

## **Sacroiliac joint fusion update 2021**

### **Clinical Expert**

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Applicant Name Randall M. Chesnut, MD  
 Address Harborview Medical Center  
325 Ninth Avenue, Box 359766  
Seattle, WA 98104

**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:

Title	Business Name & Address	Business Type
N/A	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

(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:

Business Name	Business Address	Business Type
N/A	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

**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:

Received From	Organization Address	Service Performed
Rutgers University	10 Plum Street, 9th Floor, New Brunswick, NJ 08901	Grand Rounds Lecturer
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	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.

Source Name & Address	Received By	Source Type
N/A	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

(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.](#)

[Click here to enter text.](#)

[Click here to enter text.](#)

(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.](#)

[Click here to enter text.](#)

[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.)

Lobbyist Name	Business Name	Type Business Shared
N/A	<a href="#">Click here to enter text.</a>	<a href="#">Click here to enter text.</a>
<a href="#">Click here to enter text.</a>	<a href="#">Click here to enter text.</a>	<a href="#">Click here to enter text.</a>
<a href="#">Click here to enter text.</a>	<a href="#">Click here to enter text.</a>	<a href="#">Click here to enter text.</a>

**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
N/A	<a href="#">Click here to enter text.</a>	<a href="#">Click here to enter text.</a>
<a href="#">Click here to enter text.</a>	<a href="#">Click here to enter text.</a>	<a href="#">Click here to enter text.</a>

[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:

Business Name	Business Address	Description of Business
<b>N/A</b>	<a href="#">Click here to enter text.</a>	<a href="#">Click here to enter text.</a>
<a href="#">Click here to enter text.</a>	<a href="#">Click here to enter text.</a>	<a href="#">Click here to enter text.</a>
<a href="#">Click here to enter text.</a>	<a href="#">Click here to enter text.</a>	<a href="#">Click here to enter text.</a>

**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.

Name	Description of Service
<b>N/A</b>	<a href="#">Click here to enter text.</a>
<a href="#">Click here to enter text.</a>	<a href="#">Click here to enter text.</a>
<a href="#">Click here to enter text.</a>	<a href="#">Click here to enter text.</a>

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     Randall M. Chesnut    

Check One:     Committee Member     Subgroup Member     Contractor



19 April 2021

Signature

Date




Agency medical director comments

**Sacroiliac Joint Fusion: Re-review**

**Emily Transue, MD, MHA**  
Medical Director for Employee and Retiree Benefits  
WA Health Care Authority

June 18, 2021

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### 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

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### 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 patients naïve to back surgery, 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

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### SI Fusion: 2019 HTCC review

- The Health Technology Clinical Committee reviewed this topic in January 2019
  - In adults, 18 years old and older, 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.
  - This decision does not apply to low back pain of other etiology (e.g., radiculopathy, neurogenic claudication), sacroiliac joint pain related to recent major trauma or fracture, infection, cancer, or sacroiliitis associated with inflammatory arthropathies.

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### SI Fusion: 2019 HTCC review

- Rationale for non-coverage:
  - 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
  - Low quality of evidence was a major factor in committee determination
    - Low certainty
    - High risk of bias

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### SI Fusion: 2021 HTCC re-review

- Selected for re-review on the basis of petition and public comment
- New evidence includes:
  - Additional two-year follow up on 2 RCTs (previously reviewed with 6 months of data)
  - Controlled cohort study (CCS) comparing iFuse device to Rialto Implant System
  - Some additional safety data

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## 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).*

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## Current state agency policy


Agency	27279	27280
ERB*/UNIFORM MEDICAL PLAN	Follows HTCC	Follows HTCC
MEDICAID	Follows HTCC	Follows HTCC
LABOR AND INDUSTRIES	Follows HTCC	Follows HTCC

Employee and Retiree Benefits (ERB), the HCA program encompassing the Public Employees Benefits Board (PEBB) and School Employees Benefits Board (SEBB)

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### Current utilization (unique members)

	2017	2018	2019	2020*	Total
Medicaid FFS	0	0	0	0	0
Medicaid MCO	NR	NR	13	NR	33
ERB/UMP	14	14	15	13	54**
LNI	NR	NR	NR	NR	25
<b>Total</b>	<b>24</b>	<b>27</b>	<b>36</b>	<b>31</b>	<b>112</b>

NR: Numbers under 11 not reported  
 \*Prior HTCC decision implemented in 2020  
 \*\*Unique members; may not equal sum of years

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### Cost Experience

	2017	2018	2019	2020	Average
Medicaid FFS	N/A	N/A	N/A	N/A	N/A
Medicaid MCO	NR	NR	NR	NR	\$2,517
PEBB/UMP	\$3,222	\$4,209	\$11,090	\$8,974	\$7,168
LNI	NR	NR	NR	NR	\$17,525

Average amounts paid per individual, paid amounts >0\$

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## Agency medical director concerns

**Safety = High**  
**Efficacy = High**  
**Cost = High**

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## Key questions

- What is the effectiveness and comparative effectiveness of sacroiliac (SI) joint fusion surgery on health outcomes?
  - What is the comparative effectiveness of various SI joint fusion surgeries on intermediate efficacy outcomes?
- What is the safety of SI joint fusion surgery?
  - What is the comparative effectiveness of various SI joint fusion surgeries on intermediate efficacy outcomes?
- What is the cost and cost-effectiveness of SI joint fusion?

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## 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.

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## 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
  - Van Tilburg et al. *J Back Musculoskel Rehabil* 2017; 30: 551-557
- 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.
  - Polly D et al. *Int J Spine Surg* 2016; 10:4

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## Data limitations

**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

**Lack of independent evaluator\*:**

**Controls:**

- Most available data comes from uncontrolled studies


**Funding\*:**

- All trials reviewed were funded by device manufacturer
- Significant payments to researchers (<https://openpaymentsdata.cms.gov>)

\*Note that neither funding nor lack of independent evaluator are included in the evidence reviewer’s assessment rubric for risk of bias

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## 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; crossover rates were high, severely confounding long term comparisons
  - Conservative management not fully standardized; highly evidence-based treatments such as cognitive behavioral therapy (CBT) not consistently included
  - Concern for lack of equipoise around description of severe adverse events (severe adverse events from physical therapy, etc)

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### INSITE trial (2013-14 entry, 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**
  - 79.5% crossover at 1 year, 88.6% crossover at 2 years, i.e. 142/148 eligible eventually had surgery
- **Conservative mgt:**
  - Meds per site PI; PT per PT ass'n guidelines; steroid inj; ablation
  - CBT-based treatments not used as they were deemed "unstandardizable, impracticable and unrepresentative of modern US healthcare"

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### iMIA trial (2013-15 entry, mult European sites)

- iFuse vs. non-operative treatment
- 9 centers, 103 patients, ~35% with prior lumbar fusion
- Dx: Fortin finger test, 3 of 5 provocative joint findings, 50% reduction in pain with block
- **Conservative rx: optimized medical rx, individualized PT at least 2/w for 8 weeks; CBT allowed not required**
- **Crossover allowed at 6 months; 43% crossover at 1 yr**

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Washington State Health Care Authority

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

INSITE	Pain (VAS)	Disability (ODI)	ODI ARD 15+ pt impr	QOL EQ-5D	QOL SF-36	Opioid use
1 mo	-36.2	-13.7				
3 mo	-37.9	-19.2				
6 mo	-40.5	-25.4	59.6%	-.24	11.5 ph 5.6 mh	-9% vs +7.5%
1 yr*	-32.6*	-0.4**	64.5%	-.11	7.7 ph	
2 yrs*	NR		60.7%			
<b>iMIA</b>						
1 mo	-35.3					
3 mo	-38.6					
6 mo	-38.1	-19.8	46.7%	-.21		
1 yr*	-27.6	-20.1		-.22		
2 yrs*	-34	NR	39.9%	-.24		-23% vs -1.4%

**New data since last review highlighted**  
 Minimal clinically important differences:  
 VAS:8-11 ; ODI: 8-11; SF-36: 3; EQ-5D ~0.4 19

\*Crossovers excluded  
 \*\*Small #s; 95% CI -18-+19

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Washington State Health Care Authority

## Safety

- Most evidence is for iFuse
- No common protocols for data assessment or standardized definitions
- Broad range of incidence in different trials; frequency of severe or serious adverse events 0-46%
- Most common complications: Neuritis, radiculitis, sciatica, neuralgia
- Revisions:
  - Post-market surveillance: 2.8% revisions over median 4 year f/u
  - Uncontrolled cohort studies 0-8%, 63% of those within 1 year
  - New study: 2015-2018 (14,210 pts) 3.1% total revision, annual revision 1% (iFuse-3D), 1.5% (iFuse)
- Evidence reviewer’s confidence on safety data decreased over the time since the last review

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### New study: iFuse vs Rialto

- Only study comparing minimally invasive implant systems
- Compared iFuse (triangular dowel, lateral transiliac approach) to Rialto (cylindrical threaded, post. oblique)
- High risk of bias
- No significant differences found in pain, function, disability, quality of life, hospital stay
- Revision surgery more common with Rialto than iFuse (6.1% vs 2.4%) but not statistically significant

Claus et al, World Neurosurg, 2020. 21


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

- These are passively reported events, most often from the manufacturer; cannot derive rates
- The event description almost always states that the event is not related to defects in the implants
- Over the past year April 2020-March 2021 there were 130 reports of severe adverse events specific to I-Fuse
- Events include malpositioning with impingement on the foramen, infection, unusual sacral fractures which may or may not be related to the implant
- This does not include events related to any other of the dozens of manufacturers of these devices which have been approved by the FDA


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

- “In (b)(6) 2020, the patient had left side si joint arthrodesis where three implants were installed. The patient later complained of radicular pain symptoms. The surgeon determined that the **superior positioned implant was impinging on the neuroforamen causing radicular pain symptoms**. In (b)(6) 2021, the surgeon performed a revision procedure where he removed the superior positioned implant **using chisels**. No bone graft was placed in the explant void. No other preexisting implants were adjusted or removed. The patient is doing well following the revision procedure.”
- “In (b)(6) 2020 the patient had left side si joint arthrodesis where three implants were installed. The patient initially did well after the procedure but later reported left side radicular pain. The surgeon determined that the caudal positioned implant was **malpositioned and impinging on the neuroforamen causing radicular pain**. In (b)(6) 2021, the surgeon performed a revision procedure where he removed the caudal positioned implant. No other preexisting implants were adjusted or removed. No additional hardware was added. The status of the patient following the revision procedure is not known.”

