

<b>Medical Benefit</b>		<b>Effective Date:</b> 07/01/18	<b>Next Review Date:</b> 03/21
<b>Preauthorization</b>	Yes	<b>Review Dates:</b> 09/09, 05/10, 05/11, 01/12, 01/13, 03/13, 01/14, 09/14, 09/15, 09/16, 09/17, 03/18, 03/19, 03/20	

***Preauthorization is required.***

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Populations	Interventions	Comparators	Outcomes
Individuals: • With suspected sacroiliac joint pain	Interventions of interest are: • Diagnostic sacroiliac joint block	Comparators of interest are: • Standard of care	Relevant outcomes include: • Test validity • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With sacroiliac joint pain	Interventions of interest are: • Therapeutic corticosteroid injections	Comparators of interest are: • Physical therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With sacroiliac joint pain	Interventions of interest are: • Radiofrequency ablation	Comparators of interest are: • Conservative therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With sacroiliac joint pain	Interventions of interest are: • Sacroiliac joint fixation/fusion with a triangular implant	Comparators of interest are: • Conservative therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With sacroiliac joint pain	Interventions of interest are: • Sacroiliac joint fixation/fusion with a cylindrical threaded implant	Comparators of interest are: • Conservative therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity

**DESCRIPTION**

Sacroiliac joint (SIJ) arthrography using fluoroscopic guidance with an injection of an anesthetic has been explored as a diagnostic test for SIJ pain. Duplication of the patient's pain pattern with the injection of contrast medium suggests a sacroiliac etiology, as does relief of chronic back pain with injection of local anesthetic. Treatment of SIJ pain with corticosteroids, radiofrequency ablation (RFA), stabilization, or minimally invasive SIJ fusion has also been explored.

**SUMMARY OF EVIDENCE****DIAGNOSTIC**

For individuals who have suspected SIJ pain who receive a diagnostic sacroiliac block, the evidence includes systematic reviews. Relevant outcomes are test validity, symptoms, functional outcomes, quality of life (QOL), medication use, and treatment-related morbidity. Current evidence is conflicting on the diagnostic utility of SIJ blocks. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical input obtained in 2014 supported the use of controlled diagnostic blocks with at least 75% pain reduction for diagnosis of sacroiliac pain. Based on clinical input and the established use of injections to diagnose pain in other joints, controlled diagnostic (two blocks with anesthetics of different duration) may be considered medically necessary for the diagnosis of SIJ pain.

**THERAPEUTIC**

For individuals who have SIJ pain who receive therapeutic corticosteroid injections, the evidence includes small randomized controlled trials (RCTs) and case series. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. In general, the literature on injection therapy of joints in the back is of poor quality. Results from two small RCTs showed that therapeutic SIJ steroid injections were not as effective as other active treatments. Larger trials, preferably using sham injections, are needed to determine the degree of benefit of corticosteroid injections over placebo. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical input obtained in 2014 supported the use of corticosteroids for the treatment of SIJ pain. Based on clinical input and the established use of injections to treat pain in other joints, therapeutic (corticosteroid) injections may be considered medically necessary for the treatment of SIJ pain.

For individuals who have SIJ pain who receive RFA, the evidence includes four small RCTs using different radiofrequency applications and case series. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. For RFA with a cooled probe, the two small RCTs reported short-term benefits, but these are insufficient to determine the overall effect on health outcomes. The RCT on palisade RFA of the SIJ did not include a sham control. Another sham-controlled randomized trial showed no benefit from RFA. Further high-quality controlled trials are needed to compare this procedure in defined populations with sham control and alternative treatments. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have SIJ pain who receive SIJ fixation/fusion with a triangular implant, the evidence includes two nonblinded RCTs of minimally invasive fusion and two case series with more than 85% follow-up at two to three years. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. Both RCTs reported superior short-term results for fusion, however, a preferable design for assessing pain outcomes would be independent, blinded assessment of outcomes or, when feasible, a sham-controlled trial. Longer-term follow-up from these RCTs has indicated that the results obtained at six months persist to two years. An additional cohort study and case series, with sample sizes ranging from 45 to 149 patients and low dropout rates (less than 15%), have also shown reductions in pain and disability at two years. One

small case series showed outcomes that persisted to five years. The cohort studies and case series are consistent with the durability of treatment benefit. Analysis of an insurance database reported an overall incidence of complications to be 16.4% at six months and the cumulative revision rate at four years of 3.54%. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Clinical input obtained in 2017 supports that the following indication provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice:

- Use of fusion/stabilization of the sacroiliac joint using percutaneous and minimally invasive techniques for carefully selected patients as outlined in statements from the North American Spine Society.

