the incidence of revision based on the manufacturer's post-market surveillance database over the years 2009 to 2014. Of 11,388 participants who underwent an initial procedure with iFuse, 320 Sacroiliac Joint Fusion: Draft evidence report Page 31	event data is provided in Appendix C, Table C-12. The range of overall adverse events from the studies that reported this data indeed ranges from 0% to 30%. We have added the study citations that this range references. The Gaetani et al. study reports a 30% incidence of post-operative complications. The Rudolf et al. study reports an incidence of 20%. The other studies report incidences that vary from 2.2% to 7.2%. Note, several studies did not report an overall incidence of adverse events, they only report the incidence of specific adverse events (for example, Sachs reports the incidence of numerous events which range from 0.7% to 3.5% for each individual event). The heterogeneity in monitoring and reporting very much limits drawing

Name (#)	Public Comment	Response
		definitive conclusions from this body of evidence.
Lorio (5)	With the recommended edits and revisions, overall, we support the findings of this evidence report and welcome it as justification for continued research and study of minimally invasive SI joint fusions. Thank you for the opportunity to provide comments and edits and please do not hesitate to contact ISASS with any questions or with follow up at the staff contact below.	Thank you.

WSCA | WASHINGTON STATE CHIROPRACTIC ASSOCIATION

October 29, 2018

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Dear Committee Members:

I congratulate the Health Technology Assessment Committee (HTAC) in their continued effort to assess and recommend safe and effective devices and procedures for the citizens of the State of Washington. Upon review of the recent recommendation concerning Sacroiliac Joint Fusion I have some concerns.

The conclusion, noted on page A-1 (pg47) stated that upon "meeting *diagnostic criteria* for SI joint pain or dysfunction, minimally invasive SI joint fusion surgery with the IFuse Implant System is more effective than conservative management". This statement is inaccurate since no study compared conservative care until after 6 months of conservative care. Perhaps amending the conclusion to have "….is more effective than conservative management after 6 months" would be more reflective of the evidence.

It is mentioned in 1.3 Technology Description, that "SI joint fusion procedures are typically reserved for persons who fail less invasive treatments" where manipulative therapy is mentioned.

The Conclusion lacks a discussion on requirements for conservative care prior to the authorization of this surgery. While there is very little literature documenting appropriate conservative care avenues, there is a review that was not discussed in the committee's review that recommends 6 months of exercise and manipulation [1]. Similarly, the SI joint is commonly placed in a broad "Low Back Pain" category in the literature and there is demonstration of the benefits of chiropractic management of low back condition reducing disability in the working population with low back pain [2].

The few studies HTA includes around conservative care show that after a point around 6 months, conservative care doesn't seem to offer a lot of benefit and only at that point would it be appropriate to consider a fusion. Even after 6mo, 1yr and 2yr follow-ups, the conservative group only has very small improvements. At that point, they should have responded to conservative care and consideration of surgery could be appropriate for some patients [3,4,5]. This 6mo conservative care trial that all studies have used is not reflected in the HTA's conclusion.

It is important to keep in mind that these are patients with chronic (in pain >3 months). Most of the recommendations by other insurers cited in the HTA report (pg. 45 of the draft document) only

approve this procedure after 6 months of conservative care failure. My experience with surgeons that do this procedure is that they usually refer out for conservative care for a number of months before they book the pre-surgical evaluation.

Perhaps our recommendation could be that the conclusions of the HTA should be similar to those of other major carriers like Regence and United that require an initial conservative management for up to 6 months (Regence guidelines Pg. 45 of draft) prior to authorization of this procedure.

