Sacroiliac joint fusion

Clinical Expert

Conor P. Kleweno, MD
Assistant Professor, Department of Orthopaedics and Sports Medicine
University of Washington School of Medicine
Orthopaedic Trauma Surgeon
Harborview Medical Center
WA - Health Technology Assessment

Applicant Name: Conor Kleweno
Address: 325 9th ave
Seattle wa 98104
Department of Orthopaedics and Sports Medicine

1. Business Activities
(a) If you or a member of your household was an officer or director of a business during the immediately preceding calendar year and the current year to date, provide the following:

<table>
<thead>
<tr>
<th>Title</th>
<th>Business Name &amp; Address</th>
<th>Business Type</th>
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<tbody>
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(b) If you or a member of your household did business under an assumed business name during the immediately preceding calendar year or the current year to date, provide the following information:

<table>
<thead>
<tr>
<th>Business Name</th>
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<th>Business Type</th>
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2. Honorarium
If you received an honorarium of more than $100 during the immediately preceding calendar year and the current year to date, list all such honoraria:

<table>
<thead>
<tr>
<th>Received From</th>
<th>Organization Address</th>
<th>Service Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>AO North America</td>
<td>435 Devon Park Drive Building 800, Suite 820 Wayne, PA 19087</td>
<td>Educational lecturer</td>
</tr>
</tbody>
</table>

| AO North America | Click here to enter text. | Click here to enter text. |
| AO North America | Click here to enter text. | Click here to enter text. |

3. Sources of Income
(a) Identify income source(s) that contributed 10% or more of the combined total gross household income received by you or a member of your household during the immediately preceding calendar year and the current year to date.

<table>
<thead>
<tr>
<th>Source Name &amp; Address</th>
<th>Received By</th>
<th>Source Type</th>
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</thead>
<tbody>
<tr>
<td>University of Washington</td>
<td>Myself</td>
<td>Salary</td>
</tr>
<tr>
<td>UW Physicians</td>
<td>Myself</td>
<td>Salary</td>
</tr>
</tbody>
</table>
(b) Does any income source listed above relate to, or could it reasonably be expected to relate to, business that has, or may, come before the Committee?

☐ Yes  ☒ No

If “yes”, describe:  Click here to enter text.
Sometimes I treat SI joint injuries

(c) Does an income source listed above have a legislative or administrative interest in the business of the Committee?

☐ Yes  ☒ No

If “yes”, describe:  Click here to enter text.

4. Business Shared With a Lobbyist

If you or a member of your household shared a partnership, joint venture, or similar substantial economic relationship with a paid lobbyist, were employed by, or employed, a paid lobbyist during please list the following:

( Owning stock in a publicly traded company in which the lobbyist also owns stock is not a relationship which requires disclosure.)

<table>
<thead>
<tr>
<th>Lobbyist Name</th>
<th>Business Name</th>
<th>Type Business Shared</th>
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<tbody>
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</table>

Provide the information requested in items 5, 6, and 7 below only if:

(a) Your response involves an individual or business if you or a member of your household did business with, or reasonably could be expected to relate to business that has or may come before the Health Technology Clinical Committee.
(b) The information requested involves an individual or business with a legislative or administrative interest in the Committee.

5. Income of More Than $1,000

List each source (not amounts) of income over $1,000, other than a source listed under question 3 above, which you or a member of your household received during the immediately preceding calendar year and the current year to date:
Income Source | Address | Description of Income Source
--- | --- | ---
Globus Medical | 2560 General Armistead Avenue, Audubon, PA 19403 | Consultant for design of tibia fracture nail
| phone: (610) 930-1800 | |
| Click here to enter text. | Click here to enter text. | Click here to enter text.

6. Business Investments of More Than $1,000

(Do not list the amount of the investment or include individual items held in a mutual fund or blind trust, a time or demand deposit in a financial institution, shares in a credit union, or the cash surrender value of life insurance.)

If you or a member of your household had a personal, beneficial interest or investment in a business during the immediate preceding calendar year of more than $1,000, list the following:

<table>
<thead>
<tr>
<th>Business Name</th>
<th>Business Address</th>
<th>Description of Business</th>
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<tbody>
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7. Service Fee of More Than $1,000

(Do not list fees if you are prohibited from doing so by law or professional ethics.)

List each person for whom you performed a service for a fee of more than $1,000 in the immediate preceding calendar year or the current year to date.

<table>
<thead>
<tr>
<th>Name</th>
<th>Description of Service</th>
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</table>

I certify that I have read and understand this Conflict of Interest Form and the information I have provided is true and correct as of this date.

Print Name: Conor Kleweno

Check One: □ Committee Member □ Subgroup Member □ Contractor

Clinical Expert

Signature

Date 1/9/19
Curriculum Vitae

Conor Patrick Kleweno, MD
Assistant Professor
Harborview Medical Center
Department of Orthopaedics and Sports Medicine
325 Ninth Avenue, Box 359798
Seattle, Washington 98104
Phone: 206.744.5707
Fax: 206.744.3227
ckleweno@uw.edu

EDUCATION

MD
Harvard Medical School, Boston, MA
Doctor of Medicine (MD)
Cum Laude

Undergraduate
University of Washington, Seattle, WA
BSE Bioengineering
Magna Cum Laude

POSTGRADUATE TRAINING

Fellowship
Orthopaedic Trauma Fellowship
R Adams Cowley Shock Trauma Center
University of Maryland Medical Center
Baltimore, MD
Program Director: Robert O’Toole
8/1/2012 – 7/31/2013

Residency
Combined Orthopaedic Residency Program
Harvard University
Boston, MA
6/17/2008 – 6/30/2012

Internship
General Surgery Internship Program
Beth Israel Deaconess Hospital
Harvard University
Boston, MA

FACULTY POSITIONS HELD

Assistant Professor
Department of Orthopaedics and Sports Medicine
Harborview Medical Center
University of Washington School of Medicine
Seattle, Washington
9/5/2013 – Present
HOSPITAL POSITIONS HELD

Attending Orthopaedic Surgeon
University of Washington
Department of Orthopaedics
Northwest Hospital and Medical Center
Seattle, Washington 11/15/13 – Present

Attending Orthopaedic Surgeon
University of Washington
Department of Orthopaedics
Harborview Medical Center
Seattle, Washington 9/5/2013 – Present

Attending Orthopaedic Surgeon
University of Washington
Department of Orthopaedics
University of Washington Medical Center
Seattle, Washington 9/5/2013 – Present

HONORS AND AWARDS

2018 AOA Traveling Fellowship Recipient
In association with Japanese Orthopaedic Association 5/2018

Orthopaedic Trauma Association
Nominated to Membership Committee 3/10/18 - Present

Western Orthopaedic Association
Nominated as Board Member 6/5/17 - Present

AO Trauma North America
Nominated to Fellowship Committee Member 6/2017 - Present

2016 Washington State Orthopaedic Association
Nominated as Board Member 9/18/16 - Present

2016 Washington State Medical Association
Nominated to Young Physician Section Council Member 9/12/16 – 10/28/17

2016 Washington State Medical Association
Leadership Development Conference Scholarship Recipient 2/19/16

UW Medicine Fall Cares Award
Harborview Medical Center
Seattle, WA. 9/2014

Best Trauma Poster Award, AAOS 2014 Meeting
New Orleans, LA 3/11/14

William Thomas Award, Overall Outstanding Resident 2012
Harvard Combined Orthopaedic Residency Program

Chief Resident 2011
Harvard Combined Orthopaedic Residency Program

Resident Leadership Forum Nominee 2011
American Orthopaedic Association (AOA)

Candidate, Health Policy Center of Expertise Certificate Program 2011
Massachusetts General Hospital

Partners in Excellence Award for Quality Treatment and Service 2010
Massachusetts General Hospital

Participant, Value-based Health Care Delivery Intensive Seminar 2010
Harvard Business School

1st Place, Top Research Award in Orthopaedics 2006
National Student Research Forum

1st Place, Best Overall Clinical Science Presentation 2006
Eastern-Atlantic Student Research Forum

Doris Duke Clinical Research Fellowship 2005
Columbia University College of Physicians & Surgeons

Rhodes Scholarship Competition 2001
Washington State Finalist

Howard Wahl Endowed Scholarship: Top bioengineering student 2000

Bioengineering Education Technologies Summer Program Scholar 2000
Northwestern University

Barry M. Goldwater National Research Scholarship 1999

Howard Hughes Medical Research Summer Scholarship 1998-1999

NSF Research Experience for Undergraduates (REU) 1999
University of Washington

CERTIFICATIONS

American Board of Orthopaedic Surgery: Board Certified 2011
Part I (Written): Passed 7/12/2012
Part II (Oral): Passed 7/23/2015

CURRENT LICENSE

Washington 60378333 2011
6/27/2013 – Present

Conor Patrick Kleweno
Last Updated: 10/3/18
PREVIOUS LICENSE(S)


PROFESSIONAL ORGANIZATIONS

**National**
American Academy of Orthopaedic Surgeons, Fellow and Active Member

AOTrauma, Faculty

AOTrauma North America, Board Member
Trauma Fellowship Board Member (2017 – Present)

Orthopaedic Trauma Association, Active Member
Membership Committee Member (9/2018 – 9/2021)

**Regional**

Western Orthopaedic Association
- Board Member 6/5/17 - Present

Washington State Orthopaedic Association
- Board Member 9/18/16 - Present

Washington State Medical Association
- Young Physician Section Council Member 9/12/16 – 10/28/17

RESEARCH

**Actively Funded**
Validation of PROMs in Trauma Patients with Pelvic and Acetabular Fractures. OREF Prospective Clinical Research Grant. Cizik AM (PI), Kleweno CP (Co-PI). $150,000. 7/1/18 – 6/30/21.

