

# LCD - Sacroiliac Joint Injections and Procedures (L39383)

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CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
<a href="#">CGS Administrators, LLC</a>	MAC - Part A	15101 - MAC A	J - 15	Kentucky
<a href="#">CGS Administrators, LLC</a>	MAC - Part B	15102 - MAC B	J - 15	Kentucky
<a href="#">CGS Administrators, LLC</a>	MAC - Part A	15201 - MAC A	J - 15	Ohio
<a href="#">CGS Administrators, LLC</a>	MAC - Part B	15202 - MAC B	J - 15	Ohio

## LCD Information

### Document Information

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**LCD Title**

Sacroiliac Joint Injections and Procedures

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**Issue**

**Issue Description**

Limited coverage for sacroiliac joint injections and procedures as described in the coverage indications of the policy.

**CMS National Coverage Policy**

This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for EPIDURAL procedures for pain management. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for EPIDURAL procedures for pain management and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies may be found in the following Internet-Only Manuals (IOMs) published on the CMS Web site:

**IOM Citations:**

- CMS IOM Publication 100-08, *Medicare Program Integrity Manual*, ~ Chapter 13, 13.5.4 Reasonable and Necessary Provision in an LCD

**Social Security Act (Title XVIII) Standard References:**

- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.
- Title XVIII of the Social Security Act: Sec. 1861.(s)(2) Part E—Miscellaneous Provisions: Definitions of Services I, etc. 2021

**Code of Federal Regulations (CFR) References:**

CFR, Title 42, Ch. IV, § 410.74 Physician assistants’ services, §410.75 Nurse practitioners’ services and § 410.76 Clinical nurse specialists’ services.

**Coverage Guidance**

**Coverage Indications, Limitations, and/or Medical Necessity**

Compliance with the provisions in this LCD may be monitored and addressed through post payment data analysis and subsequent medical review audits.

**History/Background and/or General Information**

Low back pain (LBP) is highly prevalent in the Medicare population with reports of 50 to 84% of adults experiencing

back pain at some point and is the highest cause of disability globally. Approximately 15% to 30% of patients with persistent mechanical LBP below L5 have pain arising from their sacroiliac joints (SIJ). SIJ dysfunction is common after spinal fusion; and reported in up to 40% in some studies.<sup>1</sup> The SIJ is a complex structure; it is a diarthrodial joint with matching articulate surfaces between the sacrum and ilium separated by synovial fluid and surrounded by a fibrous capsule. It is only a true synovial joint in the anterior portion, due to discontinuity of the posterior capsule. It serves as the biomechanical mediator between the spine and the pelvis. The joint is responsible for flexion and extension of the sacrum with counterrotation of the ilium and there is only a small amount of movement. The complexity of the joint is in the small degree of movement of the joint and the functional supporting structures of the joint (mainly the muscles, fascia and ligamentous connections).

The sacroiliac (SI) joint goes through many changes throughout life. In early childhood, the surfaces of the joint are smooth and allow gliding motions in many directions. After puberty, the surface of the ilium becomes rougher and coated with fibrous plaques that will restrict motion significantly. These age-related changes will increase in the third and fourth decade and by the sixth decade motion may become noticeably restricted. By the eighth decade, plaque will form and erosions will be present.<sup>2</sup> The SI joint has variable joint capacity as the SI joint degenerates with age and has varied from 0.5-2.5 ml.

The exact pattern of innervation of the joint is unclear, but the subchondral bone, capsule and surrounding ligaments are innervated by spinal nerves with nociceptor and proprioceptors and therefore can be a source of pain from the SIJ complex may arise from the posterior extraarticular elements that are innervated by the lateral branches of S1-S3 and L5 dorsal ramus or the anterior complex innervated by spinal nerves, branches of the gluteal and obturator nerves and lumbosacral trunks known as the intra-articular elements.<sup>1</sup> The spectrum of pain and dysfunction from SIJ pain is variable but can be debilitating.

In addition to conservative and surgical modalities, interventional procedures are used for treatment of SIJ pain. This includes SIJ injections and radiofrequency (RFA) ablation of the SIJ joint. Injections typically are intra-articular and contain anesthetic and corticosteroids. Ablation relies on radiofrequency-generated thermal energy to ablate the sensory nerve fibers of the sacroiliac joint, thereby interrupting nociceptive signals.

The treatment of individuals with spinal disorders, including pain, can be complex, and it is recommended that all individuals being considered for interventional spinal procedures undergo a thorough evaluation and be treated following development of a comprehensive care plan.

## Covered Indications

A. Sacroiliac joint injections (SIJI) will be considered medically reasonable and necessary when all the following requirements are met:

1. Moderate to severe low back pain primarily experienced over the anatomical location of the SI joints between the upper level of the iliac crests and the gluteal fold, **AND**
2. Low back pain duration of at least three (3) months, **AND**
3. Low back pain below L5 without radiculopathy, **AND**
4. Clinical findings and/or imaging studies do not suggest any other diagnosed or obvious cause of the lumbosacral pain (such as central spinal stenosis with neurogenic claudication/myelopathy, foraminal

- stenosis or disc herniation with concordant radicular pain/radiculopathy, infection, tumor, fracture, pseudoarthrosis, or pain related to spinal instrumentation), **AND**
5. At least three positive findings with provocative maneuvers: FABER, Gaenslen, Thigh Thrust or Posterior Shear, SI Compression, SI Distraction and Yeoman Tests,<sup>3,4</sup> **AND**
  6. Low back pain persists despite a minimum of four weeks of conservative therapies.<sup>5</sup>

## B. Diagnostic Sacroiliac Joint Injections

Diagnostic SIJI is used to determine if the etiology of pain is from the sacroiliac joint complex.<sup>3</sup>

Diagnostic SIJI are considered reasonable and necessary for patients who meet ALL the following criteria:

1. The patient must meet the above criteria for Covered Indications for SIJI, **AND**
2. The SI joint injections must be performed under CT or fluoroscopy image guidance with contrast, except ultrasound guidance may be considered reasonable and necessary when there is a documented contrast allergy or pregnancy, since the accuracy with ultrasound guidance is inferior to fluoroscopic guidance,<sup>6</sup> **AND**
3. SI joint injection are not performed with other musculoskeletal injections in the lumbosacral spine, **AND**
4. The documentation should show direct causal benefit from the SI joint injection and not from other musculoskeletal injections or treatments, **AND**
5. The diagnostic SIJI provided a minimum of 75% relief of primary (index) pain with the diagnostic SIJI (a positive diagnostic response is defined as  $\geq 75\%$  sustained and constant pain relief for the duration of the local anesthetic and  $\geq 75\%$  sustained and constant pain relief for the duration of the anti-inflammatory steroid) was measured by the SAME pain scale\* at baseline. The measurements of pain must be taken pre-injection on the day of the SIJ injection, post-intervention on the day of the injection, and the days following the injection to substantiate and corroborate the pain scores consistent with the pain relief for the duration of the local anesthetic and/or steroid used.

Limitation: No more than two (2) diagnostic joint sessions, unilateral or bilateral. To clarify, two unilateral sessions, if performed on one side at one session and on the opposite side at a different session, would meet the limitation of two (2) diagnostic sessions.

## C. Therapeutic SIJI:

Therapeutic SIJI will be considered medically reasonable and necessary for patients who meet **ALL** the following criteria:

1. The patient must meet the above criteria of Covered Indications for SIJI, **AND**
2. The diagnostic SIJI provided a minimum of 75% relief of primary (index) pain with the diagnostic SIJI (a positive diagnostic response is defined as  $\geq 75\%$  sustained and constant pain relief for the duration of the local anesthetic and  $\geq 75\%$  sustained and constant pain relief for the duration of the anti-inflammatory steroid) was measured by the SAME pain scale\* at baseline. The measurements of pain were taken pre-injection on the day of the diagnostic SIJ injection, post-intervention on the day of the diagnostic injection, and the days following the diagnostic SIJ injection to substantiate and corroborate consistent pain relief for the duration of the local

anesthetic and/or steroid used, **AND**

3. Subsequent therapeutic SIJI are considered medically reasonable and necessary when the subsequent SIJI are provided at the same anatomic site as therapeutic SIJI, **AND** the therapeutic SIJI produced at least consistent 50% pain relief **or** at least 50% consistent improvement in the ability to perform previously painful movements and activities of daily living (ADLs) for at least three (3) months from the proximate therapeutic SIJI procedure and compared to baseline measurements for ADLs and painful movements or pain relief using the same pain scale\* **AND**
4. The SI joint injections must be performed under CT or fluoroscopy image guidance with contrast, except ultrasound guidance may be considered reasonable and necessary when there is a documented contrast allergy or pregnancy, since the accuracy with ultrasound guidance is inferior to fluoroscopic guidance.<sup>6</sup>

Limitations: No more than four (4) therapeutic SIJI sessions, unilateral or bilateral, will be reimbursed per rolling 12 months. To clarify, a therapeutic SIJI session if performed on one side first and then on the opposite side at a different session would qualify as two (2) sessions for the limitation of four (4) therapeutic SIJ sessions per rolling 12 months.