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### Costs/Cost-effectiveness: iFuse vs. non-operative

- Very low quality of evidence
- Commercial population (Ackerman):
  - iFuse \$14,545 more over 3 years
  - iFuse \$6,137 more over 5 years
- Medicare (Ackerman): iFuse \$3,358 less over lifetime
- Cost-effectiveness (Cher, Blisset): iFuse vs. non-operative
  - \$2,697 to \$13,313 per QALY

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## Pending evidence

- Multiple ongoing studies (detailed in evidence report)
- iFuse vs sham study now recruiting, completion expected 4/2023

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## Coverage comparisons for minimally invasive SI fusion

- Medicare:
  - No national coverage determination
  - No current local coverage determination

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Washington State  
Health Care Authority

### Coverage comparisons: Min. invasive SI fusion

	Aetna	Cigna	Kaiser	Premera	Regence	United
Covered	"Fusion (e.g. iFuse)"	FDA-appr. implant	No	Titanium triangular (iFuse)	Titanium triangular (iFuse)	Per MCG
Diagnosis	SI syndrome	Degen. Sttis or disruption		Localized SI px	SI pain	SI pain
ADL interference	Yes				Yes	
Adults 18+	Yes					
Chronicity	6 mos	6 mos		6 months	6 months	
Pain score 0-10	5+			5+	5+	5+
Conservative Rx	6 mos, specific	6 mos MD guided		6 mos specific	6 mos specific	6 mos PT or steroid or rhiz.
Physical findings		Specific		Specific	Specific	3+ provocative exams
Rad. findings		Specific		Specific	Specific	
Injection response		75% to 2, 2 months apart, guided		75% to 2, guided; prior steroid	75% to 2, guided, 1 prior steroid	75% to 1
Exclusions		MH, px syndrome, smoking		Generalized px d/o		Alternative dx present

MCG Milliman Care Guidelines: 27

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- Washington State  
Health Care Authority
- ### 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. (2017)
    - iFuse: Supported by evidence. Leads to improved pain relief, better QOL and less disability vs nonsurgical mgt. (2018)
  - **Int'l Soc for the Advancement of Spine Surgery**
    - Lateral transiliac may be med nec w failure 6 mos conservative mgt; QOL/ADL impact; 3+ provocative tests; 50% relief w block done under imaging. Posterior fusion unproven. (2020)
  - **AIM Specialty Health**
    - iFuse may be med nec w persistent pain interfering with function; failure 6 months conservative mgt; confirmatory physical exam; imaging w degeneration and no other cause; at least 75% pain reduction following image-guided SI injection on 2 separate occasions (2020)
  - **Evicore:** Similar to AIM, adds nonsmoking, absence of BH and surgeon requirements
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AGENCY MEDICAL DIRECTOR GROUP  
Recommendation: Sacroiliac Joint Fusion (p. 1 of 2)


- In adults, 18 years old and older, 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.
- This decision does not apply to low back pain of other etiology (e.g., radiculopathy, neurogenic claudication), sacroiliac joint pain related to recent major trauma or fracture, infection, cancer, or sacroiliitis associated with inflammatory arthropathies.

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AGENCY MEDICAL DIRECTOR GROUP  
Recommendation: Sacroiliac Joint

- 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.
  - Additional evidence since the prior review is very limited, and does not address the concerns that led to the prior determination.

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Questions?

More Information:  
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THE CECIL G. SHEPS CENTER FOR  
HEALTH SERVICES RESEARCH

RTI-University of North Carolina  
Evidence-based Practice Center

# Sacroiliac Joint Fusion Update

Health Technology Assessment

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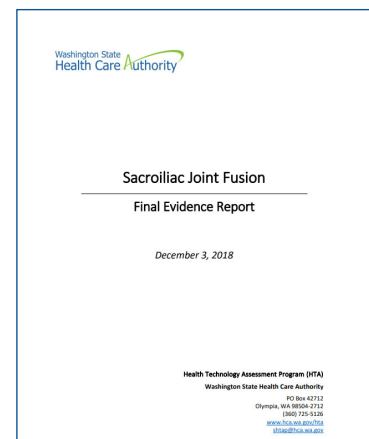
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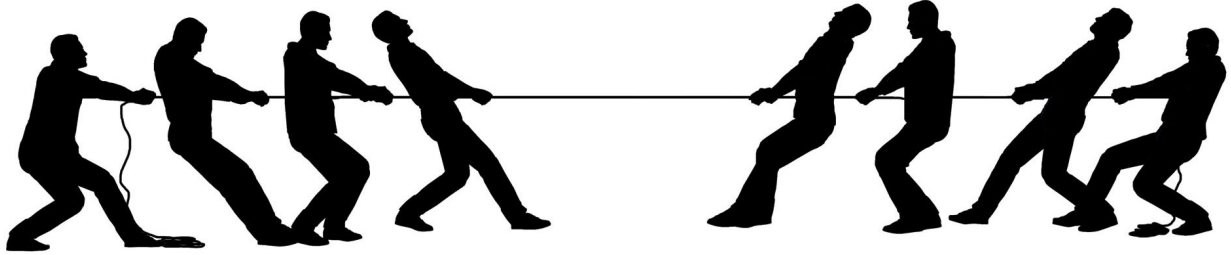
## Overview of Presentation

- Background
  - Contextual Question Regarding Diagnosis
- Methods
- Results
- Discussion
  - Clinical practice guidelines
  - Limitations

## 2018 HTA Report



## Conflicts of Interest



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## Background

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## Chronic Sacroiliac (SI) Joint Pain

- Believed to originate from one or both surfaces of the SI joint and/or the SI joint complex
- May be caused by degenerative sacroiliitis or joint dysfunction from repeated axial loading and rotation
- Clinical presentation of pain varies
  - Buttock pain extending into posterolateral thigh is most common
- Estimated by some to be the primary source of pain in 10%-38% of patients with mechanical low back pain

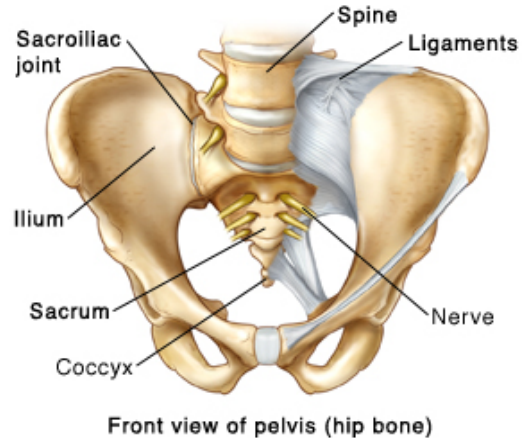


Image source: <https://www.saintlukeskc.org/health-library/anatomy-sacroiliac-joint>

## Contextual Question: SI joint pain diagnosis and test accuracy

- Clinical diagnosis based on history, exam and diagnostic tests
  - No single pathognomonic finding
- Guidelines and experts recommend:
  - History of pain in appropriate location and distribution
    - Fortin Finger Test (pain over the SI joint)
    - Pain often extending into the posterolateral thigh
  - Provocative physical exam tests
    - Gaenslen maneuver
    - Distraction test
    - Compression test
    - Sacral thrust test
    - Thigh thrust or femoral shear test
    - FABER (flexion, abduction, external rotation)
  - Imaging to rule out alternative diagnoses
  - Diagnostic joint injection



Gaenslen maneuver

Source: [https://commons.wikimedia.org/wiki/File:Gaenslen%27s\\_test.jpg](https://commons.wikimedia.org/wiki/File:Gaenslen%27s_test.jpg)

## Diagnostic SI Joint Injection

- Pain relief from SI joint injection is the current reference standard for diagnosis
  - Intraarticular placement of a local anesthetic (with or without steroids) under imaging guidance
  - Volume of injectate matters (no more than 2.5 ml recommended)
  - Relative amount of pain relief for positive test varies from 50% to 80%
    - Threshold used has minimal impact on prevalence estimates
    - Patients who varied in the % of pain relief beyond 50% after diagnostic injection had similar outcomes after SI joint fusion
  - Repeat/confirmatory injections reduces the false positive rate

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Pages 48-49

Abbreviations: ml = milliliters; SI = sacroiliac

## Diagnosis Bottomline

- Making a diagnosis of chronic joint pain/dysfunction is complicated
- Current approaches to diagnosis have limitations and the case definition may not be an ideal standard
- No studies or commentaries identified to suggest that current guidance related to diagnosis is fatally flawed

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Pages 47-49



## SI Joint Pain Management

- Nonsurgical options for management
  - Analgesics and anti-inflammatory medications
  - Physical therapy
  - Pelvic belts and girdles
  - Therapeutic joint injection
  - Prolotherapy
  - Radiofrequency denervation
- Fusion of SI joint
  - Reserved for people who fail nonsurgical treatments
  - Open procedure
    - Not used for chronic pain, reserved for trauma, infections, tumors
  - Minimally invasive fusion procedures (MI SIJF)

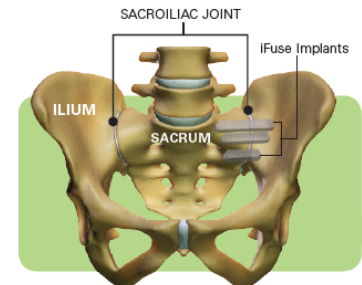
## Surgical Systems for MI SI Joint Fusion

### Numerous proprietary devices

- 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
- Surgical approach used varies
  - Lateral transiliac
  - Posterior (dorsal)
- Some systems combine immediate fixation with decortication and bone graft insertion

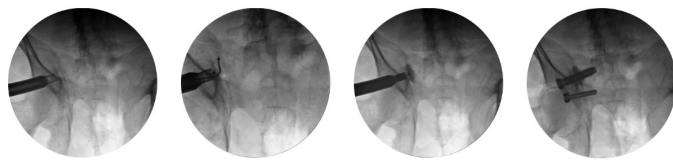
### Example: iFuse Implant System (SI-BONE)

Image source: <https://si-bone.com/si-joint-pain-treatment/ifuse-implant-system/>.