For individuals who have SIJ pain who receive SIJ fusion/fixation with a cylindrical threaded implant, the evidence includes a prospective cohort. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. The prospective cohort study will follow patients for two years following implantation of slotted screws filled with autologous bone. Results at one year are consistent with findings from the studies using a triangular implant. However, longer follow-up and controlled trials are needed to evaluate this type of implant. The evidence is insufficient to determine the effects of the technology on health outcomes.

## POLICY

Arthrography of the sacroiliac joint is considered **investigational**.

Radiofrequency denervation of the sacroiliac joint is considered **investigational**.

Sacroiliac (SI) joint injection *using fluoroscopic guidance\** may be **medically necessary** in the absence of significant lumbar spine (LS) disease and/or hip disease which may cause back, buttock or hip pain, if ALL of the following have been done:

- History and physical findings, including three or more positive provocation tests (see Policy Guidelines), AND
- A trial of physical therapy/exercise therapy/chiropractic treatment for four to six weeks with no improvement, AND
- A trial of nonsteroidal anti-inflammatory medications (NSAIDS) for four to six weeks with no improvement.

SI joint injection *using fluoroscopic guidance\** may be **medically necessary**, in the presence of significant lumbar spine disease and/or hip disease which may cause back, buttock or hip pain, if ALL of the following have been done:

- History and physical findings, including three or more positive provocation tests (see Policy Guidelines), AND
- A trial of physical therapy/exercise therapy/chiropractic treatment for four to six weeks with no improvement, AND
- A trial of anti-inflammatory medications (NSAIDS) for four to six weeks with no improvement, AND
- Epidural spinal injection (ESI) if significant LS spine findings for which the injection is indicated or lumbar spine surgery if indicated. After therapy, patient must have persistence of pain or a component of pain attributable to possible SI disease rather than LS spine disease, AND/OR
- Intra-articular injection of hip or hip surgery if indicated. After therapy, patient must have persistence of pain or a component of pain attributable to possible SI disease rather than hip disease.

If the above criteria are not met, then sacroiliac joint injection is considered **investigational**.

Sacroiliac joint injection performed without fluoroscopic guidance is considered **investigational**.

Minimally invasive fixation/fusion of the sacroiliac joint using a titanium triangular implant may be considered **medically necessary** when ALL of the following criteria have been met:

- Pain is at least five on a zero to 10 rating scale that impacts quality of life or limits activities of daily living; AND
- There is an absence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders (e.g., fibromyalgia); AND
- Patients have undergone and failed a minimum six months of intensive nonoperative treatment that must include medication optimization, activity modification, bracing, and active therapeutic exercise targeted at the lumbar spine, pelvis, sacroiliac joint, and hip, including a home exercise program; AND
- Pain is caudal to the lumbar spine (L5 vertebra), localized over the posterior sacroiliac joint, and consistent with sacroiliac joint pain; AND
- A thorough physical examination demonstrates localized tenderness with palpation over the sacral sulcus (Fortin's point) in the absence of tenderness of similar severity elsewhere; AND
- There is a positive response to a cluster of three provocative tests (e.g., thigh thrust test, compression test, Gaenslen sign, distraction test, Patrick test, posterior provocation test); AND
- Diagnostic imaging studies include ALL of the following:
  - Imaging (plain radiographs and computed tomography or magnetic resonance imaging) of the sacroiliac joint excludes the presence of destructive lesions (e.g., tumor, infection) or inflammatory arthropathy of the sacroiliac joint; AND
  - Imaging of the pelvis (anteroposterior plain radiograph) rules out concomitant hip pathology; AND
  - Imaging of the lumbar spine (computed tomography or magnetic resonance imaging) is performed to rule out neural compression or other degenerative condition that can be causing low back or buttock pain; AND
  - Imaging of the sacroiliac joint indicates evidence of injury and/or degeneration; AND
- There is at least a 75% reduction in pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular sacroiliac joint injection on two separate occasions; AND
- A trial of a therapeutic sacroiliac joint injection (i.e., corticosteroid injection) has been performed at least once.

Fixation/fusion of the sacroiliac joint for the treatment of back pain presumed to originate from the sacroiliac joint is considered **investigational** when the above criteria are not met and with any other devices not listed above.