D. SIJ Denervation (also called Radiofrequency Ablation or RFA) is not considered reasonable and necessary.

\*Note: The scales used to measure of pain and/or disability must be documented in the medical record. Acceptable scales include but are not limited to: verbal rating scales, Numerical Rating Scale (NRS) and Visual Analog Scale (VAS) for pain assessment, and Pain Disability Assessment Scale (PDAS), Oswestry Disability Index (ODI), Oswestry Low Back Pain Disability Questionnaire (OSW), Quebec Back Pain Disability Scale (QUE), Roland Morris Pain Scale, Back Pain Functional Scale (BPFS), and the PROMIS profile domains to assess function.

## E. Requirements

- The SIJI must be performed under CT or fluoroscopy image guidance with contrast, unless the patient has a documented contrast allergy or pregnancy where ultrasound guidance without contrast may be considered.<sup>6</sup>
- The SIJ procedure(s) should be performed in conjunction with conservative treatments.<sup>7</sup>
- Patient should be part of an ongoing, and be actively participating in a rehabilitation program, home exercise program or functional restoration program.<sup>8,9</sup>
- SIJ primary index pain must be measured prior to the injection at the beginning of the session.
- The post procedure pain level must be measured after the SIJ injection at the conclusion of the session.
- SIJI may be performed unilateral or bilateral if clinically indicated within the same session.
- The documentation must have the radiographic films (i.e. fluoroscopy images) of the procedure in at least two (2) views (i.e., the pre and post contrast injection views in the AP and oblique planes) to confirm intraarticular injection of contrast and the treatment agent(s) used.
- When documenting the percentage of pain relief from the primary (index) pain compared to the post-injection pain levels, it is insufficient to report only a percentage of pain relief and/or a nonspecific statement of the duration of pain relief. The documentation should include a specific assessment of the duration of relief being consistent or inconsistent with the agent used for the injection and the specific dates the measurements were obtained using the SAME pain scale\* used at baseline.
- When documenting the ability to perform previously painful movements and activities of daily living (ADLs) it is insufficient to provide a vague or nonspecific statement regarding the improvement of previously painful movements and activities of daily living (ADLs). The documentation should include a functional assessment to show clinically meaningful improvement with painful movements and ADLs, if this metric is used to justify the

efficacy of the SIJI procedure. Providers should use established and measurable goals and objective scales to assess functionality and ADLs measures.

## Limitations

1. Injections performed without radiographic image guidance are not considered reasonable and necessary.<sup>6</sup>
2. A SIJI involves the use of an anesthetic, corticosteroid, and contrast agent and does not include injections of biologics (e.g., platelet rich plasma, stem cells, amniotic fluid, etc.) and/or any other injectates.
3. It is not considered medically reasonable and necessary to perform multiple blocks (ESI, sympathetic blocks, facet blocks, trigger point injections, etc.) during the same session as SIJs injections and during the post-SJI injection efficacy assessment period.
4. Use of Moderate or Deep Sedation, General Anesthesia, and Monitored Anesthesia Care (MAC) is usually unnecessary or rarely indicated for SIJ injections and therefore not considered medically reasonable and necessary.<sup>10</sup> Even in patients with a needle phobia and anxiety, typically oral anxiolytics suffice.<sup>9</sup>
5. SIJIs to treat non-specific low back pain (LBP), axial spine pain primary above the level of L5, complex regional pain syndrome, widespread diffuse pain, chronic pain syndrome, and pain from neuropathy are considered investigational and therefore are not considered medically reasonable and necessary.
6. SIJIs used as part of a series of lumbar spine and musculoskeletal injections to treat nonspecific or chronic low back pain is not considered reasonable and necessary.
7. In patients with implanted electrical devices, (i.e., spinal cord stimulation, peripheral nerve stimulation, cardiac devices, etc.) and intrathecal pump delivery devices, providers should follow manufacturer instructions and extra planning as indicated to ensure safety of the procedure.
8. Patients with coexisting psychological conditions or depression related illness should be treated and stabilized prior to proceeding with interventional procedures.<sup>11</sup> Multidisciplinary biopsychosocial rehabilitation principles should be provided to these patients.
9. It generally would not be considered medically reasonable and necessary for treatment with SIJIs to extend beyond 12 months. Frequent continuation of SIJIs injections over 12 months may trigger a focused medical review. Use beyond twelve month requires the following:
  - a. Pain is severe enough to cause a significant degree of functional disability or vocational disability and providers use established and measurable goals and objective scales to assess functionality and ADLs measures.
  - b. SIJIs provides at least 50% sustained and consistent improvement of pain and/or 50% sustained and consistent objective improvement in function (using same scale as baseline) for at least three (3) months.
  - c. Rationale for the continuation of SIJIs including but not limited to patient who are high-risk surgical candidates, the patient does not desire surgery, and/or the recurrence of pain in the same location was sustained and consistently relieved with the SIJIs for at least three (3) months.
  - d. The primary care provider should be notified regarding continuation of procedures and prolonged repeat steroid use to allow for systematic care delivery treatment surveillance and multidisciplinary biopsychosocial rehabilitation (MBR).
10. A subsequent diagnostic SIJI is not reasonable and necessary when the initial diagnostic block does not produce a positive response of  $\geq 75\%$  pain reduction.
11. A subsequent therapeutic SIJI is not reasonable and necessary when the proximate SIJI did not provide at least a consistent 50% pain relief or at least a 50% consistent improvement in the ability to perform previously painful movements and activities of daily living (ADLs) for at least three (3) months compared to baseline objective measurements for ADLS and painful movements or pain relief using the same pain scale\*

## Provider Qualifications

The Medicare Program Integrity Manual states services will be considered medically reasonable and necessary only if performed by appropriately trained providers.

Patient safety and quality of care mandate that healthcare professionals who perform SIJ injections/procedures for chronic pain (not surgical anesthesia) are appropriately trained and/or credentialed by a formal residency/fellowship program and/or are certified by either an accredited and nationally recognized organization or by a post-graduate training course accredited by an established national accrediting body or accredited professional training program whose core curriculum includes the performance and management of the procedures addressed in this policy. Credentialing or privileges are required for procedures performed in inpatient and outpatient settings.<sup>12</sup>

All aspects of care must be within the provider's medical licensure and scope of practice. Reimbursement for procedures utilizing imaging techniques may be made to providers who meet training requirements for the procedures in this policy only if their respective state allows such in their practice act and formally licenses or certifies the practitioner to use and interpret these imaging modalities (ionizing radiation and associated contrast material, magnetic resonance imaging, ultrasound). At a minimum, training must cover and develop an understanding of anatomy and drug pharmacodynamics and kinetics as well as proficiency in diagnosis and management of disease, the technical performance of the procedure, and utilization of the required associated imaging modalities.

**Notice:** Services performed for any given diagnosis must meet all the indications and limitations stated in this LCD, the general requirements for medical necessity as stated in CMS payment policy manuals, all existing CMS national coverage determinations, and all Medicare payment rules.

## Summary of Evidence

### Definitions

**Acute Pain** – an unpleasant sensory and emotional experience associated with actual or potential tissue damage which is present for up to six (6) weeks.<sup>13</sup>

**Baseline Pain:** An initial measurement of the pain which is taken at a specified time point and used for comparison over time to look for changes in the pain levels.