PREVENTion of CLot in Orthopaedic Trauma (PREVENT CLOT): A Randomized Pragmatic Trial Comparing the Complications and Safety of Blood Clot Prevention Medicines Used in Orthopaedic Trauma Patients (As part of the Major Extremity Trauma Research Consortium (METRC)). Kleweno CP (Site administrative Co-PI). $11.2million (multicenter), 2016

An imaging framework for clinically testing new treatments to prevent post-traumatic arthritis (multi-center study). Kleweno CP (Site PI). $79,000 OTA Grant, 2017
Patient Reported Outcome Measures in Pelvis and Acetabular Fracture Patients Using the PROMIS Physical Function Test. **Kleweno CP (PI).** $15,500. 5/2015

Johns Hopkins University. **Streamlining Trauma Research Evaluation with Advanced Measurement: STREAM Study. Kleweno CP (Site PI).** 4/24/14

University of Washington New Faculty Research Grant. **A Novel Teaching Simulator for Percutaneous Placement of Iliosacral Screws. Kleweno CP (PI).** $12000. 3/2014

Johns Hopkins University. **Supplemental Perioperative Oxygen to Reduce Surgical Site Infection After High Energy Fracture Surgery. Kleweno CP (Site CO-Investigator).** 12/11/13

Previously Funded
Johns Hopkins University. **A Prospective Randomized Trial to Assess PO versus IV Antibiotics for the Treatment of Early Post-op Wound Infection after Extremity Fractures. Kleweno CP (CO-PI).** 11/13/13

BIBLIOGRAPHY

Part A: Peer Reviewed Journal Articles

1. **Kleweno CP, Murr K, Refaat M, Githens M, Thayer MK, Davies J.** Are retrograde nails better for distal femur fractures in obese patients? (In submission)

2. Refaat M, Thayer MK, Firoozabadi R, **Kleweno CP,** Githens M. Nail or Plate? Supracondylar Distal Femur Fractures in the Elderly. (In submission)


**Part B: Non-Peer Reviewed Articles**


**Part C: Book Chapters**


**Part D: Recent Abstracts**


TEACHING RESPONSIBILITIES

Part A: Invited Lectures, Courses and Grand Rounds


3. AO Trauma Course Basic Principles of Fracture Management. Invited Lecturer and Table Instructor. Phoenix, AZ. 9/14/17 – 9/17/17.


10. AOTrauma Course Advanced Principles of Fracture Management. *International Invited Course Faculty.* Queenstown, New Zealand. 8/30/16 – 9/2/16

11. AOTrauma Basic Principles of Fracture Management. *Invited Lecturer and Table Instructor.* Minneapolis, MN. 8/17/16 – 8/21/16

12. AAOS/OTA Orthopaedic Trauma Update. *Invited Lecturer and Table Instructor.* La Jolla, CA. 3/31/16 – 4/2/16


15. AO Basic Principles of Fracture Management Course for Residents. *Invited Lecturer and Table Instructor.* Atlanta, GA. 10/23/14 – 10/26/14

**Part B: National Meeting Invited Panel Discussions**


Part C: National Teaching Responsibilities


4. 1st Annual Pre-SIGN Fracture Care Hands-On Cadaveric Course. Course Co-Chair. Seattle Science Foundation. Seattle, WA. 9/19/16 – 9/20/16


7. 2015 Orthopaedic Trauma Association Boot Camp Skills Lab. Nailing Proximal Tibia. 2015 Annual OTA Meeting. San Diego, CA. Lab Table Instructor. 10/8/15


Part D: Other Local Teaching Responsibilities

1. Continuing Paramedic Education Series. Pelvis Fractures: From Field to Operating Room. Program put on by the Michael K. Copass, MD Paramedic Training Program to further the ongoing education of Paramedics. (More than 100 paramedics attended in person, and the program was broadcasted throughout the WWAMI States. Invited Lecturer. 11/7/17

2. Resident Conference: Acetabular Fracture Management. Harborview Medical Center. Seattle, WA. Lecturer. 5/9/16

3. Resident Conference: Pelvic Ring. Seattle, WA. Harborview Medical Center. Lecturer. 4/25/16

4. Pelvic Fractures. Physical Therapy All Staff Meeting. Seattle, WA. Lecturer. 1/13/16
5. DePuy Synthes Lower Extremity SMART Lab. Seattle, WA. Table Instructor, Lecturer. 9/12/15

6. Resident Cadaver Session: Acetabular Surgical Approaches. Harborview Medical Center, Seattle, WA. Lecturer. 6/22/15

7. Musculoskeletal Systems HuBio Course 553 (University of Washington Medical Center), Seattle, WA. “Hip and Thigh/Sacral Plexus, Gluteal and posterior Thigh Living and Gross Sessions.” Table Instructor and Lecturer. 2/19/15

8. Musculoskeletal Systems HuBio Course 553 (University of Washington Medical Center), Seattle, WA. “Lumbar Plexus and Thigh Living and Gross Sessions.” Table Instructor and Lecturer. 2/12/15


13. University of Washington Junior Resident Friday Morning Teaching Session (Harborview Medical Center), Seattle, WA. “Femoral Shaft Fractures.” Group Discussion Leader. 4/25/14

14. Musculoskeletal Systems HuBio Course 553 (University of Washington Medical Center), Seattle, WA. “Knee Joint and Leg Gross Session.” Table Instructor and Lecturer. 2/27/14

15. Musculoskeletal Systems HuBio Course 553 (University of Washington Medical Center), Seattle, WA. “Hip and Thigh Living and Gross Sessions.” Table Instructor and Lecturer. 2/20/14

16. Pelvis/Acetabulum Fellow Session (Harborview Medical Center), Seattle, WA. “Recent Acetabular Fractures Case Presentations.” Group Discussion Leader. 2/6/14


18. Pelvis/Acetabulum Fellow Session (Harborview Medical Center), Seattle, WA. “Pelvic Ring Disruptions.” Group Discussion Leader. 12/19/13

19. University of Washington Junior Resident Friday Morning Teaching Session (Harborview Medical Center), Seattle, WA. “Pathologic Fractures.” Group Discussion Leader. 9/27/2013

Presentations

Part A: International Presentations


Part B: National Presentations


Part C: Regional Presentations


6. Kleweno CP. Pelvic Surgery. Harborview Medical Center Clinical Education In-Service Presentations. Seattle, WA. 7/30/14

8. Kleweno CP. Pelvic Injuries: Field to Operating Room. Harborview Medical Center Paramedic Lecture Series. Seattle, WA. 5/6/14


10. Kleweno CP. Orthopaedic Trauma: What We Do and How We Fix Things. Seattle Central Community College SURG 123 Course, Seattle, WA. 3/17/14


EDITORIAL RESPONSIBILITIES

Journal of the American Academy of Orthopaedic Surgeons Reviewer 6/2017 - Present


SPECIAL INTERNATIONAL RESPONSIBILITIES

AOSpine Sacral Classification Working Group Invited panelist and member for the international expert committee creating the AO Sacral Fracture Classification System 5/14/15 – Present

SPECIAL NATIONAL RESPONSIBILITIES

AO Trauma Fellowship Committee Member 6/2017 - Present

Orthopaedic Trauma Association Nominated to Membership Committee 3/10/18 - Present

Major Extremity Trauma Research Consortium (METRC) Local Principle and Co-Principle Investigator 10/2013 - Present

SPECIAL LOCAL RESPONSIBILITIES

Departmental

Director Quality Improvement Orthopaedic Trauma
Department of Orthopaedic Surgery
Harborview Medical Center 1/1/2017 – Present

Orthopaedic Resident Clinical Competency Committee
Department of Orthopaedics and Sports Medicine 10/2015 - Present
University of Washington

Resident Selection Committee  2013 – Present
Department of Orthopaedics and Sports Medicine
University of Washington

Trauma Fellow ACE Selection Committee  2013 – Present
Harborview Medical Center
University of Washington

SERVICE ACTIVITIES

Summer Health Professions Education Program (SHPEP)  6/1/16 – Present
Faculty Mentor/Supervisor
University of Washington
Seattle, WA

- Supervise and mentor undergraduate students, including overseeing their shadowing/observation experience in a clinical/OR setting, to help foster the development of underrepresented student's interest in professions in the medical field.

Northwest Healthcare Network’s Disaster Clinical Advisory Committee  3/16/18 – Present
Disaster Clinical Advisory Committee Surgical Subcommittee
Harborview Medical Center

- Help hospitals throughout the region and the state prepare for mass casualty incidents, disasters, and pandemics. Create best practice guidelines for hospitals to follow in the event of limited resources, mass casualty events, or natural disasters.
Agency medical director comments

Sacroiliac Joint Fusion

Emily Transue, MD, MHA
Associate Medical Director, WA Health Care Authority

January 18, 2019

Background

• Low back pain: High burden of disease and disability (4-25% prevalence in adults)
• SI joint has been implicated as a pain source (some studies suggest 10-30% of low back pain may be from SI)
• Strong desire by patients and providers for effective treatments
• History of procedural overuse (spinal fusion, etc) with high costs and harm to patients highlights need for rigor in assessing evidence for treatment options
Sacroiliac joint fusion

- Theorizes that pain in the sacroiliac (SI) region is related to instability in the SI joint, and that mechanically stabilizing the joint with a screw or specialized device will decrease pain.
- Candidates include surgically naïve patients, and also a significant number of patients with sacroiliac pain after lumbar fusion.
- A variety of devices as well as surgical screws have been used, but trial data is almost exclusively about a specific device (iFuse), consisting of 2-4 triangular rods placed across the joint via minimally invasive surgery.

