

# Health Technology Assessment Program

## **Selected technologies 2020 (updated December 1, 2020)**

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**STATE OF WASHINGTON  
HEALTH CARE AUTHORITY**

626 8th Avenue, SE • P.O. Box 45502 • Olympia, Washington 98504-5502

December 1, 2020

To whom it may concern:

**RE: Update to Health Technology Assessment Topic Selection - 2020**


As the Director of the Health Care Authority, I select technologies for review by Health Technology Clinical Committee in consultation with other agencies and the Committee itself (70.14 RCW). Technologies are selected when there are concerns about safety, efficacy or value (cost-effectiveness), when state expenditures are or could be high, and when there is adequate evidence to conduct a review. Technologies are selected for re-review when new evidence is available that could change a previous determination.

In August 2020, **sacroiliac joint fusion**, which was reviewed in 2019, was pending further review of the evidence submitted by stakeholders. A formal scan of the literature was conducted by an independent technology assessment center. This review is available on our [webpage](#). Based on my review of the literature scan, petition, and public comments received, I have selected this topic for re-review by the Health Technology Clinical Committee.

Upon publication of this notice to grant the petition to re-review **sacroiliac joint fusion**, a 30-day comment period will begin whereby any interested person or group may provide information to be considered in the review of the selected topic.

Should you have any questions or concerns, please contact Josh Morse, HTA Program Director, by telephone at 360-725- 0839 or via email at [shtap@hca.wa.gov](mailto:shtap@hca.wa.gov).

Sincerely,

  
Susan E. Birch, MBA, BSN, RN  
Director

cc: Josh Morse, HTA Program Director, CQCT, HCA



STATE OF WASHINGTON  
**HEALTH CARE AUTHORITY**

626 8th Avenue, SE • P.O. Box 45502 • Olympia, Washington 98504-5502

August 11, 2020

To whom it may concern:

**SUBJECT: Health Technology Assessment Topic Selection, 2020**

As the Director of the Health Care Authority, I select technologies for review by the Health Technology Clinical Committee in consultation with other agencies and the Committee itself (70.14 RCW). Technologies are selected when there are concerns about safety, efficacy or value (cost-effectiveness), when state expenditures are or could be high, and when there is adequate evidence to conduct a review. Technologies are selected for re-review when new evidence is available that could change a previous determination.

For the current selection cycle, I reviewed the proposed topics and the comments received from interested individuals and groups who responded in the public comment period (July 15 to July 28). Based on this review I have selected the following technologies for assessment:

Technology	<u>Primary criteria ranking</u>		
	Safety	Efficacy	Cost
<b>1 Non-invasive testing for coronary artery disease</b>	<b>Med</b>	<b>Med</b>	<b>High</b>
Coronary artery disease (CAD) is the narrowing or blockage of the coronary arteries, which over time can reduce the flow of blood to the heart muscle. Accurate and early diagnosis of CAD can lower the risk of heart attack or the development of more severe heart disease. Many types of tests may be conducted to diagnose CAD. Some tests may be more appropriate than others depending on the indication and can support more appropriate risk stratification.			
This topic is proposed with medium concerns for safety and efficacy, high concerns for cost, and to support adoption of optimal testing strategies for evaluation of coronary artery disease that is evidence-based and aligns with current clinical guidelines and practice. The scope of this review will include re-reviews of prior HTCC topics ( <a href="#">cardiac nuclear imaging</a> and <a href="#">computed tomographic angiography</a> ), and may include other anatomic and/or functional imaging tests.			

At this time, **Sacroiliac joint fusion**, which was reviewed in 2019, is pending further review of the evidence submitted by stakeholders. **Chronic migraine and chronic tension type headache**, which was reviewed in 2017, is not selected for re-review at this time. Based on review of new information available and consideration by the participating agencies, it was

Health Technology Assessment Topic Selection

August 11, 2020

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determined that new evidence is not likely to change the previous determination. The HTA program will continue to monitor the literature on this topic.

Upon publication of the selected list of technologies, a 30-day comment period will begin whereby any interested person or group may provide information to be considered in the review of the selected topic(s).

Should you have any questions or concerns, please contact Britt Redick, HTA Program Manager by telephone at 360-725-0793 or via email at [shtap@hca.wa.gov](mailto:shtap@hca.wa.gov).

Sincerely,

A black rectangular redaction box covers the signature of Susan E. Birch.

Susan E. Birch MBA, BSN, RN  
Director

By email

cc: Josh Morse, Section Manager/HTA Director, CQCT, HCA

## Technology selection background summary

### Technology topics selected

Technology	Primary criteria ranking		
	Safety	Efficacy	Cost
<p><b>1 Non-invasive testing for coronary artery disease</b></p> <p>Coronary artery disease (CAD) is the narrowing or blockage of the coronary arteries, which over time can reduce the flow of blood to the heart muscle. Accurate and early diagnosis of CAD can lower the risk of heart attack or the development of more severe heart disease. Many types of tests may be conducted to diagnose CAD. Some tests may be more appropriate than others depending on the indication and can support more appropriate risk stratification. This topic is proposed for medium concerns for safety and efficacy, high concerns for cost, and to support adoption of optimal testing strategies for evaluation of coronary artery disease that is evidence-based and aligns with current clinical guidelines and practice. The scope of this review will include re-reviews of prior HTCC topics (<a href="#">cardiac nuclear imaging</a> and <a href="#">computed tomographic angiography</a>), and may include other anatomic and/or functional imaging tests.</p>	Med	Med	High

### New technology topics considered, not proposed

Technology
1 Allergy testing
2 Automated computed tomography (CT) perfusion imaging
3 Denervation of the sacroiliac joint
4 Fractional excretion of nitric oxide for asthma
5 Hypoglossal nerve stimulation for sleep apnea
6 Infra-low frequency neurofeedback
7 Molecular profiling of tumors
8 Multiplex respiratory viral panel testing
9 Portable magnetic resonance imaging (MRI) (Hyperfine)
10 Tissue-based regenerative therapy

## Re-review technologies

Technologies are considered for re-review at least once every eighteen months based on availability of new evidence that may change the decision. All technologies with determinations beyond 18 months since the final determination previously reviewed by the Health Technology Clinical Committee (HTCC) are listed below, along with information on whether they have been selected for re-review.

Technology	HTCC review history	Re-review?
<b>1 Cardiac nuclear imaging</b> New literature appears to support re-review at this time. Review of cardiac imaging topics will be combined into a single, comprehensive review of non-invasive testing for coronary artery disease.	HTCC reviewed in 2013.	Yes
<b>2 Computed tomographic angiography (CTA)</b> New literature appears to support re-review at this time. Review of cardiac imaging topics will be combined into a single, comprehensive review of non-invasive testing for coronary artery disease.	HTCC reviewed in 2008.	Yes
<b>3 Artificial disc replacement</b> Review of literature submitted by stakeholder petition conducted in Summer 2020. New information does not support re-review at this time.	HTCC re-reviewed in 2017. Literature scan conducted in 2016. HTCC first reviewed in 2008.	No
<b>4 Chronic migraine and chronic tension-type headache</b> Review of literature submitted by stakeholder petition conducted in Spring 2020. New information does not support re-review at this time.	HTCC reviewed in 2017.	No
<b>5 Coronary calcium scoring</b> <a href="#">Literature scan</a> conducted in Spring 2020. New information does not support re-review at this time.	Literature scan conducted in 2020. HTCC reviewed in 2009.	No
<b>6 Facet neurotomy</b> <a href="#">Literature scan</a> conducted in Spring 2020. New information does not support re-review at this time.	Literature scan conducted in 2020. HTCC reviewed in 2014.	No
<b>7 Peripheral nerve ablation for limb pain</b> Review of literature submitted by stakeholder petition conducted in Spring 2020. New information does not support re-review at this time.	HTCC reviewed in 2019.	No

Technology	HTCC review history	Re-review?
<b>8 Sacroiliac joint fusion</b> <a href="#">Literature scan</a> conducted in Fall 2020. Review of literature submitted by stakeholder petition conducted in Summer 2020. New information appears to support re-review at this time.	HTCC reviewed in 2019.	Yes
<b>9 Vertebroplasty, kyphoplasty and sacroplasty</b> <a href="#">Literature scan</a> conducted in Spring 2020. New information does not support re-review at this time.	Literature scan conducted in 2020, 2016, and 2017. HTCC reviewed in 2011.	No

At this time, the program has not received or identified new evidence to support re-review of the following:

HTA decisions	Latest review or literature scan
1 Applied behavioral analysis (ABA) therapy for autism	June 2011
2 Appropriate imaging for breast cancer screening in special populations	March 2015
3 Arthroscopic knee surgery	August 2008
4 Autologous blood/ platelet-rich plasma injections	May 2016
5 Bariatric surgery and pediatric bariatric surgery	May 2015
6 Bone growth stimulators	August 2009
7 Bone morphogenic proteins for use in spinal fusion	March 2012
8 Breast MRI	October 2010
9 Bronchial thermoplasty for asthma	May 2016
10 Cardiac stents	January 2016
11 Carotid artery stenting	September 2013
12 Catheter ablation procedures for supraventricular tachyarrhythmia (SVTA) including atrial flutter, atrial fibrillation	May 2013
13 Cervical spinal fusion for degenerative disc disease	March 2013
14 Cochlear implants: bilateral versus unilateral	May 2013
15 Computed Tomographic Angiography (CTA)	November 2008
16 Discography	February 2008
17 Electrical Neural Stimulations (ENS)	October 2009
18 Extracorporeal membrane oxygenation	March 2016
19 Extracorporeal shock wave therapy for musculoskeletal conditions	March 2017
20 Fecal microbiota transplantation	November 2016

HTA decisions	Latest review or literature scan
21 Functional neuroimaging for primary degenerative dementia and mild cognitive impairment	January 2015
22 Gene expression profile testing of cancer tissue	March 2018
23 Genomic micro-array	January 2018
24 Glucose monitoring	January 2018
25 Hip resurfacing	November 2013
26 Hyaluronic acid/viscosupplementation	November 2013
27 Hyperbaric oxygen (HBO2) treatment for tissue damage	March 2013
28 Imaging for rhinosinusitis	May 2015
29 Implantable infusion pumps	August 2008
30 Intensity modulated radiation therapy (IMRT)	September 2012
31 Knee joint replacement or knee arthroplasty (Total knee arthroplasty)	October 2010
32 Lumbar fusion for degenerative disc disease	November 2015
33 Microprocessor-controlled lower limb prosthetics - knee	November 2011
34 Negative pressure wound therapy	November 2016
35 Non-pharmacologic treatments for treatment resistant depression	March 2014
36 Osteochondral allograft / autograft transplantation knee	January 2018
37 Pharmacogenetic testing for selected conditions: behavioral health treatments	January 2017
38 Pharmacogenetic testing for selected conditions: oral anticoagulants	May 2018
39 Positron emission tomography (PET) scans for lymphoma	November 2018
40 Robotic assisted surgery	May 2012
41 Routine ultrasound for pregnancy	October 2010
42 Screening and monitoring tests for osteopenia/ osteoporosis	November 2014
43 Sleep apnea diagnosis and treatment in adults	March 2012
44 Spinal cord stimulation	July 2018
45 Spinal injections	March 2016
46 Stereotactic radiation surgery and stereotactic body radiation therapy	January 2017
47 Surgery for lumbar radiculopathy/ sciatica	May 2018
48 Testosterone testing	January 2019
49 Treatment of chronic migraine and chronic tension-type headaches	July 2018
50 Tumor treating fields: Optune	November 2018
51 Tympanostomy tubes in children	November 2015
52 Upper endoscopy for GERD and GI symptoms	May 2012
53 Upright / positional magnetic resonance imaging (MRI)	June 2012



