

**Health Technology Clinical Committee
Findings and Decision**

Topic: Sacroiliac joint fusion
Meeting date: January 18, 2019
Final adoption: May 17, 2019

Meeting materials and transcript are available on the [HTA website](#).

Number and coverage topic:

20190118A – Sacroiliac joint fusion*

HTCC coverage determination:

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**.

HTCC reimbursement determination:

Limitations of coverage: N/A

Non-covered indicators: N/A

* 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.

Agency contact information:

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

Final

HTCC coverage vote and formal action:

Committee decision

Based on the deliberations of key health outcomes the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee decided that the current evidence on sacroiliac joint fusion is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for the use of sacroiliac joint fusion. The committee considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to not cover minimally invasive or open sacroiliac joint fusion for sacroiliac chronic joint pain related to degenerative sacroiliitis and/or sacroiliac joint disruption for adults 18 years old and older.

	Not covered	Covered under certain conditions	Covered unconditionally
Sacroiliac joint fusion	11	0	0

Discussion

The committee reviewed and discussed the available studies for use of sacroiliac joint fusion for chronic sacroiliac joint pain related to degenerative sacroiliitis and/or sacroiliac joint disruption. Details of study design, inclusion criteria, outcomes and other factors affecting study quality were discussed. 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.

Limitations

N/A

Action

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). There is no Medicare NCD for sacroiliac joint fusion for sacroiliac joint pain related to degenerative sacroiliitis and/or sacroiliac joint disruption.

The committee discussed clinical guidelines identified for sacroiliac joint fusion from the following organizations:

- National Institute for Health and Care Excellence (NICE) *Minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain - Intervention Procedure Guidance 578, (2017)*
- AIM Specialty Health *Musculoskeletal Program Clinical Appropriateness Guidelines: Sacroiliac Joint Fusion, (2018)*

The committee's determination is not consistent with the NICE and AIM guidance. The HTCC determination included consideration of local, clinical expert considerations related to the complexities of revision surgeries, concerns related to diffusion and uncertainty of evidence for safety and cost-effectiveness. The quality of evidence assessment was either not performed or not reported for these guidelines.

The committee chair directed HTA staff to prepare a findings and decision document on use of sacroiliac joint fusion for public comment to be followed by consideration for final approval at the next public meeting.

Health Technology Clinical Committee Authority:

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that takes public input at all stages.

Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Director.

Key Questions and Background

Sacroiliac Joint Fusion

Background

Sacroiliac joint fusion is a surgical treatment sometimes used to address pain that may be originating from the joint between bones in the spine and hip (sacrum and ilium). The sacroiliac joint (SIJ) is a diarthrodial joint with two surfaces and a fibrous capsule containing synovial fluid.^{1,2} Functionally, the SIJ supports the upper body and dampens forces related to walking; numerous ligaments support the joint and provide it with strength but also limit its mobility. The clinical presentation of SIJ pain and dysfunction varies from patient to patient but buttock pain extending into the posterolateral thigh is the most common pattern.¹ The etiology of SIJ pain and dysfunction is thought to be related to axial loading and rotation, but studies suggest the entire SIJ complex (i.e., capsule, ligaments, subchondral bone) is innervated with nociceptors providing multiple locations for pain.¹⁻³ Aside from major trauma events resulting in serious pelvic injury, several predisposing factors for SIJ pain and dysfunction exist, including leg length discrepancies, gait abnormalities, persistent strain/low-grade trauma (i.e., running), scoliosis, pregnancy, and prior spine surgery (particularly spinal fusion).¹