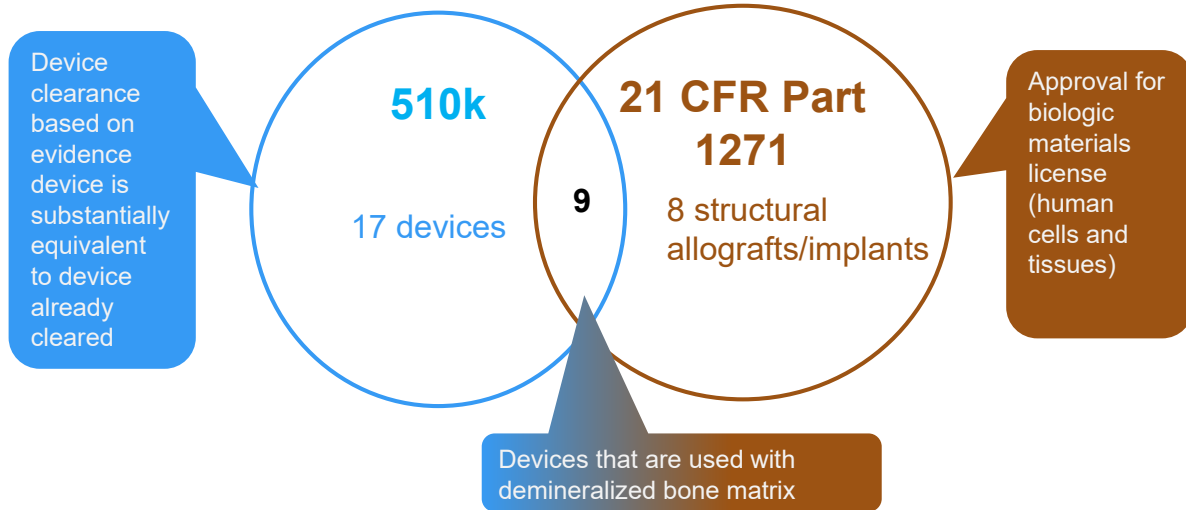


### Example: SImmetry (Zyga)

Image source: <https://zyga.com/providers-doctors/simmetry-solution-sacroiliac-joint-dysfunction/true-si-joint-arthrodesis/>



## Regulatory Status



N=34 products currently marketed specifically for SI joint fusion in US

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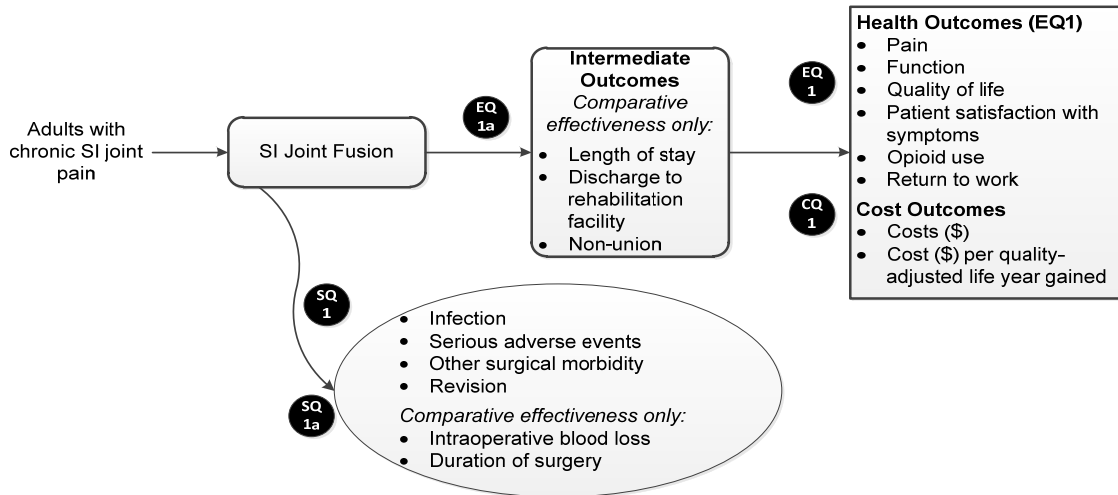
Pages 2-6,  
Table 1

Abbreviations: SI = sacroiliac

## Methods

12

## Analytic Framework



13 Page 8, Figure 1

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

## Search and Study Selection

### Update Search:

Medline, Embase, Cochrane, Trials Registry covering 1/1/2018 to 1/31/2021

**Population** Adults with  $\geq 3$  months SI joint pain diagnosed using a standard approach

**Intervention** Open SI joint fusion; minimally invasive SI joint fusion

**Comparator** Active treatment; placebo; no treatment

**Outcomes**  
EQ1: Pain; function; quality of life; patient satisfaction; opioid use; return to work, intermediate outcomes (comparisons of alternative procedures only)  
SQ1: Adverse events, revision surgery  
CQ: Cost; cost per quality-adjusted life year gained; cost per disability-adjusted life year gained

**Study Design**  
EQ: Controlled trials, controlled cohort studies  
SQ: All of the designs listed for EQ plus studies without a comparator group  
CQ: Cost-effectiveness analysis, cost-utility analysis, cost-benefit analysis

**Setting** Countries categorized as "very high" on United Nations Human Development Index

14 Pages 9-11, Table 2

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
  - Cochrane Risk of Bias version 2.0 instrument for RCTs
  - ROBINS-I tool for non-randomized comparative studies
  - Quality of Health Economic Studies instrument for cost analyses
- Each study assessed as having one of the following risks:
  - High risk of bias
  - Some concerns for bias
  - Low risk of bias

### ROB domains

- Randomization
- Allocation concealment
- Performance bias (e.g., blinding)
- Deviations from intervention
- Missing data and attrition
- Outcome measure validity and assessor blinding
- Selective outcome report
- Confounding (for observational studies)

## Risk of Bias Assessments-Continued

- Outcome-level ROB assessments where appropriate (long term followup in presence of crossovers)
- Risk of bias is on a continuum and focus is on whether bias could substantively influence outcomes
- No current, internationally recognized ROB assessment instrument considers study sponsorship or source of funding as a consideration for evaluating the risk of bias.
  - Concerns over industry sponsorship are concerns about conflicts of interest
  - Some evidence that industry sponsored studies document more favorable outcomes compared to studies without competing financial interests and these findings are independent of risk of bias or design

## Certainty of the Evidence – GRADE approach

- **Domains assessed:**

- Risk of bias
- Consistency
- Directness
- Precision
- Publication bias

- **Certainty of evidence**

- ⊕○○○ VERY LOW
- ⊕⊕○○ LOW
- ⊕⊕⊕○ MODERATE
- ⊕⊕⊕⊕ HIGH

- Bodies of RCT evidence start at **HIGH**
- Observational studies start at **LOW** because of limitations with this study design
- Certainty level may be downgraded based on domain assessments:
  - No concerns
  - Serious concerns (↓ one level)
  - Very serious concerns (↓ two levels)
- Observational evidence may be upgraded based on:
  - Large effect (↑ one level)
  - Dose response (↑ one level)
  - Plausible confounding and bias accounted for (↑ one level)

17 Pages 13-14

Abbreviations: GRADE = Grading of Recommendations Assessment, Development, and Evaluation; RCT = randomized controlled trial

## Results

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## Search Results

- Titles/abstracts screened: **233**
- Full text articles screened: **50**
- Full text studies included from 2018 HTA report: **43 studies (50 articles)**
- Cumulative evidence included: **57 studies (67 articles)** 14 new studies (in 17 articles)

**EQ:**  
2 RCTs  
7 CCS

**SQ:**  
2 RCTs  
7 CCS  
43 uncontrolled studies

**CQ:**  
5 cost studies

## Comparisons and Outcomes 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, SQ)

### MI SI joint fusion compared to open fusion

- EQ, SQ

### Comparing alternative MI SI joint fusion procedures

- EQ, SQ

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

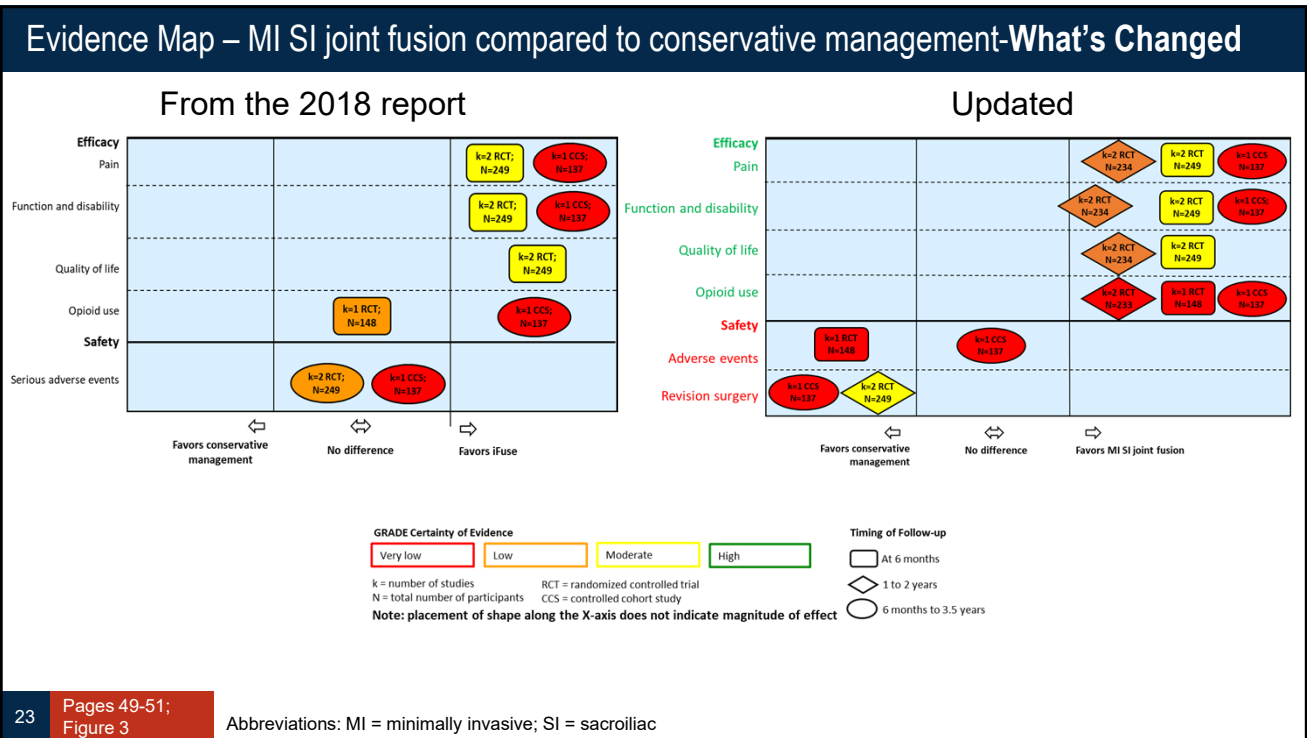
Study (Year) Risk of Bias Sponsor	Study Design	Setting/ Time Period	Intervention (N analyzed) Comparator (N analyzed)
INSITE (Whang, 2015) Some concerns for outcomes ≤ 6 mos.; high for outcomes > 6 mos. SI-Bone	RCT	19 U.S. centers, 2013 to 2014	MI SIJF with iFuse (102) CM (46) Crossovers from CM to MI SIJF allowed after 6 mos. (39)
iMIA (Dengler, 2016) Some concerns for outcomes ≤ 6 mos.; high for outcomes > 6 mos. SI-Bone	RCT	9 European centers, 2013 to 2015	MI SIJF with iFuse (52) CM (51) Crossovers from CM to MI SIJF allowed after 6 mos. (21)
Vanaclocha (2018) High Not reported	CCS (retrospective)	Single center in Spain, 2007 to 2015	MI SIJF with iFuse (27) Radiofrequency denervation (47) CM (63)

21 Pages 21-23; Table 7 Abbreviations: CCS = controlled cohort study; CM = conservative management; MI SIJF = minimally invasive sacroiliac joint fusion; mos. = months; N = number of participants; RCT = randomized controlled trial; U.S. = United States

## 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
  - Baseline VAS ≥ 50, ODI ≥ 30
- Mean duration of pain 3 to 7 years
- About 1/3 of participants had a history of prior lumbar fusion
- Mean VAS pain score was 82 mm in both groups on a scale of 0 mm [no pain] to 100 mm [worse pain ever]