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HTA decisions	Latest review or literature scan
54 Varicose veins	July 2017
55 Virtual colonoscopy or computed tomographic colonography (CTC)	February 2008
56 Vitamin D screening and testing	November 2012

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## Response to public comments

This document responds to comments received on the prospective 2020 HTA technology topics. Public comments were accepted from July 15 through July 28, 2020. Comments focused on two previously reviewed topics: **Sacroiliac joint fusion** and **Treatment of chronic migraine and chronic tension type headache**. All comments were presented to the Director for consideration. The Director did not select **Treatment of chronic migraine and chronic tension-type headache** for re-review at this time. The Director is considering **Sacroiliac joint fusion**, pending further review of the evidence received during the public comment period. Comments received during the public comment period are included in this document.

Public comments were received from these individuals and groups:

Commenter	Topic
1 Jeffrey D. Zigler, Vice President, Market Access and Reimbursement, SI Bone	Sacroiliac joint fusion
2 David W. Polly, Jr., James W. Ogilvie Professor and Chief of Spine Surgery, Catherine Mills Davis endowed Professor Department of Orthopaedic Surgery, Professor (w) of Neurosurgery, University of Minnesota	Sacroiliac joint fusion
3 Morgan Lorio, MD, FACS, Chair, ISASS Task Force Coding & Reimbursement International Society for the Advancement of Spine Surgery (ISASS) Matthew Twetten, ISASS Coding and Task Force Liaison	Sacroiliac joint fusion
4 Randy Miller	Sacroiliac joint fusion
5 David E. Baker, MD, Fourth Corner Neurosurgery Associates	Sacroiliac joint fusion
6 Thomas R. Flory, Executive Director, Fourth Corner Neurosurgery Associates	Sacroiliac joint fusion
7 John-David Black, MD, Director of Orthopaedic Trauma, Kadlec Northwest Orthopaedic Trauma and Sports Medicine	Sacroiliac joint fusion
8 Tung M. Ha, DO, Fourth Corner Neurosurgery Associates	Sacroiliac joint fusion
9 Jana Wiley, RN, MS, AEMP, licensed acupuncturist	Treatment of chronic migraine and chronic tension-type headache
10 Leslie Emerick, Public Policy Director, Washington Acupuncture and Eastern Medicine Association (WAEMA)	Treatment of chronic migraine and chronic tension-type headache
11 Charis Wolf, MSTCM, DACM-s, LAc, Dipl Ac (NCCAOM) Board Member; American Society of Acupuncturists Immediate Past President; Washington acupuncture and Eastern Medicine Association Mark Soddors, DAOM, Dipl OM (NCCAOM) Postdoctoral Scholar, University of Washington, Seattle, Washington	Treatment of chronic migraine and chronic tension-type headache

A summary of comments received and HTA responses are contained in the table below. The full text of all comments, references and attachments follows.

Commenter	Topic	Comment	HTA program response
<b>Jeffrey D. Zigler</b> , Vice President, Market Access and Reimbursement, SI Bone	Sacroiliac joint fusion	Complete comments included below.	Thank you for providing comment and evidence for this proposed re-review. All information provided will be considered in any future re-review of sacroiliac joint fusion.
<b>David W. Polly, Jr.</b> , James W. Ogilvie Professor and Chief of Spine Surgery, Catherine Mills Davis endowed Professor Department of Orthopaedic Surgery, Professor (w) of Neurosurgery, University of Minnesota	Sacroiliac joint fusion	Complete comments included below.	Thank you for providing comment and evidence for this proposed re-review. All information provided will be considered in any future re-review of sacroiliac joint fusion.
<b>Morgan Lorio</b> , MD, FACS, Chair, ISASS Task Force Coding & Reimbursement International Society for the Advancement of Spine Surgery (ISASS) <b>Matthew Twetten</b> , ISASS Coding and Task Force Liaison	Sacroiliac joint fusion	Complete comments included below.	Thank you for providing comment and evidence for this proposed re-review. All information provided will be considered in any future re-review of sacroiliac joint fusion.
<b>Randy Miller</b>	Sacroiliac joint fusion	Submitted letter in support of reconsideration of sacroiliac joint fusion. The letter contains personal health information and therefore is not included below.	Thank you for providing comment for this proposed re-review. The program appreciates your perspective and the time you took to share your experience living with chronic back pain.
<b>David E. Baker</b> , MD, Fourth Corner Neurosurgery Associates	Sacroiliac joint fusion	Complete comments included below.	Thank you for providing comment and evidence for this proposed re-review. All information provided will be considered in any future re-review of sacroiliac joint fusion.
<b>Thomas R. Flory</b> , Executive Director, Fourth Corner Neurosurgery Associates	Sacroiliac joint fusion	Complete comments included below.	Thank you for providing comment for this proposed re-review. All information provided will be considered in any future re-review of sacroiliac joint fusion.
<b>John-David Black</b> , MD, Director of Orthopaedic Trauma, Kadlec Northwest Orthopaedic Trauma and Sports Medicine	Sacroiliac joint fusion	Complete comments included below.	Thank you for providing comment for this proposed re-review. All information provided will be considered in any future re-review of sacroiliac joint fusion.

Commenter	Topic	Comment	HTA program response
<b>Tung M. Ha, DO, Fourth Corner Neurosurgery Associates</b>	Sacroiliac joint fusion	Complete comments included below.	Thank you for providing comment for this proposed re-review. All information provided will be considered in any future re-review of sacroiliac joint fusion.
<b>Jana Wiley, RN, MS, AEMP, licensed acupuncturist</b>	Treatment of chronic migraine and chronic tension-type headache	Complete comments included below.	Thank you for providing comment for this proposed re-review. All information provided will be considered in any future re-review of treatment for chronic migraine and chronic tension-type headache.  Thank you for the additional comment about your experience providing public comment at the May 15 and June 12 HTCC meetings. Unfortunately, acupuncture was not within the scope of the review for non-pharmacologic treatments for tinnitus.
<b>Leslie Emerick, Public Policy Director, Washington Acupuncture and Eastern Medicine Association (WAEMA)</b>	Treatment of chronic migraine and chronic tension-type headache	Complete comments included below.	Thank you for providing comment and evidence for this proposed re-review. All information provided will be considered in any future re-review of treatment for chronic migraine and chronic tension-type headache.
<b>Charis Wolf, MSTCM, DACM-s, LAc, Dipl Ac (NCCAOM), Board Member; American Society of Acupuncturists Immediate Past President; WAEMA</b> <b>Mark Sodders, DAOM, Dipl OM (NCCAOM), Postdoctoral Scholar, University of Washington, Seattle, Washington</b>	Treatment of chronic migraine and chronic tension-type headache	Complete comments included below.	Thank you for providing comment and evidence for this proposed re-review. All information provided will be considered in any future re-review of treatment for chronic migraine and chronic tension-type headache.

**From:** Jeff Zigler <jzigler@si-bone.com>  
**Sent:** Tuesday, July 28, 2020 8:25 AM  
**To:** Redick, Brittney (HCA); Morse, Josiah (HCA)  
**Cc:** HCA ST Health Tech Assessment Prog  
**Subject:** RE: Petition for re-review - sacroiliac joint fusion  
**Attachments:** SIBN Cover Letter - WA HCA petition for re-review\_6.12.20jz.pdf

Britt, Josh and the HCA SHTAP Team,

Thank you. I appreciate this response, as well as your overall responsiveness throughout this process. On behalf of SI-BONE, as well as the Washington health care providers and patients we work with, we encourage the Washington HCA to reconsider its denial of our petition to re-review the **sacroiliac joint fusion** topic, as do a number of other stakeholders to this process. During this most recent comment period, and in the months following the last HTCC meeting convened on this topic in January 2019, we believe you would have heard from the following stakeholders which might prompt a re-review of **sacroiliac joint fusion** at this time:

1. **Professional spine societies**, including [ISASS](#) (July 23, 2020) and [AANS](#) (on behalf of AAOS, AANS, CNS, DSPN and WSANS) (February 20, 2019) among others have offered insight into their own clinical guidelines, [each agreeing with the draft and final 2018 RTI HTA report](#), BUT also expressing concern that the last HTCC meeting and final decision by the HCA in early 2019 is not in keeping with the current medical practice, nor is it reflective of the literature on sacroiliac joint fusion which shows the iFuse procedure is highly effective for well selected patients suffering from SIJ pain and dysfunction.
2. **Individual surgeons with significant experience performing the procedure** have sent in comments, some of whom are Washington-area providers, others who are not practicing in Washington but are experts and thought leaders on this procedure and have had direct involvement with the HCA process (like Dr. David Polly, Univ of MN, as referenced in the 2/20/19 AANS letter to the HCA), offering their input as to why the HTCC should reconvene on this topic following an updated evidence report.
3. **Patients** with degenerative sacroiliitis or sacroiliac dysfunction (not a result of direct severe trauma, necessarily) who are on Washington Medicaid or are pursuing L&I workers compensation claims for chronic SIJ pain have written in. They are currently being adversely affected by the non-coverage position the HCA takes on this topic, and are being denied coverage for this last-resort surgical treatment option which their surgeons are actively wishing to provide.
4. **SI-BONE**, manufacturer of iFuse and upon which a vast majority of the 2018 RTI Final Evidence Report written for the HCA was based, provided a June 12, 2020 petition to the HCA (attached) to have this topic added to the list of topics for upcoming review, including the following updates and evidence:
  - Newly published clinical literature (Level I-IV evidence) including complications and revisions data showing **5-year outcomes** from prospective study with excellent and sustained results; and **FDA post-market surveillance published data** which shows low incidence and low rates of adverse events in the several years following iFuse surgery. This data compares well relative to other spine and orthopedic procedures, and the professional spine societies' guidelines and recommendations on this topic are all favorable for *\*well-selected\** chronic SIJ pain patients.
  - **New payers** (local/regional and national) now covering the iFuse procedure for MIS SI joint fusion.

