**Protocol**

**Diagnosis and Treatment of Sacroiliac Joint Pain**

<table>
<thead>
<tr>
<th>Medical Benefit</th>
<th>Effective Date: 07/01/18</th>
<th>Next Review Date: 03/20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preauthorization</td>
<td>Yes</td>
<td>Review Dates: 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</td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| 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.

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, buttocok 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, buttocok 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:
  o 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

  o Imaging of the pelvis (anteroposterior plain radiograph) rules out concomitant hip pathology; AND

  o 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

  o 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. 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 (>=) 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 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 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 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 (this is because there is 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 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 code: GXD.

A number of percutaneous or minimally invasive fixation/fusion devices have been cleared for marketing by FDA through the 510(k) process. They include the iFuse® Implant System (SI Bone), the Rialto™ SI Joint Fusion System (Medtronic), SII-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

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.


35. Cher DJ, Reckling WC, Capobianco RA. Implant survivorship analysis after minimally invasive sacroiliac joint fusion using the iFuse Implant System ((R)). Med Devices (Auckl). Dec 2015;8:485-492. PMID 26648762