22 Pages 21-23; Table 7; Appendix C-1, C-6 Abbreviations: mm= millimeter; ODI = Oswestry Disability Index (0 to 100); SI = sacroiliac; VAS = visual analog scale (0 to 100)



## 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 mm)**

**2 RCTs: INSITE, iMIA** • Significantly larger improvements with MI SIJF; between-group difference

⊕⊕⊕○ MODERATE  
 Favors MI SIJF

- -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

**Threshold improvement in pain at 6 mos. (at least 20 mm improvement on Visual Analog Scale)**

INSITE: 82% vs. 27% (calculated RR 3.0, 95% CI, 1.8 to 4.9)

iMIA: 79% vs. 22% (calculated RR 3.5, 95% CI, 2.1 to 6.0)

24    Pages 17-20, 25-27; Tables 5, 8    Abbreviations: CI = confidence interval; CM = conservative management; MI SIJF = minimally invasive sacroiliac fusion; MID = minimally important difference; mm = millimeters; mos. = months; NR = not reported; RR = risk ratio



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

### Change in pain at 1 yr. (Visual Analog Scale, MID = 7 to 11 mm)

2 RCTs: INSITE, iMIA  
⊕⊕○○ LOW  
Favors MI SIJF

- Significantly larger improvements with MI SIJF; between-group difference
  - -32.6 mm (95% CI, -58.7 to -6.6, P = 0.01) in one study for MI SIJF compared to CM participants who did not cross over; no difference when compared to CM participants who crossed over
  - -27.6 mm (95% CI NR, P < 0.0001) in other study (LOCF)

### Threshold improvement in pain at 2 yrs. (at least 20 mm improvement on Visual Analog Scale)

2 RCTs: INSITE, iMIA  
⊕⊕○○ LOW  
Favors MI SIJF

- Significantly higher proportion achieved threshold improvement with MI SIJF
  - 83% vs. 10% (calculated RR 8.3, 95% CI, 3.3 to 21.2) in other study (crossovers considered failures)
  - 79% vs. 24% (calculated RR 3.3, 95% CI, 1.92 to 5.6) in 1 study (LOCF)

25

Pages 17-20, 25-27;  
Tables 5, 8

Abbreviations: CI = confidence interval; CM = conservative management; LOCF = last observation carried forward; MI SIJF = minimally invasive sacroiliac fusion; MID = minimally important difference; mm = millimeters; mos. = months; RCT = randomized controlled trial; RR = risk ratio

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

### Change in pain at 6 mos. to 3.5 yrs. (Visual Analog Scale, MID = 7 to 11 mm)

1 CCS: Vanaclocha  
⊕○○○ VERY LOW  
Favors MI SIJF

- Significantly larger improvement with MI SIJF
  - Compared to conservative management (between-group difference: -60 mm, P < 0.001)
  - Compared to denervation (between-group difference: -45 mm, P < 0.001)

26

Pages 17-20, 25-27;  
Tables 5, 8

Abbreviations: CCS = controlled cohort study; CM = conservative management; MI SIJF = minimally invasive sacroiliac fusion; MID = minimally important difference; mos. = months; mm = millimeters; 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)

**2 RCT: INSITE, iMIA**  
⊕⊕⊕○ MODERATE  
Favors MI SIJF

- Significantly larger improvement with MI SIJF, between-group difference
  - -25.4 points (95% CI, -32.5 to -18.3, P < 0.0001) in 1 study
  - -19.8 points (95% CI NR, P < 0.0001) in other study

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Pages 17-20, 25-27;  
Tables 5, 8

Abbreviations: CI = confidence interval; CM = conservative management; MI SIJF = minimally invasive sacroiliac fusion; MID= minimally important difference; mos. = months; NR = not reported; RCT = randomized controlled trial

## MI SI Joint Fusion compared to CM [Physical Function]

### Change in physical function at 1 yr. (Oswestry Disability Index, MID 8 to 11)

**2 RCT: INSITE, iMIA**  
⊕○○○ VERY LOW  
Mixed findings

- Significantly larger improvement with MI SIJF, between-group difference -20.1 (P < 0.0001) in 1 study
- No difference for MI SIJF compared to conservative management in other study
  - Compared to crossovers: -1.1, 95% CI, -8.9 to 6.7, P = 0.78
  - Compared to non-crossovers: -0.4, 95% CI, -18.5 to 17.7, P = 0.97

### Threshold improvement in physical function at 2 yrs. (at least 15-point improvement on Oswestry Disability Index)

**2 RCT: INSITE, iMIA**  
⊕⊕○○ LOW  
Favors MI SIJF

- Significantly higher proportion of participants achieved threshold improvement with MI SIJF compared to CM
  - 64% vs. 24% (calculated RR 2.7, 95% CI, 1.5 to 4.7) in 1 study
  - 68% vs. 8% (calculated RR 9.1, 95% CI, 3.0 to 27.2) in other study (crossovers considered as failures)

28

Pages 17-20, 25-27;  
Tables 5, 8

Abbreviations: CI = confidence interval; CM = conservative management; MI SIJF = minimally invasive sacroiliac fusion; MID= minimally important difference; RCT = randomized controlled trial; RR = risk ratio; yrs. = years

## MI SI Joint Fusion compared to CM [Physical Function]

### Change in physical function at 6 mos. to 3.5 yrs. (Oswestry Disability Index MID 8 to 11)

**1 CCS: Vanaclocha**  
⊕○○○ VERY LOW  
Favors MI SIJF

- Significantly larger improvement with MI SIJF
  - Compared to conservative management (between-group difference: -24 points [P < 0.001])
  - Compared to denervation (between-group difference: -17 points [P < 0.001])

29

Pages 17-20, 25-27;  
Tables 5, 8

Abbreviations: CCS = controlled cohort study; CI = confidence interval; CM = conservative management; MI SIJF = minimally invasive sacroiliac fusion; MID = minimally important difference; mos. = months; yrs. = years

## 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], MID 0.18; SF-36, 0 [lowest QOL] to 100 [best QOL], MID 3)

**2 RCT: INSITE, iMIA**  
⊕⊕⊕○ MODERATE  
Favors MI SIJF

- Significantly larger improvement with MI SIJF compared to CM
  - EQ-5D between-group difference
    - 0.24 (95% CI, 0.16 to 0.32) in 1 study
    - 0.21 (95% CI NR, P < 0.0001) in other study
  - SF-36 calculated between group difference in 1 study
    - PCS 11.5 (95% CI, 8.1 to 14.9)
    - MCS 5.6 (95% CI, 1.8 to 9.4)

30

Pages 17-20, 25-27;  
Tables 5, 8

Abbreviations: CI = confidence interval; CM = conservative management; EQ-5D = EuroQOL measure of generic health status; MCS = mental component summary scale; MI SIJF = minimally invasive sacroiliac fusion; MID = minimally important difference; mos. = months; NR = not reported; PCS = physical component summary scale; QOL = quality of life; RCT = randomized controlled trial; SF-36 = short form survey

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

### Change in quality of life at 1 to 2 yrs. (EQ-5D, MID 0.18; SF-36, MID 3)

**2 RCT: INSITE, iMIA**

⊕⊕○○ LOW  
 Favors MI SIJF

- Significantly larger improvement with MI SIJF compared to CM
  - EQ-5D between-group difference
    - 0.22 (95% CI NR, P = 0.0009) at 1 yr. and 0.24 (95% CI NR, P < 0.001) at 2 yrs. in 1 study
    - 0.01 (P NR; crossovers) and 0.11 (P NR; non-crossovers) at 1 yr. in other study
  - SF-36 PCS calculated between-group difference in 1 study
    - 1.1 (P NR; crossovers) and 7.7 (P NR; non-crossovers) at 1 yr.

Abbreviations: CI = confidence interval; CM = conservative management; EQ-5D = EuroQOL measure of generic health status; MI SIJF = minimally invasive sacroiliac fusion; MID = minimally important difference; NR = not reported; PCS = physical component summary scale; QOL = quality of life; RCT = randomized controlled trial; SF-36 = short form survey; yrs. = years

31

Pages 17-20, 25-27;  
 Tables 5, 8

## MI SI Joint Fusion compared to CM [Opioid Use]

### Opioid use at 6 mos.

**1 RCT: INSITE**  
 ⊕○○○ VERY LOW  
 Favors MI SIJF

- Larger decrease in percentage of participants using opioids but not statistically significant
  - Proportion using decreased by 9% points among MI SIJF participants and increased 8% points among CM participants (P = 0.08)

### Opioid use at 1 to 2 yrs.

**2 RCTs: INSITE, iMIA**  
 ⊕○○○ VERY LOW  
 Favors MI SIJF

- Larger decrease in percentage of participants using opioids, but not statistically significant and somewhat ambiguously reported data
  - Use decreased by 16.6% among MI SIJF participants at 1 yr. and 20.3% by 2 yrs.; use decreased 8% among CM at 1 yr. but unclear which participants were included (crossovers, non-crossovers, or both)
  - Calculated -23% vs. -1.4% (calculated RR 0.75, 95% CI, 0.45 to 1.24) at 2 yrs. in the other study (LOCF approach for crossovers)

32

Pages 17-20, 25-27;  
 Tables 5, 8

Abbreviations: CI = confidence interval; CM = conservative management; LOCF = last observation carried forward; MI SIJF = minimally invasive sacroiliac fusion; mos. = months; RCT = randomized controlled trial; RR = risk ratio; yrs. = years

## MI SI Joint Fusion compared to CM [Opioid Use]

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

**1 CCS: Vanaclocha**  
 ⊕○○○ VERY LOW  
 Favors MI SIJF

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

33

Pages 17-20, 25-27;  
 Tables 5, 8

Abbreviations: CCS = controlled cohort study; CM = conservative management; mg = milligrams; MI SIJF = minimally invasive sacroiliac joint fusion; yrs. = years

## MI SI Joint Fusion compared to CM [Adverse Events]

### Adverse Events at 6 mos.

**2 RCTs: INSITE, iMIA**  
 ⊕○○○ VERY LOW  
 Favors CM

	Arm (N)	Total events	# events related to device/procedure	Mean # events/person	# severe events	# severe events related to device or procedure
INSITE	MI SIJF (102)	129	22	1.5	22	6
	CM (46)	49	5	1.3	8	1
	P value	NR	NR	0.2253	0.60	NR
iMIA	MI SIJF (52)	20	4	0.33	16	4
	CM (51)	17	0	0.38	11	0
	P value	NR	NR	0.6644	NR	NR

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Pages 17-20, 30-31;  
 Tables 5, 9

Abbreviations: CM = conservative management; MI SIJF = minimally invasive sacroiliac joint fusion; mos. = months; N = number of participants; NR = not reported; RCT = randomized controlled trial

## MI SI Joint Fusion compared to CM [Adverse Events]

### Adverse Events at 2 yrs.

**2 RCT: INSITE, iMIA**  
⊕○○○ VERY LOW  
Unable to determine  
directionality

- In one study
  - 55 severe events among 102 MI SIJF participants with followup (5 related to device or procedure)
  - 23 severe events among 46 CM participants (includes crossovers)
- In other study
  - 54 events among 52 MI SIJF participants; 4 related to device or procedure, and 39 considered severe
  - 47 events among 51 CM participants (includes crossovers); 3 related to device or procedure, and 27 considered severe