**Chronic Pain** – The temporal definition of pain persisting at least 12 weeks after the onset of the acute pain.

**Complex Regional Pain Syndrome (CRPS)-** an array of painful conditions that are characterized by continuing regional pain that is seemingly disproportionate in the time or degree to the usual course of any known trauma or other lesion. Pain is regional and usually has distal predominance of abnormal sensory, motor, sub motor, vasomotor and or trophic findings.<sup>14</sup>

**Conservative Therapy** – Consists of an appropriate combination of medication in therapeutic dosages (for example, non-steroidal anti-inflammatory [NSAIDs], analgesics, etc.) administered for a sufficient amount of time to determine

efficacy, in addition to physical therapy, spinal manipulation therapy, cognitive behavioral therapy (CBT), home exercise program, or other interventions based on the individual's specific presentation, physical findings, and imaging results.

**Consistent Improvement** – The percentage of improvement must have an unchanging benefit and effect during the defined time period.

**Cryoanalgesia-** (cryoneurolysis) uses extreme cold (–70°F to –180°F) to freeze nerves in an ice ball with the intent of interrupting transmission along that nerve for pain reduction,

**Disability** – Activity limitations and/or participation restrictions in an individual with a health condition, disorder or disease.<sup>15</sup>

**Discogenic pain** – Pain originating from damaged vertebral disc, particularly, but not always, due to degenerative disc disease.

**Efficacy Assessment Period** - The duration of time the day before the SIJI to weeks following the SIJI where assessments are made to determine the degree of sustained and constant pain relief.

**Functional Impairment:** A physical or functional or physiological impairment causes deviation from the normal function of a tissue or organ. This results in a significantly limited, impaired or delayed capacity to move, coordinate actions or perform physical activities and is exhibited by difficulties in one or more of the following areas: physical and motor tasks; independent movement; performing basic life functions.<sup>15</sup>

**GRADE** – A system developed by the GRADE Working Group to address the shortcomings of present grading systems in healthcare. The GRADE system uses a common, sensible, and transparent approach to grading the quality of evidence. The results of applying the GRADE system to clinical trial data are displayed in a table known as a GRADE profile.

**Multidisciplinary Biopsychosocial Rehabilitation (MBR)** – Targets physical as well as psychological and social aspects of pain and involves a team of healthcare providers with different professional backgrounds and training.<sup>8</sup>

**Nonspecific low back pain** – Back pain that cannot be attributed to a specific disease or spinal pathology.

**Radiofrequency Ablation-** A procedure that uses radio waves that traveled through electrodes to ablate (destroy) target tissue. For pain management, radiofrequency-generated thermal energy is used to ablate the sensory nerve fibers thereby interrupting nociceptive signals. Used interchangeably with radiofrequency neurotomy in literature and policy.

**Primary (index) pain** – the level of pain measured prior to the injection (aka baseline pain)

**Post-intervention Pain** - the level of pain measured immediately after the injection

**Sacroiliac Joint-** The synovial joint formed at the juncture of the sacrum and ilium.

**Sacroiliac Joint Complex-** The articular portion of the joint, including bone, articular cartilage and joint capsule and the posterior extraocular structures which include the overlying dorsal ligaments, regional muscles, and tendons.



**Sacroiliac Joint Pain-** Pain from nociceptive signaling within and surrounding a sacroiliac joint(s).<sup>16</sup>

**Sacroiliitis-** Inflammation in one or both sacroiliac joints.

**Session-** A session is a time period, which includes all procedures (i.e., SIJIs and RFA ablations) that are performed during the same day.

**Sustained and Constant Pain Relief** - The pain relief must continue for the defined time period and without interruption or regression to the primary (index) pain.

**Spondylarthritis-** A group of inflammatory arthritis affecting the axial skeleton including the sacroiliac joint and spine with or without peripheral joints and is often associated with HLA- B27.<sup>17</sup>

**Subacute Pain** – The temporal definition of pain occurring during the six (6) to twelve-week (12) time period.

### **Contractor Advisory Committee Meeting 3/10/2022**

A Multi-jurisdictional contract advisory committee meeting of subject matter experts (SMEs) was convened on 3/10/22 regarding sacroiliac joint injections and procedures. The transcript, voting results, and audio are available on each MACs website. The panel consisted of experts in pain management including anesthesiology and physical medicine and rehabilitation, as well as neuroradiology, rheumatology, neurosurgery and a certified nurse anesthetist with representation throughout the country and also included representation from major pain societies. The panel will be referred to as SMEs, and their input incorporated through the review to correlate the evidence with expert input.

### **Diagnosis**

SIJ disorders typically present with pain below the L5 level without numbness or paresthesia and low back pain which is worse after prolonged sitting, bending forward and transitions from sitting to standing. Pain also may be worsened by weight bearing exercises including climbing stairs or even prolonged walking. Gait compromise and referred pain to the buttocks, groin, thigh and occasionally behind the knee are common. There is not a gold standard for the diagnosis of SIJ pain. A combination of physical exams and provocative tests (FABER, Gaenslen, Thigh Thrust or Posterior Shear, Compression, Distraction and Yeoman Tests) are essential components to determining SIJ disorders.<sup>3</sup> Multiple studies show that 3 out of 5 tests are suggestive of SIJ dysfunction with about 85% pretest probability that SIJ injection will be successful,<sup>3,4,16,18</sup> however this trend was not found to be statistically significant.<sup>6</sup> One meta-analysis showed that the thigh thrust test, the compression test, and 3 or more positive stress tests have discriminative power for diagnosing SIJ pain.<sup>4</sup> A 2021 SR and MA assessing clusters of pain provocation tests for SIJ dysfunction reported a 35% certainty of having correctly identified SIJ pain from positive cluster testing with GRADE rating for the outcomes of very low certainty.<sup>19</sup> A small diagnostic validity study to evaluate clinical examination using double diagnostic injections as the reference standard reported a sensitivity of 91% (62-98) and specificity of 83% (68-96) and positive likelihood ratio (95% confidence intervals) of 9.97 (2.70-20.27) supporting the role of clinical examination for diagnosis of SIJ pain.<sup>20</sup>

Imaging of the SIJ joint has the capability to confirm abnormalities in the joint but is limited as it may not be diagnostic for SIJ disorders. Conventional radiographs often do not correlate with the presence of low back pain and can be abnormal in 25% of asymptomatic patients and CT scans can be abnormal in up to 77% of asymptomatic

individuals. Low sensitivity (57%) and specificity (69%) of CT scans have been reported in patients with SIJ pain.<sup>21,22</sup> For patients with severe and intractable pain syndromes who have failed medical/interventional treatment or for patients for whom there is a concern for trauma, fracture, malignancy, or infection advanced imaging may be required.<sup>22</sup> If interventional therapy is planned, MRI of the lumbar spine is recommended to rule out neural compression especially if the L5 nerve root is involved.<sup>3</sup> The diagnosis of spondylarthritis is characterized by sacroiliitis on plain radiographs with or without bridging syndesmophytes, however early in disease there may not be radiographic findings and MRI may detect changes earlier than plain film.<sup>23</sup> Imaging also plays a role in differential diagnosis and exclusion of other lumbar spinal pathologies that may be causing symptoms.

A 2021 prospective evaluation reviewed over 2 dozen demographic, clinical and technical factors on the treatment outcomes for 3 procedures epidural steroid injections, sacroiliac joint injections, and facet interventions in 346 patients. The initial block contained steroid and local anesthetic. A block was considered positive when there was greater than 50% pain reduction lasting at least 3 hours after the initial injection. Mean age was below the average Medicare population. They determined that patients with greater disease burden, depression and obesity were more likely to fail intervention. Sixty-four percent of treatment failures were in obese patients compared to 35.8% of successful procedures ( $p = 0.039$ ). Obese patients also had a longer duration of pain 6.7 years compared to 4.7 years ( $p = 0.01$ ) in the non-obese population. The authors observed that the higher threshold for blocks were associated with higher likelihood of success with RFA, but at the risk of excluding patients who may benefit. They did not find there was a statistically separate 1 month outcome from using a  $< 80\%$  relief point out for SIJ pain unlike those who obtained between 50% and 79% pain relief, experiencing  $\geq 80\%$  immediate pain relief did not statistically separate on 1 month outcome from having  $< 80\%$  relief, suggesting that many of these patients may have been placebo responders.<sup>11</sup>