Designated CPT/HCPCS

27279
Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device (effective January 1, 2015).

27280
Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed (effective January 1, 1989).
### Current state agency policy

<table>
<thead>
<tr>
<th>Agency</th>
<th>27279</th>
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<tbody>
<tr>
<td>PEBB/UMP</td>
<td><strong>Covered</strong></td>
<td>Prior Auth</td>
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<td></td>
<td>* Prior Auth required after 2/28/2019</td>
<td></td>
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<tr>
<td>MEDICAID</td>
<td><strong>Not Covered</strong></td>
<td>Not Covered</td>
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<tr>
<td>LABOR AND INDUSTRIES</td>
<td><strong>Covered</strong></td>
<td>Prior Auth</td>
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<td>With substantial trauma and demonstrated SI joint disruption</td>
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### Current utilization

**2014 – 2017 Claims for Sacroiliac Joint Fusion**

Fewer than 11 procedures paid by state-covered programs (threshold for public reporting of data)
Cost experience (HCA)

- Minimally invasive/closed fusion
  - Median billed charges: $19,000
  - Median allowed amount: $10,500

Agency medical director concerns

- Safety = High
- Efficacy = High
- Cost = High
Key questions

- What is the evidence of efficacy and effectiveness for SI fusion compared to other active interventions, placebos, sham procedures, or no treatment?
- What direct harms are associated with SI fusion?
- Do important patient efficacy/effectiveness outcomes or direct harms from SI fusion vary by:
  - Indication, and
  - Patient characteristics
- What are the cost-effectiveness and other economic outcomes of SI fusion?

FDA approval limitations

- All devices were approved using 510(k) approval ("substantial equivalence" to other treatment or device on the market prior to 1976); none have had premarket approval (PMA) studies.
Limitations: lack of diagnostic gold standard

- Inclusion criteria vary: typically a combination of physical exam tests (3 out of 5 tests positive) and reduction of pain (variable degree, often 50% or 80%) with SI anesthetic injection (imaging-guided requirement variable)
- Poor reliability of physical exam: Kappa values for pooled parameters of inter-rater reliability for physical exam for SI joint pain <0.20
- An analysis using combined data from 2 trials (1 RCT [INSITE] and 1 uncontrolled trial [SIFI], total N = 320) found no relationship between level of immediate response to SI joint block (average percent decrease in pain after injection from 40% to 100%) and 6- and 12-month pain and disability scores among patients undergoing SI joint fusion.

Data limitations

- Every study evaluated (except cost studies) had “serious” or “very serious” risk of bias:
  Comparator:
  - “Conservative management” comparator defined at providers’ discretion, not an evidence-based multidisciplinary management program
  Lack of blinding:
  - No sham studies performed
  - Providers, patients, and evaluators unblinded to study arm
  Controls:
  - Most available data comes from uncontrolled studies
  Funding:
  - All trials reviewed were funded by device manufacturer
Effectiveness: key studies

- 2 RCTs, both comparing iFuse to conservative mgt (CM)
  - Both studies are ongoing prospective, open-label, multicenter randomized controlled trials
  - Unblinded (patient and evaluator); no independent assessment of outcome
  - Manufacturer funded
  - Crossovers allowed after 6 months
  - Conservative management at provider discretion, not standardized

INSITE trial (2015, US)

- iFuse vs. non-operative treatment
- 19 centers, 148 patients, ~38% with prior lumbar fusion
- Dx: Hx SI joint pain, 3 of 5 provocative joint findings, 50% reduction in pain with block
- Crossover allowed at 6 months
  - 88.6% crossover at 2 years, i.e. 142/148 eligible got eventually surgery
  - Conservative mgt: CBT-based treatments were not used as they were deemed “unstandardizable, impracticable and unrepresentative of modern US healthcare”

iMIA trial (2017, mult European sites)

- iFuse vs. non-operative treatment
- 9 centers, 101 patients, ~35% with prior lumbar fusion
- Dx: Fortin finger test, 3 of 5 provocative joint findings, 50% reduction in pain with block
- Crossover allowed at 6 months; 43% crossover at 1 yr


**RCT results: iFuse vs non-operative management**

<table>
<thead>
<tr>
<th>INSITE</th>
<th>Pain (VAS)</th>
<th>Disability (ODI)</th>
<th>Quality of Life (SF-36)</th>
<th>Opioid use</th>
</tr>
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<tbody>
<tr>
<td>1 mo</td>
<td>-35.9</td>
<td>-13.7</td>
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<tr>
<td>3 mo</td>
<td>-38.0</td>
<td>-19.2</td>
<td></td>
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<tr>
<td>6 mo</td>
<td>-40.5</td>
<td>-25.4</td>
<td>11.5 physical</td>
<td>-9% vs +7.5% CM</td>
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<tr>
<td></td>
<td></td>
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<td>5.6 mental</td>
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**IMIA**

<table>
<thead>
<tr>
<th>INSITE</th>
<th>EQ-5D</th>
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<tr>
<td>1 mo</td>
<td>-35.3</td>
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<tr>
<td>3 mo</td>
<td>-38.6</td>
</tr>
<tr>
<td>6 mo</td>
<td>-38.1</td>
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<tr>
<td>1 yr</td>
<td>-27.6</td>
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Minimal clinically important differences:

VAS: 8-11; ODI: 8-11; SF-36 3
Safety

- No common protocols for data assessment or standardized definitions
- Range of adverse events for iFuse: 0 to 30%
- One study based on CPT codes post minimally invasive SI fusion found 13% complications at 90 days, 16.4% at 6 months
- Most common complications: neuritis or radiculitis
- Post-market surveillance: 2.8% revisions over median 4 year f/u

FDA MAUDE Adverse Event data on the SI-BONE IFuse implant system

Sample of cases reported in Nov, 2018

- MDR key 8081562-In 2012 left SI joint arthrodesis with 3 implants 2012; patient later reported no pain relief; In 2018 new surgeon “removed all three implants using chisels as they were all solidly fixed in bone”

- MDR key 8081596-2017 Left side SI joint arthrodesis with 3 implants-pain 6 weeks after procedure. CT showed cranial positioned implant impinging on neural foramen. “In 2018, the surgeon performed a revision procedure where he removed the cranial positioned implant using osteotomes as it was solidly fixed in bone”
Differential impact by population

• No data available

Cost effectiveness

• Very low quality of evidence
• 1 study on cost (Ackerman): iFuse vs. non-operative commercial population:
  – iFuse $15,545 more over 3 years,
  – $6,137 more over 5 years
  – Medicare: iFuse costs $3,358 less over lifetime
• 1 study on cost-effectiveness: iFuse vs. non-operative
  – $13,313 per QALY
  – Break even at 13 years
Coverage comparisons for minimally invasive SI fusion

• Medicare:
  – No national coverage determination
  – Local coverage decision: Covered when all of these met:
    a) Failed 6 months intensive non-operative treatment (meds, activity mod., and active PT);
    b) Classical symptoms of SI pain
    c) Localized SI tenderness without tenderness elsewhere or other sources of pain
    d) Provocative signs/symptoms
    e) Absence of generalized pain behavior (e.g. somatoform disorder) or generalized pain disorders (e.g. fibromyalgia)
    f) Imaging excludes infection, tumor, inflammatory process, hip OA, I-spine compression
    g) 75% reduction of pain with imaging-guided anesthetic

Coverage comparisons for minimally invasive SI fusion

• Aetna, Cigna, Kaiser, Premera:
  Covered only for instability associated with major trauma (pelvic ring fracture, etc.), as adjunctive therapy for infection/sepsis, or malignancy; not covered for mechanical low back pain, SI joint syndrome, radiculopathy

• Regence:
  Covers when all of the following: ADLs impacted, 6 months non-operative treatment, 75% pain reduction with imaging-guided anesthetic, at least 1 steroid injection, lack of generalized pain syndrome, and a list of clinical findings to indicate likely SI pain
Guidelines: minimally invasive SI fusion

- **National Institute for Health and Care Excellent (NICE):**
  Current evidence is adequate to support this procedure; should only be done by experienced surgeons.

- **AIM Specialty Health Musculoskeletal Program Clinical Appropriateness Guidelines**
  May be considered medically necessary when: persistent pain interfering with function; failure 6 months conservative mgt; confirmatory physical exam; at least 75% pain reduction following image-guided SI injection on 2 separate occasions

---

**Sacroiliac joint fusion is covered with conditions**

SI joint fusion with iFuse or open fusion is medically necessary when all of the following are met:

- Appropriate imaging studies demonstrate localized SI joint pathology; AND

  - ONE of the following:
    - Post-traumatic injury of the SI joint (e.g. following pelvic ring fracture) with radiological evidence of joint disruption
    - As an adjunctive treatment for SI joint infection or sepsis
    - Management of sacral tumor
    - When performed as part of multi-segmental long fusions for correction of spinal deformity
SI joint fusion is not covered for any other indication, including the following, because it is considered experimental and investigational:
- Mechanical low back pain
- SI joint syndrome
- Degenerative SI joint
- Radicular pain syndrome

Rationale:
- Evidence for efficacy in these conditions is based on unblinded, manufacturer-funded trials with high risk of bias and lack of objective data. Serious adverse events may be underreported in trials.
**Order of scheduled presentations:**

Sacroiliac joint fusion

<table>
<thead>
<tr>
<th></th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>David W. Polly, Jr., MD</td>
</tr>
<tr>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>
Disclosure
Any unmarked topic will be considered a “Yes”.