Thank you,

J. Michael Schweitzer, DC
WSCA President

1) Vanelderen P[1]2010, Sacroiliac joint pain Pain Pract. Sep-Oct;10(5):470-8.
2) Turner JA[1], 2008, ISSLS prize winner: early predictors of chronic work disability: a prospective, population-based study of workers with back injuries. SPINE Volume 33, Number 25, pp 2809–2818
3) Dengler JD 2017, 1-Year Results of a Randomized Controlled Trial of Conservative Management vs. Minimally Invasive Surgical Treatment for Sacroiliac Joint Pain. Pain Physician. Sep;20(6):537-550.
4) Polly DW, 2016, 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. Aug 23;10:28
5) Sturesson B, 2017, Six-month outcomes from a randomized controlled trial of minimally invasive SI joint fusion with triangular titanium implants vs conservative management, Eur Spine J. Mar;26(3):708-719

November 9, 2018

Josiah Morse, MPH, Program Director
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Via e-mail: shtap@hca.wa.gov

Subject: Washington State Health Care Authority Draft Technology Report on Sacroiliac Joint Fusion

Dear Mr. Morse:

On behalf of the American Academy of Orthopaedic Surgeons (AAOS), American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS), AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves (DSPN), North American Spine Society (NASS) and Washington State Association of Neurological Surgeons (WSANS), we appreciate the opportunity to submit comments regarding the Washington State Health Care Authority (HCA) Draft Evidence Report on Sacroiliac (SI) Joint Fusion Surgery, which was prepared by RTI International–University of North Carolina Evidence-based Practice Center.

We agree with the authors of the Washington State HCA Draft Evidence Report who conclude that minimally invasive SI joint fusion procedures provide significant benefit to carefully selected patients. We recognize that there is a relative paucity of high quality randomized controlled studies at the current time and the best available studies focus on one particular product from one manufacturer. These studies show clear evidence of benefit for the procedure in terms of pain control and functional improvement compared to conservative management. In addition, we also agree with the finding that comparative studies between minimally invasive SI joint fusion and open joint fusion procedures show a preference for the minimally invasive option regarding improved postoperative pain and shorter length of hospital stay. Equally important is the fact that current evidence supports minimally invasive SI joint fusion procedures as safe and cost-effective for pain management and improved quality of life for patients with chronic SI joint dysfunction. Furthermore, we found the literature search and data extraction in the report to be up to date and comprehensive.

We recognize the limitations of the currently existing evidence, which makes it difficult to generalize the findings to all minimally invasive SI joint fusion products and procedures. However, the concept of creating an arthrodesis across the SI joint has been demonstrated to be clinically efficacious, and it would be difficult to dismiss other products that accomplish that same task. The summary of evidence clearly shows a need for continued development of well-designed controlled studies to explore several

aspects of SI joint fusion. The draft evidence report justifies continued research into SI joint fusion products and procedures based on the promising results from one manufacturer to evaluate whether other products can provide equal benefit to patients when compared to either conservative management or the currently tested system itself. Additional and continuing studies will be important to examine the long-term effects of these procedures to determine both the durability of pain relief and functional improvement compared to long-term conservative management. We also recognize that further evaluation of the diagnostic criteria used for patient selection will both validate these criteria and hopefully provide additional guidance for appropriate patient selection for SI joint fusion procedures.

Overall, we support the findings of this evidence report and welcome it as justification for continued research and study of minimally invasive SI joint fusion procedures.

Sincerely,

[redacted]

Robert H. Quinn, MD, Chairman
American Academy of Orthopaedic Surgeons
Council on Research and Quality

[redacted]

Shelly D. Timmons, MD, PhD, FAANS, President
American Association of Neurological Surgeons

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Ganesh Rao, MD, FAANS, President
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November 8, 2018

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Subject: Washington State Health Care Authority Draft Technology Report on Sacroiliac Joint Fusion

Dear Mr. Morse:

On behalf of the International Society for Advance of Spine Surgery, we appreciate the opportunity to submit comments regarding the Washington State Health Care Authority (HCA) Draft Evidence Report on Sacroiliac (SI) Joint Fusion Surgery prepared by RTI International–University of North Carolina Evidence-based Practice Center.