SIJ pain and dysfunction is thought to be the primary source of pain for between 10 to 30 percent of cases of mechanical low back pain.^{3,4} However, estimating an accurate prevalence of SIJ pain and dysfunction is challenging because no universally accepted gold standard for diagnosis exists. Debate exists about the accuracy of history and physical exam for establishing a diagnosis of SIJ pain and dysfunction; thus, the current reference standard for diagnosis is anesthetic and provocative SIJ injections.³ However, this diagnostic standard is invasive, expensive, and may not be widely available as a primary diagnostic modality. Thus, provocative physical exam tests (e.g., distraction, FABER, etc.) may have a role as part of a step-wise approach to diagnosis.⁴ Imaging is generally not helpful in establishing a diagnosis, but may be helpful in ruling out other etiologies of low back pain.³

Several treatments for SIJ pain and dysfunction are available. These include pelvic belts and girdles; analgesics and anti-inflammatory medication; physical therapy to address strength, flexibility, or biomechanical deficits; manual manipulation; therapeutic joint injection; prolotherapy; radiofrequency denervation or ablation; and fusion surgery.^{2,4-6} Surgery, specifically SIJ fusion, is typically reserved for persons who fail conservative and less invasive treatments. Fusion of the SIJ can be performed as an open procedure, or since the late 1990s as a minimally-invasive procedure using proprietary surgical systems consisting of two to three specialized implants or screws inserted directly into the SIJ through small incisions under imaging guidance.^{2,4}

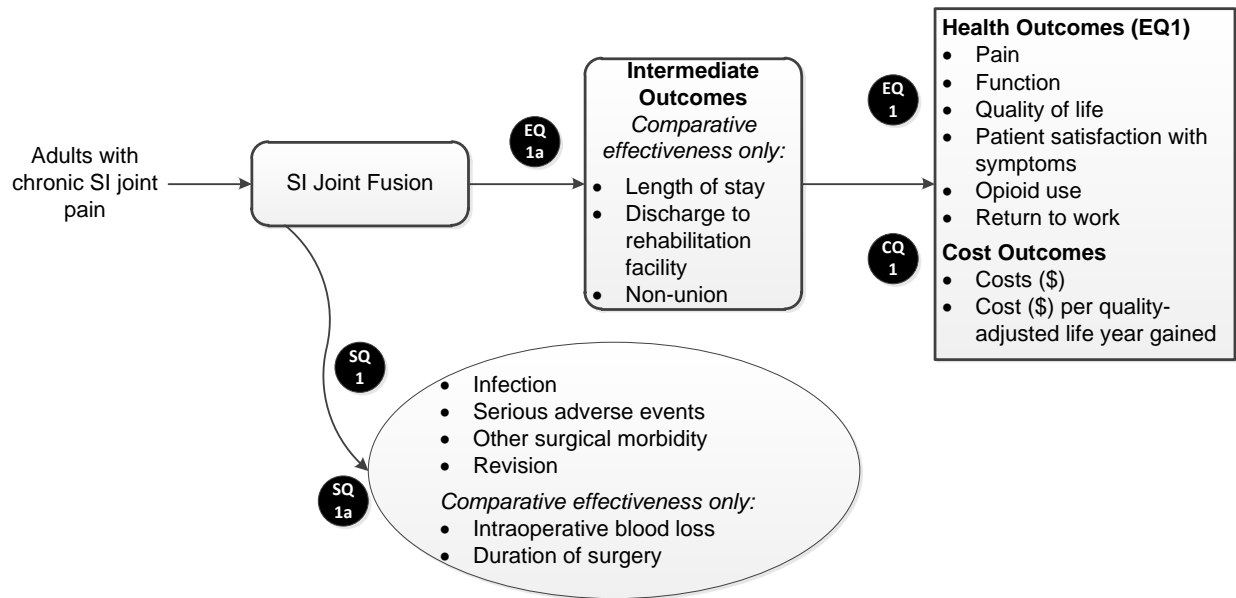
Policy Context

The State of Washington Health Care Authority selected SIJ Fusion as a topic for a health technology assessment because of high concerns for safety, efficacy, and cost.

Scope of this HTA

The analytic framework (**Figure 1**), research questions, and key study selection criteria are listed in this section.