<table>
<thead>
<tr>
<th>Potential Conflict Type</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Salary or payments such as consulting fees or honoraria in excess of $10,000.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>2. Equity interests such as stocks, stock options or other ownership interests.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>3. Status or position as an officer, board member, trustee, owner.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>4. Loan or intellectual property rights.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>5. Research funding.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>6. Any other relationship, including travel arrangements.</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

There is a PhD graduate student who receives funding from SI Bone for a basic science project. I am on his advisory committee.

<table>
<thead>
<tr>
<th>Potential Conflict Type</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. Representing a person or organization.</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

If yes, provide the name and funding source(s) (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).

- **American Academy of Orthopaedic Surgeons** - funded by member dues, industry advertising and educational grants
- **International Society for the Advancement of Spinal Surgery** - funded by member dues, industry advertising and educational grants
- **American Association of Neurological Surgeons and Congress of Neurological Surgeons** - funded by member dues, industry advertising and educational grants

If you believe that you do not have a conflict, but are concerned that it may appear that you do, you may attach additional sheets explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

Signature: ____________________________ Date: 12/31/2018 Print Name: ____________________________

So we may contact you regarding this information, please provide the following:

Email Address: **pollydw@umn.edu**

Phone Number: **(612) 273-8095**
Comments on Washington State HTA on SI Joint Fusion

David W. Polly, Jr., MD
James W. Ogilvie Professor and Chief of Spine Surgery
Catherine Mills Davis endowed chair
Department of Orthopaedic Surgery
Professor of Neurosurgery (W)
University of Minnesota

Also representing:
American Academy of Orthopaedic Surgeons 34,000 members
American Association of Neurological Surgeons and Congress of Neurological Surgeons 4,000 members
International Society for the Advancement of Spine Surgery 2,100 members
Washington State Association of Neurological Surgeons

Disclosures

• Springer textbook royalties
Summary Comments

• Rigorous methodology reviewing existing published peer reviewed data
• Conclusions are supported by the data
  • The highest quality clinical data are about the trans-iliac trans-sacral approach using triangular titanium rods
  • Unclear if this is generalizable to other devices or approaches

Criteria for surgical treatment

• We agree with the criteria listed of:
  • Positive Fortin finger test
  • Positive 3 out of 5 or greater physical exam maneuvers
  • Positive 50% or greater pain relief with injection
Concerns

- While the data is good for patients who meet the inclusion criteria from the RCT's, there are patients who do not meet those specific criteria who may also benefit.
- The data to support continued non-surgical management of those who have failed an initial course is perhaps of lower quality than the surgical data.
- What treatment will be allowed for these patients?
- Perhaps the state of Washington might consider a strategy of coverage with evidence development to generate meaningful real world data on this cohort.
Overview of Presentation

- Background
- Methods
- Results
  - Primary research synthesis
  - Clinical practice guideline synthesis
- Discussion
Background

Sacroiliac (SI) Joint Pain

• Estimated to be the primary source of pain in 10%-30% of patients with mechanical low back pain

• Originates from one or both surfaces of the SI joint and/or the SI joint complex

• Clinical presentation of pain varies
  o Buttock pain extending into posterolateral thigh is most common

Image source: https://www.saintlukeskc.org/health-library/anatomy-sacroiliac-joint
Etiology

• Thought to be caused by degenerative sacroiliitis or joint dysfunction from repeated axial loading and rotation

• Several predisposing factors:
  o History of serious pelvic trauma
  o Leg length discrepancies
  o Gait abnormalities
  o Persistent strain/low-grade trauma (i.e., running)
  o Scoliosis
  o Pregnancy
  o Prior spine surgery (especially spinal fusion)

Contextual Question 1: SI joint pain diagnosis and test accuracy

• Currently, no universally accepted gold standard for diagnosis

• Clinical practice guidelines and experts recommend:
  o History of pain in appropriate distribution
  o Physical exam provocation tests
    • Gaenslen maneuver
    • Distraction test
    • Compression test
    • Sacral thrust test
    • Thigh thrust or femoral shear test
    • FABER (flexion, abduction, external rotation)

Diagnostic SI Joint Injection

- SI joint injection is the current reference standard for diagnosis
  - Intraarticular placement under imaging guidance
  - Volume of injectate used varies
  - Pain relief threshold required for positive test varies from 50% to 80% but, appears to have minimal impact on prevalence estimates
  - Double or confirmatory injections reduces the false positive rate

- Patients who varied in the % of pain relief after diagnostic injection had similar outcomes after SI joint fusion
  - Implication: using a very high threshold for pain relief after diagnostic injection may exclude some patients that might benefit from surgery

Physical exam test accuracy

- Accuracy of physical exam elements compared to reference standard of diagnostic SI joint injection

<table>
<thead>
<tr>
<th>Clinical Test</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fortin finger test (1 study; n=88)</td>
<td>76% (65 to 85)</td>
<td>47% (35 to 57)</td>
</tr>
<tr>
<td>Thigh thrust test (3 studies pooled; n=242)</td>
<td>91% (79 to 97)</td>
<td>66% (53 to 77)</td>
</tr>
<tr>
<td>Compression test (2 studies pooled; n=202)</td>
<td>63% (47 to 77)</td>
<td>69% (57 to 80)</td>
</tr>
<tr>
<td>3 or more positive tests (4 studies pooled; n=304)</td>
<td>85% (75 to 92)</td>
<td>76% (68 to 84)</td>
</tr>
</tbody>
</table>

Studies varied in threshold of pain relief required for a positive reference test (range 50% to 80% pain relief).
Contextual Question 2: Diagnosis in usual practice

• We found no data describing typical patterns in clinical practice for diagnosing SI joint pain

SI Joint Pain Management

• Nonsurgical options for management
  o Analgesics and anti-inflammatory medications
  o Physical therapy
  o Pelvic belts and girdles
  o Therapeutic joint injection
  o Prolotherapy
  o Radiofrequency denervation

• Fusion of SI joint
  o Typically reserved for people who fail less invasive treatment
  o Open procedure
  o Minimally invasive procedure
    ▪ Represents 39% of all SI fusions in 2009 increasing to 88% in 2012
Numerous proprietary surgical systems exist:

- Typically consist of 2-3 specialized implants or screws to span SI joint and create immediate fixation, with specialized designs or coatings to promote bone growth and bony fusion.

- Some combine immediate fixation with decortication and bone graft insertion to promote bone growth and bony fusion.

Example: iFuse Implant System (SI-BONE)

Example: Simmetry (Zyga)

Regulatory Status

- 15 devices with FDA 510k clearance* currently on the market in the U.S.
- 5 devices with Title 21 CFR Part 1271 FDA approval** currently on the market in the U.S.
- 2 devices not currently on the market: SI-DESIS (has FDA 510k approval, but unavailable) and DIANA (available for use in Europe).
- Open procedures could be performed with cleared or approved devices, but they may also be performed with orthopedic plates, screws, and instruments that are already cleared by FDA but which may not be designed specifically for SI Joint Fusion.

* 510(k) approval is based on evidence that the device is ‘substantially equivalent’ to a device that the FDA has already cleared or that was marketed before 1976

** Title 21 CFR Part 1271 applies to devices that are designed to be used with allografts or other biologic materials.
Policy Context for Washington

• This topic was selected for review by the state because of:
  o High concerns for safety
  o High concerns for efficacy
  o High concerns for cost

Methods

1. Primary Research Synthesis
2. Synthesis of Relevant Clinical Practice Guidelines
**Analytic Framework**

Adults with chronic SI joint pain → SI Joint Fusion → Intermediate Outcomes

- EQ 1a: Comparative effectiveness only:
  - Length of stay
  - Discharge to rehabilitation facility
  - Non-union

Intermediate Outcomes → Health Outcomes (EQ1)

- EQ 1: Pain, Function, Quality of life, Patient satisfaction with symptoms, Opioid use, Return to work

Intermediate Outcomes → Cost Outcomes

- SQ 1: Infection, Serious adverse events, Other surgical morbidity, Revision

Comparative effectiveness only:

-EQ 1a: Intraoperative blood loss, Duration of surgery

Abbreviations: CQ = cost question; EQ = efficacy question; SI = sacroiliac; SQ = safety question

---

**Study Selection for Primary Research Synthesis**

<table>
<thead>
<tr>
<th><strong>Population</strong></th>
<th>Adults with ≥ 3 months SI joint pain diagnosed using a standard approach</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intervention</strong></td>
<td>Open SI joint fusion; minimally invasive SI joint fusion</td>
</tr>
<tr>
<td><strong>Comparator</strong></td>
<td>Active treatment; placebo; no treatment</td>
</tr>
<tr>
<td><strong>Outcomes</strong></td>
<td>EQ: Pain; function; quality of life; patient satisfaction; opioid use; return to work</td>
</tr>
<tr>
<td></td>
<td>SQ: Adverse events, revision surgery</td>
</tr>
<tr>
<td></td>
<td>CQ: Cost; cost per quality-adjusted life year gained; cost per disability-adjusted life year gained</td>
</tr>
<tr>
<td><strong>Study Design</strong></td>
<td>EQ: Controlled trials, controlled cohort studies</td>
</tr>
<tr>
<td></td>
<td>SQ: All of the designs listed for EQ plus studies without a comparator group</td>
</tr>
<tr>
<td></td>
<td>CQ: Cost-effectiveness analysis, cost-utility analysis, cost-benefit analysis</td>
</tr>
<tr>
<td><strong>Setting</strong></td>
<td>Countries categorized as “very high” on United Nations Human Development Index</td>
</tr>
</tbody>
</table>