35

Pages 17-20, 30-31;  
Tables 5, 9

Abbreviations: CM = conservative management; MI SIJF = minimally invasive sacroiliac joint fusion; RCT = randomized controlled trial; yrs. = years

## MI SI Joint Fusion compared to CM [Adverse Events]

### Serious Adverse Events

**1 CCS: Vanaclocha**  
⊕○○○ VERY LOW  
No difference

- No serious adverse events reported in either group

36

Pages 17-20, 30-31;  
Tables 5, 9

Abbreviations: CCS = controlled cohort study; CM = conservative management; MI SIJF = minimally invasive sacroiliac joint fusion

## MI SI Joint Fusion compared to CM [Revision Surgery]

### Revision Surgery at 2 yrs.

**2 RCT: INSITE, iMIA**  
 ⊕⊕⊕○ MODERATE  
 Favors CM

- In one study
  - Incidence 3.4% among 89 MI SIJF participants with follow-up data
  - Incidence 2.6% among 39 CM participants who crossed over to surgery
- In other study
  - Incidence 3.8% among 52 MI SIJF participants with follow-up data
  - Incidence 4.8% among 21 CM participants who crossed over to surgery

**1 CCS: Vanaclocha**  
 ⊕○○○ VERY LOW  
 Favors CM

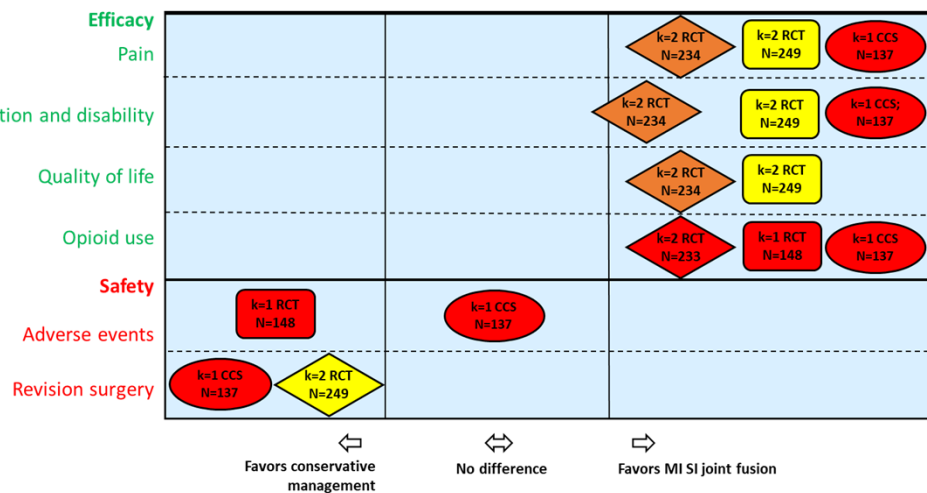
- No revision surgery reported among participants who received MI SIJF

37

Pages 17-20, 30-31;  
 Tables 5, 9

Abbreviations: CCS = controlled cohort study; CM = conservative management; MI SIJF = minimally invasive sacroiliac joint fusion; RCT = randomized controlled trial; yrs. = years

## Evidence Map – MI SI joint fusion compared to conservative management



38

Page 50; Figure 3

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

Study (Year) Risk of Bias Sponsor	Study Design	Key Parameters	Intervention Comparator
Ackerman (2014) Low SI-Bone	Comparative cost analysis	Payer perspective, 2012 USD Time horizon: 3 to 5 years Commercially insured, mean age 45.2 years	MI SIJF with iFuse Nonoperative care
Ackerman (2013) Low SI-Bone	Comparative cost analysis	Payer perspective, 2012 USD Time horizon: lifetime Medicare, starting age 70 with life expectancy age 84	MI SIJF with iFuse Nonoperative care
Blissett (2020) Low SI-Bone	Cost-effectiveness analysis	Payer perspective, 2018 GBP Time horizon: 5 years Utility measure: EQ-5D	MI SIJF with iFuse Stepped care PT/injections or RFA RFA only

39 Pages 44-45; Table 21

Abbreviations: CQ = cost question; EQ-5D = EuroQOL measure of generic health status; GBP = Great Britain pound; MI SIJF = minimally invasive sacroiliac joint fusion; PT = physical therapy; RFA = radiofrequency ablation; USD = United States dollars

## SI Joint Fusion compared to Nonoperative care [Cost] (continued)

Study (Year) Risk of Bias Sponsor	Study Design	Key Parameters	Intervention Comparator
Buysman (2018) High SI-Bone	Retrospective analysis of actual costs	Payer perspective, 2016 USD Time horizon: 1 year before and 1 year after MI SIJF Commercially insured, most patients age 45 to 64	Costs after MI SIJF Costs before MI SIJF
Cher (2016) Low SI-Bone	Cost-effectiveness analysis	Payer perspective, 2015 USD Time horizon: 5 years Utility measure: EQ-5D	MI SIJF with iFuse Nonoperative care

40 Pages 44-45; Table 21

Abbreviations: CQ = cost question; EQ-5D = EuroQOL measure of generic health status; MI SIJF = minimally invasive sacroiliac joint fusion; USD = United States dollars



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

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

1 CCA: Ackerman  
⊕○○○ VERY LOW

- MI SIJF with iFuse costs \$14,545 more over 3 years and \$6,137 more over 5 years

### Lifetime costs in a Medicare population

1 CCA: Ackerman  
⊕○○○ VERY LOW

- MI SIJF with iFuse costs \$3,358 less than nonoperative care

41

Pages 43-45; Tables  
20, 21

Abbreviations: CCA = comparative cost analysis; MI SIJF = minimally invasive sacroiliac joint fusion

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

### Cost-effectiveness over 5 years

2 CEA: Blissett, Cher  
⊕○○○ VERY LOW

- MI SIJF with iFuse costs range from \$2,697 to \$13,313 per QALY gained

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Pages 43-45; Tables  
20, 21

Abbreviations: CEA = cost-effectiveness analysis; MI SIJF = minimally invasive sacroiliac joint fusion; QALY = quality-adjusted life year

## Comparisons and Outcomes 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, SQ)

### MI SI joint fusion compared to open fusion

- EQ, SQ

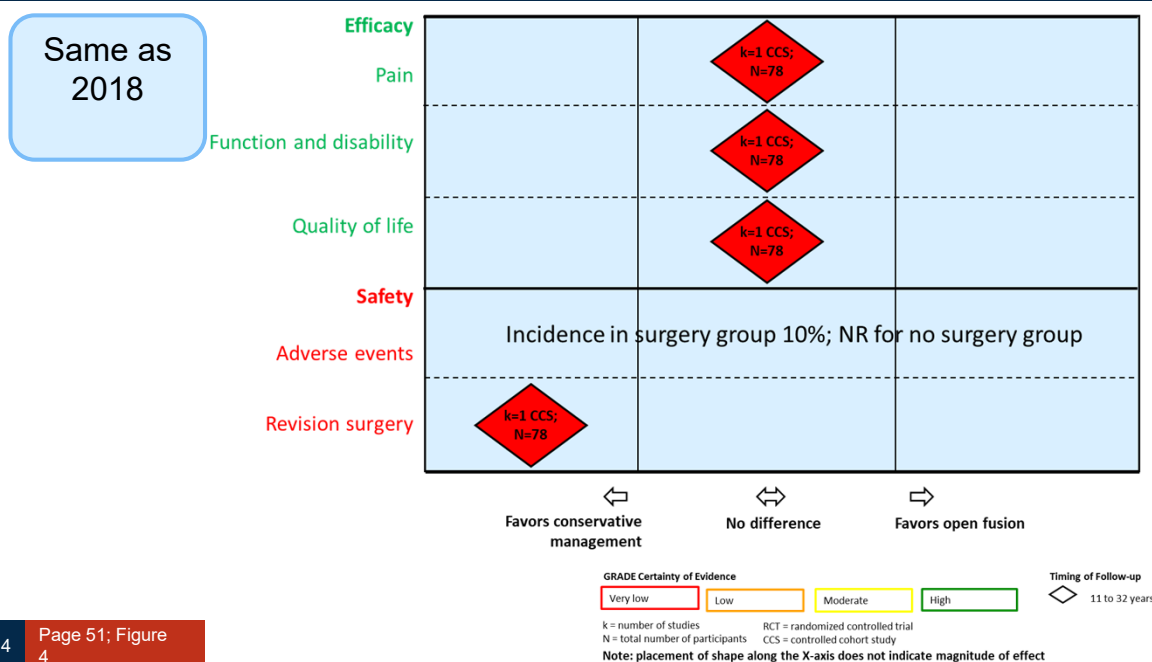
### Comparing alternative MI SI joint fusion procedures

- EQ, SQ

43

Abbreviations: CM = conservative management; CQ = cost question; EQ = efficacy question; MI = minimally invasive; SI = sacroiliac; SQ = safety question

## Evidence Map – Open SI joint fusion compared to conservative management



44

Page 51; Figure 4

## Comparisons and Outcomes 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, SQ)

### MI SI joint fusion compared to open fusion

- EQ, SQ

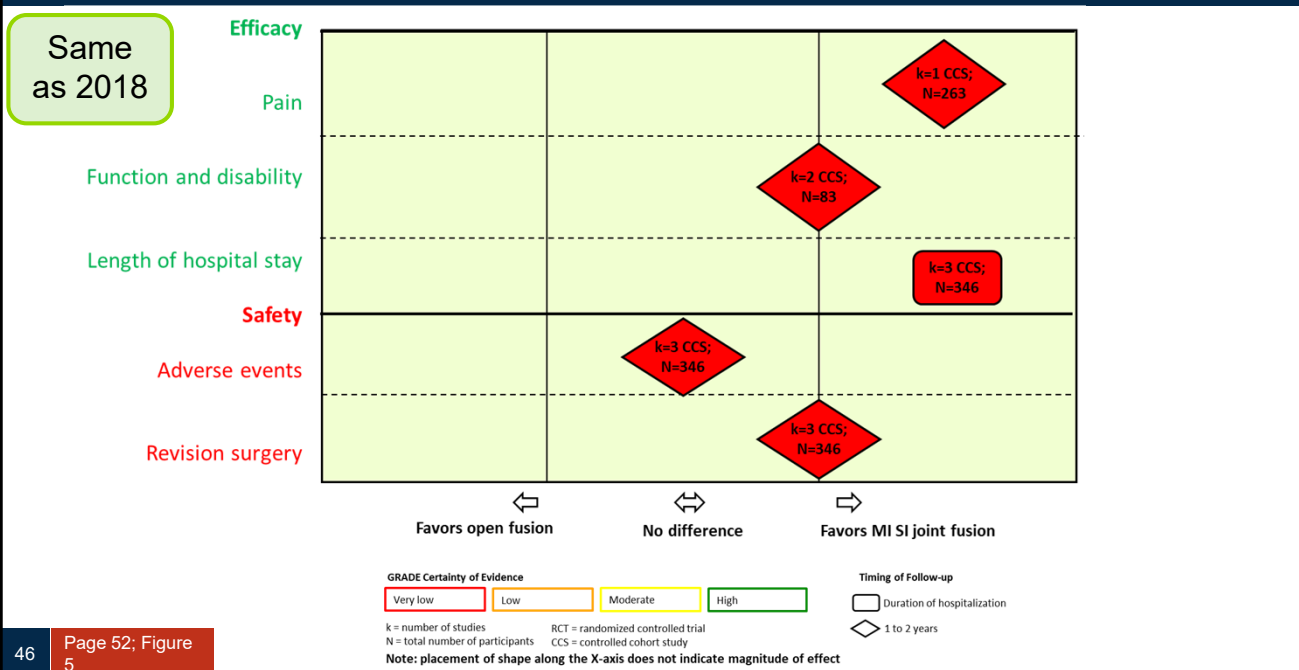
### Comparing alternative MI SI joint fusion procedures