- **Oregon Medicaid's review** of this same topic, almost exactly parallel in time to the HCA's review, yet where a different conclusion was reached by the HERC (i.e., finding for coverage and funding of MIS SI joint fusion procedures).

Our understanding of the HCA process is that the petition to re-review must first be accepted, before the HTCC would reconvene on a topic like this again. We hope this new input from spine specialty societies, surgeons and patients helps support the HCA's decision to reconsider its denial of our petition to re-review the sacroiliac joint fusion, and include it on the list of prospective technology topics.

Please let me know if I can provide any additional information, or support this process in any other way.

Sincerely,

**Jeffrey D. Zigler**

Vice President, Market Access and Reimbursement

**SI-BONE**

Mobile: (214) 454-4761

Email: [jzigler@si-bone.com](mailto:jzigler@si-bone.com)

**From:** Jeff Zigler <jzigler@si-bone.com>  
**Sent:** Wednesday, July 15, 2020 9:34 AM  
**To:** Morse, Josiah (HCA)  
**Cc:** HCA ST Health Tech Assessment Prog  
**Subject:** RE: Petition for re-review - sacroiliac joint fusion

Josh,

I appreciate you informing us of the deadlines to submit the SI joint fusion topic for re-review in 2021. We noticed that SI joint fusion was not considered for re-review in 2021 at this time. Reason: review of the literature submitted this spring 2020 “does not support re-review at this time.”

Is there a way we can appeal the decision not to re-review, or what are the steps we can take to learn the reasons why? We think our rationale for re-review in terms of (1) the new clinical evidence, (2) the new regional payers covering the procedure, and (3) the OHA and HERC favorable review on this topic as laid out in our cover letter, **all of which occurred since the last Sept 2018 review you did** should provide ample foundation for a re-review by the HCA.

The background material on updates to the literature and payer coverage scanning we’ve provided constitutes 150 pages of the 227 in the [prospective topics document](#). How does that not rise to the level of a re-review?

We think you should reconsider this, and allow public stakeholder comments between now and July 28<sup>th</sup>. Please let us know what is possible for a reconsideration to possibly occur.

Thank you,  
Jeff Zigler

**Jeffrey D. Zigler**  
Vice President, Market Access and Reimbursement

**SI-BONE**

Mobile: (214) 454-4761  
Email: [jzigler@si-bone.com](mailto:jzigler@si-bone.com)







June 12, 2020

Washington Health Care Authority  
ATTN: Health Technology Assessment  
[shatap@hca.wa.gov](mailto:shatap@hca.wa.gov)

VIA ELECTRONIC EMAIL

**RE: SI-BONE Petition for Washington HCA Technology Re-review –  
Sacroiliac Joint Fusion (iFuse)**

Dear Josh and the Washington HCA Team,

We appreciate the opportunity to provide updates to the clinical evidence supporting the re-review by the HCA of the sacroiliac joint (SIJ) fusion topic, and specifically the triangular iFuse Implant System used for SIJ fusion procedures to treat individuals with chronic and acute SIJ pain or dysfunction. The landscape of evidence supporting this treatment option has significantly improved since June 2018 and January 2019, the dates of literature cut-off for the Final Evidence Report, and the last meeting by the HTCC on this topic, respectively. Enclosed and below is information and detail in connection with this request, along with new key evidence highlights.

**New evidence enclosed:** As part of the ongoing research and evaluation of this treatment option, we believe the HCA team should take careful note of **Whang et al 2019**, the published results from the LOIS study's 5-year, long-term clinical and radiographic iFuse patient outcomes from a prospective, multicenter trial (ClinicalTrials.gov [NCT02270203](https://clinicaltrials.gov/ct2/show/study/NCT02270203)). Highlights of ongoing evaluation of iFuse patients in the LOIS study include the following:

- Persistent, long-term reduction in SI joint pain and disability
- Persistent, long-term improvements in quality of life
- Absence of device-related serious adverse events
- Absence of surgical revision
- High proportion of patients returned to work
- Marked reduction in proportion of patients using opioids

In addition to Whang et al 2019, the HCA team should consider another 15 new, peer-reviewed scientific articles published on this topic since the last review's publication cut-off date (after June 20, 2018). This includes Level I through Level IV evidence, as well as other review articles that give helpful context as to the use and acceptance of this treatment option by clinicians around the country and around the world, for patients with acute dysfunction as well as for those with chronic SIJ pain. We have enumerated and listed each of these 15 new articles in our petition for re-review.

In total, the number and type of published papers on this topic (all-time) now includes:

10 – Level I (RCT)

9 – Level II (Prospective)



7 – Level III (Comparison)  
19 – Level IV (Case Series)  
8 – Reviews  
6 – Economics  
10 – Biomechanics  
14 – Other  
**83 TOTAL**

The publication of 16 new peer-reviewed articles noted above may be enough, by itself, to prompt the HCA’s re-review on this topic. However, in addition, since the time of the last HTCC meeting on this topic in January 2019, additional evidence which would have better informed the committee at that time has now become available. These new data points span the following four (4) key areas of analysis and re-review the HCA should conduct:

1. [Sept 2018 and ongoing] Published data, as well as SI-BONE postmarket surveillance, specific to iFuse complications and revisions rates discussed at the HTCC meeting;
2. [Not yet addressed] Clinical guidelines and evidence-based recommendations from professional spine societies, and more evaluations from health technology assessment organizations;
3. [Jan 2019 and ongoing] More local/area and national U.S. payers that were specifically on the HTCC worksheets in Jan 2019 now cover the procedure than were covering during the initial HTCC meeting, including Premera BCBS, the #1 commercial payer in Washington, with published clinical criteria;
4. [Eff Jan 2020] Oregon Health Authority Health Evidence Review Commission (HERC) finding for CPT 27279 on the Prioritized List of Health Services, and funding (Note 161) for chronic SIJ pain cases, with applicable Oregon Health Plan (OHP) coverage.

### 1. Revisions and Complications Data

Published in **September 2018**, **Cher et al** published on the SI-BONE postmarket surveillance data we maintain in compliance with FDA and other requirements.<sup>1</sup> Researchers found the 1-year cumulative probability of surgical revision was low (1% to 1.5%) for iFuse Implant System devices, notably finding:

- ✓ No implant breakages or migrations; and
- ✓ Overall rates of revisions and complications were similar (relatively low in spine and orthopedics), compared to previously published reporting.

As part of its ongoing commitment to the evaluation and quality of iFuse, SI-BONE continues to collect postmarket surveillance data and to track revisions (albeit uncommon), as it is an appropriate, accepted approach to estimating uncommon events. Still, iFuse continues to show

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<sup>1</sup> Cher D, Wroe K, Reckling WC, Yerby S. Postmarket surveillance of 3D-printed implants for sacroiliac joint fusion. Med Devices (Auckl). 2018;11:337-343.



similar or lower rates of revisions as was reported in 2018. As such, this data and these updates should become part of the HCA's update and re-review on this topic.

## 2. Clinical Guidelines and Recommendations

Published and updated **since the June 2018** cut-off date for the HCA's Final Evidence Report and review on this topic, the following health technology assessment organizations and clinical practice guidelines development groups have published updates on this topic of SIJ fusion for chronic SIJ pain patients, or otherwise were not reviewed by the HCA in the last review:

1. NICE Medical Technologies Guidance (MTG): iFuse for treating chronic sacroiliac joint pain [MTG39] (**Oct 2, 2018**)<sup>2</sup>
2. eviCore updates to MSK Spine Surgery guidelines on sacroiliac joint fusion (published revision **Oct 15, 2019**, effective 2/14/20)<sup>3</sup>
3. MCG guidelines (provided to SI-BONE by UHC medical director Dr. Wendy MacLeod) on General Recovery Guidelines (GRG) related to SIJ fusion topic.<sup>4</sup>

As it relates to professional societies' clinical guidelines on this topic, the ISASS Policy Statement and NASS Coverage Policy Recommendations guidelines<sup>5</sup> have both been widely used and cited by the nation's payers and other HTAs / review organizations as the authoritative, evidence-based opinions directly from spine and orthopedic clinical experts. Both NASS and ISASS want payers and review organizations such as the Washington HCA to have free copies of these recommendations and guidelines. We noticed that the last review by the HCA did not include NASS guidelines, due to the perception of a paywall. In the Clinical Practice Guideline Synthesis section of the report, it was stated incorrectly that the NASS recommendations document was "only available by subscription." However this is not the case, as NASS specifically states on its website that payers may request a free copy at all times. We highly encourage the HCA to do so. In fact, NASS' Manager of Health Policy, Amanda Weiler, confirmed in a 6/12/20 email that *"any payor can access free NASS Coverage Recommendations by going to this website <https://www.spine.org/coverage>. Once there, they will click on the 'Request Access' button for*

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<sup>2</sup> NICE MTG39 Medical Technologies Guidance: iFuse for treating chronic sacroiliac joint pain:

<https://www.nice.org.uk/guidance/mtg39>

<sup>3</sup> eviCore [https://www.evicore.com/-/media/files/evicore/clinical-guidelines/solution/msk--advance/2020/evicore\\_spinesurgery\\_eff02142020\\_pub101519.pdf](https://www.evicore.com/-/media/files/evicore/clinical-guidelines/solution/msk--advance/2020/evicore_spinesurgery_eff02142020_pub101519.pdf)

<sup>4</sup> SI-BONE has received a letter from UHC medical director Dr. Wendy MacLeod, regarding sacroiliac joint fusion as being covered by UHC per MCG Health (Milliman Care Guidelines). Though the MCG guidelines are proprietary, the letter provided to SI-BONE has been attached for the HCA's review on this topic, and consideration.

<sup>5</sup> 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.

NASS Coverage Policy Recommendations: Percutaneous Sacroiliac Joint Fusion (June 9, 2015).

<https://www.spine.org/Product-Details?productid=%7B9EAC3FC6-AF81-E611-851E-005056AF031E%7D>

(**NOTE**: the CPRs only cost money for industry. Payers (and WA HCA) may receive free access to the coverage recommendations, per NASS' website); visit <https://www.spine.org/coverage> for more information.



payors and fill out the form accordingly. Once the form is submitted, we will provide them log-in information to access whichever Coverage Recommendations they select on the form.”

The rigors applied to both NASS’ and ISASS’ processes are well enumerated and relied upon broadly.<sup>6</sup> We believe it would benefit the HCA to speak directly with leadership at NASS and ISASS, and to learn from them how their guidelines and recommendations coincide with the AGREE tenets. They make public their methodology and would be glad to review it with you live. In our view, both NASS and ISASS meet AGREE’s 23 tenet Items (“check the boxes”), and should be relied upon by the HCA or at least further explored by speaking to NASS and ISASS leadership, as part of the re-review.