Abbreviations: CQ = cost question; EQ = efficacy question; SI = sacroiliac; SQ = safety question
Risk of Bias Assessment

• Risk of bias is assessed at the individual study level
  o Cochrane Risk of Bias version 2.0 instrument for RCTs
  o ROBINS-I tool for non-randomized comparative studies
  o Quality of Health Economic Studies instrument for cost analyses

• Each study assessed as having one of the following risks:
  o High risk of bias
  o Some concerns for bias
  o Low risk of bias

Quality of the Evidence – GRADE approach

• Domains assessed:
  o Risk of bias
  o Consistency
  o Directness
  o Precision
  o Publication bias

• Quality of evidence
  o VERY LOW
  o LOW
  o MODERATE
  o HIGH

• Bodies of RCT evidence start at HIGH
• Observational studies start at LOW because of limitations with this study design

• Quality level may be downgraded based on domain assessments:
  o No concerns
  o Serious concerns (↓ one level)
  o Very serious concerns (↓ two levels)

• Observational evidence may be upgraded based on:
  o Large effect (↑ one level)
  o Dose response (↑ one level)
  o Plausible confounding and bias accounted for (↑ one level)
GRADE interpretation

<table>
<thead>
<tr>
<th>Grade</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>We are very confident that the estimate of effect lies close to the true effect for this outcome. The body of evidence has few or no deficiencies. We believe that the findings are stable, that is, another study would not change the conclusions.</td>
</tr>
<tr>
<td>Moderate</td>
<td>We are moderately confident that the estimate of effect lies close to the true effect for this outcome. The body of evidence has some deficiencies. We believe that the findings are likely to be stable, but some doubt remains.</td>
</tr>
<tr>
<td>Low</td>
<td>We have limited confidence that the estimate of effect lies close to the true effect for this outcome. The body of evidence has major or numerous deficiencies (or both). We believe that additional evidence is needed before concluding either that the findings are stable or that the estimate of effect is close to the true effect.</td>
</tr>
<tr>
<td>Very Low</td>
<td>We have very limited confidence that the estimate of effect lies close to the true effect for this outcome. The body of evidence has numerous major deficiencies. We believe that substantial additional evidence is needed before concluding either that the findings are stable or that the estimate of effect is close to the true effect.</td>
</tr>
</tbody>
</table>

Clinical Practice Guideline Quality Appraisal

- Appraisal of Guidelines for Research & Evaluation (AGREE-II)
  - Overall score of 1 (lowest possible quality) to 7 (highest possible quality)
Results

1. Primary Research Synthesis
2. Synthesis of Relevant Clinical Practice Guidelines

Search Results

• Primary Research Synthesis
  o Titles/abstracts screened: 662
  o Full text articles screened: 113
  o Full text studies included: 43 studies (50 articles)

  | EQ: 2 RCTs 5 CCS |
  | SQ: 2 RCTs 5 CCS 32 Uncontrolled studies |
  | CQ: 3 cost analyses |

• Clinical Practice Guidelines: 2*

*Publicly available guidelines
Abbreviations: CCS = controlled cohort study; CQ = cost question; EQ = efficacy question; RCT = randomized controlled trial; SQ = safety question
Comparisons evaluated

**SI joint fusion compared to conservative management or no surgery**
- Minimally invasive fusion compared to CM (EQ, SQ, CQ)
- Open fusion compared to no surgery (EQ and SQ)

**Minimally invasive SI joint fusion compared to open fusion**
- EQ and SQ

**Minimally invasive SI joint fusion with implants compared to screws**
- SQ

---

### Abbreviations:
CM = conservative management; CQ = cost question; EQ = efficacy question; SQ = safety question

### SI Joint Fusion compared to Conservative Management (CM)

<table>
<thead>
<tr>
<th>Study (Year) Risk of Bias Funding</th>
<th>Study Design</th>
<th>Setting/Time Period</th>
<th>Intervention (N analyzed) Comparator (N analyzed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>INSITE (Whang, 2015) Some concerns SI Bone, Inc.</td>
<td>RCT</td>
<td>19 U.S. centers, 2013 to 2014</td>
<td>iFuse (102) CM (46 at 6 mos.) Crossovers from CM to iFuse allowed after 6 mos.</td>
</tr>
<tr>
<td>iMIA (Dengler, 2016) Some concerns SI Bone, Inc.</td>
<td>RCT</td>
<td>9 European centers, 2013 to 2015</td>
<td>iFuse (52) CM (49 at 6 mos.) Crossovers from CM to iFuse allowed after 6 mos.</td>
</tr>
</tbody>
</table>

---

Abbreviations: CCS = controlled cohort study; CM = conservative management; RCT = randomized controlled trial
Characteristics of Enrolled Participants

- Diagnosis/study entry criteria
  - Chronic symptoms
  - Positive Fortin finger test
  - At least 3 positive provocative physical exam findings
  - At least 50% reduction in pain after diagnostic SI joint block
  - Other sources of back pain ruled out
- Mean duration of pain 3 to 7 years
- Mean pain score (Visual Analog Scale) was 82 mm in both groups on a scale of 0 mm [no pain] to 100 mm [worse pain ever]
- About 1/3 of participants had a history of prior lumbar fusion

MI SI Joint Fusion compared to CM [Pain]

Change in pain at 6 mos. (Visual Analog Scale, 0 mm [no pain] to 100 mm [worse pain], MID = 7 to 11)

2 RCT: INSITE, iMIA
★★★★ MODERATE
Favors iFuse

- Significantly larger improvements with iFuse; between-group difference
  - -40.5 mm (95% CI, -50.1 to -30.9) in 1 study
  - -38.1 mm (95% CI NR, P < 0.0001) in other study

Change in pain at 6 mos. to 3.5 yrs. (Visual Analog Scale, 0 to 10 cm)

1 CCS: Vanaclocha
★★★★★★ VERY LOW
Favors iFuse

- Significantly larger improvement with iFuse
  - Compared to conservative management (between-group difference: -6 cm, P < 0.001)
  - Compared to denervation (between-group difference: -4.5 cm, P < 0.001)

Abbreviations: CI = confidence interval; CM = conservative management; cm = centimeters; MI = minimally invasive; MID = minimally important difference; mm = millimeters; mos = months; NR = not reported; yrs = years
## MI SI Joint Fusion compared to CM [Physical Function]

### Change in physical function at 6 mos. (Oswestry Disability Index, 0 [no disability] to 100 [complete disability], MID 8 to 11)

<table>
<thead>
<tr>
<th>Study</th>
<th>Rating</th>
<th>Quality</th>
<th>Favors</th>
<th>Between-group Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>INSITE, iMIA</td>
<td>2 RCT</td>
<td>MODERATE</td>
<td>iFuse</td>
<td>-25.4 points (95% CI, -32.5 to -18.3, P &lt; 0.0001) in 1 study</td>
</tr>
<tr>
<td>iMIA</td>
<td>-</td>
<td></td>
<td>iFuse</td>
<td>-19.8 points (95% CI NR, P &lt; 0.0001) in other study</td>
</tr>
</tbody>
</table>

### Change in physical function at 6 mos. to 3.5 yrs. (Oswestry Disability Index)

<table>
<thead>
<tr>
<th>Study</th>
<th>Rating</th>
<th>Quality</th>
<th>Favors</th>
<th>Between-group Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vanaclocha</td>
<td>1 CCS</td>
<td>VERY LOW</td>
<td>iFuse</td>
<td>Compared to conservative management (between-group difference: -24 points [P &lt; 0.001])</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Compared to denervation (between-group difference: -17 points [P &lt; 0.001])</td>
</tr>
</tbody>
</table>

## MI SI Joint Fusion compared to CM [QOL]

### Change in quality of life at 6 mos. (EQ-5D, <0 [worse than death] to 1 [perfect health]; SF-36, 0 [lowest QOL] to 100 [best QOL], MID 3)

<table>
<thead>
<tr>
<th>Study</th>
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<th>Quality</th>
<th>Favors</th>
<th>Between-group Difference</th>
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<tbody>
<tr>
<td>INSITE, iMIA</td>
<td>2 RCT</td>
<td>MODERATE</td>
<td>iFuse</td>
<td>EQ-5D between-group difference</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.24 (95% CI, 0.16 to 0.32) in 1 study</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.21 (95% CI NR, P &lt; 0.0001) in other study</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SF-36 between group difference in 1 study</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>PCS 11.5 (95% CI, 8.1 to 14.9)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MCS 5.6 (95% CI, 1.8 to 9.4)</td>
</tr>
</tbody>
</table>
MI SI Joint Fusion compared to CM [Opioid Use]

**Opioid use at 6 mos.**

1 RCT: INSITE  
ロー・ロー・ロー LOW  
No difference

- No significant difference in percentage of participants using opioids  
  - ARD -12.0% (95% CI, -28.6% to 4.5%)  
  - RR 0.83 (95% CI, 0.64 to 1.07)

**Opioid use at 6 mos. to 3.5 yrs.**

1 CCS: Vanaclocha  
ロー・ロー・ロー・ロー・ロー VERY LOW  
Favors iFuse

- Significant difference (P < 0.001) between groups in oral morphine equivalents used at the time of last follow-up  
  - iFuse (3.1 mg/day)  
  - CM (38.5 mg/day)  
  - Denervation (32.2 mg/day).