#### **POLICY GUIDELINES**

\*Sacroiliac joint injections must be done *with fluoroscopic guidance* as not using guidance results in a successful injection only 22% of the time.

**Note:** To ensure the integrity of results, other diagnostic and therapeutic injections (such as ESI) should not be administered at the same time as a diagnostic or therapeutic SI joint injection.

This protocol does not address treatment of pain in the sacroiliac joint due to infection, trauma, or neoplasm.

SIJ fixation/fusion with a triangular implant is a technically demanding procedure and should only be done by

surgeons who have specific training and expertise in minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac joint pain and who regularly use image-guidance for implant placement.

Pain provocation tests include:

#### COMPRESSION TEST

With the patient in a side-lying position, downward pressure is applied to the uppermost iliac crest, directed toward the opposite iliac crest. It is intended to stretch the posterior sacroiliac ligaments and compress the anterior SI joint. Pain in the SI joint is felt to represent a positive test. But this test has a sensitivity and specificity of only about 60 – 70%.

#### THIGH THRUST TEST

This is more sensitive (~90%) but has similar specificity to the compression test. With the patient supine, the hip is flexed to 90° and the knee is bent. The examiner applies posterior shearing stress to the SI joint through the femur. Excessive adduction of the hip is avoided, as combined flexion and adduction is normally painful.

#### GAENSLEN'S TEST

With the patient supine, the hip is maximally flexed on one side, and the opposite hip is extended. This maneuver stresses both SI joints simultaneously by counterrotation at the extreme range of motion. This test also stresses the hip joints and stretches the femoral nerve on the side of hip extension, so care is taken to ensure normal hip findings and the absence of neurologic conditions affecting the femoral nerve.

#### DISTRACTION TEST

This test is performed with the patient supine. A posterior and lateral force is applied to both anterior superior iliac spines to stretch the anterior sacroiliac ligaments and synovium.

#### PATRICK'S SIGN

Patrick's sign is elicited by stressing the hip and SI joint by flexion, abduction, and external rotation of the hip. A positive test reproduces back or buttock pain, whereas groin pain is more indicative of hip joint pathology.

### MEDICARE ADVANTAGE

Sacroiliac (SI) joint injections would be considered **medically necessary** for the diagnosis and/or treatment of chronic low back pain that is considered to be secondary to suspected sacroiliac joint dysfunction. (See Medicare Advantage Policy Guidelines)

Diagnostic blocks of a sacroiliac joint can be **medically necessary** to determine whether it is the source of low back pain. (See Medicare Advantage Policy Guidelines)

Therapeutic sacroiliac (SI) joint injections of an anesthetic and/or steroid to block the joint for immediate, and potentially long lasting, pain relief are considered **medically necessary** if it is determined that the SI joint is the source of pain in the lower back.

If previous diagnostic or therapeutic SI injections of an anesthetic and/or steroid to block the joint for immediate, and potentially long lasting, pain relief have not effectively relieved the pain, further injections would **not be considered medically necessary**.

Minimally-invasive surgical (MIS) fusion of the sacroiliac (SI) joint is considered **medically necessary** when ALL of the following criteria are met:

- Have moderate to severe pain with functional impairment and pain persists despite a minimum six months of intensive nonoperative treatment that must include medication optimization, activity modification, bracing, and active therapeutic exercise targeted at the lumbar spine, pelvis, SIJ and hip including a home exercise program
- Patient's report of typically unilateral pain that is caudal to the lumbar spine (L5 vertebrae), localized over the posterior SIJ, and consistent with SIJ pain
- A thorough physical examination demonstrating localized tenderness with palpation over the sacral sulcus (Fortin's point, i.e., at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine or PSIS) in the absence of tenderness of similar severity elsewhere (e.g., greater trochanter, lumbar spine, coccyx) and that other obvious sources for their pain do not exist
- Positive response to a cluster of three provocative tests (e.g., thigh thrust test, compression test, Gaenslen's test, distraction test, Patrick's sign, posterior provocation test)
- Absence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders (e.g., fibromyalgia)
- Diagnostic imaging studies that include ALL of the following:
  - Imaging (plain radiographs and a CT or MRI) of the SI joint that excludes the presence of destructive lesions (e.g., tumor, infection), fracture, traumatic SIJ instability, or inflammatory arthropathy that would not be properly addressed by percutaneous SIJ fusion
  - Imaging of the pelvis (AP plain radiograph) to rule out concomitant hip pathology
  - Imaging of the lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that can be causing low back or buttock pain
- At least 75 percent reduction of pain for the expected duration of two anesthetics (on separate visits each with a different duration of action), and the ability to perform previously painful maneuvers, following an image-guided, contrast-enhanced intra-articular SIJ injection
- A trial of at least one therapeutic intra-articular SIJ injection (i.e., corticosteroid injection).