We are in general agreement with the authors of the Washington State HCA Draft Evidence Report who conclude that Minimally Invasive Surgery Sacroiliac Joint (MIS SIJ) Fusion procedures provide significant benefit to carefully selected patients. Although we recognize the best available studies utilize one particular device from one manufacturer, ISASS policy does not endorse any specific MIS SIJ System. There are numerous devices available that have received FDA 510(k) clearance for use in minimally invasive joint fusion (MIS SIJ) stabilization. The clinical concept of creating a true arthrodesis (either anatomic or extra-anatomic) across the SI joint have been reported with favorable outcomes at one year[1] which are sustained long term (up to 5 years)[2] [3]. Of importance is the clinically documented opioid reduction for low back pain patients as a result of this procedure, agnostic to the specific MIS SIJ system [4] [5]. ISASS recommends that WSHCA revise the wording in the draft "conclusions and summary of evidence" sections to refer to MIS SIJ Fusion "procedurally" where it currently refers specifically to the "i-Fuse technology."

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[1] Richard A. Kube[1] and Jeffrey M. Muir. Sacroiliac Joint Fusion: One Year Clinical and Radiographic Results Following Minimally Invasive Sacroiliac Joint Fusion Surgery *The Open Orthopaedics Journal, 2016, 10, 679-689*

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In addition, we also agree with the finding that comparative studies between minimally invasive SI joint fusion and open joint fusion procedures show a preference for the minimally invasive option in terms of improved post-operative pain and shorter length of hospital stay. Equally important is that the current evidence supports that the minimally invasive SI joint fusion procedure is safe and cost effective for pain management and improved quality of life for patients with chronic SI joint dysfunction.

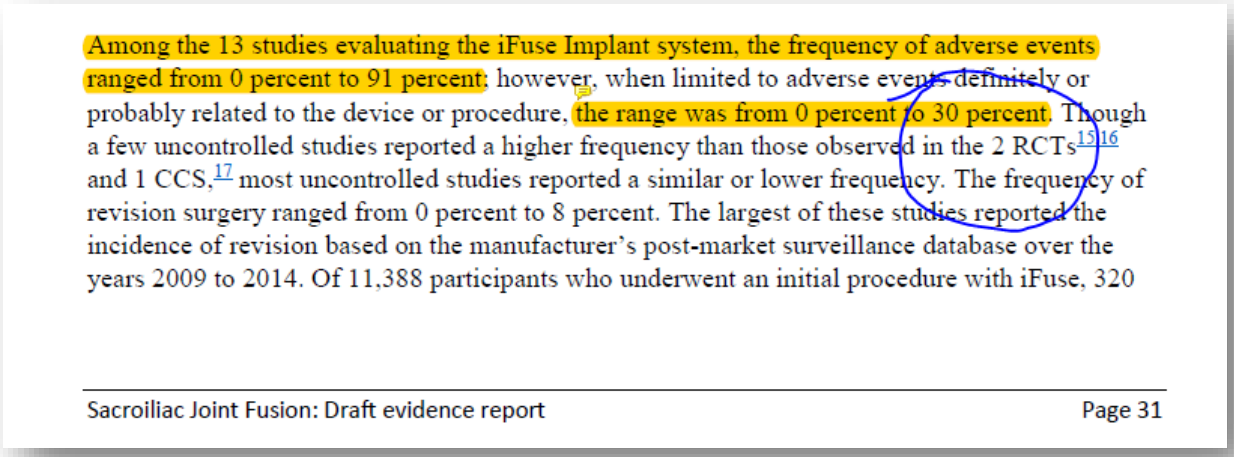
We found the literature search and data extraction that was the basis of this report to be comprehensive; however, we would recommend updated wording in the summary of evidence section and the addition of specific citations within that section (E1.4) as suggested below.