MI SI Joint Fusion compared to CM [Adverse Events]

**Serious Adverse Events**

2 RCT: INSITE, iMIA  
ロー・ロー・ロー LOW  
No difference

- In one study, 21 serious events among 102 iFuse participants and 6 serious events among 46 conservative management participants (p=0.3241)  
- In other study, 8 events among 52 iFuse participants and 10 events among 49 conservative management participants

1 CCS: Vanaclocha  
ロー・ロー・ロー・ロー・ロー VERY LOW  
No difference

- No serious adverse events reported in either group

Abbreviations: ARD = absolute risk difference; CI = confidence interval; CM = conservative management; mg = milligrams; MI = minimally invasive; mos = months; RR = relative risk; yrs = years
**MI SI Joint Fusion compared to CM [Revision Surgery]**

### Revision Surgery

**2 RCT: INSITE, iMIA**

- In one study
  - Incidence 3.4% at 2 yrs. among 89 iFuse participants with follow-up data
  - Incidence 2.6% among 30 CM participants that crossed over to surgery
- In other study
  - No revisions among 52 iFuse participants
  - 1 revision among 21 CM participants that crossed over to surgery

**1 CCS: Vanaclocha**

- No revision surgery reported among participants who received iFuse

---

**Abbreviations:** CCS = controlled cohort study; CM = conservative management; MI = minimally invasive

---

**MI SI Joint Fusion compared to CM - Trial outcomes after 6 mos.**

- Crossovers from CM to surgery allowed after 6 months in both RCTs
  - Participants who crossed over had higher mean VAS pain and ODI scores at 6 months compared to participants who did not cross over
- Changes in VAS low back pain scores observed at 6 months persisted at 1 year among those allocated to fusion
- At least 20 mm improvement on VAS pain scale at 1 year
  - iMIA: 69% of those allocated to fusion vs. 27% of those allocated to CM who did not cross over
  - INSITE: 81.6% of those allocated to fusion vs. 12.5% of those allocated to CM (all crossovers considered failures for this analysis)
- Similar pattern observed for physical function as measured by ODI

---

**Abbreviations:** CM = conservative management; ODI = Oswestry Disability Index; VAS = visual analog scale
## Open SI Joint Fusion compared to No Surgery

<table>
<thead>
<tr>
<th>Study (Year) Risk of Bias Funding</th>
<th>Study Design</th>
<th>Setting/Time Period</th>
<th>Intervention (N analyzed) Comparator (N analyzed)</th>
</tr>
</thead>
</table>

¹ Norwegian Foundation for Health and Rehabilitation and Sophies Minde Ortopedi AA. Abbreviations: CCS = controlled cohort study

## Open Fusion compared to No Surgery (continued)

### Pain at 11 to 23 yrs. (Visual Analog Scale, 0 mm [no pain] to 100 mm [worse pain], MID = 7 to 11)

1 CCS: Kibsgard ♦️️️️️ VERY LOW No difference

• No significant between-group difference: -6 mm (95% CI, -10.2 to 22.2).

### Physical Function at 11 to 23 yrs. (Oswestry Disability Index 0 [no disability] to 100 [complete disability], MID 8 to 11)

1 CCS: Kibsgard ♦️️️️️ VERY LOW No difference

• No significant between-group difference; -4 points (95% CI, -9.1 to 17.1).

### Quality of Life at 11 to 23 yrs. (SF-36)

1 CCS: Kibsgard ♦️️️️️ VERY LOW No difference

• No significant between-group differences in any of the 8 subscale scores.

Abbreviations: CCS = controlled cohort study; CI = confidence interval; MID = minimally important difference; SF-36 = short form survey
### MI SI Joint Fusion compared to Open Fusion

<table>
<thead>
<tr>
<th>Study (Year)</th>
<th>Risk of Bias</th>
<th>Study Design</th>
<th>Setting/Time Period</th>
<th>Intervention (N analyzed)</th>
<th>Comparator (N analyzed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ledonio (2014) High Not reported</td>
<td>CCS (retrospective)</td>
<td>Single U.S. center, 2006 to 2011</td>
<td>IFuse (22)</td>
<td>Open anterior ilioinguinal approach (22)</td>
<td></td>
</tr>
<tr>
<td>Ledonio (2014) High Not reported</td>
<td>CCS (retrospective)</td>
<td>2 U.S. centers, 2006 to 2012</td>
<td>IFuse (17)</td>
<td>Open anterior ilioinguinal approach (22)</td>
<td></td>
</tr>
<tr>
<td>Smith (2013) High SI Bone, Inc.</td>
<td>CCS (retrospective)</td>
<td>7 U.S. centers, 1994 to 2012</td>
<td>IFuse (114)</td>
<td>Open posterior approach (149)</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: CCS = controlled cohort study; MI = minimally invasive

### MI SI Joint Fusion compared to Open Fusion [Pain & Function]

**Change in pain over 2 yrs. (Visual Analog Scale, 0 cm [no pain] to 10 cm [worse pain], MID = 0.7 to 1.1)**

1 CCS: Smith  

- Significantly larger improvement for IFuse; repeated measures between-group difference -3.0 cm (95% CI, -2.1 to -4.0)

**Change in physical function at 13 to 15 months (Oswestry Disability Index 0 [no disability] to 100 [complete disability], MID 8 to 11)**

2 CCS: Ledonio, Ledonio  

- Significantly larger improvements for IFuse in 1 study (between-group difference -33 points, P < 0.0008)  
- Similar improvements in other study (between-group difference 4.9 points, P = 0.272)

Abbreviations: CCS = controlled cohort study; CI = confidence interval; cm = centimeters; MI = minimally invasive
### MI SI Joint Fusion compared to Open Fusion [Length of Stay]

**Length of Hospital Stay**

<table>
<thead>
<tr>
<th>Source</th>
<th>Rating</th>
<th>Comparison</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 CCS: Smith, Ledonio, Ledonio</td>
<td>⬤★★★★★</td>
<td>VERY LOW</td>
<td>Favors iFuse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Significantly shorter length of stay for iFuse participants</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>○ Range of differences was 1.3 to 3.8 days across studies</td>
</tr>
</tbody>
</table>

Abbreviations: CCS = controlled cohort study; MI = minimally invasive

### MI SI Joint Fusion compared to Open Fusion [Safety]

**Adverse Events**

<table>
<thead>
<tr>
<th>Source</th>
<th>Rating</th>
<th>Comparison</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 CCS: Smith, Ledonio, Ledonio</td>
<td>⬤★★★★★</td>
<td>VERY LOW</td>
<td>No difference</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• No intraoperative complications reported in any study</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Frequency of postoperative complications similar between groups and ranged from 2.3% to 35% across groups and studies</td>
</tr>
</tbody>
</table>

### Revision Surgery

<table>
<thead>
<tr>
<th>Source</th>
<th>Rating</th>
<th>Comparison</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 CCS: Smith, Ledonio, Ledonio</td>
<td>⬤★★★★★</td>
<td>VERY LOW</td>
<td>Mixed findings</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Infrequent revision in both groups in two studies (1 to 2 per group)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Significantly fewer revisions with iFuse in third study</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>○ ARD -51.3% (95% CI, -60.1% to -42.4%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>○ RR 0.10 (95% CI, 0.04 to 0.26)</td>
</tr>
</tbody>
</table>

Abbreviations: ARD = adjusted risk difference; CCS = controlled cohort study; CI = confidence interval; MI = minimally invasive; RR = relative risk
## MI SI Joint Fusion with Implants Compared to Screw Fixation

<table>
<thead>
<tr>
<th>Study (Year)</th>
<th>Risk of Bias</th>
<th>Setting/Time Period</th>
<th>Intervention (N analyzed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spain (2017)</td>
<td>Some concerns</td>
<td>Single U.S. center, NR</td>
<td>iFuse (263) Percutaneous fixation with screws (29)</td>
</tr>
<tr>
<td>SI Bone, Inc.</td>
<td><strong>VERY LOW</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Revision Surgery at 2.8 to 4.6 yrs.