Their literature includes diagnosis of sacroiliitis, spondylosis, and inflammatory spondyloarthropathies. Inflammatory arthritis as well as axial and peripheral spondyloarthropathies may affect the SIJ joint. Our SMEs confirm that inflammatory back pain may be due to inflammation at the site of tendon attachments throughout the spine, with SIJ being one of the most common sites. These patients warrant systemic treatment due to risk of developing permanent bony damage that may be reduced or prevented with the availability of highly effective therapies. Patients with symptoms of axial spondyloarthropathies (SpA) are typically  $< 45$  years-old and should be evaluated for these underlying conditions with appropriate laboratory, imaging and genetic testing.<sup>24</sup> Early disease may not have radiographic findings with MRI being the most sensitive for detection of SIJ joint inflammation leading to the Assessment of Spondylarthritis International Society (ASAS) criteria to strongly recommend MRI of the SI joints for determination of sacroiliitis.<sup>25</sup>

## **Conservative Management**

A significant portion of the patient population would be expected to improve with time with or without intervention.<sup>26</sup> Therefore, a trial of conservative management is an accepted standard despite paucity of studies on conservative measures. SMEs agreed that 4 weeks was a reasonable time for conservative management in most cases. There was not sufficient literature to support specific medications except topical capsaicin and NSAIDs with societal support for muscle relaxants, and non-opioids and limited opioids as second-third line options.<sup>27,28</sup> There was evidence to support physical therapy (PT) with a SR finding benefit of PT to reduce pain and dysfunction.<sup>29</sup> SME review concludes low quality, but existing, data to support PT, manual therapies, and exercise interventions as potentially beneficial.<sup>30</sup>

## Diagnostic Injections

Due to the lack of definitive history, physical exam, or radiological evidence for SIJ dysfunction, diagnostic injections are recommended to rule out other etiologies and ensure improvement in the SI joint to confirm diagnosis. In a 2021 review, accuracy of the injections was significantly improved by the use of fluoroscopy and was more accurate than ultrasound (98% versus 87%).<sup>3</sup> The number of diagnostic injections and percentage of pain relief is controversial. In Buchanan's review the authors report Level II evidence for dual diagnostic blocks with at least a 70% pain relief and Level III evidence for single diagnostic blocks with 75% pain relief.<sup>3</sup> The SI joint has both anterior and posterior innervation with the joint itself being innervated anteriorly by the lumbosacral trunks, obturator nerve and gluteal nerves. This differs from the posterior innervation referred to as the posterior sacral network consisting of the S1-S3 dorsal rami, and in some cases, fibers of the L5 dorsal ramus. Therefore, there are 2 different pain generators with different innervations.<sup>6,31-33</sup> Diagnostic and therapeutic intraarticular injections placed directly into the sacroiliac joint cavity anesthetizing the articular nerves and potentially the surrounding ligaments but does not access the posterior sacral network.

A single double blinded RCT with twenty subjects reported on the effectiveness of multi-site, multi-depth sacral lateral branch injections into the interosseous (IO) and dorsal sacroiliac (DSI) ligaments. Half of the subjects received injections with corticosteroids while the other half received injection with saline utilizing a multi-site, multi-depth lateral branch injection technique followed by provocation testing which was compared to baseline testing. They reported 70% effectiveness rate and that the intra-articular portion of the SIJ is not blocked suggesting that multi-site multi-depth lateral branch blocks to the IO and DSI are necessary to select patients for RFA which target the posterior region of the SIJ complex.<sup>34</sup>

A 2019 comprehensive review acknowledged shortcomings of current literature. The lack of consistent diagnostic criteria with approximately half of the patients having a single diagnostic block before proceeding with RFA and high risk of false positive rate compared to dual blocks throughout spine literature may impact the overall outcome rates. The authors acknowledge the limitation of current literature due to suboptimal/inconsistent selection criteria, variable techniques and reliability creating lesions that will denervate the SLBs as well as variability in assessment of response to treatment resulting in a wide variety of outcomes within the literature. They conclude this may underestimate success rates but report there is still therapeutic effect with treatment responder rate ranging from 32% to 89%.<sup>31</sup>

In a 2015 systematic review, 10 reviewers assessed 45 publications on diagnostic validity or effectiveness of fluoroscopically guided interarticular SIJ injections.<sup>6</sup> Papers were divided by degree of pain relief required for positive response and presence or absence of controlled injections. The authors concluded that controlled (dual) diagnostic block had a positive response rate between 10% to 33% (with one outlier at 45%) while uncontrolled (single) blocks reported a positive response rate between 29% to 63% demonstrating that dual blocks significantly decrease the positive response rate compared to single blocks. The investigators also reported increasing the percentage of pain relief required for a positive block (>75% versus >50%) decreased the reported prevalence of SIJ pain.

A 2012 systematic review of literature from 1996 to 2011 included patients with back pain for 3 months or more and failed conservative measures using a modification of the United States Preventive Services Task Force (USPSTF) methods to rate quality of evidence.<sup>35</sup> Limitations included the paucity of literature, and variations in technique and criteria for diagnosis of sacroiliac joint pain. The authors rate the evidence for diagnostic accuracy for sacroiliac joint injections as good, however that was based largely on observational studies with only one placebo-controlled trial and no blinded studies. They also rated the evidence for provocative maneuvers as fair, imaging as limited and concluded support for fluoroscopic guidance of the injection. They conclude no significant difference when 70% or greater relief was used as the criterion standard with dual blocks as compared 50% or greater pain relief reporting good evidence based on multiple high-quality studies. However, this was based on one placebo-controlled study with small numbers (n=40) and the remaining literature was observational or retrospective. The authors concluded that

the use of multiple blocks and high cutoff thresholds would reduce the false-positive rate, however a stricter diagnostic criterion may result in more false-negatives, and the potential to withhold treatment from a patient who might benefit.

A second systematic review in 2015 by the same authors was conducted to evaluate the diagnostic accuracy and therapeutic effectiveness of sacroiliac joint interventions.<sup>36</sup> Eleven diagnostic accuracy studies were included, most of which were also included in the 2012 SR and the same placebo-controlled study. There was high heterogeneity between the studies, therefore, a meta-analysis could not be performed. The authors concluded Level II evidence for diagnostic accuracy is Level II for dual diagnostic blocks with at least 70% pain relief as the criterion standard and Level III evidence for single diagnostic blocks with at least 75% pain relief as the criterion standard using a modified approach to grading evidence. The Level II was based on 2 studies considered high quality diagnostic studies with 70 (n=158) and 75% (n=150) pain relief supported by dual blocks and prevalence of 26% and false-positive rate of 20-26%. The single block studies showed a prevalence of 10-35%, with a wide variability and inconsistencies. The authors acknowledge the controversy surrounding the diagnostic accuracy of controlled local blocks however they opine that this is the best available tool to identify SIJ pain.

A 2020 review and algorithm for the diagnosis and treatment of SIJ pain discusses the issue of intra-articular versus sacral lateral branch blocks and the need to target the portion of the joint that is the pain generator.<sup>37</sup> They refer to Dreyfuss's study that found lateral sacral branch blocks were more effective at preventing SIJ pain secondary to extra-articular (i.e., ligamentous) stimulation than from capsular distension.<sup>34</sup> They also reviewed a 2015 SIJ fusion study that included 77 subjects and concluded that more than half of the patients continue to experience at least 50% relief >6 months post procedure. Predictors of treatment failure were the elderly, higher pre-procedure pain scores, opioid usage, and pain radiating beyond the knee.<sup>37</sup> They attributed this failure to the possibility that the RFA that targets the posterior nerve supply of the joint and fails to address pain from the anterior portion of joint with different innervation.

The SME panel presented both sides of the controversial topic of the number of diagnostic joint injections and the percent pain relief required. Several panel members felt that a single diagnostic injection was sufficient and supported by evidence using a cutoff between 30 to 50%. They argue that the higher false negative rate with dual blocks would exclude patients who may benefit from the procedures and other procedures use a cutoff as low as 30%. Other panelists felt that this would increase the incidence of false positives and patients may be subject to repetitive procedures without definitive diagnosis being established. Most of the literature as well as most guidelines, utilized dual diagnostic blocks. The panel discussed sequential care starting with conservative management and if no success proceeding to diagnostic blocks, progression to therapeutic injections, then RFA and finally fusion if pain relief is obtained but not sustained. In this case, a single block may be sufficient because the next step in the algorithm would be therapeutic injection which could also be a confirmatory injection. The panel stated there was not specific evidence in terms of the duration of time between the diagnostic blocks although standard practice is typically 2 weeks. The response to blocks varies greatly depending on the type of anesthetic used and whether corticosteroids were used, and that pain and improvement must be measured before and after the block to determine success of the block.