- EQ, SQ

45

Abbreviations: CM = conservative management; CQ = cost question; EQ = efficacy question; MI = minimally invasive; SI = sacroiliac; SQ = safety question

## Evidence Map – MI SI joint fusion compared to open fusion



46

Page 52; Figure 5

## Comparisons and Outcomes 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,SQ)

### MI SI joint fusion compared to open fusion

- EQ, SQ

### Comparing alternative MI SI joint fusion procedures

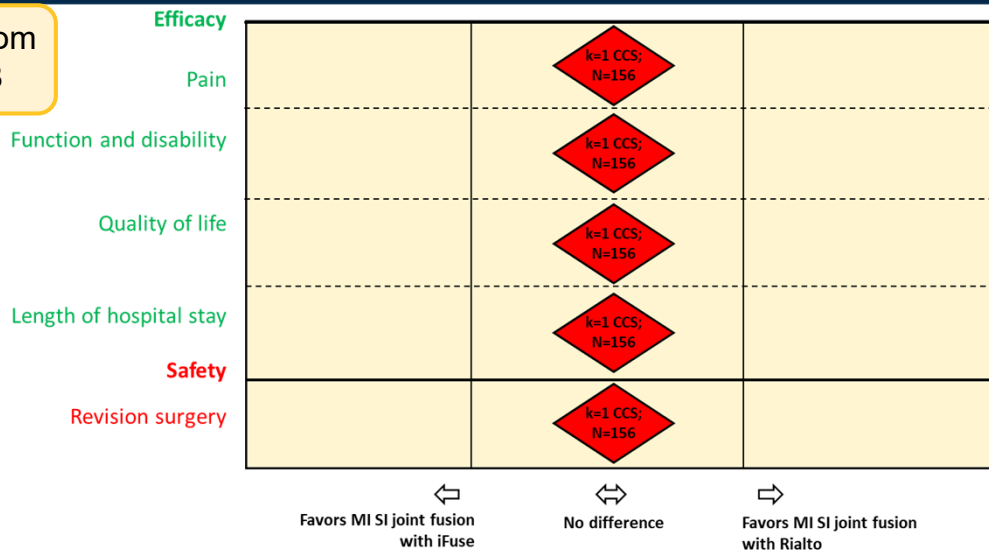
- EQ, SQ

47

Abbreviations: CM = conservative management; CQ = cost question; EQ = efficacy question; MI = minimally invasive; SI = sacroiliac; SQ = safety question

## Evidence Map – MI SI joint fusion with iFuse Implant System to Rialto Implant System

New from 2018



48

Pages 53,  
Figure 6

GRADE Certainty of Evidence: Very low, Low, Moderate, High. Timing of Follow-up: Up to 1 year. k = number of studies, N = total number of participants, RCT = randomized controlled trial, CCS = controlled cohort study. Note: placement of shape along the X-axis does not indicate magnitude of effect.

## Comparing Alternative MI SI Joint Fusion Procedures

Study (Year) Risk of Bias Sponsor	Study Design	Setting/ Time Period	Intervention (N analyzed) Comparator (N analyzed)
Spain (2017) Some concerns SI-Bone	CCS	Single U.S. center, NR	iFuse (263) Percutaneous fixation with screws (29)
Claus (2020) High Not reported	CCS	Single U.S. center, 2012 to 2018	Rialto (74) iFuse (82)

49 Pages 37-38; Table 16

Abbreviations: CCS = controlled cohort study; MI = minimally invasive; NR = not reported; N = number of participants; SI = sacroiliac; U.S. = United States

## iFuse compared to Rialto Implant Systems [Pain & Function]

### Change in pain at 6 mos. to 1 yr. (Visual Analog Scale, MID = 7 to 11)

1 CCS: Claus

⊕○○○ VERY LOW  
No difference

- No significant differences between Rialto and iFuse
  - Between-group difference at 6 mos.: 4.3 mm (95% CI, -8.7 to 17, P = 0.53)
  - Between-group difference at 1 yr.: -3.7 mm (95% CI, -23 to 15, P = 0.70)

### Change in physical function at 6 mos. to 1 yr. (Oswestry Disability Index, MID 8 to 11)

1 CCS: Claus

⊕○○○ VERY LOW  
No difference

- No significant differences between Rialto and iFuse
  - Between-group difference at 6 mos.: 3.0 (95% CI, -2.1 to 8.1, P = 0.25)
  - Between-group difference at 1 yr.: -2.1 (95% CI, -9.2 to 4.9, P = 0.55)

50 Pages 36, 38-39;  
Tables 14, 17

Abbreviations: CCS = controlled cohort study; CI = confidence interval; MI = minimally invasive; MID = minimally important difference; mos.= month; mm= millimeter; RR = relative risk; yr. = year

## iFuse compared to Rialto Implant Systems [QOL & Length of Stay]

### Change in quality of life at 6 mos. to 1 yr. (SF-12)

1 CCS: Claus

⊕○○○ VERY LOW  
 No difference

- No significant differences between Rialto and iFuse
  - Between-group difference at 6 mos.: 1.7 (95% CI, -1.5 to 4.9, P = 0.28)
  - Between-group difference at 1 yr.: 3.0 (95% CI, -0.48 to 6.5, P = 0.09)

### Length of stay

1 CCS: Claus

⊕○○○ VERY LOW  
 No difference

- No significant differences between Rialto (1.7 days) and iFuse (1.8 days) (P = 0.42)

51

Pages 36, 38-39;  
 Tables 14, 17

Abbreviations: CCS = controlled cohort study; CI = confidence interval; MI = minimally invasive; QOL = quality of life; mos. = months; SF-12 = short form survey; yr. = year

## iFuse compared to Alternative MI SI Joint Fusion Procedures [Safety]

### Revision Surgery (Compared to Rialto)

1 CCS: Claus

⊕○○○ VERY LOW  
 No difference

- No significant differences between Rialto (6.1%) and iFuse (2.4%)
  - Calculated ARD -5.7% (95% CI, -12.7% to -1.4%)
  - Calculated RR 0.30 (95% CI, 0.06 to 1.44)

### Revision Surgery at 2.8 to 4.6 yrs. (Compared to percutaneous screw fixation)

1 CCS: Spain

⊕○○○ VERY LOW  
 Favors iFuse

- Significantly fewer revisions with iFuse (4.6%) compared to screws (65.5%)
  - Calculated ARD -61.0% (95% CI, -78.4% to -43.5%)
  - Calculated RR 0.07 (95% CI, 0.04 to 0.13)

52

Pages 36-37, 40;  
 Tables 14, 15, 18

Abbreviations: ARD = adjusted risk difference; CCS = controlled cohort study; CI = confidence interval; MI = minimally invasive; RR = risk ratio; SI = sacroiliac; yrs. = years

## Safety Outcomes from Uncontrolled Studies

53

### Procedures Evaluated in Uncontrolled Studies

Procedure	Number of Studies
Open fusion	9 studies total: 2 studies using posterior approach 3 studies using anterior approach 1 study using anterior approach with symphysiodesis 1 study using Verral and Pitkin technique(bilateral) 1 study using modified Smith-Petersen technique 1 study using distraction interference arthrodesis
iFuse Implant System (triangular, titanium coated implants)	20 studies total: 19 studies using iFuse only; 1 study using iFuse or Samba
Slimmetry System (titanium cannulated and antirotational implants with surface roughness)	3 studies
Percutaneous fusion using hollow modular anchorage screw	3 studies
SI-LOK Sacroiliac Joint Fusion System	3 studies
Rialto system (cylindrical threaded implants)	1 study
INTERFIX system (single-threaded titanium cage filled with rhBMP-2)	1 study
Fusion using dual fibular dowel allografts	1 study
Fusion using threaded fusion cages	1 study
Various minimally invasive procedures based on CPT code 27279	1 study

54

Page 41; Table 19

Abbreviations: CPT = current procedural terminology; rhBMP-2 = recombinant human Bone Morphogenetic Protein-2

## 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 joint fusion (based on CPT code) from 2007 to 2014
  - Incidence of complications likely attributable to device or procedure was 13.2% at 90 days and 16.4% at 6 months
    - Most common complication: neuritis or radiculitis
    - Estimates are higher than what was observed in the 2 RCTs likely reflecting use in actual practice

55 Pages 41-43

Abbreviations: CPT = Current Procedural Terminology; MI = minimally invasive; RCT = randomized controlled trial; SI = sacroiliac

## Safety Outcomes from Uncontrolled Studies (continued)

- Among the 20 studies using iFuse
  - Incidence of adverse events ranges from 0% to 92%
  - Incidence of severe adverse events ranges from 0% to 46%
  - 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
      - 14,210 participants between 2015 and 2018: 3.1% incidence overall; 1.0% to 1.5% 1-year cumulative incidence (depending on device)
      - 11,388 participants between 2009 and 2014: 2.8% incidence overall
      - Similar to the incidence reported in trials

56 Pages 41-43



## Discussion

57

## Ongoing Studies

Sponsor	Description	Number of Participants	Completion Date
<b>Globus Medical, Inc.</b>	Uncontrolled trial of SI-LOK joint fixation system	55	11/2018
<b>Zyga Technology, Inc.</b>	Prospective, non-randomized postmarket study to collect data following implant of the SImmetry device	250	8/2020 (estimated)
<b>Evolve Restorative Center</b>	Prospective, multisite, single-arm study intended to collect clinical outcomes data associated with the treatment of sacroiliac disease with the LinQ fusion procedure	100	3/2022 (estimated)
<b>Oslo University Hospital</b>	Prospective, double-blind randomized controlled multicenter study examining treatment of sacroiliac pain using iFuse versus sham operation	60	4/2023 (estimated)

58

Pages 64-65;  
 Table 26

## Clinical Practice Guideline Synthesis

Year	Organization	AGREE-II Rating*	Recommendation
2020	International Society for the Advancement of Spine Surgery	4	Lateral MI SIJF is medically necessary when criteria met; dorsal MI SIJF not recommended
2020	North American Spine Society	4	No recommendation for/against (scope of their review was narrowly focused)
2018	National Institute for Clinical Excellence (U.K.)	4	Current evidence supports efficacy of iFuse (with criteria and caveats)
2017	National Institute for Clinical Excellence (U.K.)	4	Current evidence supports the efficacy and safety of MI SIJF (with criteria and caveats)

\*1 poorest quality; 7 highest quality

Two other CPGs (AGREE-II ratings of 3) in full report also conclude MI SIJF medically necessary when criteria are met.