### 3. Payers Now Covering SIJ Fusion for Chronic SIJ Pain Patients

Since the Jan 2019 HTCC meeting, an addition 10 payers across the U.S., several of which operate with some significance in the Washington market, have commenced covering SI joint fusion (with numerous requiring the iFuse triangular implant):

<u>Payers Covering (Jan 2019 to Today)</u>	<u>Date Commenced Covering</u>
BCBS-MD-CareFirst-MD, DC, VA	1/1/2019
BCBS-NY-Excellus BlueCross BlueShield	1/15/2019
BCBS-Premera	2/1/2019
BCBS-AL-Blue Cross and Blue Shield of Alabama	3/18/2019
BCBS-Wellmark Blue Cross Blue Shield (IA/SD)	7/1/2019
BCBS-CA-Blue Shield of California	7/3/2019
BCBS-RI-Blue Cross Blue Shield of Rhode Island	11/1/2019
CIGNA	12/10/2019
Oregon Medicaid	1/1/2020
Aetna	5/28/2020

Among the newly covering 10 payers above, **Premera**, **Cigna** and **Aetna** each have significant numbers of covered lives in Washington. Also, all 7 Medicare Administrative Contractors (MACs) allow coverage for CPT 27279<sup>7</sup>, some with criteria under applicable Local Coverage Determinations (LCDs), and some with no LCDs but which allow coverage of the CPT code.

### 4. OHA and HERC Analysis of SIJ Fusion Topic

Finally, during nearly the exact same time period the HCA was reviewing this topic, the Oregon Health Authority and HERC also reviewed the SI joint fusion topic. Based on a review of the evidence, HERC determined that minimally invasive joint surgery is effective in reducing pain

<sup>6</sup> NASS Coverage Recommendations Methodology:

<https://www.spine.org/Portals/0/Assets/Downloads/PolicyPractice/CoverageRecommendations/CoveragePolicyMethodology.pdf>

<sup>7</sup> MACs and current status of CPT 27279 (all cover): CGS L36494; FCSO A55120; NGS L36406; Noridian LCD; Novitas covers; Palmetto A53452; WPS A57596.



and increasing function for patients with SI joint dysfunction. In light of this evidence, HERC created a new line above the funding line for the surgical treatment of SI joint dysfunction using minimally invasive joint surgery. HERC created a guideline to prevent inappropriate use of this procedure.

We appreciate the opportunity to provide our key evidence, our thoughts, and to give inputs into the tremendous and detailed work the HCA team does in reviewing the evidence for this important therapy option. At this time, there are numerous clinical guidelines and assessments of this therapy option; there is independent clinical consensus on the diagnosis of SIJ pain as qualifying as a Clinical Diagnostic Rule<sup>8</sup> for low back pain, with well established clinical criteria required to identify medical necessity for the procedure by payers around the country; and importantly, there are now **83 peer-reviewed, published articles** that report on iFuse patient outcomes, safety/complaints, technique, biomechanics, economics, and/or use iFuse data – 16 of which the Washington HCA has yet to review.

In light of all the reasons noted in this letter and in our petition, we believe a re-review of this topic is warranted at this time, and would appreciate your consideration for including it in the next possible upcoming opportunity for calendaring. We think the earliest possible re-review by the Washington HCA on this topic would best serve the approach currently being taken by health care providers, and the clinical need of patients actively seeking this treatment option.

Thank you again, and we look forward to learning the outcome of your re-review of sacroiliac joint fusion and iFuse.

Sincerely,



Jeffrey Zigler  
Vice President, Market Access and Reimbursement  
SI-BONE, Inc.

Attachments:

1. WA HCA petition for technology re-review
2. Bibliography of all known iFuse SI joint fusion publications. Includes links to open source papers where available.
3. A copy of SI-BONE's literature synopsis and Clinical Value dossier for iFuse Implant System®
4. A copy of the latest LOIS study results paper, Whang 2019 (Level II evidence), showing excellent 5-year results for iFuse patients.
5. Email exchange with NASS' Manager of Health Policy, Amanda Weiler in re: WA HCA requesting a copy of the NASS CPR on sacroiliac joint fusion topic.
6. A copy of the letter from UHC medical director Dr. Wendy MacLeod referencing the MCG-GRG guidelines on this topic, which confers coverage by UHC for SIJ fusion procedures for treatment of chronic SIJ pain.

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<sup>8</sup> Laslett M. Evidence-based diagnosis and treatment of the painful sacroiliac joint. J Man Manip Ther. 2008;16(3):142-152.



**From:** [David Polly Jr. MD](#)  
**To:** [HCA ST Health Tech Assessment Prog](#)  
**Subject:** Minimally invasive SI joint fusion  
**Date:** Tuesday, July 21, 2020 5:28:26 PM

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July 20, 2020

To: Washington Health Care Authority  
ATTN: Health Technology Assessment  
[shtap@hca.wa.gov](mailto:shtap@hca.wa.gov)

**RE: WA HCA re-review of Sacroiliac joint fusion**

Dear Washington Health Care Authority Leaders,

My name is David Polly, MD. I am an orthopedic surgeon, as well as a professor and chief of spine surgery in the Department of Orthopedic Surgery at the University of Minnesota. I have had extensive experience in performing the SI joint fusion procedure, having performed more than 200 iFuse procedures over the past nine years. I am reaching out to you about your recent decision not to re-review **Sacroiliac Joint Fusion** during this upcoming annual topics review window. It is my opinion that your organization should conduct a re-review of this topic immediately, because so much has changed since the last time the HCA conducted a literature search, and the HTCC committee convened on coverage conditions. The current position of the HCA is that, for patients with chronic sacroiliac joint pain related to degenerative sacroiliitis and/or sacroiliac joint disruption, minimally invasive and open sacroiliac joint fusion procedures is **NOT** a covered benefit.

I was a telephone observer to the previous review of SI joint fusion. I found it unusual that the organization rejected the organization sponsored evidence review done by ECRI that found there was moderate evidence at that time to support minimally invasive SI joint fusion. It appeared that the opinion of the panel was swayed by the orthopaedic trauma surgeon from Harborview who was the expert for the panel. This individual acknowledged that he had never actually done this procedure. He expressed concern about the ability to revise a failed procedure, not ever having done a revision procedure either. His comments were not representative of those who have had experience with primaries or revisions. Revisions are harder than primaries, just as revision of total joint arthroplasty is harder than primary total joint arthroplasty. I personally spoke to Greg Brown, MD, PhD, who led that panel and he acknowledged that the proceedings were 'unusual'. It was not clear that there was a way to acknowledge that unusual process of rejecting your own commissioned study by an independent, non-biased agency.

After considering all the new evidence and key updates since 2018, including long-term follow-up on how patients are performing after receiving this therapy, and hearing from surgeons like me who routinely perform this procedure, can the Washington HCA make informed decisions on this topic. As of today, the WA HCA is not staying abreast of the literature; nor is it covering this procedure in the same or similar way as are a majority of other government and commercial health insurers and health technology assessment organizations across the U.S., and in the Pacific Northwest region.

Earlier this year, we learned that Aetna now covers this procedure once patients meet specific clinical criteria: [http://www.aetna.com/cpb/medical/data/1\\_99/0016.html](http://www.aetna.com/cpb/medical/data/1_99/0016.html). **Today, nearly 300 million Americans with degenerative sacroiliitis or dysfunction have access to the sacroiliac joint fusion surgery from 113 different payers, whether they have benefits through Medicare, Medicaid, TRICARE, or from commercial insurers such as from Aetna, United Healthcare, Cigna, BCBS plans including Regence and Premera, as well as many others.**

**However, patients with plans falling under the HCA's authority unfortunately still do not have access**

**to this treatment.**

Since the last HCA review of literature on this topic in 2018, there have been a number of high-quality clinical studies of SI joint fusion patients published, especially those treated with the iFuse Implant (SI-BONE), a triangular-shaped device that is inserted via a minimally invasive surgical approach. With prospective follow-up of patients now out to 5 years, the patients studied do quite well across a number of key measures used in spine studies. I encourage you to reconsider the decision not to re-review this treatment option, and allow potentially for revised guidelines for well selected patients, as soon as possible.

A re-review of this topic at this time is paramount. The most recent decision by the committee, finding for non-coverage on 1/18/19, is inadequate, does not reflect the literature review the HCA team itself conducted in 2018, and does not follow any spine societies' guidance on the topic. The decision states that:

**“A majority of committee members found the evidence sufficient to determine that use of sacroiliac joint fusion for chronic sacroiliac joint pain related to degenerative sacroiliitis and/or sacroiliac joint disruption unproven for being safer, more efficient or more cost-effective than comparators.**

Over the past several years, there have been numerous, key updates to the scientific literature on SI joint fusion surgery provided to the Washington HCA policy team, in particular the high-quality evidence supporting the triangular titanium iFuse Implant used for minimally invasive procedures. **There are now ten published-peer-reviewed papers constituting “Level I Evidence” for iFuse patients, which is significant and should confer coverage in and of itself.** This is the highest level of peer-review rigor that exists, and all these papers conclude that this is a good surgery to offer the right patients, with long-term results that show the patients do very well and see significant reductions from pre-operative steroid injections, opioid use, among other healthcare services. Most payers cover it, for degenerative sacroiliitis patient types, with pre-operative requirements and exclusions on the policy, which limit exposure and ensure good utilization.

There are nearly 300 million covered lives with access to this procedure through government or commercial health plans. Also, favorable surgical specialty society guidelines and assessments have been performed by

- North American Spine Society (NASS)
- International Society for the Advancement of Spine Surgery (ISASS)
  
- BlueCross Blue Shield Association (BCBSA)
  
- AIM Specialty Health
  
- Milliman Care Guidelines (MCG)
  
- ECRI Institute
- eviCore
- National Institute for Health and Care Excellence (NICE)

The current Washington HCA policy statement that sacroiliac joint fusion is not a covered benefit is neither evidence-based, nor is it supportable based on numerous professional clinical guidelines, nationally recognized utilization and technology assessment guidelines. It is simply not in keeping with current medical practice or the latest thinking and research on this topic. The first step in your process to adjust for this is a thorough and balanced re-review of the sacroiliac joint fusion topic at this time.

Thank you for your time and consideration of our request. If you have any questions or require additional information, please contact me. I would personally love to be considered for expert testimony given directly



to the HTCC during any future opportunities.

