

## 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.<sup>1,2</sup> 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.<sup>1</sup> 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.<sup>1-3</sup> 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).<sup>1</sup>

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.<sup>3,4</sup> 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.<sup>3</sup> 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.<sup>4</sup> Imaging is generally not helpful in establishing a diagnosis, but may be helpful in ruling out other etiologies of low back pain.<sup>3</sup>

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.<sup>2,4-6</sup> 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.<sup>2,4</sup>

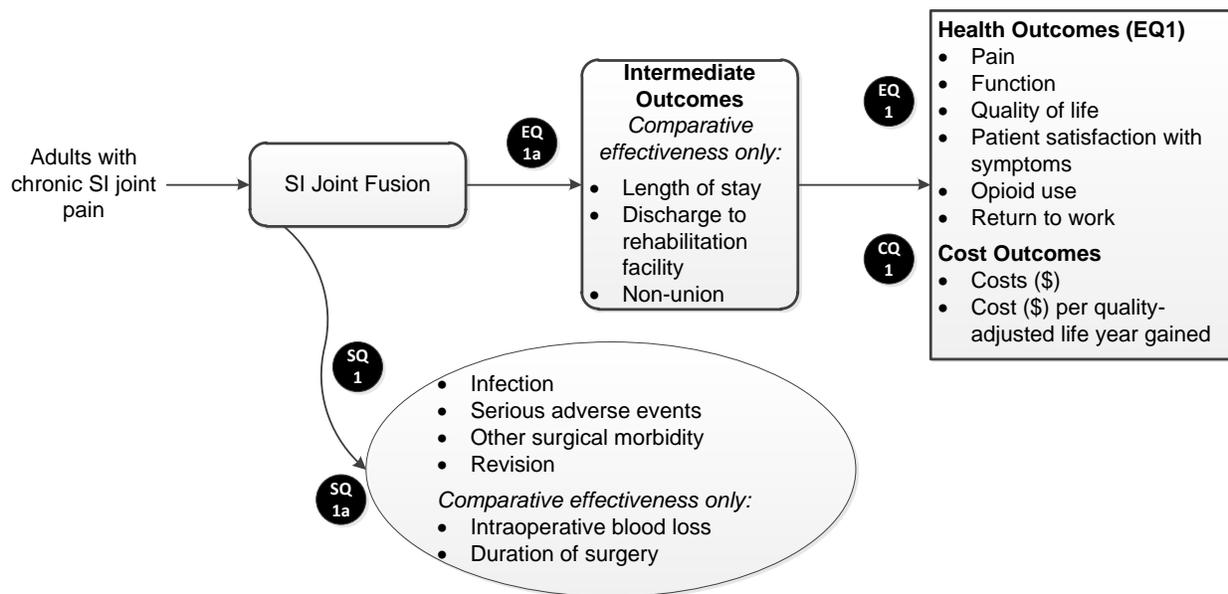
**Policy Context**

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
<b>Population</b>	<ul style="list-style-type: none"> <li>• Adults age 18 years and over with chronic (≥3 months) SI joint pain related to degenerative sacroiliitis and/or SI joint disruption</li> <li>• 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.</li> </ul>	<ul style="list-style-type: none"> <li>• Less than 18 years old</li> <li>• Low back pain of other etiology (e.g., radiculopathy, neurogenic claudication)</li> <li>• SI joint pain related to recent major trauma or fracture, infection, cancer, or sacroiliitis associated with inflammatory arthropathies.</li> <li>• Patients without clear diagnosis of SI joint pain/disruption or diagnosis based on criteria other than those listed in the inclusion column.</li> </ul>
<b>Intervention</b>	<ul style="list-style-type: none"> <li>• Open SI joint fusion</li> <li>• Minimally-invasive SI joint fusion</li> </ul>	Other spine surgeries, non-surgical interventions to treat SI Joint pain
<b>Comparator</b>	<ul style="list-style-type: none"> <li>• Active Treatment                             <ul style="list-style-type: none"> <li>- Physical therapy</li> <li>- Chiropractic therapy</li> <li>- Acupuncture</li> <li>- Analgesic and anti-inflammatory medication</li> <li>- Orthotics (e.g., pelvic girdles, belts)</li> <li>- Therapeutic joint injection</li> <li>- Neurotomy/denervation (e.g., radiofrequency ablation)</li> </ul> </li> <li>• Placebo or no treatment</li> </ul>	<i>EQ1 and 1a:</i> No comparator group
<b>Outcomes</b>	<p><i>EQ1:</i></p> <ul style="list-style-type: none"> <li>• Pain</li> <li>• Physical functioning</li> <li>• Quality of life</li> <li>• Patient satisfaction with symptoms</li> <li>• Opioid use</li> <li>• Return to work</li> </ul>	<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.<sup>7,8</sup></p>

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

	<p><i>EQ1a only:</i></p> <ul style="list-style-type: none"> <li>• Length of stay</li> <li>• Non-union</li> <li>• Discharge to acute or sub-acute rehabilitation facility</li> </ul> <p><i>SQ1:</i></p> <ul style="list-style-type: none"> <li>• Infection</li> <li>• Serious adverse events (e.g., cardiovascular events, thromboembolism, etc.)</li> <li>• Other surgical morbidity</li> <li>• Revision</li> </ul> <p><i>SQ1a only:</i></p> <ul style="list-style-type: none"> <li>• Intraoperative blood loss</li> <li>• Duration of surgery</li> </ul> <p><i>CQ1:</i></p> <ul style="list-style-type: none"> <li>• Costs</li> <li>• Cost per quality-adjusted life year gained</li> <li>• Cost per disability-adjusted life year gained</li> </ul>	
<b>Setting</b>	Inpatient or outpatient settings in countries categorized as “very high” on UN Human Development Index. <sup>9</sup>	Studies conducted in countries not categorized as “very high” on UN Human Development index.
<b>Study Design and Risk of Bias Rating</b>	<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>
<b>Language and Time Period</b>	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

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