## **Therapeutic SIJ Injections**

Despite the common use of SIJI for management of SIJ complex pain there are few studies that evaluate the effectiveness of SIJIs. There are 2 controlled studies, both too small to determine statistical significance, and the remaining studies are open and rarely prospective. The literature on SIJI is challenged by lack of standardized patient selection, different kinds of steroids in varying doses, different injection procedures, variability in use of imaging to guide the procedure, various mechanisms, and duration for assessment of response and risk of bias.<sup>6</sup>

Regarding the use of SIJI for axial SpA our SMEs explained that current guidelines support the role of injections as an adjunctive role to aid in acute pain relief, but not to replace systemic treatment which is the main stay of treatment. The American College of Rheumatology Treatment Guidelines for Axial Spondyloarthritis offers a conditional recommendation for SIJI is based on 2 small RCTs with high risk of bias due to lack of blinding concluding low quality evidence.<sup>39</sup> This is supported by observational studies as well. The SME conclude that SIJIs are appropriate for axial SpA conditions with sacroiliitis as predominant or only feature while awaiting medication to take effect or if there is contraindication for systematic therapy, but not as a monotherapy due to high risk of disease outside the SIJ joint.<sup>39-41</sup>

#### Randomized Controlled Trials with Placebo Arm

A 1996 double blinded RCT on 10 patients with sacroiliitis (13 injections) performed under fluoroscopic guidance reporting a 70% improvement at one month for 5/6 that received steroids compared to 0/7 for those that received placebo.<sup>42</sup> Improvement was maintained at 3 and 6 months in around 60% of injected joints. While their results were calculated to be statically significant the small sample size was not adequate and there were no diagnostic injections used.

In 1999 a RCT with 20 patients with seronegative spondylarthropathy and clinical sacroiliitis (10 in each group) reported significant improvement in Visual Analog Score (VAS) and pain index in those receiving unguided steroid and lidocaine injection versus lidocaine and saline injection at 2 months.<sup>43,44</sup>

In 2002 the same group did another double blind, controlled study to investigate the effect of SIJIs of corticosteroids and lidocaine (n=13) versus lidocaine with saline (n=13) for non-spondylarthropathic patients with chronic pain.<sup>44</sup>

Clinical assessment at the onset of the study and after one month included VAS score and pain index. At one month both the VAS (p = 0.047) and the pain index (0.017) had improved significantly in the corticosteroid group compared with the placebo group. This study was limited by small sample size and minimal follow up duration.

#### Systematic Reviews

Hansen et al.<sup>45</sup> conducted a systematic review to evaluate the accuracy of imaged guided therapeutic sacroiliac joint interventions in patients with back pain for at least 3 months. The primary outcome measures were short term (<6 months) and long term per study descriptor (>6 months) pain relief, and secondary outcome measures were improvement in functional status, psychological status, return to work, and reduction in opioid intake.<sup>45</sup>

The authors conclude the evidence was fair in favor of cooled radiofrequency neurotomy and limited (or poor) for short-term and long-term relief from intra-articular steroid injections, periarticular injections with steroids or botulin toxin, pulsed radiofrequency, and conventional radiofrequency neurotomy.

Nine studies met the inclusion criteria and were clinically relevant; and the small sample sizes, widespread variations in methodology, selection criteria, outcome measures, and technique were limitations of the literature reviewed.

Dhir et al.<sup>17</sup> conducted a systematic review to summarize the efficacy and safety of systemic glucocorticoids (GC) and local injections of GC in spondyloarthritis (SpA). Fourteen studies were identified using systemic GC in SpA (364 patients); including two RCTs of oral prednisolone. On pooling data from 2 placebo-controlled RCTs (= 24 weeks), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI50) was 4.2 times more likely to show improvement (95% CI 1.5 to 11.5) and Ankylosing Spondylitis Disease Activity Score 20 (ASAS) was twice more likely (95% CI 1.1 to 3.64) to improve high-dose oral prednisolone ( $\pm$  taper). Pulsed GC led to dramatic improvements that lasted a few weeks to a few months and there were no deaths or major adverse events. There were 10 studies (560 patients) on

local GC delivered by intra-articular injections in SpA with sustained improvement in 51.5 to 90% joints at 6 months. Despite known limitations the authors concluded there was good evidence of efficacy with use of high-dose systemic GC in the short term (= 6 months) in SpA. Intra-articular or enthesal injections seemed safe and effective.<sup>17</sup>

A systematic review was done to evaluate evidence on the comparative effectiveness of surgery versus SIJIs for injection confirmed non-traumatic sacroiliac joint pain.<sup>46</sup> Twelve articles (7 surgical and 5 injection treatment) were included, and most studies reported over 40% improvement in pain and over 20% improvement in function as measured by Visual Analog Scale or Numeric rating Scale score regardless of the type of treatment. Most complications were reported in the surgical studies. No studies were identified that compared surgical treatment with injection treatment in the same patient population, so conclusions regarding the comparative effectiveness of the treatments are not possible. Most studies were low quality (mostly case series) and comprised small sample sizes and short follow-up time, bringing into question the duration of treatment effect. Direct comparisons of the interventions were difficult to interpret as the study population was heterogeneous in terms of diagnosis, previous spinal surgery, procedural details in the injection studies, and limited imaging prior to fusion in some studies.

### Other Studies

A 2022 retrospective review was conducted with 96 patients (107 injections) with Ankylosing Spondylitis (AS) diagnosed by a rheumatologist with history, physical exam and laboratory testing or by a radiologist with radiographic evidence of bone marrow edema/osteitis on MRI who failed medical management and underwent intra-articular sacroiliac joint injections.<sup>46</sup> Limitations of this study include the retrospective analysis, the inability to determine if improvements were related to medication changes versus the injectable treatment, especially since some patients were started on biological agents during this time and 30% of patients had only been diagnosed for one month or less so effectiveness of prior treatment could not yet be determined, and mean age of 25 which is not representative of the Medicare population.

There are multiple open studies with concordant results demonstrating a high percentage of patient improvement lasting several months providing some confirmation of these results.<sup>40</sup>

A retrospective review concluded that extra-articular sources for sacroiliac region pain exists, and intra-articular anesthetic blockade may underestimate the true prevalence of sacroiliac region pain. Using 2 large case series (n=120) patient responses to intra-articular injection versus combined intra-articular and peri-articular injection of anesthetic and corticosteroid were compared. For intra-articular injection alone, the rate of positive response at 3 months was 12.50% versus 31.25% for the combined injection (P=.025). Positive response was defined as greater than 50% drop in VAS pain score or improvement in ADLs. Anesthetic response rates were higher in the combined injection group (62.5% vs 42.5%; P=.037).<sup>48</sup> Limitations include study design, self-reported patient outcomes, and short follow up.

In a single blinded randomized trial by Visser et al. short-term therapeutic efficacy of physiotherapy, manual therapy and image guided intra-articular injection with local corticosteroids were compared. Patients were selected based on a consistent diagnostic criterion including physical examination, provocation test, X ray of the pelvis and MRI of the lumbar spine and SIJ joints as well as laboratory testing to exclude other rheumatological conditions. Out of 51 patients 25 (56%) were successfully treated based on VAS score improvement: physiotherapy (PT) was successful in 20% (3/15), manual therapy (manipulations) in 72% (13/18), and intra-articular injections in 50% (9/18). The authors concludes that manual therapy appears to be the treatment of choice for SIJ related leg pain with second line therapy being injection.<sup>7</sup> Limitations include the lack of control group, small sample size, and short-term follow-up.