1 CCS: Spain

- **Very Low** Favors iFuse

- Significantly fewer revisions with iFuse (4.6%) compared to screws (65.5%)
  - ARD: -57.5% (95% CI, -74.8% to -40.2%)
  - RR: 0.40 (95% CI, 0.26 to 0.63)

Abbreviations: ARD = adjusted risk difference; CCS = controlled cohort study; CI = confidence interval; MI = minimally invasive; RR = relative risk
Safety Outcomes from Uncontrolled Studies

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Number of Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open fusion</td>
<td>8 studies total: 2 studies using posterior approach 2 studies using anterior approach 1 study using anterior approach</td>
</tr>
<tr>
<td></td>
<td>with symphysiodesis 1 study using Verral and Pitkin technique(bilateral) 1 study using modified Smith-Petersen technique</td>
</tr>
<tr>
<td></td>
<td>1 study using distraction interference arthrodesis</td>
</tr>
<tr>
<td>iFuse Implant System (triangular, titanium coated implants)</td>
<td>13 studies total: 12 studies using iFuse only; 1 study using iFuse or Samba</td>
</tr>
<tr>
<td>Simmetry System (titanium cannulated and antirotational implants with</td>
<td>3 studies</td>
</tr>
<tr>
<td>surface roughness)</td>
<td></td>
</tr>
<tr>
<td>Percutaneous fusion using hollow modular anchorage screw</td>
<td>3 studies</td>
</tr>
<tr>
<td>SH-LOK Sacroiliac Joint Fusion System</td>
<td>1 study</td>
</tr>
<tr>
<td>iINTERFIX system (single-threaded titanium cage filled with rhBMP-2)</td>
<td>1 study</td>
</tr>
<tr>
<td>Fusion using dual fibular dowel allografts</td>
<td>1 study</td>
</tr>
<tr>
<td>Fusion using threaded fusion cages</td>
<td>1 study</td>
</tr>
<tr>
<td>Various minimally invasive procedures based on CPT code 27279</td>
<td>1 study</td>
</tr>
</tbody>
</table>

Abbreviations: CPT = current procedural terminology
Safety Outcomes from Uncontrolled Studies

- Heterogenous adverse event ascertainment methods and reporting a major limitation of this body of evidence

- Using insurance claims from 469 beneficiaries who underwent MI SI fusion (based on CPT code) from 2007 to 2014
  - Incidence of complications 13.2% at 90 days and 16.4% at 6 months
    - Most common complication: neuritis or radiculitis

Safety Outcomes from Uncontrolled Studies (continued)

- Among the 13 studies using iFuse
  - Incidence of device or procedure-related adverse events ranged from 0% to 30%
  - Incidence of revision surgery ranged from 0% to 8%
    - Post-market surveillance database of 11,388 participants that received iFuse
      - Incidence of revision 2.8% over 4 years follow-up
      - 63% of revisions occurring within the first year
## Cost Question

---

## SI Joint Fusion compared to Nonoperative care [CQ]

<table>
<thead>
<tr>
<th>Study (Year)</th>
<th>Risk of Bias</th>
<th>Study Design</th>
<th>Key Parameters</th>
<th>Intervention Comparator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ackerman (2014)</td>
<td>Low</td>
<td>SI Bone, Inc.</td>
<td>Comparative cost analysis</td>
<td>Payer perspective, 2012 USD Time horizon: 3 to 5 years Commercially insured, mean age 45.2 years</td>
</tr>
<tr>
<td>Ackerman (2014)</td>
<td>Low</td>
<td>SI Bone, Inc.</td>
<td>Comparative cost analysis</td>
<td>Payer perspective, 2012 USD Time horizon: lifetime Medicare, starting age 70 with life expectancy age 84</td>
</tr>
</tbody>
</table>

Abbreviations: CQ = cost question; EQ-5D = EuroQOL measure of generic health status; MI = minimally invasive; USD = United States dollars
### MI SI Joint Fusion compared to Nonoperative care [Cost]

#### Costs over 3 to 5 years in a commercially-insured population

<table>
<thead>
<tr>
<th>1 CCA: Ackerman</th>
<th>Minimally invasive SI joint fusion with iFuse costs $14,545 more over 3 years and $6,137 more over 5 years.</th>
</tr>
</thead>
</table>

#### Lifetime costs in a Medicare population

<table>
<thead>
<tr>
<th>1 CCA: Ackerman</th>
<th>Minimally invasive SI joint fusion with iFuse costs $3,358 less than nonoperative care.</th>
</tr>
</thead>
</table>

Abbreviations: CCA = comparative cost analysis; MI = minimally invasive

### MI SI Joint Fusion compared to Nonoperative care [Cost-effectiveness]

#### Cost-effectiveness over 5 years

| 1 CEA: Cher | Minimally invasive SI joint fusion with iFuse costs $13,313 per QALY gained  
Breakeven costs at 13 years |
|-------------|-------------------------------------------------------------------------------|

Abbreviations: CEA = cost-effectiveness analysis; MI = minimally invasive; QALY = quality-adjusted life year
Clinical Practice Guideline Synthesis

- National Institute for Health and Care Excellence (U.K.)
  - Intervention Procedure Guidance 578: Minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain
    - Quality Rating 4 out of 7 on AGREE-II (7 = highest quality)
    - “Current evidence is adequate to support this procedure”

Clinical Practice Guideline Synthesis (continued)

- AIM Specialty Health
  - “Musculoskeletal Program Clinical Appropriateness Guidelines: Sacroiliac Joint Fusion”
    - Quality Rating 3 out of 7 on AGREE-II (7 = highest quality)
    - “Percutaneous/minimally invasive SI joint fusion with iFuse may be considered medically necessary when clinical criteria are met”
      - Persistent pain more than 6 months that interferes with function and has documented VAS pain score of 5 cm or greater and ODI of 30 or greater
      - Failure of 6 months of conservative management
      - Confirmation of pain (typical pattern, positive Fortin test, at least 3 positive provocative physical exam tests, and other causes excluded)
      - Imaging indicates evidence of injury/degeneration and excludes other sources
      - At least 75% pain reduction following image-guided SI joint injection on 2 separate occasions

Abbreviations: AGREE-II = Appraisal of Guidelines for Research & Evaluation II; U.K. = United Kingdom; VAS = visual analog scale
Discussion

Evidence Map – SI joint fusion with iFuse compared to conservative management

Efficacy
- Pain
  - k=2 RCT; N=249
  - k=3 CCS; N=137
- Function and disability
  - k=2 RCT; N=243
  - k=1 CCS; N=137
- Quality of life
  - k=2 RCT; N=249
- Opioid use
  - k=1 RCT; N=148
  - k=1 CCS; N=137
Safety
- Serious adverse events
  - k=2 RCT; N=249
  - k=1 CCS; N=137

Legend:
- GRADE Quality of Evidence
  - Very low
  - Low
  - Moderate
  - High
- k = number of studies
- N = total number of participants
- RCT = randomized controlled trial
- CCS = controlled cohort study

Timing of follow-up:
- Short to medium term (up to 6 months)
- Long term (1 year or longer)
- Short, medium, and long term
Evidence Map – Open SI joint fusion compared to conservative management

Evidence Map – SI joint fusion with iFuse compared to open fusion
Limitations of the Evidence Base

- Most studies were uncontrolled
  - Small sample sizes, heterogeneity in ascertainment and reporting of adverse events and revision surgery
- All controlled studies of minimally invasive fusion evaluated the iFuse implant system, unclear generalizability to other devices/techniques
- Limited outcomes reported by studies of open fusion
- Risk of bias limitations:
  - RCT evidence
    - Lack of blinding
    - Crossovers after 6 months
  - Controlled observational studies
    - Confounding and selection bias
- No prespecified subgroup analyses

Payer Coverage (through October 1, 2018)

- CMS: No national coverage determination, but several Medicare Administrative Contractors (MAC) do cover this procedure
  - Including 1 in the State of Washington (Noridian Healthcare Solutions)
- Two payers cover minimally invasive fusion when certain clinical criteria are met

<table>
<thead>
<tr>
<th>Payor</th>
<th>Coverage status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare</td>
<td>–</td>
</tr>
<tr>
<td>Medicaid</td>
<td>Covered in 44 states</td>
</tr>
<tr>
<td>Aetna</td>
<td>X</td>
</tr>
<tr>
<td>Cigna</td>
<td>X</td>
</tr>
<tr>
<td>Humana</td>
<td>X</td>
</tr>
<tr>
<td>Kaiser</td>
<td>X</td>
</tr>
<tr>
<td>Noridian Healthcare Solutions (MAC)</td>
<td>✓</td>
</tr>
<tr>
<td>Premera</td>
<td>X</td>
</tr>
<tr>
<td>Regence</td>
<td>✓</td>
</tr>
<tr>
<td>TRICARE</td>
<td>✓</td>
</tr>
<tr>
<td>UnitedHealthcare (Commercial)</td>
<td>–</td>
</tr>
<tr>
<td>United Healthcare (Medicare Advantage)</td>
<td>X</td>
</tr>
</tbody>
</table>

Notes: ✓ = covered; X = not covered; – = no policy identified
# Ongoing Studies

<table>
<thead>
<tr>
<th>Sponsor</th>
<th>Description</th>
<th>Number of Participants</th>
<th>Estimated Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Globus Medical, Inc.</td>
<td>Uncontrolled trial of SI-LOK joint fixation system</td>
<td>55</td>
<td>11/2018</td>
</tr>
<tr>
<td>SI-BONE, Inc.</td>
<td>Extended follow-up from 2 ongoing multicenter prospective U.S. clinical trials to evaluate long-term safety and effectiveness of iFuse Implant System</td>
<td>103</td>
<td>12/2019</td>
</tr>
<tr>
<td>Zyga Technology, Inc.</td>
<td>Prospective, non-randomized postmarket study to collect data following implant of the Simmetry device</td>
<td>250</td>
<td>8/2020</td>
</tr>
</tbody>
</table>

## Limitations of this Health Technology Assessment

- **Scope**
  - English-language articles only
  - Did not seek unpublished data or data presented only in conference abstracts
  - Excluded efficacy outcomes from uncontrolled studies
- **Process**
  - Search limited to 3 databases
- **Analysis**
  - Did not GRADE the body of evidence from uncontrolled studies
  - Limitations of AGREE-II tool for appraising clinical practice guidelines