Sincerely,

David W. Polly, Jr., MD

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David W. Polly, Jr, MD

James W. Ogilvie Professor and

Chief of Spine Surgery

Catherine Mills Davis endowed Professor

Department of Orthopaedic Surgery

Professor (w) of Neurosurgery

University of Minnesota

Past President

Scoliosis Research Society 2015-2016





*Via email*

July 23, 2020

Washington Health Care Authority  
Health Technology Clinical Committee  
[shtap@hca.wa.gov](mailto:shtap@hca.wa.gov)

**Re: Sacroiliac joint fusion**

Dear Washington HCA Director and Clinical Leadership,

On behalf of the International Society for the Advancement of Spine Surgery (ISASS), we would like to comment publicly on the topic of **sacroiliac joint fusion**. We understand the re-review request for this topic has been denied by the Health Care Authority (HCA). **We encourage the Washington HCA to reconsider its denial of re-review for this topic of minimally invasive sacroiliac joint fusion, which would be of significant benefit to Washington Medicaid members, or falling under workers compensation or other benefits plans controlled by the HCA's decisions.** We believe there is ample rationale for the HCA and the HTCC to revise its current policy and position on this topic, and to adopt coverage criteria that includes SI joint pain and dysfunction due to degenerative conditions not limited to patients with a history of direct trauma or injury to the pelvic girdle. With Level I and II evidence showing the immediate as well as long-term impact this important treatment option has had on a mostly degenerative sacroiliitis population, including more than 80 papers published in peer-reviewed journals with follow-up of 5 years prospectively, we believe there is sufficient rationale for Washington HCA's coverage with adequate pre-operative criteria.

During the last HTCC meeting convened on this topic in January 2019, there were two issues seeming to confound the data and Final Evidence Report's conclusions, in the opinion of the clinical committee members:

1. Complication types, rates and incidence, and the revisability of the SIJ Fusion procedure; and
2. Sponsor bias and why a sham study was not advisable or possible in key studies; and, whether the level of evidence is sufficient to support broader coverage of this topic

Within this letter, we address these two items and hope to continue the discussion in support of Washington HCA's ongoing review of this topic.

**1. Complications and Revisions for MIS-SIJ Fusion**



In 2018, the Washington HCA conducted a comprehensive review of the literature on this topic. The [report finalized in December 2018](#) following this review was favorable for SI joint fusion, yet when the Washington HCA HTCC meeting was convened on this topic on January 18, 2019, the committee decided against its broader application for conditions other than trauma. Certain committee members questioned the complications resulting from this procedure, characterizing them as significant, and occurring with significant frequency. No references were provided in support of these statements, certainly none as strong as those supporting the broader population of mostly degenerative sacroiliitis patients. Also, they argued the procedure was not easily revisable.

The safety of any product and procedure is of critical importance. There are numerous FDA-cleared devices indicated for SI joint fusion that are available on the U.S. market. Speaking to relevant and available safety data, unfortunately data on this procedure is not available, other than for those using iFuse. The safety of the iFuse Implant System [Miller 2013<sup>65</sup>, Cher 2015<sup>66</sup>] [Cher 2018<sup>67</sup>] has been demonstrated with low complication and revision rates. Notably, the complication and revision rates for iFuse-3D are the same as for iFuse Implants [Cher 2018<sup>67</sup>]. The revision rate for iFuse has been shown to be better than a majority of spine and orthopedic procedures. The safety profile for iFuse implants and the procedure is supported by multiple publications<sup>1-3,5,6,8,60,65-67,87,88,96</sup> as summarized in the table below; ISASS 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/percutaneous sacroiliac joint fusion stabilization.

Safety & Revision Rate Profile			
<i>Article</i>	<i>Description</i>	<i>Adverse Events (AEs)</i>	<i>Revision Rate</i>
<b>Cher 2018<sup>67</sup></b>	Postmarket surveillance of complaints for iFuse-3D Implants, and comparison to iFuse Implants (n=14,210) 11,070 cases using iFuse Implants 3,140 cases using iFuse-3D Implants	~1.3% overall complaint rate. <0.5% pain-related complaints for both iFuse and iFuse-3D. No implant breakages or migrations	One-year cumulative probability of revision: 1.5% iFuse Implants 1.0% iFuse-3D Implants
<b>Darr 2018b<sup>5</sup></b>	Prospective, multicenter (n=93) 4-year results	No new device- or procedure-related AEs during follow-up year 4. (AEs for year 3 reported in Darr 2018a, and through 2 years were reported in SIFI and INSITE publications.)	<1% (1 subject underwent revision at year 3.8)
<b>Darr 2018a<sup>6</sup></b>	Prospective, multicenter (n=103) 3-year results	No new device- or procedure-related AEs during follow-up year 3.	<1% (1 subject underwent revision at year 3.8)

<b>Dengler 2017b<sup>2</sup></b>	Prospective, multicenter, RCT (n=52 iFuse, n=51 CM) 1-year results	(AEs through 2 years were reported in SIFI and INSITE.) Within first 200 days, 17 AEs in each group. By 6 months, mean number of AEs per patient was 0.33 in both groups (p=0.9549 for rate diff).	3.8% (2 of 52 iFuse patients within 1 year)
<b>Polly 2016<sup>1</sup></b>	Prospective, multicenter, RCT (n=102 iFuse, n=46 NSM) 2-year results	Within first 180 days: 1.5 per iFuse subject 1.3 per NSM subject (p=0.2253)	3% (3 of 102 iFuse patients within 2 years)
<b>Sachs 2016<sup>60</sup></b>	Retrospective, multicenter (n=107) 3.7-year follow-up	3 (2.8%) procedure-related complications	4.7% (5 of 107 patients)
<b>Duhon 2016<sup>3</sup></b>	Prospective, multicenter, single-arm, clinical trial (n=172) 2-year results	2.9% probably/definitely device-related 12.2% probably/definitely procedure-related	4.7% (8 of 172 patients)
<b>Cher 2015<sup>66</sup></b>	4-year survivorship analysis (free from revision surgery) n=11,388	-NA-	3.5% cumulative rate (96.5% survivorship, free from revision, adjusted 4-year rate) <i>NOTES</i> • Likelihood of revision has decreased annually since 2009 • Rate did not differ by age (< or > 65 years old) or sex
<b>Miller 2013<sup>65</sup></b>	Retrospective complaints database analysis (n=5319)	3.8% overall complaint rate	1.8%

Specifically looking at 4-year cumulative revision rates, the 3.5% iFuse Procedure revision rate [Cher 2015<sup>66</sup>] is favorable when compared with revision rates of other accepted and common lumbar surgeries: decompression (10-12%) and fusion (12-14%) [Martin 2007<sup>123</sup>, Deyo 2011<sup>124</sup>, Basques 2015<sup>125</sup>]. Most manufacturers provide revision kits in the event a revision is necessary, however as previously mentioned the relative rate of revision procedures is exceedingly low.

The Washington HCA committee members also expressed some concern about study bias issues with the iFuse procedure, and the decision by investigators not to compare the procedure to a sham surgery. More on this is discussed in the following section.

### **3. Sponsor Bias, Sham Study Design and Level of Evidence**

The effectiveness of SI joint fusion is well established in numerous prospective trials, producing Level I and II evidence on this topic from research conducted ethically and with adequate controls:



- 1 **INSITE** is a prospective multicenter randomized controlled trial conducted at 19 centers in the US. Two-year results showed that SIJ Fusion surgery provided markedly superior pain and disability relief compared to state-of-the art non-surgical treatment.
- 2 **iMIA** is a prospective multicenter randomized controlled trial conducted at 9 centers in Europe. The design of iMIA was very similar to INSITE, but control treatment focused on intensive physical therapy. This study also showed marked superiority of surgical vs. non-surgical treatment. Two-year data were just published in *Journal of Bone and Joint Surgery*.
- 3 **SIFI** is a prospective multicenter single-arm clinical trial in the same patient population. SIFI results confirmed the above two randomized trials.
- 4 **LOIS** is a 5-year follow-up study of patients prospectively enrolled in INSITE and SIFI.

The prospective and RCT study of iFuse patients has yielded more than 80 papers published in peer-reviewed, scientific journals, including Level I and II evidence. As a result, many U.S. payers and health technology assessment organizations cover or recommend the procedure. An additional 15 to 20 papers have been published on other FDA/510k cleared MIS-SIJ Fusion systems as well.

Below are direct responses to some of the objections about the study design, and the industry sponsor bias relating to the study of SIJ Fusion:

- **Sham surgery as control.** In 2012, when INSITE was designed, investigators refused to do sham surgery as unethical. It is unclear whether IRBs would have approved such a study. Moreover, it is unclear whether patients participating in such a study would be representative of all patients in general. Notably, sham is not necessarily a requirement for evaluation; no other spine surgical procedure has been subjected to a sham-control trial. A meta-analysis of numerous orthopedic sham trials found these studies have significant methodologic deficiencies that may invalidate their conclusions.<sup>137</sup> The favorable method for studying spine and orthopedic therapies is the randomized, controlled trials with valid control groups to study the experimental arms – of which there are numerous on this topic, all supporting the use of SI joint fusion for well selected patients.
- **Placebo effect.** Large effect sizes were seen in INSITE. While some placebo effect might be present, the sheer size of the effect speaks against any of the observed effect being due to placebo. From a payer perspective, it may not be necessary to determine the proportion of the observed effect that is directly attributable to the device as opposed to placebo. Treated patients feel and perform better.
- **Cross-over to surgery.** Additionally, investigators were still able to draw conclusions after 6 months due to high crossover. While it is true that INSITE has high crossover, the crossover rate in iMIA was substantially lower. Analyses published at 1 year<sup>11</sup> and 2 years<sup>12</sup> in the *Journal of Bone and Joint Surgery* show that the superiority of SI joint fusion persists at 2 years. Moreover, there is very little evidence that chronic SIJ pain resolves on its own. Thus, the expectation in the control group is continued pain and disability.
- **Industry sponsorship and bias.** The vast majority of high-quality trials of spine surgery-related devices are industry sponsored.<sup>40</sup>



**We respectfully propose the HCA reconsider the recent decision to deny a re-review of this important topic, and potentially a very helpful and efficacious treatment option for Washington patients.** As appendices to this letter, enclosed is a listing of references as well as a summary of ISASS and NASS recommendations and guidelines on this topic. Please do not hesitate to contact us if we may provide any additional information ([mloriomd@gmail.com](mailto:mloriomd@gmail.com)) or be of help in your review process.

Sincerely,

A solid black rectangular redaction box covering the signature area.

Morgan Lorio, MD, FACS  
Chair, ISASS Task Force Coding & Reimbursement



## Appendix – References

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137. Sochacki KR, et al. Sham studies in orthopedic surgery may just be a sham: a systematic review of randomized placebo-controlled trials.