A prospective randomized control trial comparing patients with sacroiliac joint pain confirmed by diagnostic block of local anesthetic with 50% improvement lasting three months or longer and failed conservative treatment received image guidance SIJs or prolotherapy biweekly for a maximum of 3 injections. Pain and disability scores were assessed at baseline, 2 weeks and monthly for 12 months. Twenty-three patients were randomized to the

prolotherapy group and 25 to the steroid group with improvement in scores in both groups at 2 weeks. Cumulative incidence of greater than 50% pain relief at 15 months was 58.7% in the prolotherapy group and 10.2% in the steroid group. The authors conclude prolotherapy provided significant relief of sacroiliac joint pain while the effects of steroids were low in this study. Limitations included small sample size and mean age was less than the Medicare mean population.<sup>49</sup>

## **SIJ Denervation**

The posterior sacral network, which is the target of sacral lateral branch radiofrequency ablation (SLBRFA), is innervated the S1-S3 dorsal rami, and in some cases, fibers of the L4-L5 dorsal ramus. Systematic review analyzing pooled data on the effectiveness of SLBRFA report approximately 50% of patients report greater than 50% pain relief reduction at 3 months which is less than the pain relief achieved with lumbar and cervical spine facet blocks. The decrease in effectiveness may be due to limitations in patient selection criteria, variations and procedural techniques and technology is utilized. Most studies evaluating SLBRFA utilize single or dual intra articular blocks for diagnosis of SIJ pain. This is problematic in that the intraarticular blocks, which enter the SIJ joint and anesthetizes the anterior complex, do not diagnose, or treat posterior sacral network pain. While utilizing dual diagnostic blocks, also referred to as double infiltration technique, has been suggested to improve selection of patients who may benefit from RFA it is still not targeting the nerve that is being ablated and the utility of this approach has been questioned.<sup>4,34,50,51</sup> It is proposed that sacral lateral branch blocks would better identify candidates for SLBRFA, however there are no placebo controlled trials of sacral nerve blocks to confirm this theory.<sup>51</sup> In a 2009 double blinded RCT by Dreyfuss et al. multi-site multi-depth sacral lateral branch blocks were evaluated in asymptomatic volunteers. Seventy percent of the active group achieved loss of sensation within the interosseous and dorsal sacroiliac ligaments and 86% retained the ability to feel repeat capsular distention despite insensate dorsal SIJ complex. The authors concluded that multi-site, multi-depth lateral branch blocks were 70% effective and do not effectively block the intraarticular portion of the SIJ joint. The authors predicted this could be a potential tool to identify patients who may benefit from SLBRFA.<sup>34</sup> However, there are no studies that evaluate multi-site, multi depth or any other form of sacral lateral branch blocks to predict success with SLBRFA.<sup>4</sup> Multiple guidelines have suggested this is a superior approach for patient selection for SLBRFA, however there is not supporting data to confirm. And while studies have shown some predictive value of diagnostic intra articular blocks variations in patient selection, criteria for positive SIJ block, radiofrequency ablation technique and assessment tools are highly variable limiting the ability to produce reliable meta-analysis and confirmatory results in the current literature.

Several different techniques for radiofrequency neurotomy including monopolar, bipolar, cooled and palisade (strip) lesions have been utilized. There is not sufficient evidence to state one technique is superior to the others. Cooled RF is a novel technique in which internally cooled RF probes produce larger lesions than is possible with other approaches. The primary advantage of cooled RF technology is that it doubles the lesion's diameter and enhances the volume by a factor of 8, making it more likely to interrupt the nociceptive input from the sacroiliac joints. A different procedure called cryoanesthesia, has been proposed for SIJ pain. There is minimal literature on the role of cryoanesthesia for SIJ pain and the SMEs agree there is not sufficient evidence to support cryoanesthesia of SIJ.

### Randomized Controlled Trials with Placebo Arm

Our subject matter expert reported 5 sham-controlled studies regarding the efficacy of SI joint RFA.<sup>52-55</sup> The first 2 sham control trials published show that in pooled, between-group comparisons, those treated with RFA were approximately 4 times more likely to achieve =50% pain reduction at 3 months compared with sham.<sup>52-54</sup> Four of the 5 trials showed statistically better outcomes for RFA compared to sham. Meta-analysis is limited by the high heterogeneity within this literature, and various techniques for the ablation.

Cohen et al.<sup>52,53</sup> performed a randomized placebo-controlled study to determine whether sacroiliac joint denervation is a viable treatment for patients with chronic, intractable sacroiliac joint pain. Participants included 28

patients with injection-diagnosed sacroiliac joint pain using 75% or greater improvement after a single diagnostic SIJ injection. Under local anesthetic block, 14 patients received L4–L5 primary dorsal rami and S1–S3 lateral branch radiofrequency denervation using cooling probe technology, and 14 patients received placebo denervation. One, 3, and 6 months after the procedure, 11(79%), 9 (64%), and 8 (57%) radiofrequency-treated patients experienced pain relief of 50% or greater measured by Numeric Rating Score (NRS) and significant functional improvement measured by Oswestry Disability Index score (ODI). In contrast, only 2 patients (14%) in the placebo group experienced significant improvement at their 1-month follow-up, and no patient experienced benefit 3 months after the procedure. Eleven crossed-over and were treated with radiofrequency denervation using conventional technology of which 7 (64%), 6 (55%), and 4 (36%) experienced improvement 1, 3 and 6 months, respectively after the procedure. One year after treatment, only 2 patients (14%) in the treatment group continued to demonstrate persistent pain relief. This was the first RCT with placebo suggesting that RFA may provide intermediate-term pain relief and functional benefit in selected patients with suspected sacroiliac joint pain and the authors called for larger studies to confirm these results and to determine the optimal candidates and treatment parameters acknowledging the limitation of the study due to small sample size and inadequate blinding technique.

Patel et al.<sup>53,54</sup> performed the second placebo controlled randomized trial of 51 subjects with chronic axial back pain and positive response to dual lateral branch blocks with cutoff level of 75% or greater pain relief on NRS. Thirty-four subjects were randomized to lateral branch neurotomy and 17 to sham procedure. At 3 months subjects in the placebo group were allowed to crossover and 16/17 subjects preceded with lateral branch neurotomy. At 3 months 47% of treated subjects and 12% of sham achieved treatment success at 6 and 9 months, respectively, 38 and 59% of treated subjects achieved success defined by a statistically significant decrease in NRS, and disability and physical function improvements between groups at 3-month follow-up. Strengths of this study include the study design with a placebo-controlled arm, consistent criteria for diagnosis, image guided injections with consistent protocol, and standardized assessment for pain. Limitations include the small sample size and cross-over design. Author concludes the results supports the recommendation of cooled RF lateral branch neurotomy for persistent SIJ pain.

Patel et al. published on twelve-month outcomes from the 2012 participants and reported that the initial RFA group compared to baseline results were favorable, with a mean 2.7 point drop in the NRS score, a 13.9 decrease in the ODI, and a 15.8 increase in Short Form 36-physical functioning (SF36-PF). In the crossover study group, 6-month outcomes were also favorable, with a mean NRS score decrease of 2.5 points, a reduction in ODI of 8.8, and an increase in SF36-BP of 11.9.<sup>56</sup>

van Tilberg et al. reported in a double blinded randomized placebo controlled multi-centered study which enrolled 60 patients with history and physical exam suggestive of SIJ pain for greater than 3 months with a reduction of at least 2 points on NRS after a single diagnostic SIJI.<sup>55</sup> Thirty patients underwent percutaneous radiofrequency ablation applied to the lateral branches S1-S4 and posterior rami of S5 while 30 underwent sham procedure. A crossover to RFA was provided for 19 of the sham operated group at 3 months. No statistically significant differences in pain level, satisfaction or other outcomes measured over time between the groups nor within the treatment groups were found. Unlike the other studies, the proportion of patients who reported significant pain relief was higher in the sham group compared to the RFA group where 43.3% experienced improvement. In the crossover group, 42.1% experienced a reduction in NRS of 2 or more at 1 month ( $P = 0.65$ ) which was consistent with the primary treatment group results. The authors conclude no pain difference between treatment and sham groups reporting a level 1A evidence. One possible explanation of the differences in this study could be the use of a decrease in NRS of two rather than 50-80% used in other studies resulting a high rate of false-positive diagnostic blocks with 86% of SIJ test blocks being positive. Also, the S4 branch could not be consistently reached with radiofrequency probe. This study was not included in the analysis.

A 2018 prospective, double blinded randomized sham-controlled trial with 30 subjects who underwent dual intra-articular blocks using 80% pain relief as cut off with seventeen reporting improvement.<sup>56</sup> Eleven subjects were treated with the radiofrequency ablation with a strip lesioning device (includes S1-S3 and L5 dorsal rami) and 6 underwent sham procedure. At 3 months, the mean NRS-11 score for the active group had decreased significantly, from 8.1 ( $\pm 0.8$ ) at baseline to 3.4 ( $\pm 2.0$ ) ( $P < 0.001$ ) while the sham group did not experience a statistically or



clinically meaningful decrease in mean NRS-11 from baseline ( $7.3 \pm 0.8$ ) to 3 months ( $7.0 \pm 1.7$ ). Subjects who had RFA moved from borderline anxiety at baseline ( $9.4 \pm 5.9$ ) to no anxiety ( $6.6 \pm 6.3$ ) at 3 months, but this was not statistically significant. While results were reported to be similar at 6 months the sham group was allowed to cross-over at 3 months so comparative data was not available. Eight non-serious adverse events were reported in the RFA group including pain and flare up at the site and one developed L5-S1 disc prolapse on the same side. Limitations small sample size below minimum to detect clinical difference, short-term follow-up, and mean age below Medicare population.