Radiofrequency ablation used for sacroiliac joint pain is considered **investigational** whether performed using traditional, cooled, or pulsed radiofrequency.

#### MEDICARE ADVANTAGE POLICY GUIDELINES

Diagnostic and therapeutic injections of the SI joint would not likely be performed unless conservative therapy and noninvasive treatments (i.e., rest, physical therapy, NSAIDs, etc.) have failed.

Arthropathy (joint disease) is diagnosed through a double-comparative local anesthetic blockade of the joint by the intra-articular injection of a small volume of local anesthetics of different durations of actions. A positive response should demonstrate initial pain relief greater than or equal to ( $\geq$ ) 75-100% and the ability to perform previously painful maneuvers. Steroids may be injected in addition to the local anesthetic.

SI joint arthrography and/or therapeutic injection of an anesthetic/steroid are only appropriate when imaging confirmation of intra-articular needle positioning with applicable radiological and/or fluoroscopic procedures have been performed.

## BACKGROUND

### SACROILIAC JOINT PAIN

Similar to other structures in the spine, it is assumed the sacroiliac joint (SIJ) may be a source of low back pain. In fact, before 1928, the SIJ was thought to be the most common cause of sciatica. In 1928, the role of the intervertebral disc was elucidated, and from that point forward, the SIJ received less research attention.

#### Diagnosis

Research into SIJ pain has been plagued by a lack of a criterion standard to measure its prevalence and against which various clinical examinations can be validated. For example, SIJ pain is typically without any consistent, demonstrable radiographic or laboratory features and most commonly exists in the setting of morphologically normal joints. Clinical tests for SIJ pain may include various movement tests, palpation to detect tenderness, and pain descriptions by the patient. Further confounding the study of the SIJ is that multiple structures, (e.g., posterior facet joints, lumbar discs) may refer pain to the area surrounding the SIJ.

Because of inconsistent information obtained from history and physical examination, some have proposed the use of image-guided anesthetic injection into the SIJ for the diagnosis of SIJ pain. Treatments being investigated for SIJ pain include prolotherapy (see the Prolotherapy Protocol), corticosteroid injection, radiofrequency ablation, stabilization, and arthrodesis. Some procedures have been referred to as SIJ fusion but may be more appropriately called fixation due to little to no bridging bone on radiographs. Devices for SIJ fixation/fusion that promote bone ingrowth to fixate the implants include a triangular implant (iFuse Implant System) and cylindrical threaded devices (Rialto, Simmetry, Silex, SambaScrew, SI-LOK). Some devices also have a slot in the middle where autologous or allogeneic bone can be inserted. This added bone is intended to promote the fusion of the SIJ.

## REGULATORY STATUS

A number of radiofrequency generators and probes have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. In 2005, the SInergy® (Halyard; formerly Kimberly-Clark), a water-cooled single-use probe, was cleared by the FDA, listing the Baylis Pain Management Probe as a predicate device. The intended use is in conjunction with a radiofrequency generator to create radiofrequency lesions in nervous tissue. FDA product codes: GXD, GXI.

A number of percutaneous or minimally invasive fixation/fusion devices have been cleared for marketing by the FDA through the 510(k) process. They include the iFuse® Implant System (SI Bone), the Rialto™ SI Joint Fusion System (Medtronic), SIJ-Fuse (Spine Frontier), the Simmetry® Sacroiliac Joint Fusion System (Zyga Technologies), Silex™ Sacroiliac Joint Fusion System (XTANT Medical), SambaScrew® (Orthofix), and the SI-LOK® Sacroiliac Joint Fixation System (Globus Medical). FDA product code: OUR.

## RELATED PROTOCOLS

Facet Joint Denervation

Percutaneous Vertebroplasty and Sacroplasty

Prolotherapy

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Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary

Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

## REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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51. National Government Services, Inc. (Primary Geographic Jurisdiction 06 & K - Illinois, Minnesota, Wisconsin, Connecticut, New York - Entire State, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont) Local Coverage Determination (LCD): Pain Management (L33622), Revision Effective Date for services performed on or after 10/01/2019.