

Protocol

Diagnosis and Treatment of Sacroiliac Joint Pain

Medical Benefit		Effective Date: 01/01/17	Next Review Date: 09/17
Preauthorization	Yes	Review Dates: 09/09, 05/10, 05/11, 01/12, 01/13, 03/13, 01/14, 09/14, 09/15, 09/16	

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 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 fusion	Comparators of interest are: • Conservative therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity

Description

Sacroiliac joint arthrography using fluoroscopic guidance with injection of an anesthetic has been explored as a diagnostic test for sacroiliac joint 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 sacroiliac joint pain with corticosteroids, radiofrequency ablation (RFA), stabilization, or minimally invasive arthrodesis has also been explored.

Summary of Evidence

The evidence for therapeutic corticosteroid injections in patients who have sacroiliac joint pain includes small randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life,

medication use, and treatment-related morbidity. In general, the literature regarding injection therapy on joints in the back is of poor quality. Results from the small trials on therapeutic sacroiliac joint injections are insufficient to permit conclusions on the effect of this procedure. Larger trials, preferably using sham injections, are needed to determine the degree of benefit over placebo. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for radiofrequency ablation in patients who have sacroiliac joint pain includes two small RCTs using a cooled radiofrequency probe and an RCT that used palisade sacroiliac joint radiofrequency neurotomy. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. For RFA with a cooled probe, the two small RCTs report short-term benefit, but these are insufficient to determine the overall effect on health outcomes. The RCT on palisade RFA of the sacroiliac joint did not include a sham-control. Further high-quality controlled trials are needed that compare this procedure in defined populations with placebo and with alternative treatments. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for sacroiliac joint fusion in patients who have sacroiliac joint pain includes one RCT on minimally invasive fusion, one cohort study comparing open and minimally invasive sacroiliac fusion, and a number of case series. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The RCT reported superior short-term results for fusions, but there is a high potential for bias in this nonblinded study with subjective outcome measures. Follow-up of all patients will continue through 24 months. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy

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 (see Policy Guidelines), AND
- A trial of physical therapy/exercise therapy/chiropractic 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 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 (SI) joint injection is considered **investigational**.

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

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

Fusion/stabilization of the sacroiliac joint for the treatment of back pain presumed to originate from the SI joint is considered **investigational**, including but not limited to percutaneous and minimally invasive techniques.

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.

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:
 - o 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
 - o Imaging of the pelvis (AP plain radiograph) to rule out concomitant hip pathology
 - o 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.

No more than four therapeutic injections (interlaminar or caudal epidural, transforaminal epidural, paravertebral facet joint or nerve, and/or sacroiliac joint) per region per patient per year are anticipated for the majority of patients.

Background

Similar to other structures in the spine, it is assumed that the sacroiliac joint may be a source of low back pain. In fact, prior to 1928, the sacroiliac joint 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 sacroiliac joint received less research attention.

Research into sacroiliac joint pain has been thwarted by any criterion standard to measure its prevalence and against which various clinical examinations can be validated. For example, sacroiliac joint 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 sacroiliac joint pain may include various movement tests, palpation to detect tenderness, and pain descriptions by the patient. Further confounding the study of the sacroiliac joint is that multiple structures, such as posterior facet joints and lumbar discs, may refer pain to the area surrounding the sacroiliac joint.

Because of inconsistent information obtained from history and physical examination, some have proposed the use of image-guided anesthetic injection into the sacroiliac joint for the diagnosis of sacroiliac joint pain. Treatments being investigated for sacroiliac joint pain include prolotherapy, corticosteroid injection and radiofrequency ablation, stabilization, and arthrodesis.

Regulatory Status

A number of radiofrequency generators and probes have been cleared for marketing through the U.S. Food and Drug Administration's (FDA) 510(k) process. In 2005, the SInergy® (Halyard; formerly Kimberly Clark) a water-cooled single-use probe, was cleared by 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 code: GXD.

Several percutaneous or minimally invasive fixation/fusion devices have received marketing clearance by the FDA. These include the SI-FIX Sacroiliac Joint Fusion System (Medtronic), the IFUSE Implant System (SI Bone), the SImmetry Sacroiliac Joint Fusion System (Zyga Technologies), Silex™ Sacroiliac Joint Fusion System (X-Spine Systems) and the SI-LOK Sacroiliac Joint Fixation System (Globus Medical). FDA Product Code: OUR.

Related Protocols

Facet Joint Denervation

Percutaneous Vertebroplasty and Sacroplasty

Prolotherapy

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment 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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