A large 2017 trial on RFA for facet, SIJ and intravertebral disc reported on 681 subjects and reported no clinically important improvement in low back pain compared to standardized exercise program alone. The mean difference in pain intensity between the RFA and control groups at 3 months was  $-0.71$  (95%CI,  $-1.35$  to  $-0.06$ ) in sacroiliac joint trial.<sup>58</sup> Diagnosis was made by history and physical exam and one diagnostic injection with 50% improvement in pain. Of 110 subjects who received SNRFA 81 received palisade RFA and 6 cooled RFA with 116 included in the intention-to-treat analysis. Patients older the age of 70 and BMI  $>35$  were excluded. The authors conclude radiofrequency ablation should not be performed outside of research setting and that additional research is necessary for better patient selection and improvement in techniques. This study benefited from large sample size, randomization, and standard measuring tools for outcomes, but limited by lack of blinding, and too small of a sample to distinguish any difference related to palisade vs cooled RFA technique.

All studies required a single or dual diagnostic injection for diagnosis of SIJ pain. Three studies used threshold of 75% or greater cut off for pain while one study required a decrease in NRS of 2 or more points. Denervation techniques varied between studies with all studies targeting S1 to S3 lateral branch and the L5 dorsal ramus, and variability in S4 and L4 nerve roots which also may have contributed to variability in results. High crossover without intent-to-treat analysis limits the data to short term analysis at a maximum of 3 months. Additionally, while there were no serious adverse outcomes reported, the small sample sizes were not sufficient to determine long term safety of the denervation procedure.

GRADE evidence analysis using GradePro software<sup>59</sup> was conducted. Only studies that offered a sham arm were included as these are the highest quality studies available. Three placebo controlled RCTs were included. There was no SR/MA that included all sham controlled RCT trials on RFA for SIJ pain, however since there are no current studies to suggest one method of RFA is superior to the others evaluation of all studies increases the pooled data to better understand the available evidence. The first outcome of interest was pain relief measured by NRS which was used in all the sham controlled RCTs studies. NRS average at baseline and three months was reported by the authors which was used to calculate a sum of difference between baseline and 3 months. These values were then averaged to produce the final values. In the Mehta study, data points were different in abstract than text, and data was obtained from the text.<sup>56</sup> The 2015 study by Patel was not included in evidence analysis with GRADE since it was the same population as the Patel 2012 study and only the initial subjects were included in analysis due to cross-over.<sup>53,54</sup> The study by van Tilburg<sup>55</sup> was a placebo-controlled study in which cross-over occurred at 3 month and did not show a difference between sham and RFA group for NRS at 1 month, however there was no NRS data past 1 month so was not included in the analysis. This study also had the highest adverse events reported. Quality of evidence for RFA compared to placebo for suspected SIJ pain was very low quality. The very low quality was a result of downgrading due to risk of bias, missing outcome data, differences in interventions, and small sample size (serious risk). Even removal of the difference in intervention from the downgrading, a known factor in pooling this data, does not change the very low-quality rating. The second outcome was adverse events with low quality evidence. While there were few adverse events in the study population the evidence was downgraded due to small sample size with less than 50 subjects undergoing RFA in the pooled population and not sufficient data to be confident the data represents the true risk of adverse events.

## **Figure 1: Summary of Findings Table for RFA compared to placebo using GRADE<sup>59</sup>**

## Summary of findings:

### RFA (any type) compared to placebo for suspected SIJ pain in the Medicare population for effective pain relief

**Patient or population:** suspected SIJ pain in the Medicare population for effective pain relief

**Setting:**

**Intervention:** RFA (any type)

**Comparison:** placebo

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with placebo	Risk with RFA (any type)				
Pain Relief assessed with: Numeric Rating Scale (NRS) Scale from: 0 to 10 follow-up: range baseline Baseline to 3 months	The mean pain relief by NRS was <b>-0.7</b>	Mean pain relief by NRS was <b>3.6 lower</b> (0 to 0 )	-	96 (3 RCTs)	Very low 52,53,56,a,b,c	Small number of studies with small sample size, crossover design, inconsistent. Adverse events reported but lack detail such as which study arm subject was assigned.
Adverse events	81 per 1,000	<b>0 per 1,000</b> (0 to 0)	not estimable	96 (3 RCTs)	Low <sup>53</sup>	Mehta-8 non-serious AEs reported by 8 patients (47.0%) (5 in the active, 3 in the sham group). Cohen-no serious complications reported for either group. In the radiofrequency treatment group, one patient reported transient nonpainful. Patel-subjects reported soreness or numbness at the introducer sites in the 2 weeks following treatment.1 subject

Summary of findings:

RFA (any type) compared to placebo for suspected SIJ pain in the Medicare population for effective pain relief

**Patient or population:** suspected SIJ pain in the Medicare population for effective pain relief

**Setting:**

**Intervention:** RFA (any type)

**Comparison:** placebo

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with placebo	Risk with RFA (any type)				
						developed shingles was deemed unrelated to treatment. <sup>52,53,56</sup>

\*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

**CI:** confidence interval

GRADE Working Group grades of evidence

- High certainty:** we are very confident that the true effect lies close to that of the estimate of the effect.
- Moderate certainty:** we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
- Low certainty:** our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
- Very low certainty:** we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

- a. Risk of Bias downgrade due to detection bias (blinding), incomplete outcomes data.
- b. Indirectness due to differences in interventions.
- c. Imprecision downgraded due to small sample size.

The Agency for Healthcare Research and Quality<sup>60</sup> (AHRQ) SR/MA included evaluation of cooled radiofrequency ablation procedures for sacroiliac joint pain. Evaluation of the Cohen<sup>52</sup> and Patel<sup>53</sup> placebo-controlled RCT were included and both were rated fair quality using AHRQ Methods Guide. The report states cooled RFA for SIJ pain compared to sham (2 trials, N=79); demonstrates short term outcomes improvements at 1- and 3-months reporting strength of evidence moderate for pain and function at 3 months and low for function at 1 month. Additionally, they report that harms were not well reported but usually temporary and related to increased pain with no serious complications reported with strength of evidence low. They also point out that the mean age of participants in these studies ranged from 52-59 which is below the Medicare population.

Chen et al.<sup>61</sup> conducted a meta-analysis to compare the clinical effectiveness of radiofrequency (RF) neurotomy versus conservative nonsurgical approaches for the management of chronic lumbar and sacroiliac joint pain. Five of 15 studies included reported sacroiliac joint pain with the rest on lumbar facet joint pain. In the pooled data authors conclude patients treated with radiofrequency neurotomy have significant greater improvement in ODI scores, pain scores and QoL measurements compared with controls however, this data was limited by significant heterogeneity from the pooled eligible studies, inability to separate the SIJ data despite sub analysis and high risk of bias necessitating larger studies are needed to confirm these findings.

Yang et al. conducted a SR on sacral lateral branch RFA and reported that the targeted nerve branches treated in the 32 studies varied with 5 studies targeting the L4 medial branch, one study targeting the S4 sacral lateral branch, 24/32 studies included the L5 dorsal ramis, and all studies included the S1 to S3 sacral lateral branches except for 2.<sup>31</sup> Most studies were observational and uncontrolled and only 2 placebo-controlled trials were available. The type of radiofrequency ablation technology varied between the studies and included conventional monopolar RFA, conventional bipolar RFA, cooled RFA and stripped lesions. While the authors conclude RFA can provide relief from posterior SIJ complex pain they found concern with the poor selection rigor which they propose may explain the variability in success of the RFA with positive outcomes ranging from 32 to 89%. They suggest improved diagnostic protocols, the specific nerves targeted for ablation, and the types of RFA technology and technique utilized may help to improve appropriate patient selection and outcomes.