Figure 1. Analytic Framework Depicting Scope of Proposed Health Technology Assessment



Efficacy Question 1 (EQ 1). What is the effectiveness and comparative effectiveness of sacroiliac joint fusion surgery on health outcomes?

Efficacy Question 1a (EQ 1a). What is the comparative effectiveness of various sacroiliac joint fusion surgeries on intermediate efficacy outcomes?

Safety Question 1 (SQ 1). What is the safety of sacroiliac joint fusion surgery?

Safety Question 1a (SQ 1a). What is the comparative effectiveness of various sacroiliac joint fusion surgeries on intermediate safety outcomes?

Cost Question 1 (CQ 1). What is the cost and cost-effectiveness of sacroiliac joint fusion surgery?

In addition, we will address the following contextual questions:

Contextual Questions:

1. What are the recommended ways to diagnose SI joint pain or disruption, and what is the accuracy of various diagnostic tests?
2. What is known about the frequency of various diagnostic approaches to SI joint pain or disruption in usual clinical practice?

Contextual questions will not be systematically reviewed and are not shown in the analytic framework.

Study Selection Criteria

Table 1 provides the study selection criteria we will use to include studies in the HTA; these criteria are organized by population, intervention, comparator, outcomes, timing, setting, and study design and risk of bias criteria.

Table 1. Proposed Population, Intervention, Comparator, Outcome, Timing, and Setting for HTA on Sacroiliac Joint Fusion

Domain	Included	Excluded
Population	<ul style="list-style-type: none"> • Adults age 18 years and over with chronic (≥ 3 months) SI joint pain related to degenerative sacroiliitis and/or SI joint disruption • Diagnosis based on positive findings on provocative physical exam tests and reduction/amelioration of pain after local SI joint injection or leakage of contrast from joint. 	<ul style="list-style-type: none"> • Less than 18 years old • Low back pain of other etiology (e.g., radiculopathy, neurogenic claudication) • SI joint pain related to recent major trauma or fracture, infection, cancer, or sacroiliitis associated with inflammatory arthropathies. • Patients without clear diagnosis of SI joint pain/disruption or diagnosis based on criteria other than those listed in the inclusion column.
Intervention	<ul style="list-style-type: none"> • Open SI joint fusion • Minimally-invasive SI joint fusion 	Other spine surgeries, non-surgical interventions to treat SI Joint pain
Comparator	<ul style="list-style-type: none"> • Active Treatment <ul style="list-style-type: none"> - Physical therapy - Chiropractic therapy - Acupuncture - Analgesic and anti-inflammatory medication - Orthotics (e.g., pelvic girdles, belts) - Therapeutic joint injection - Neurotomy/denervation (e.g., radiofrequency ablation) • Placebo or no treatment 	<i>EQ1 and 1a:</i> No comparator group
Outcomes	<p><i>EQ1:</i></p> <ul style="list-style-type: none"> • Pain • Physical functioning • Quality of life • Patient satisfaction with symptoms • Opioid use • Return to work <p><i>EQ1a only:</i></p> <ul style="list-style-type: none"> • Length of stay • Non-union • Discharge to acute or sub-acute rehabilitation facility <p><i>SQ1:</i></p> <ul style="list-style-type: none"> • Infection • Serious adverse events (e.g., cardiovascular events, thromboembolism, etc.) • Other surgical morbidity • Revision <p><i>SQ1a only:</i></p> <ul style="list-style-type: none"> • Intraoperative blood loss • Duration of surgery <p><i>CQ1:</i></p> <ul style="list-style-type: none"> • Costs 	<p>Other outcomes not specifically listed as eligible.</p> <p>Pain, quality of life, and functional outcomes not measured using valid and reliable instruments or scales.^{7,8}</p>

Table 1. Proposed Population, Intervention, Comparator, Outcome, Timing, and Setting for HTA on Sacroiliac Joint Fusion