## Appendix– Comparison of ISASS and NASS Coverage Criteria for Minimally Invasive SI Joint Fusion

Criteria	International Society for the Advancement of Spine Surgery (ISASS)	North American Spine Society (NASS)
<b>GUIDELINES</b>	<p>ISASS Policy 2016 Update – Minimally Invasive Sacroiliac Joint Fusion: Coverage Indications, Limitations, and/or Medical Necessity (Updated July 5, 2016)<sup>1</sup></p> <p>(This supplements the ISASS Policy Statement – Minimally Invasive Sacroiliac Joint Fusion published in <i>Int J Spine Surg</i> in 2014)</p> <p>Patients who have all of the following criteria may be eligible for minimally invasive SIJ fusion:</p>	<p>NASS Coverage Policy Recommendations: Percutaneous Sacroiliac Joint Fusion (June 9, 2015)<sup>2</sup></p> <p>Percutaneous (also referred to as minimally invasive) SIJ fusion (e.g., insertion of a metallic device across the SIJ that is intended to fuse to the bone or lead to fusion of the joint itself, in distinction from insertion of screws without bone graft across the SIJ which are intended to stabilize but not fuse the joint) is indicated for the treatment of SIJ pain for patients with low back/buttock pain who meet ALL of the following criteria:</p>
<b>TREATMENT PRIOR TO SURGERY</b>	<p>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;</p> <p><i>Note: Additional ISASS Documentation Requirements are outlined on page 4 of this document.</i></p>	<p>Have undergone and failed a minimum six months of intensive nonoperative treatment that must include medication optimization, activity modification, bracing, and active therapeutic exercise targeted at the lumbar spine, pelvis, SIJ, and hip including a home exercise program.</p> <p>A trial of at least one therapeutic intra-articular SIJ injection (i.e. corticosteroid injection).</p> <p><i>Note: Traditional care for the treatment of pain arising from the sacroiliac joint not due to an infectious or neoplastic process begins with physical therapy and activity modification. Analgesic medication including NSAIDS, acetaminophen, or opioids could be considered depending on each patient's medical history and symptom severity. Alternative treatments such as sacroiliac support belts and manual medicine may be considered as well. It is important to note that while these treatments are utilized routinely, no comparative</i></p>
<b>SI JOINT PAIN</b>	<p>Significant SIJ pain (e.g., pain rating at least 5 on the 0-10 numeric rating scale where 0 represents no pain and 10 represents worst imaginable pain) that impacts quality of life or significantly limits activities of daily living.</p> <p><i>(Patients with SI joint pain typically report pain in the buttocks, with possible radiation into the groin or upper legs.)</i></p>	<p>Patient's report of typically unilateral pain that is caudal to the lumbar spine (L5 vertebrae), localized over the posterior SIJ, and consistent with SIJ pain.</p>

Criteria	International Society for the Advancement of Spine Surgery (ISASS)	North American Spine Society (NASS)
<b>DIAGNOSTIC INJECTION</b>	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.	At least 75 percent reduction of pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular SIJ injection on two separate occasions.
<b>PHYSICAL EXAM</b>	SIJ pain confirmed with at least 3 physical examination maneuvers that stress the SIJ ( <i>e.g.</i> , distraction test, compression test, thigh thrust, FABER (Patrick's test), Gaenslen's maneuver, sacral sulcus tenderness) and reproduce the patient's typical pain.	Positive response to a cluster of 3 provocative tests ( <i>e.g.</i> , thigh thrust test, compression test, Gaenslen's test, distraction test, Patrick's sign, posterior provocation test). <i>(Note that the thrust test is not recommended in pregnant patients or those with connective tissue disorders.)</i> A thorough physical examination demonstrating localized tenderness with palpation over the sacral sulcus (Fortin's point, <i>i.e.</i> , at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine or PSIS) in the absence of tenderness of similar severity elsewhere ( <i>e.g.</i> , greater trochanter, lumbar spine, coccyx) and that other obvious sources for their pain do not exist
<b>DIAGNOSTIC IMAGING</b>	Imaging of the SIJ typically does not provide valuable diagnostic information. Rather imaging is used to ensure that the patient does not have alternative diagnoses that could mimic SIJ pain ( <i>e.g.</i> , hip osteoarthritis, occasionally L5/S1 spine degeneration).	Diagnostic imaging studies have not been shown to reliably predict pain arising from the SI joint, but are sometimes necessary to identify other pathologic conditions that may be the source of the patient's back pain. <b>Diagnostic imaging studies that include ALL of the following:</b> Imaging (plain radiographs and a CT or MRI) of the SI joint that excludes the presence of destructive lesions ( <i>e.g.</i> , tumor, infection) or inflammatory arthropathy that would not be properly addressed by percutaneous SIJ fusion Imaging of the pelvis (AP plain radiograph) to rule out concomitant hip pathology. Imaging of the lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that can be causing low back or buttock pain. Imaging of the SI joint that indicates evidence of injury and/or degeneration. Note: NASS guidance - Diagnostic imaging studies have not been shown to reliably predict SI joint pain.



Criteria	International Society for the Advancement of Spine Surgery (ISASS)	North American Spine Society (NASS)
<b>OTHER DIAGNOSES CONSIDERED</b>	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.	Absence of generalized pain behavior (somatoform disorder) or generalized pain disorders (e.g., fibromyalgia).
<b>Not indicated for patients with the following scenarios:</b>	Minimally invasive SIJ fusion is NOT indicated for patients with the following: <ul style="list-style-type: none"> <li>• Less than 6 months of SIJ pain and/or functional impairment;</li> <li>• Failure to pursue conservative treatment of the SIJ (unless contra-indicated);</li> <li>• Pain not confirmed with a diagnostic SIJ block;</li> <li>• Presence of other pathology that would substantially prevent the patient from deriving benefit from SIJ fusion.</li> </ul>	Percutaneous SIJ fusion for SIJ pain is NOT indicated in ANY of the following scenarios: <ul style="list-style-type: none"> <li>• Any case that does not fulfill ALL of the above criteria</li> <li>• Presence of systematic arthropathy such as ankylosing spondylitis or rheumatoid arthritis</li> <li>• Presence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorder (e.g., fibromyalgia)</li> <li>• Presence of infection, tumor, or fracture</li> <li>• Presence of acute, traumatic instability of the SIJ</li> <li>• Presence of neural compression as seen on an MRI or CT that correlates with the patient's symptoms or other more likely source for the pain.</li> </ul>

**ISASS Documentation Requirements:**

- A complete history and physical documenting the likely existence of SIJ pain;
  - Performance of a fluoroscopically-guided SIJ block on the affected side (or both sides, see discussion above) which shows at least a 50% acute reduction in pain;
  - A course of conservative treatment to include use of non-steroidal anti-inflammatory drugs and one of the following:
    1. an adequate period of rest,
    2. an adequate course of physical therapy wherein the physical therapist specifically documents lack of response to treatment;
  - SIJ pain has continued for a minimum of six months; and
- All other diagnoses that could be causing the patient's pain have been considered and the physician believes that SIJ fusion is clinically required.

**REFERENCES**

1. ISASS Policy Statement – Minimally Invasive Sacroiliac Joint Fusion (July 2016): Coverage Indications, Limitations, and/or Medical Necessity  
Updated July 5, 2016  
<http://www.isass.org/public-policy/isass-policy-statement-minimally-invasive-sacroiliac-joint-fusion-july-2016/>



PDF version click [here](#)

Author: ISASS Task Force (Coding & Reimbursement) Chair; Morgan P. Lorio, MD, FACS.

[This supplements the ISASS Policy Statement – Minimally Invasive Sacroiliac Joint Fusion in IJSS ([Lorio MP, Rashbaum R. \*Int J Spine Surg.\* 2014;8:Article 25. doi: 10.14444/1025.2014](#))]

2. NASS Coverage Policy Recommendations: Percutaneous Sacroiliac Joint Fusion (June 9, 2015).

<https://www.spine.org/Documents/PolicyPractice/CoverageRecommendations/PercutaneousSacroiliacJointFusion.pdf>



**From:** [Baker, David E., M.D.](#)  
**To:** [HCA ST Health Tech Assessment Prog](#)  
**Cc:** [Flory, Thomas R.](#)  
**Subject:** SI joint fusion  
**Date:** Monday, July 27, 2020 11:13:42 AM

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Dear Mr. Morse,

I am a neurosurgeon writing to share my experience with performing minimally invasive SI joint fusion surgeries. In the past two 2 years, I have performed this procedure on xx well-selected patients. The patient profile for this procedure is degenerative sacroiliitis, or sacroiliac disruption and dysfunction. Few are profiled as the type of severe trauma the HCA currently intended in your current policy.

This condition can particularly affect activities of daily living for patients who have suffered for years with debilitating sacroiliac joint dysfunction or sacroiliitis (long-term back pain). With surgery, my patients have been able to regain quality of life and patient satisfaction rates are extremely high (90% in my practice) and the adverse events low (less than 2%). Return to work rates from my clinic are also excellent.

While surgery is a last-resort treatment for sacroiliac pain and dysfunction, when conservative treatments fail to bring SI joint pain relief and quality of life is impacted to a significant degree, the 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.

Please reconsider the position on this topic and this should be reviewed again at the earliest possible time frame.

Sincerely,

David E. Baker, M.D.  
4CNSA  
710 Birchwood Ave  
Suite 101  
Bellingham, WA 98225  
360-676-0922

Sent from [Mail](#) for Windows 10







## Northwest Orthopaedic and Sports Medicine

Joshua Bales, MD  
John-David Black, MD  
David J. Gibbons, MD  
Gordon H. Hsieh, DO  
Richard T. Jacobs, MD  
Brian Lloyd, NP-C  
Arash Motaghi, DO  
D. Joshua Miller, MD

Kenneth Miller, PA-C  
Timothy Nickolaus, PA-C  
Michael C. Perala, PA-C  
K. Blair Sampson, MD  
M. Lynn Scovazzo, MD  
John W. Staeheli, MD  
Jacob M. Stanfield, MD

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To: Washington Health Care Authority  
From: John-David Black, MD

**RE: Prospective technology topics (sacroiliac joint fusion)**

To Whom It May Concern,


My name is John-David, Black, MD. I am a board-certified orthopedic surgeon practicing at Kadlec Clinic (Richland, WA). I have performed over 120 minimally invasive sacroiliac joint fusion surgeries (iFuse procedure). The majority of my patients have had degenerative sacroiliitis or sacroiliac dysfunction diagnoses, not necessarily all a result of any history of direct pelvic girdle trauma or injury. I am aware that the last time this topic was reviewed by the HCA was a literature review with a cutoff date of June 2018, following by a decision made by a committee convened in January 2019, the result of which now limits access to Washington Medicaid, Washington L&I patients (workers comp), as well as other insured members with policies falling under the HCA, to trauma/injury cases only. As a surgeon sub-specializing in trauma orthopedics, I can tell you this topic is not adequately covered by the current WA HCA position. The limitations in the current WA HCA position does a serious disservice to patients who need this surgery, and who I see almost on a weekly basis. With most health plans now covering the procedure for degenerative sacroiliitis or dysfunction diagnoses (Regence, Premiera, Aetna, Cigna, UHC), and with so many third party review companies assessing the evidence for iFuse favorably based on the patient outcomes from high-level studies, it makes the decision by WA HCA not to provide a similar level of access to it that much more confusing and frankly, concerning. I cannot understand what issues, or what literature, is being misinterpreted (and by whom), for this to be today's status quo.