59

Pages 55-57;  
Table 23

Abbreviations: AGREE-II = Appraisal of Guidelines for Research & Evaluation II; MI SIJF = minimally invasive sacroiliac joint fusion; U.K. = United Kingdom

## Payer Coverage

- CMS: No national coverage determination, but all 8 Medicare Administrative Contractors (MAC) do cover this procedure
- All commercial payers, except Kaiser Permanente of Washington, cover MI SI joint fusion when certain clinical criteria are met

Device-specific coverage  
**Vs.**  
 Procedure (MI SIJ Fusion) coverage

Payor	Coverage status
Medicare (NCD)	--
Medicaid	Covered in 44 states
Aetna	✓
Cigna	✓
Humana	✓
Kaiser	X
Noridian Healthcare Solutions (MAC)	✓
Premera	✓ (iFuse only)
Regence	✓ (iFuse only)
TRICARE	✓
UnitedHealthcare (Commercial)	✓
United Healthcare (Medicare Advantage)	✓

Notes: ✓ = covered; X = not covered; -- = no policy identified

60

Pages 57-64; Table 24

Abbreviations: CMS = Center for Medicare and Medicaid Services; MAC = Medicare Administrative Contractors; MI = minimally invasive; NCD = national coverage determination; SI = sacroiliac; vs. = versus

## Limitations of the Evidence Base

- All controlled studies of MI SI joint fusion evaluated the iFuse implant system, most were sponsored by the manufacturer, and unclear generalizability of findings to other devices/techniques since only 1 comparative effectiveness study of alternative devices
- Most studies were uncontrolled
  - Small sample sizes, heterogeneity in ascertainment, reporting, and followup times of adverse events and revision surgery
- Risk of bias limitations:
  - RCT evidence
    - Lack of blinding
    - Crossovers after 6 months
  - Controlled observational studies
    - Confounding and selection bias

## Limitations of this Health Technology Assessment

- Scope
  - English-language articles only
  - Did not use unpublished data or data presented only in conference abstracts
  - Excluded efficacy outcomes from uncontrolled studies
  - Did not use data from the FDA Manufacturer and User Facility Device Experience (MAUDE) database to assess safety
- Analysis
  - Did not GRADE the body of evidence from uncontrolled studies
  - Limitations of AGREE-II tool for appraising clinical practice guidelines

## Conclusion

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

### Minimally invasive SI joint fusion vs. conservative management

Short-term (up to 6 months)

- Reduces pain more
- Improves function/disability more
- Improves quality of life more
- Reduces opioid use
- Increases adverse events

Longer-term (6 months to 2 years)

- Reduces pain more
- Improves function/disability more
- Improves quality of life more
- Reduces opioid use
- Risk of revision surgery
- Is cost-effective over a 5 yr. horizon

GRADE Certainty of Evidence

Very low

Low

Moderate

High

63 Pages 50, 65-66

## 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. Rialto

- No difference in
  - Pain
  - Function/disability
  - Quality of life
  - Length of hospital stay
  - Revision surgery

### Minimally invasive SI joint fusion with iFuse vs. percutaneous screw fixation

- Reduces incidence of revision surgery

GRADE Certainty of Evidence

Very low

Low

Moderate

High

64 Pages 52, 65-66

## Additional Slides

65

## Risk Factors

- History of serious pelvic trauma
- Leg length discrepancies
- Gait abnormalities
- Persistent strain/low-grade trauma (i.e., running)
- Scoliosis
- Pregnancy
- Prior spine surgery (especially lumbar spine fusion)

66 Page 1

## Physical exam test accuracy

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

Clinical Test	Sensitivity (95% CI)	Specificity (95% CI)
Fortin finger test (1 study)	76% (65 to 85)	47% (35 to 57)
Thigh thrust test (pooled analysis)	91% (79 to 97)	66% (53 to 77)
Compression test (pooled analysis)	63% (47 to 77)	69% (57 to 80)
3 or more positive tests (pooled analysis)	85% (75 to 92)	76% (68 to 84)

Studies varied in threshold of pain relief required for a positive reference test (range 50% to 80% pain relief).

67

Pages 48-49;  
Table 22

Abbreviations: CI = confidence interval; SI = sacroiliac

## Policy Context for Washington

- The original topic was selected by the state in 2018 because of:
  - High concerns for safety
  - High concerns for efficacy
  - High concerns for cost
- The topic was selected for re-review because of:
  - Signal search report conducted in 2020 suggested new evidence
  - Petition for re-review
  - Public comments received on the topic

68

Page 7

## GRADE interpretation

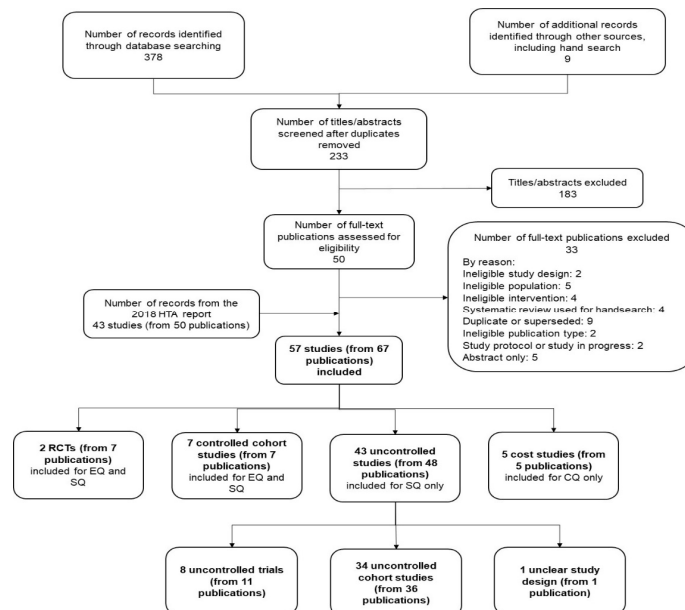
Grade	Definition
<b>High</b>	<b>We are very confident that the estimate of effect lies close to the true effect for this outcome.</b> The body of evidence has few or no deficiencies. We believe that the findings are stable, that is, another study would not change the conclusions.
<b>Moderate</b>	<b>We are moderately confident that the estimate of effect lies close to the true effect for this outcome.</b> The body of evidence has some deficiencies. We believe that the findings are likely to be stable, but some doubt remains.
<b>Low</b>	<b>We have limited confidence that the estimate of effect lies close to the true effect for this outcome.</b> 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.
<b>Very Low</b>	<b>We have very limited confidence that the estimate of effect lies close to the true effect for this outcome.</b> 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.

69

Page 13-14,  
Table 3

Abbreviations: GRADE = Grading of Recommendations, Assessment, Development, and Evaluation

## Literature Flow Diagram



70

Page 15, Figure 2

## Outcome Measures-Reference Slide

Measure	Domain	Range and Direction	MID
Visual Analog Scale (VAS)	Pain	0 (no pain) to 100 (worst pain)	7 to 11
Oswestry Disability Index (ODI)	Physical Function	0 (no disability) to 100 (complete disability)	8 to 11
Euroqol 5 item (EQ-5D)	Quality of life	0 (death) to 1 (perfect health)	0.18
Short Form-36 (SF-36)	Quality of life	0 (worst QOL) to 100 (best QOL)	3

Abbreviations: EQ-5D = EuroQOL measure of generic health status; MID = minimally important difference; ODI = Oswestry Disability Index; QOL = quality of life; SF-36 = short form survey; VAS = Visual Analog Scale

71 Page 16; Table 4

## Before and After MI SI Joint Fusion [Low back pain related costs]

Buysman (2018) U.S.

	Before Surgery	After Surgery	P Value
Mean costs (SD)	\$16,803 (\$32,144)	\$13,297 (\$28,122)	<i>P</i> =0.095
Median costs (IQR)	\$5,849 (\$2,423 to \$14,287)	\$2,269 (\$606 to \$8,855)	<i>P</i> <0.001

Abbreviations: IQR = interquartile range; MI = minimally invasive; SD = standard deviation; SI = sacroiliac; U.S. = United States

72 Pages 44-45, Table 21



## Open SI Joint Fusion compared to No Surgery

Study (Year) Risk of Bias Funding	Study Design	Setting/ Time Period	Intervention (N analyzed) Comparator (N analyzed)
Kibsgard (2013) High Various <sup>1</sup>	CCS (retrospective)	Single center in Norway, 1977 to 1998	Open fusion with dorsal approach (50) No surgery (28)

<sup>1</sup> Norwegian Foundation for Health and Rehabilitation and Sophies Minde Ortopedi AA.  
 Abbreviations: CCS = controlled cohort study; N = number of participants; SI = sacroiliac

73

Pages 22-23;  
Table 7

## Open Fusion compared to No Surgery [Pain, Function, QOL]

### Pain at 11 to 23 yrs. (Visual Analog Scale, 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, 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.

74

Pages 20-21, 25-26;  
Tables 6, 8

Abbreviations: CCS = controlled cohort study; CI = confidence interval; MID = minimally important difference; mm = millimeter; SF-36 = short form survey; QOL = quality of life; yrs. = years

## Open Fusion compared to No Surgery [Safety]

### Adverse events

1 CCS: Kibsgard

⊕○○○ VERY LOW  
 No difference

- Incidence 10% among 58 open surgery participants
- Adverse events not reported in the no surgery group

### Revision surgery

1 CCS: Kibsgard

⊕○○○ VERY LOW

- Incidence 8.4% of joints among 50 open surgery participants
- No revision surgery reported among participants who received no surgery

## MI SI Joint Fusion compared to Open Fusion

Study (Year) Risk of Bias Sponsor	Study Design	Setting/ Time Period	Intervention (N analyzed) Comparator (N analyzed)
Ledonio (2014) High Not reported	CCS (retrospective)	Single U.S. center, 2006 to 2011	iFuse (22) Open anterior ilioinguinal approach (22)
Ledonio (2014) High Not reported	CCS (retrospective)	2 U.S. centers, 2006 to 2012	iFuse (17) Open anterior ilioinguinal approach (22)
Smith (2013) High Not reported	CCS (retrospective)	7 U.S. centers, 1994 to 2012	iFuse (114) Open posterior approach (149)

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

### Change in pain over 2 yrs. (Visual Analog Scale, MID = 7 to 11)

**1 CCS: Smith**

⊕○○○ VERY LOW  
Favors MI SIJF

- Significantly larger improvement for MI SIJF; repeated measures between-group difference -30 mm (95% CI, -40 to -21)