Domain	Included	Excluded
	<ul style="list-style-type: none"> • Cost per quality-adjusted life year gained • Cost per disability-adjusted life year gained 	
Setting	Inpatient or outpatient settings in countries categorized as “very high” on UN Human Development Index. ⁹	Studies conducted in countries not categorized as “very high” on UN Human Development index.
Study Design and Risk of Bias Rating	<p><i>EQ1 and 1a and SQ1a:</i> RCTs, CCTs, CCSs, and SRs of RCTs, CCTs, or CCSs with similar scope as this HTA.</p> <p><i>SQ1:</i> RCTs, CCTs, CCSs, uncontrolled studies (e.g., case series, single-arm clinical trials or cohort studies), and SRs of any study type with similar scope as this HTA.</p> <p><i>CQ1:</i> Cost analyses, CEA, CUA, or CBA performed from the societal or payor perspective</p>	<p>Editorials, comments, letters, narrative reviews, case reports.</p> <p><i>EQ1 and 1a and SQ1a only:</i> uncontrolled studies (e.g., case series, single-arm clinical trials or cohort studies)</p>
Language and Time Period	English, no restrictions on time period included.	Languages other than English.

CBA= cost-benefit analysis; CCS = controlled cohort study, CCT=controlled clinical trial; CEA=cost-effectiveness analysis; CUA=cost-utility analysis; HTA=health technology assessment; RCT=randomized controlled trial; SR=systematic review; UN=United Nations.

Public comment and response

Two public comments were received. In response to these comments, an additional outcome “discharge to acute or subacute rehabilitation facility” has been added as an intermediate outcome for EQ1a. Please refer to the “Response to Public Comments on Draft Key Questions” document for complete details.

References

1. Cohen SP, Chen Y, Neufeld NJ. Sacroiliac joint pain: a comprehensive review of epidemiology, diagnosis and treatment. *Expert Rev Neurother.* 2013;13(1):99-116. doi: 10.1586/ern.12.148
2. Ou-Yang DC, York PJ, Kleck CJ, Patel VV. Diagnosis and Management of Sacroiliac Joint Dysfunction. *Journal of Bone and Joint Surgery-American Volume.* 2017;99(23):2027-36. doi: 10.2106/jbjs.17.00245
3. Simopoulos TT, Manchikanti L, Singh V, et al. A systematic evaluation of prevalence and diagnostic accuracy of sacroiliac joint interventions. *Pain Physician.* 2012;15(3):E305-44.
4. Bina RW, Hurlbert RJ. Sacroiliac Fusion: Another "Magic Bullet" Destined for Disrepute. *Neurosurg Clin N Am.* 2017;28(3):313-20. doi: 10.1016/j.nec.2017.02.001

5. Cher D. Rates reported by Schoell et al. are of questionable validity. *Spine Journal*. 2017;17(1):158-. doi: 10.1016/j.spinee.2016.09.006
6. Barrick EF, O'Mara JW, Lane HE, 3rd. Iliosacral screw insertion using computer-assisted CT image guidance: a laboratory study. *Comput Aided Surg*. 1998;3(6):289-96. doi: 10.1002/(sici)1097-0150(1998)3:6<289::Aid-igs2>3.0.Co;2-6
7. Vavken P, Ganal-Antonio AK, Quidde J, Shen FH, Chapman JR, Samartzis D. Fundamentals of Clinical Outcomes Assessment for Spinal Disorders: Clinical Outcome Instruments and Applications. *Global Spine J*. 2015;5(4):329-38. doi: 10.1055/s-0034-1396046
8. Department of Health and Human Services. Patient-Reported Outcomes Measurement Information System (PROMIS). <http://www.healthmeasures.net/explore-measurement-systems/promis>. 2017. Accessed November 8, 2017.
9. United Nations Development Programme. Human Development Index. Website. <http://hdr.undp.org/en/composite/HDI>. 2016. Accessed October 15, 2017.