Prior to the Jan 2019 committee decision and limitation on patients, I can recall a Washington Medicaid patient who was diagnosed with degenerative SIJ disease, and did quite well with this procedure. He reportedly slept for the "first time in 9 years" after receiving the correct treatment for the correct diagnosis. Even after this policy changed, another patient with sacroiliac joint dysfunction was denied coverage by Washington L&I. She underwent surgery anyway, by paying cash, and now is back at work and doing very well after the right surgery was performed for the correct diagnosis.

As a researcher in this area of orthopedics, I keep up with the current clinical literature on this topic. Since June 2018, the last time the HCA considered the evidence base on this topic, there have been more than a dozen papers published, at least 2-3 of which are important for understanding the long-term evidence which guides my clinical practice toward this procedure, more than ever before. The 5-year outcomes published by Whang et al (2019) should alone provide enough rationale for the HCA to pick up this topic again, and consider the evidence. I believe there have been over 45,000 iFuse procedures performed, and the SI-Bone company maintains complications reporting for FDA/MAUDE databases which shows low complication and reoperation rates. The technology is right (iFuse), the evidence is Level I and Level II (the best available), the outcomes are excellent, and the diagnosis has been vetted by numerous unbiased experts and has been deemed good as a clinical diagnostic Rule (Laslett et al 2008).

I would ask the HCA to pick up this topic for re-review again as soon as possible, and invite me and other fellow surgeons who routinely perform this surgery to talk about our patient outcomes, the complications we see in clinical practice (minimal to non-existent), and to have a real dialogue about the appropriate pre-op criteria and clinical assessment which should occur prior to a Washington Medicaid or L&I patient getting this treatment option.

Thank you for your consideration. If I can be of any further help or provide information or input, please do not hesitate to contact me.

  
John-David Black, MD

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**From:** [Flory, Thomas R.](#)  
**To:** [HCA ST Health Tech Assessment Prog](#)  
**Subject:** SI Joint Fusion  
**Date:** Monday, July 27, 2020 1:53:08 PM

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I am writing on behalf of Drs. David Baker, M.D., and Tung Ha, DO, neurosurgeons at Fourth Corner Neurosurgical Associates (Bellingham, WA), to request a formal review of the peer review clinical evidence for minimally invasive SI joint fusion (CPT 27279). Drs. Baker & Ha feel that SIJF is an important treatment option for patients who have tried and failed appropriate conservative care.

This procedure is an accepted treatment for patients who meet published medical guidelines, such as AIM, eviCore, and MCG. More than 100 health plans, including Medicare, Aetna, CIGNA, TRICARE, 23+ BCBS plans (including Regence and Premera), and UHC, cover this procedure for carefully selected patients.

In our neighboring state, Oregon Medicaid has differentiated coverage for severe SI joint conditions. This is an important procedure to offer our Apple Medicaid patients suffering from severe and disabling SI joint conditions.

Drs. Baker and Ha are available to speak with you if you would like to discuss.

We appreciate your consideration.

Tom

[Thomas Flory](#)  
[Executive Director](#)  
[Fourth Corner Neurosurgical Associates](#)  
[710 Birchwood Ave](#)  
[Suite 101](#)  
[Bellingham, WA 98225](#)  
[360-676-0922](#)

**From:** [Ha, Tung M., D.O.](#)  
**To:** [HCA ST Health Tech Assessment Prog](#)  
**Cc:** [Flory, Thomas R.](#)  
**Subject:** re: MIS SIJ Fusion  
**Date:** Tuesday, July 28, 2020 2:14:59 PM

---

Dear Washington HCA c/o Mr. Josiah Morse,

I am writing out of concern as I have just heard that the HCA Director has denied a petition to re-review the clinical evidence for Minimally Invasive Sacroiliac Joint Fusion. I am struggling to understand why this topic is not a high priority for HCA based on the robust Level 1 clinical evidence of good patient outcomes and documented savings to the healthcare system. This should be a covered benefit, but at the very least it should be re-reviewed ASAP.

Your members are my patients. Many are suffering from severe and debilitating SI joint dysfunction without access to this procedure. My patients who are insured by other carriers (including Aetna, CIGNA, Regence, Premera, Medicare, UHC, etc.) have access to this procedure when meeting criteria. Those who work for the State or who are on Medicaid or have Workman's Compensation plans, however, do not. Clearly, MIS SI joint fusion with triangular implants (iFuse Implants) is backed by dozens of published papers, clinical studies, and procedures. This procedure is safe and proven to work. WA Medicaid and Work Comp is needlessly denying patients access to an important life restoring procedure.

How many patients may be getting the wrong procedure? How many patients are developing chronic opioid addictions that could have been prevented if they were afforded the appropriate treatment? HCA should proactively educate itself and its medical reviewers that proper evaluation of lower back pain MUST include assessment of the SI joint along with the lumbar spine and hip. Better diagnosis means better targeted treatment and ultimately better patient outcomes. Please take into consideration the significant role of the SI joint in lower back pain, and make minimally invasive SI joint fusion available to patients who need it.

Thank you for your time and consideration regarding this matter.

Sincerely,

Tung M. Ha, DO





July 21, 2020

WA State Health Care Authority Director Sue Birch

WA State Health Technology Clinical Committee

WA State Legislature

**RE: Comments on the review of health technologies by Health Technology Assessment Program for 2021**

Dear Director Birch,

The Washington Acupuncture and Eastern Medicine Association (WAEMA) is submitting comments regarding the selection of which technologies are being reviewed for 2021. We are deeply saddened to see that the request to re-review acupuncture for chronic migraine and tension headaches has been rejected. WAEMA submitted 36 new studies to the HTCC beyond the initial review.

Extensive new evidence was submitted showing positive outcomes, and yet, even with the submission of additional evidence-based data, your review process continues to deny patients access to non-pharmacological treatments because the data review process is not determined by specialists in this field of medicine. Acupuncture meets the review requirements for safety, efficacy, and cost-effectiveness and should be included as a non-pharmacological alternative for patients in Washington state, as opposed to supporting the injection of a Botulinum toxin into a patient. How do the results for these two treatments compare over the long-term, especially for cost and safety?

**As specified in RCW 70.14.110 (2)(c), WAEMA would like to request that an ad hoc temporary advisory group, with specialized expertise in acupuncture, review the decision by the HTA program to reject the re-review of acupuncture as a treatment for chronic migraine and tension headaches.**

We have growing concerns about the committee review process and perceive a data bias against non-pharmaceutical alternatives. We believe that the review process has a preference towards well-funded pharmaceutical companies who have extensive resources for producing the

“evidence-based” data that is required for your review. We support evidence-based data but are concerned that the current review process does not adequately address non-pharmacological treatments such as acupuncture in their data review and inadvertently moves patients towards pharmacological treatments instead. The citizens of Washington state deserve alternatives to pharmaceuticals that often have negative side effects and can be very costly for the patient.

The effect of this bias is that even though there is extensive evidence-based data showing positive effects for acupuncture, the quality of that data is deemed “insufficient” in comparison to the pharmaceutical based studies due to subjective reasons that are not made entirely clear. This decision has led to the exclusion of acupuncture for treatments of chronic migraine and tension headaches with some insurers and has negatively impacted our patient’s ability to access non-pharmacological options at the Department of Labor and Industries. The bottom line is, how is the HTCC making sure that non-pharmacological alternatives are available to patients who want that choice?

We also want to assure that the review process used aligns with the state goals of providing non-pharmacological alternatives for pain and patient choice. On January 10, 2020 the Health Care Authority released the [“Apple Health Nonpharmacologic Pain Treatment Coverage”](#) Report to the Legislature (SSB 5380; Chapter 314; Laws of 2019; Section 35). Although the report focused on the treatment of pain and avoidance of using opioids, we believe that the intent of the state legislature was to reduce reliance on pharmaceuticals. In the report the Health Care Authority (HCA) found that: Acupuncture has evidence of treatment effectiveness, is sufficiently cost-effective, and is the least costly treatment to provide, based on expected utilization.

Thank you for your consideration of these concerns and we look forward to hearing back from you regarding the establishment of the ad hoc committee option in statute. Please feel free to contact our Public Policy Director, Leslie Emerick at 360-280-6142 or [lesemerick@lkemerick.com](mailto:lesemerick@lkemerick.com) if you have any questions.

Sincerely,

The Washington Acupuncture and Eastern Medicine Association Board of Directors

CC: Senator Annette Cleveland, Senate Health Care Committee Chair

Senator Ann Rivers

Representative Eileen Cody, House Health Care Committee Chair

Representative My-Linh Thai

Dr. Charisa Fotinos, Medical Director, Health Care Authority

Josh Morse, Health Care Authority

**From:** [janalynwiley@aol.com](mailto:janalynwiley@aol.com)  
**To:** [HCA ST Health Tech Assessment Prog](#)  
**Subject:** Migraines and Acupuncture  
**Date:** Friday, July 24, 2020 8:13:39 AM

---

To the Health Technology Assessment Committee:

I am an RN/Acupuncturist, formerly a critical care nurse, who has been practicing for almost 30 years. It is with dismay, and my patient's dismay, that I read you had decided that acupuncture was not a covered modality for the treatment of migraines.

I know that our WA State Association, WAEMA, has worked with you to provide research on this. Note, that the oldest texts that have been translated, talk about this non medicinal treatment for headaches and migraines. My teachers, elder Chinese doctors, no longer alive, some of whom escaped Chinese work camps where they had been held since the Cultural Revolution, gave extensive talks on the use of acupuncture for the debilitating symptoms of migraines. It is apparent that the HTA group is rejecting a non pharmacological treatment in favor of Botox. Allergan must have talked up a good one when the HTA embraced it. The year prior to their strong push for their product, the company predicted that the next years earnings would quadruple. And indeed they did with your help. Now patients are limited.

Two of my patients have post polio syndrome and migraines. Botox is contraindicated as their upper body strength and use of their arms is already limited.. The only thing that has helped them is acupuncture. Now, they are closed off from getting their care, which is generally about once a month or every two months.

I thought that WA State law enabled patients access to non pharmacological treatments such as acupuncture. I must be mistaken or could you clarify for me and them your decision and rationale to disallow this diagnosis from coverage.