### Change in physical function at 13 to 15 mos. (Oswestry Disability MID 8 to 11)

**2 CCS: Ledonio, Ledonio**

⊕○○○ VERY LOW  
Mixed Findings

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

77

Pages 31-34;  
Tables 10, 12

Abbreviations: CCS = controlled cohort study; CI = confidence interval; MID = minimally important difference; MI SIJF = minimally invasive sacroiliac fusion; mm = millimeters; mos. = months; yrs. = years

## MI SI Joint Fusion compared to Open Fusion [Length of Stay]

### Length of Hospital Stay

**3 CCS: Smith, Ledonio, Ledonio**

⊕○○○ VERY LOW  
Favors MI SIJF

- Statistically significantly shorter length of stay for MI SIJF participants
  - Range of differences was 1.3 to 3.8 days across studies

78

Pages 31-34;  
Tables 10, 12

Abbreviations: CCS = controlled cohort study; MI SIJF = minimally invasive sacroiliac fusion

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

### Adverse Events

**3 CCS: Smith, Ledonio, Ledonio**  
 ⊕○○○ VERY LOW  
 No difference

- No intraoperative complications reported in any study
- Frequency of postoperative complications similar between groups and ranged from 14% to 35% across groups and studies

### Revision Surgery

**3 CCS: Smith, Ledonio, Ledonio**  
 ⊕○○○ VERY LOW  
 Mixed findings

- Infrequent revision in both groups in two studies (1 to 2 per group)
- Significantly fewer revisions with MI SIJF in third study
  - Calculated ARD -40.8% (95% CI, -49.5% to -32.1%)
  - Calculated RR 0.08 (95% CI, 0.03 to 0.21)

79

Page 31-32, 35;  
 Table 10, 13

Abbreviations: ARD = adjusted risk difference; CCS = controlled cohort study; CI = confidence interval; MI SIJF = minimally invasive sacroiliac joint fusion; RR = risk ratio

## Conclusion (continued)

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

### Open fusion vs. conservative management

- No long-term (11 to 32 years) difference in
  - Pain ⊕○○○
  - Function/disability ⊕○○○
  - Quality of life ⊕○○○
  - Adverse events ⊕○○○
  - Incidence of adverse events 10% ⊕○○○
  - Incidence of revision surgery 8.4% ⊕○○○

GRADE Certainty of Evidence

Very low Low Moderate High

80

Page 50-51, 65-66

## Conclusion (continued)

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

### Minimally invasive SI joint fusion vs. open fusion

- Reduces pain more ⊕○○○
- Has uncertain impact on function/disability ⊕○○○
- Has shorter hospital length of stay ⊕○○○
- Results in no difference in adverse events ⊕○○○
- Has uncertain impact on incidence of revision surgery ⊕○○○

GRADE Certainty of Evidence

81

Pages 49, 52,  
65-66

Very low

Low

Moderate

High

# 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<sup>1</sup> as expressed by the following standards<sup>2</sup>:

- 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<sup>3</sup>:

- 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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**Based on Legislative mandate: RCW 70.14.100(2).**

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<sup>4</sup> 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.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

<sup>4</sup> Based on GRADE recommendation: <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)

Safety outcomes	Importance of outcome	Safety evidence/ confidence in evidence
Adverse events		
Revision surgery		

Efficacy – effectiveness outcomes	Importance of outcome	Efficacy / Effectiveness evidence
Pain		
Function		
QOL		
Patient satisfaction		
Opioid use		
Return to work		

Cost outcomes	Importance of outcome	Cost evidence
Cost		
Cost effectiveness		

Special population / Considerations outcomes	Importance of outcome	Special populations/ Considerations evidence
Age		
Race		
Gender		
Ethnicity		

**For safety:**

Is there sufficient evidence that the technology is safe for the indications considered?

Unproven (no)	Less (yes)	Equivalent (yes)	More in some (yes)	More in all (yes)

**For efficacy/ effectiveness:**

Is there sufficient evidence that the technology has a meaningful impact on patients and patient care?

Unproven (no)	Less (yes)	Equivalent (yes)	More in some (yes)	More in all (yes)

**For cost outcomes/ cost-effectiveness:**

Is there sufficient evidence that the technology is cost-effective for the indications considered?

Unproven (no)	Less (yes)	Equivalent (yes)	More in some (yes)	More in all (yes)

**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

[see page 64 of the final report]

- **Centers for Medicare and Medicaid Services (CMS) National Coverage Determination**

There is no national coverage determination.

**Clinical Practice Guidelines**

[see page 55 of the final report]

Title/ Organization Guideline Quality	Year Published	Excerpts of Findings	Rating/ Quality of Evidence Narrative Assessment
<p><i>Musculoskeletal Program Clinical Appropriateness Guidelines: Sacroiliac Joint Fusion</i> <sup>84</sup></p> <p>Quality rating: 3 out of 7</p> <p>AIM Specialty Health</p>	<p>2020</p>	<p>Percutaneous/minimally invasive SI joint fusion with iFuse system may be considered medically necessary when all of the following criteria are met:</p> <ul style="list-style-type: none"> <li>• Persistent pain more than 6 months that interferes with function and has documented VAS of 50 mm or greater and ODI of 30 or greater</li> <li>• Failure of 6 months of conservative management</li> <li>• Confirmation of pain (typical pattern, positive Fortin test, absence of tenderness of similar severity elsewhere in the pelvic region, at least 3 positive provocative physical exam tests, and other causes excluded)</li> <li>• Imaging indicates evidence of injury/degeneration and excludes other sources</li> <li>• At least 75% pain reduction following image-guided SI joint injection on 2 separate occasions</li> </ul>	<p>Not reported</p>
<p><i>Clinical Guidelines Spine Surgery</i> <sup>85</sup></p> <p>Quality rating: 3 out of 7</p> <p>eviCore</p>	<p>2020</p>	<p>Minimally invasive SI joint fusion using titanium triangular implants (SI BONE [iFuse Implant]) for the treatment of lumbopelvic pain originating from the SI joint is considered medically necessary when all of the following are met:</p> <ul style="list-style-type: none"> <li>• Performed by an orthopedic surgeon or neurosurgeon with specific training in percutaneous sacroiliac joint fusion surgical techniques</li> <li>• Presence of nonradiating lumbopelvic pain caudal to L5, buttock, hip, and/or groin pain without radiation into the leg(s) that impairs physical activities</li> <li>• SI joint pain interfering with activities of daily living</li> <li>• Confirmation of pain (typical pattern, positive Fortin test, absence of tenderness of similar severity elsewhere in the pelvic region, at least 3 positive provocative physical exam tests, and other causes excluded)</li> <li>• At least 75% pain reduction following image-guided SI joint injection on 2 separate occasions</li> <li>• Failure of 6 months of conservative management</li> <li>• Documentation of nicotine-free status</li> <li>• Absence of unmanaged significant behavioral health disorders</li> </ul>	<p>Not reported</p>

Title/ Organization Guideline Quality	Year Published	Excerpts of Findings	Rating/ Quality of Evidence Narrative Assessment
		<ul style="list-style-type: none"> <li>Imaging indicates evidence of injury/degeneration and excludes other sources</li> </ul>	
<p><i>International Society for the Advancement of Spine Surgery Policy 2020 Update—Minimally Invasive Surgical Sacroiliac Joint Fusion (for Chronic Sacroiliac Joint Pain): Coverage Indications, Limitations, and Medical Necessity</i><sup>4</sup></p> <p>Quality rating: 4 out of 7</p> <p>International Society for the Advancement of Spine Surgery</p>	2020	<p>Lateral transiliac minimally invasive surgical SI joint fusion may be considered medically necessary when all of the following criteria are met:</p> <ul style="list-style-type: none"> <li>Persistent pain more than 6 months that does not respond to an appropriate course of nonsurgical treatment</li> <li>Significant SI joint pain that affects quality of life or limits activities of daily living</li> <li>Confirmation of pain (at least 3 positive provocative physical exam tests and confirmed with a diagnostic SI joint block [≥50% pain reduction following fluoroscopically guided diagnostic intra-articular SI joint block])</li> <li>Imaging indicates evidence of injury/degeneration and excludes other sources</li> </ul> <p>Minimally invasive surgical posterior (dorsal) SI joint fusion is not recommended because the procedure is, as of yet, unproven. There is limited published clinical evidence supporting the safety and effectiveness of posterior (dorsal) minimally invasive surgical SI joint fusion.</p>	<p>Lateral minimally invasive surgical SI joint fusion is based on 2 RCTs, 5 multicenter prospective studies, and several comparative retrospective case series. Quality of evidence assessment not performed.</p> <p>Posterior (dorsal) minimally invasive surgical SI joint fusion is based on 1 multicenter prospective study and a small number of case series. Quality of evidence assessment not performed.</p>
<p><i>Diagnosis and Treatment of Low Back Pain</i><sup>86</sup></p> <p>North American Spine Society (NASS)</p> <p>Quality rating: 4 out of 7</p>	2020	<p>The systematic review yielded no studies to address the question regarding SI joint fusion compared to medical intervention for patients with SI joint dysfunction and no prior lumbar surgery and no lower limb pain. Therefore, a definitive statement favoring SI fusion over medical/interventional treatment in patients suffering with low back pain from an SI source cannot be made.</p>	<p>The systematic review of the literature yielded no studies with patients with no prior lumbar surgery and no lower limb pain to adequately address these questions.</p>
<p><i>iFuse for treating chronic sacroiliac joint pain</i><sup>83</sup></p> <p>National Institute for Health and Care Excellence (United Kingdom)</p> <p>Quality rating: 4 out of 7</p>	2018	<p>“The case for adopting the iFuse implant system to treat chronic sacroiliac joint pain is supported by the evidence. Using iFuse leads to improved pain relief, better quality of life and less disability compared with non-surgical management. iFuse should be considered for use in people with a confirmed diagnosis of chronic sacroiliac joint pain (based on clinical assessment and a positive response to a diagnostic injection of local anesthetic in the sacroiliac joint) and whose pain is inadequately controlled by non-surgical management.”</p>	<p>Based on 2 RCTs (n=251), 2 comparative studies, and 8 noncomparative studies. Quality of evidence assessment not performed.</p>
<p><i>Minimally invasive sacroiliac joint fusion surgery for chronic</i></p>	2017	<p>“Current evidence on safety and efficacy of minimally invasive sacroiliac (SI) joint fusion</p>	<p>Based on 2 RCTs, 2 SRs, 3 prospective cohort studies, and 2</p>

Title/ Organization Guideline Quality	Year Published	Excerpts of Findings	Rating/ Quality of Evidence Narrative Assessment
<p><i>sacroiliac pain - Intervention Procedure Guidance 578</i><sup>82</sup></p> <p>National Institute for Health and Care Excellence (United Kingdom)</p> <p>Quality rating: 4 out of 7</p>		<p>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.</p> <p>Patients having this procedure should have a confirmed diagnosis of unilateral or bilateral SI joint dysfunction due to degenerative sacroiliitis or SI joint disruption.</p> <p>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.”</p>	<p>retrospective case series. Quality of evidence assessment not performed.</p>