> ES 4.1 Summary of the Evidence. Compared to conservative management, minimally invasive SI joint fusion surgery improves pain, physical function and quality of life. The quality of evidence for these findings is moderate for outcomes at 6 months[1,2] and very low for outcomes between 6 months and 6 years[3]. Findings are mixed with respect to opioid use (modest reductions in use with low to very low quality of evidence). From both randomized trials, no differences in the rate of serious adverse events exist between surgery and conservative management (low to very low quality of evidence). Blinded randomized trials were not done, but blinding subjects would be challenging as all implant systems are highly radiopaque and obvious on any radiographic study. The incidence of revision surgery is likely no higher than 3.4 percent at 2 years[4,5] (moderate quality of evidence). Minimally invasive surgery costs $13,313 per additional quality of life-adjusted year gained compared to conservative management[6]; an amount that most would consider cost-effective. No differences exist between open fusion and conservative management with respect to pain, function, and quality of life, but this conclusion is based on one low quality evidence study[7]. Minimally invasive SI joint fusion improves pain over 2 years[8,9] or longer[3,10,11] and is associated with a shorter length of hospital stay compared to open fusion[12]. The incidence of adverse events was similar for open fusion and Minimally Invasive SI Joint Fusion,[12] but findings were mixed for the comparative incidence of revision surgery. All findings related to this comparison are based on very low quality of evidence. We limited the evidence from uncontrolled studies to safety outcomes. The heterogeneity in the reporting of adverse events across the 8 uncontrolled studies evaluating open fusion limits our ability to draw definitive conclusions from this body of evidence. Similarly, the incidence of adverse events and revision surgery reported in the 24 uncontrolled studies of minimally invasive surgery is heterogenous, likely reflecting differences in outcome definitions and ascertainment, but is generally low. The incidence of complications from minimally invasive fusion reported from an analysis of insurance claims is higher than the incidence reported in controlled studies;[14] issues regarding the identified patient population in this analysis[15] make interpretation of this result challenging. The incidence of revision surgery after fusion observed in trials is similar to the incidence reported in post-market surveillance.[4,5]

We also noted that the WA State Health Authority document cites a rate of adverse events after MIS SIJF of up to 30% in two locations; however, we are not aware of where the 30% figure comes from and believe the figure mischaracterizes the safety of most MIS procedures. Please see the abstracted sections with highlights. We recommend the Health Authority review these statements to ensure they are accurate and provide direct citations in order to allow for proper verification and documentation.

Among the 13 studies evaluating the iFuse Implant System, the frequency of adverse events that were definitely or probably related to the device or procedure ranged from 0 percent to 30 percent. One study retrospectively evaluated the frequency of adverse events after minimally invasive SI joint fusion using a large insurance claims database from 2007 to 2014.[33] Study authors could not report the specific procedures or systems used based on available data. The overall incidence of complications was 13.2 percent at 90 days and 16.4 percent at 6 months among 469 claimants that had received surgery.

Among the 13 studies evaluating the iFuse Implant System, the frequency of revision surgery ranged from 0 percent to 8 percent. The largest of these studies reported the incidence of revision based on the manufacturer's post-market surveillance database over the years 2009 to 2014. Of 11,388 participants who underwent an initial procedure with iFuse, 320 (2.8%) underwent a revision and 63% of the revisions occurred within the first year postoperatively.[34]



Among the 13 studies evaluating the iFuse Implant system, the frequency of adverse events ranged from 0 percent to 91 percent; however, when limited to adverse events definitely or probably related to the device or procedure, the range was from 0 percent to 30 percent. Though a few uncontrolled studies reported a higher frequency than those observed in the 2 RCTs[15,16] and 1 CCS,[17] most uncontrolled studies reported a similar or lower frequency. The frequency of revision surgery ranged from 0 percent to 8 percent. The largest of these studies reported the incidence of revision based on the manufacturer's post-market surveillance database over the years 2009 to 2014. Of 11,388 participants who underwent an initial procedure with iFuse, 320

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With the recommended edits and revisions, overall, we support the findings of this evidence report and welcome it as justification for continued research and study of minimally invasive SI joint fusions. Thank you for the opportunity to provide comments and edits and please do not hesitate to contact ISASS with any questions or with follow up at the staff contact below.

Sincerely,

[redacted]

Morgan Lorio, MD
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