Sincerely,

Jana Wiley, RN, MS, AEMP  
Licensed Acupuncturist

P.S. I also testified at one of your HTA meetings about tinnitus, and the Kaiser Olympia ENT findings that acupuncture was the only thing helping their patients.

The providers I spoke with a week before you tinnitus meeting stated that 3 out of 10 patients got relief from acupuncture, and that they will continue to refer patients to those few of us who specialize in this treatment. You blew my testimony off too, in favor of an option that the ENTs at Kaiser stated did not work. Does your group have some internal bias?





July 28, 2020

WA State Health Care Authority Director Sue Birch

WA State Health Technology Clinical Committee

**RE: Comments on the review of health technologies by Health Technology Assessment Program for 2021**

Dear Director Birch,

Our request for a review of additional evidence supporting acupuncture in the treatment of headaches was denied, with no rationale provided for the denial.

The initial acupuncture review included four randomized controlled trials (RCTs) for outcomes related to the treatment of migraine headaches. The criticism of each study in the report brings up concerns that the review panel does not have a familiarity with acupuncture as a system of medicine. A reason cited to rate one of the four studies as lower quality included “patients were not blinded to treatment.” Acupuncture is a process that requires needle insertion, and the blinding of study participants to the acupuncture intervention is not feasible. Another study was rated a lower quality because the patients went on to receive additional acupuncture since the treatment was working. Even while the studies reported the beneficial effects of acupuncture, judgments made on procedural issues discredited the findings of each study.

Two small RCTs submitted for tension-type headaches reported beneficial results. However, the assessment of both was that they had a moderately high risk of bias due to methodological flaws. Reasons cited to downgrade the quality of these studies were similar to the migraine headache research; some of the criticisms of the methodologies point to areas not dissociable from the practice of acupuncture.

Twenty-five new studies submitted for review and reconsideration included Literature Reviews and Meta-Analyses, all reporting on the beneficial effects of acupuncture for migraines as well as for tension-type headaches. As additional support, we included studies that examined acupuncture mechanisms for headache, providing supporting evidence for a biomedical, physical, and neural responses.

We have difficulty in understanding why the HTTC denied our request for a review of the additional evidence. Our hope as acupuncturists is to provide our medicine as an option for people seeking relief from pain. Many people would welcome the opportunity to have a non-pharmacological treatment option for care. The submitted evidence demonstrates that acupuncture is beneficial as a non-pharmaceutical option for the management of headaches. We respectfully request the review be allowed and that the panel of reviewers contain members that are familiar with acupuncture as a system of medicine.

Thank you for your consideration of these concerns. We look forward to working with you

Sincerely,

Charis Wolf, MSTCM, DACM-s, LAc, Dipl Ac (NCCAOM)

Board Member; American Society of Acupuncturists

Immediate Past President; Washington acupuncture and Eastern Medicine Association

Mark Soddors, DAOM, Dipl OM (NCCAOM)

Postdoctoral Scholar, University of Washington, Seattle, Washington

CC: Josh Morse, Health Care Authority

**From:** [Charis Wolf](#)  
**To:** [Redick, Brittney \(HCA\)](#); [Morse, Josiah \(HCA\)](#)  
**Cc:** [Mark Sodders](#); [Emerick, Leslie](#)  
**Subject:** Fwd: Acupuncture: What the Science Says  
**Date:** Wednesday, July 29, 2020 11:36:44 AM

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Hi Britt and Josh,

This email was just sent out by the NIH. I would like it to be noted that the National Institute of Health recommends acupuncture for headaches.

I know it's past the comment period- but this has to be noted. The fact that acupuncture for headaches is recognized at a national level and not in WA state quite frankly is a little embarrassing.

I pride myself in representing the profession at the national level because of quality of the medicine in WA state. It would be in the best interest for the people of Washington to know that they have a non-pharmacological treatment for headaches that works, and the practitioners are good at treating it.

Thank you for your consideration.  
Stay healthy and safe!

Best,  
Charis

\*\*\*\*\*

Charis Wolf LAc, MSTCM, Dipl. Ac.  
DAOM-s

ASA, Board member at large  
Immediate Past President WAEMA

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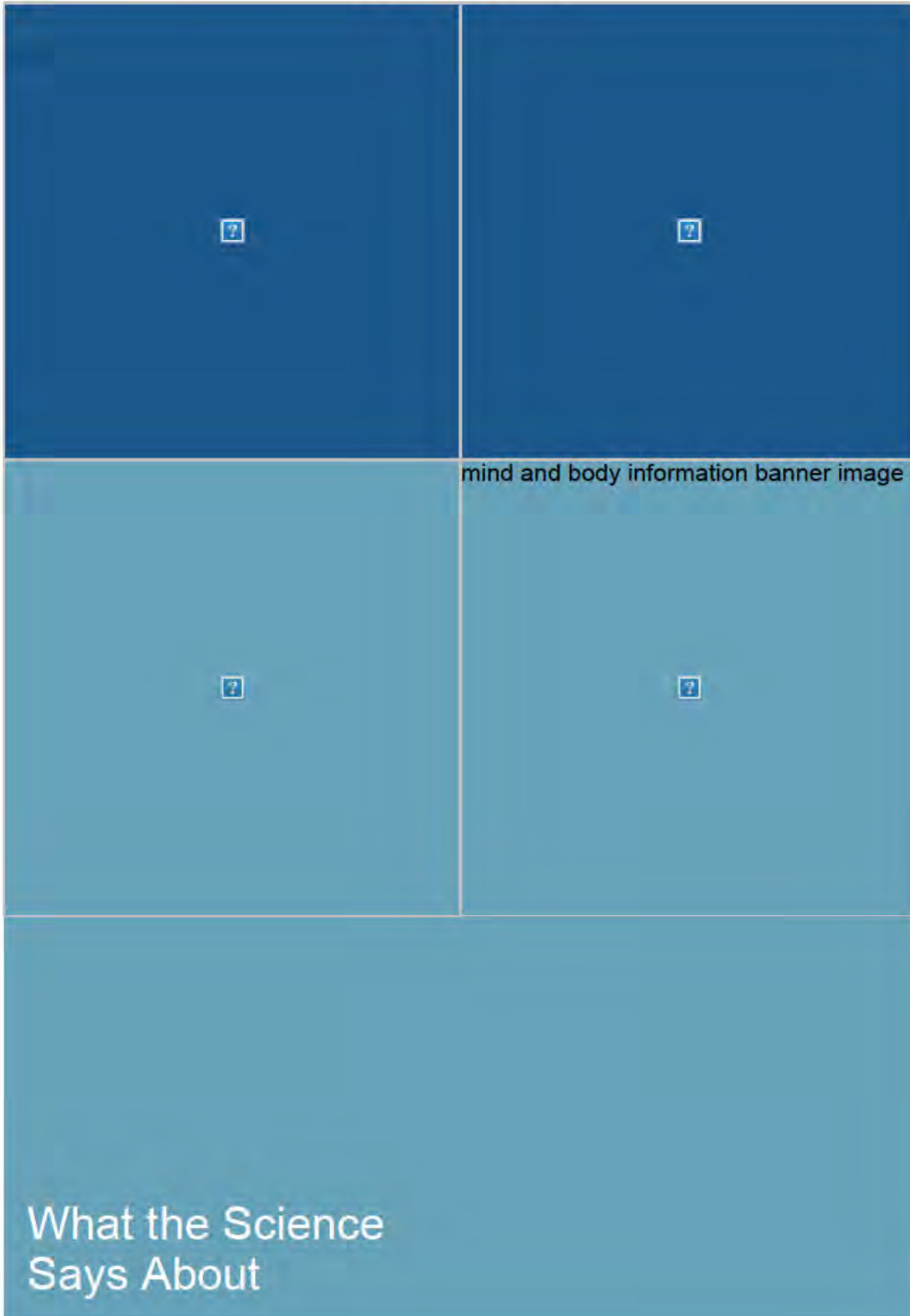
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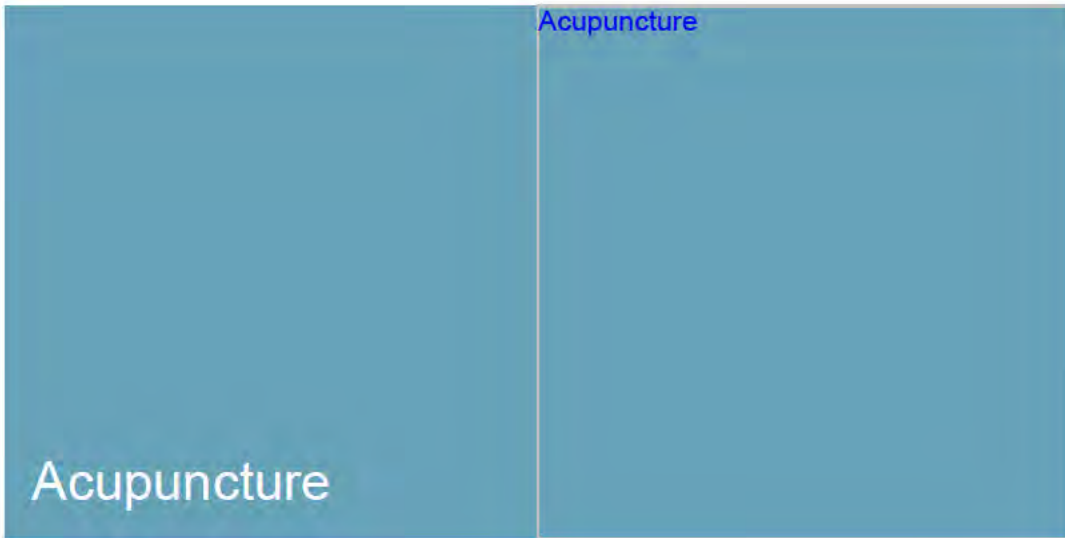


Begin forwarded message:

**From:** "National Center for Complementary and Integrative Health"  
<[NCCIH@public.govdelivery.com](mailto:NCCIH@public.govdelivery.com)>  
**Subject:** Acupuncture: What the Science Says  
**Date:** July 29, 2020 at 10:31:34 AM PDT  
**To:** [charis@chariswolfacupuncture.com](mailto:charis@chariswolfacupuncture.com)  
**Reply-To:** [NCCIH@public.govdelivery.com](mailto:NCCIH@public.govdelivery.com)

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Acupuncture is a technique in which practitioners stimulate specific points on the body—most often by inserting thin needles through the skin. It is one of the practices used in traditional Chinese medicine.

Research suggests that acupuncture can manage certain pain conditions, such as low-back pain, neck pain, knee pain associated with osteoarthritis, and headache. Evidence about its value for other health issues is uncertain.

Acupuncture is generally considered safe when performed by an experienced, well-trained practitioner using sterile needles.

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