Abbreviations: AGREE-II = Appraisal of Guidelines for Research & Evaluation II; GRADE = Grading of Recommendations, Assessment, Development, and Evaluation
Conclusion

Among patients meeting diagnostic criteria for SI joint pain who have not responded to conservative management:

**Minimally invasive SI joint fusion with iFuse (vs. conservative management)**
- Reduces pain more [GRADE: High]
- Improves function/disability more [GRADE: Moderate]
- Improves quality of life more [GRADE: Low]
- Has uncertain effects on opioid use [GRADE: Very low]
- Results in no difference in serious adverse events [GRADE: Moderate]
- Is likely cost-effective [GRADE: Low]

**Open fusion (vs. conservative management)**
- Results in no long-term difference in
  - Pain [GRADE: Very low]
  - Function/disability [GRADE: Moderate]
  - Quality of life [GRADE: Low]

Conclusion (continued)

Among patients meeting diagnostic criteria for SI joint pain who have not responded to conservative management:

**Minimally invasive SI joint fusion with iFuse (vs. open fusion)**
- Reduces pain more [GRADE: Low]
- Has uncertain impact on function/disability [GRADE: Low]
- Has shorter hospital length of stay [GRADE: Moderate]
- Results in no difference in adverse events [GRADE: Moderate]
- Has uncertain impact on incidence of revision surgery [GRADE: Low]

**Minimally invasive SI joint fusion with iFuse (vs. percutaneous screw fixation)**
- Reduces incidence of revision surgery [GRADE: Moderate]
HTCC Coverage and Reimbursement Determination

Analytic Tool

HTA’s goal is to achieve better health care outcomes for enrollees and beneficiaries of state programs by paying for proven health technologies that work.

To find best outcomes and value for the state and the patient, the HTA program focuses on three questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

**Principle One: Determinations are evidence-based**

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective\(^1\) as expressed by the following standards\(^2\):

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

**Principle Two: Determinations result in health benefit**

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms\(^3\):

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.

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\(^1\) Based on Legislative mandate: See RCW 70.14.100(2).

\(^2\) The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

\(^3\) The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm
In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.

The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

Using evidence as the basis for a coverage decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. Availability of evidence:
Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. Sufficiency of the evidence:
Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- The amount of evidence (sparse to many number of evidence or events or individuals studied);
- Consistency of evidence (results vary or largely similar);
- Recency (timeliness of information);
- Directness of evidence (link between technology and outcome);
- Relevance of evidence (applicability to agency program and clients);
- Bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

<table>
<thead>
<tr>
<th>Not Confident</th>
<th>Confident</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.</td>
<td>Very certain of evidentiary support. Further information is unlikely to change confidence</td>
</tr>
</tbody>
</table>

4 Based on GRADE recommendation:  [http://www.gradeworkinggroup.org/FAQ/index.htm](http://www.gradeworkinggroup.org/FAQ/index.htm)
3. Factors for Consideration - Importance

At the end of discussion a vote is taken on whether sufficient evidence exists regarding the technology’s safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- Risk of event occurring;
- The degree of harm associated with risk;
- The number of risks; the burden of the condition;
- Burden untreated or treated with alternatives;
- The importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- The degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- Value variation based on patient preference.

Clinical committee findings and decisions

Efficacy considerations

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value?
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests’ accuracy?
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices?
Safety

- What is the evidence of the effect of using the technology on significant morbidity?
  - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
  - Adverse effect on health that can result in lasting harm or can be life-threatening?
- Other morbidity concerns?
- Short term or direct complication versus long term complications?
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives?
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?

Next step: Cover or no cover

If not covered, or covered unconditionally, the chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next step: Cover with conditions

If covered with conditions, the committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
   - Refer to evidence identification document and discussion.
   - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
   - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.

2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
   - What are the known conditions/criteria and evidence state
   - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.
## Clinical committee evidence votes

### First voting question

The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

**Discussion document:** What are the key factors and health outcomes and what evidence is there? (Applies to the population in the PICO for this review)

<table>
<thead>
<tr>
<th>Safety outcomes</th>
<th>Importance of outcome</th>
<th>Safety evidence/confidence in evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serious adverse events</td>
<td></td>
<td></td>
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<td>Other surgical morbidity</td>
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<td>Revision surgery</td>
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<tr>
<td>Blood loss</td>
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<tr>
<td>Duration</td>
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<table>
<thead>
<tr>
<th>Efficacy – effectiveness outcomes</th>
<th>Importance of outcome</th>
<th>Efficacy / Effectiveness evidence</th>
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<tbody>
<tr>
<td>Pain</td>
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<tr>
<td>Function</td>
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<td>QOL</td>
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<td>Patient satisfaction</td>
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<td>Opioid use</td>
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<td>Return to work</td>
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<table>
<thead>
<tr>
<th>Cost outcomes</th>
<th>Importance of outcome</th>
<th>Cost evidence</th>
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<tbody>
<tr>
<td>Cost</td>
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<tr>
<td>Cost-effectiveness</td>
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</table>
### Health Technology Evidence Identification

<table>
<thead>
<tr>
<th>Special population / Considerations outcomes</th>
<th>Importance of outcome</th>
<th>Special populations/ Considerations evidence</th>
</tr>
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</table>

**For safety:**
Is there sufficient evidence that the technology is safe for the indications considered?

<table>
<thead>
<tr>
<th>Unproven (no)</th>
<th>Less (yes)</th>
<th>Equivalent (yes)</th>
<th>More in some (yes)</th>
<th>More in all (yes)</th>
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**For efficacy/ effectiveness:**
Is there sufficient evidence that the technology has a meaningful impact on patients and patient care?

<table>
<thead>
<tr>
<th>Unproven (no)</th>
<th>Less (yes)</th>
<th>Equivalent (yes)</th>
<th>More in some (yes)</th>
<th>More in all (yes)</th>
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</table>

**For cost outcomes/ cost-effectiveness:**
Is there sufficient evidence that the technology is cost-effective for the indications considered?

<table>
<thead>
<tr>
<th>Unproven (no)</th>
<th>Less (yes)</th>
<th>Equivalent (yes)</th>
<th>More in some (yes)</th>
<th>More in all (yes)</th>
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Discussion
Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second Vote
Based on the evidence about the technologies’ safety, efficacy, and cost-effectiveness, it is

_____ Not covered _____ Covered unconditionally _____ Covered under certain conditions

Discussion item
Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Next step: proposed findings and decision and public comment
At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

1) Based on public comment was evidence overlooked in the process that should be considered?
2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

Next step: final determination
Following review of the proposed findings and decision document and public comments:

Final vote
Does the committee approve the Findings and Decisions document with any changes noted in discussion?

If yes, the process is concluded.
If no, or an unclear (i.e., tie) outcome chair will lead discussion to determine next steps.
**Medicare Coverage**  
*From page 23 of the final evidence report:*

The Center for Medicare & Medicaid Services does not have a national coverage determination for SI joint fusion procedures though several Medicare Administrative Contractors (MAC) do cover this procedure, including 1 that operates in the State of Washington (Noridian Healthcare Solutions).

**Guidelines**  
*From page 58 of the final evidence report:*

**Table 1. Clinical practice guidelines related to sacroiliac joint fusion**

<table>
<thead>
<tr>
<th>Title/Organization Guideline Quality</th>
<th>Year Published</th>
<th>Excerpts of Findings</th>
<th>Rating/Quality of Evidence Narrative Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain - Intervention Procedure</td>
<td>2017</td>
<td>“Current evidence on safety and efficacy of minimally invasive sacroiliac (SI) joint fusion surgery for chronic SI pain is adequate to support use of this procedure, provided that standard arrangements are in place for clinical governance, consent, and audit. Patients having this procedure should have a confirmed diagnosis of unilateral or bilateral SI joint dysfunction due to degenerative sacroiliitis or SI joint disruption. This technically challenging procedure should only be done by surgeons who regularly use image-guided surgery for implant placement. The surgeons should also have had specific training and NICE expertise in minimally invasive SI joint fusion surgery for chronic SI pain.” NICE expects to release a guidance document focuses specifically on iFuse in October 2018.</td>
<td>Based on 2 RCTs, 2 SRs, 3 prospective cohort studies, and 2 retrospective case series; quality of evidence assessment not performed.</td>
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<tr>
<td>Nordic Institute for Health and Care Excellence (United Kingdom)</td>
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<td>Quality Rating: 4 out of 7</td>
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| Musculoskeletal Program Clinical Appropriateness Guidelines: Sacroiliac Joint Fusion | 2018 | Percutaneous/minimally invasive SI joint fusion with iFuse system may be considered medically necessary when all of the following criteria are met:  
- Persistent pain more than 6 months that interferes with function and has documented VAS of 5 cm or greater and ODI of 30 or greater  
- Failure of 6 months of conservative management  
- Confirmation of pain (typical pattern, positive Fortin test, at least 3 positive provocative physical exam tests, and other causes excluded)  
- Imaging indicates evidence of injury/degeneration and excludes other sources  
- At least 75% pain reduction following image-guided SI joint injection on 2 separate occasions | Not reported |
| AIM Specialty Health | | | |
| Quality Rating: 3 out of 7 | | | |

**Abbreviations:** AIM = acronym not defined; cm = centimeters; NICE = National Institute for Health and Care Excellence; ODI = Oswestry Disability Index; RCTs = randomized clinical trials; SI = sacroiliac; SR = systematic reviews; VAS = visual analog scale.