In Simopoulos et al.<sup>36</sup> SR 14 therapeutic studies were reviewed using a modified grading approach described in the paper. The authors conclude the evidence for cooled radiofrequency neurotomy is level II-III. The evidence for conventional radiofrequency neurotomy, intra-articular steroid injections and periarticular injections with steroids or botulism toxin is limited at level III to IV.

A 2015 SR using GRADE to assess the evidence of validity of sacral lateral branch blocks and the effectiveness of sacral lateral branch thermal radiofrequency neurotomy for sacroiliac complex pain.<sup>32</sup> For multi-site, multi-depth SLBBs the authors conclude moderate quality evidence based on positive evidence from a single, well-designed RCT for therapeutic procedures.<sup>34</sup> In consideration of 15 studies on RFA the authors find moderate evidence for sacral lateral branch thermal radiofrequency neurotomy, however evidence shows relief is limited in extent and duration and the indication for the procedure are not clear. They conclude that local anesthetic injections with or without steroids are not sufficient for patient selection unless they are multisite, multi-depth SLBBs which they feel is the only valid test for diagnosis of sacral lateral branch pain. While this SR utilized GRADE criteria the only included RCT accessing the validity of sacral lateral branch blocks was challenged by small sample size with only twenty patients enrolled (ten in active arm) and did not evaluate to role of sacral lateral branch blocks in predicting SLBRFA success.

In a 2010 meta-analysis to assess the effectiveness of RFA of the SIJ for reduction of pain by  $\geq 50\%$  post-RFA procedure at 3 and 6 months included 10 articles (1 RCT, 4 prospective observational and 5 retrospective studies).<sup>62</sup> They conclude the MA demonstrated that RFA is an effective treatment for SI joint pain at 3 months and 6 months.

This was limited by lack of randomized controlled trials, and the lack of standardization among the studies for diagnostic criteria, RFA lesion techniques, pain scale and outcome measures resulting in high heterogeneity which reduces the reliability of the MA.

A 2018 SR/MA on cooled radiofrequency ablation included 240 subjects from retrospective, observational and two small RCTs.<sup>1</sup> Due to pooling of studies with different designs, high heterogeneity and small samples sizes the results may not be valid.<sup>63</sup> The author's acknowledge additional studies are needed to confirm their conclusion that cooled RFA is safe and effective for SIJ pain.<sup>1</sup>

A 2020 systematic review with meta-analysis designed to compare different radiofrequency ablation techniques used for treatment of lumbar facet joint and sacroiliac joint pain was conducted. A meta-analysis was conducted performed despite but high heterogeneity which limits the analysis with  $I^2 = 92\%$  and  $96\%$  for thermal and cooled RFA respectively. The authors recognize the lack of standards in the RFA techniques may be a cause of the high heterogeneity and that "our results may not be reliable". They report a comparison of cooled radiofrequency ablation, thermal radio frequency and pulsed radio frequency results in improvement for lumbar facet joint and sacroiliac joint pain for up to 6 months. However, the authors acknowledge that a comparison of the efficacy among 3 radiofrequency techniques in the treatment of low back pain has not been well investigated, and acknowledge the results lack a high level of evidence and more high-quality trials are needed.<sup>64</sup>

A 2022 systematic review pairing thermal versus cooled radiofrequency ablation in patients with sacroiliac joint pain included nine studies with a total of 276 patients. The meta-analysis reported overall pain reduction from the random effects model was  $-3.485$  (95% CI  $-4.144, -2.286$ ) for VAS scores with high heterogeneity ( $I^2=75.65\%$ ,  $P<0.001$ ). There was also reported improvement in OID scores of  $-29.809$  ( $-42.906, -16.713$ ) with high heterogeneity ( $I^2=97.02\%$ ,  $P<0.001$ ) The meta-analysis included all literature types including case series with one RCT (Ib) and remaining literature graded II-III using Cochrane's risk-of-bias tool. The authors conclude there was no statistical difference between the two techniques examined and the literature is currently lacking calling for additional studies period.<sup>65</sup> This meta-analysis is limited by pooling data from multiple study types and very high heterogeneity. While meta-analysis has been conducted the results must be interpreted with caution in light of this degree of heterogeneity, multiple different types of literature pooled together, small sample sizes and high risk of bias which limits reliability of meta-analysis and calls for further investigation as stated by the study authors.<sup>63</sup>

A 2022 SR reviewed acknowledge the evidence to support RFA, in the form of RCT, is "both thin and mixed" and state the lack of evidence beyond 12 months post-intervention 16 RCTs were included of which 15 reported positive results for RFA. Of significance many of the included studies reported RFA outcomes for facet, SIJ, intravertebral disc or a combination and were not specific to SIJ. The review did not breakdown the number of patients in each study that had SNRFA specifically, with a larger portion undergoing facet RFA. The reviewers included the largest study ( $n=681$ ) which reported "no clinically important improvement" from the RFA but reported valid criticism of the lack of blinding of both the patients and investigators.<sup>66</sup> The author acknowledges the studies in Figure 1 above as the only sham-controlled studies specific to SNRFA population. Meta-analysis was not conducted which was appropriate given the high heterogeneity of the included studies. The SR concludes "taken in aggregate" the total body of research supports this intervention however one cannot draw conclusions about pooled data in this setting as they are reporting a positive trend in RFA among several anatomical locations. The inclusion of studies that evaluate facet which has a more robust body of literature to support RFA than SIJ RFA and without a separate analysis of the SIJ specific literature makes results inconclusive.

#### Randomized Controlled Trials with comparative arm (non-placebo)

A randomized blinded study with 30 patients with chronic low back pain requiring regular analgesia and single

positive diagnostic SIJ block requiring 75% or greater pain relief.<sup>67</sup> Fifteen underwent radiofrequency generation of S1 to L3 lateral sacral branch and L4-5 primary dorsal rami and 15 underwent fluoroscopic guided SIJI with corticosteroids. Twelve patients in the steroid group crossed over to receive RFA at 1 month and one at 3 months. In the RFA group at 1, 3, and 6 months post-intervention, 73%, 60% and 53% of patients, respectively, gained >50% pain relief. In the steroid group, at 1-month postintervention follow-up, only 20% gained >50% pain relief. The authors report failure to show any improvement at 3 month and 6 month follow-up in the steroid group but given cross-over data was not analyzed the value of this data past 1 month is not contributory. Most patients did not have pain relief past 6 months in the RFA group. The study was limited by small sample size and while there were no adverse outcomes, the sample size was too small to assess safety and mean age was lower than Medicare population.

Another randomized prospective study with 30 patients with a single diagnostic block using 80% or greater pain relief to confirm SIJ dysfunction were randomly assigned to articular steroid injections or pulse RFA of S1-S3 lateral sacral branches and L4-L5 dorsal rami.<sup>68</sup> In the steroid group NRS scores decreased from baseline ( $7.133 \pm 1.060$ ) at 15 days ( $3.333 \pm 0.4880$ ) and one-month ( $3.333 \pm 0.4880$ ) post-procedure with increase at three-months ( $4.400 \pm 0.9856$ ). In the RFA group NRS scores also decreased from baseline ( $7.067 \pm 1.033$ ) to 15 days ( $3.200 \pm 0.4140$ ) with further decrease at 1 month ( $2.933 \pm 0.5936$ ) and stable at 3 months ( $3.067 \pm 0.8837$ ) which was a statistically significant difference compared to the SIJI group. At 6 months pain scores rose in both groups. ODI Score global perceived effect showed greater improvement in the RFA group compared to injection. The study was limited by small sample size, short duration of follow-up and lack of blinding introducing risk of bias. While there were no adverse outcomes, the sample size was too small to assess safety and the mean age was lower than Medicare population.

In another 2016 prospective, randomized comparative study of thermal radiofrequency with sacroiliac joint block compared SIJI to bipolar thermal radiofrequency.<sup>69</sup> Sixty subjects with clinical exam suspicious for SIJ pain and Visual Analogue Scale [VAS] > 6 and pain lasting more than 3 months were randomized into three groups (n = 20 in each group): ultrasound guided SIJI with local anesthetic/corticosteroid, conventional or modified (needle distance >1cm) bipolar radiofrequency "palisade" of S1, S2, and S3 evaluated at 1, 3 and 12 months. At 1 month there was >50% reduction in pain in all 3 groups (p < .001). The SIJI did not result in relief of pain at 3 and 12 months. The conventional RFA group reported pain relief at 3 months but not sustained at 12 months. The modified RFA group reported improvement at both 3 and 12 months (p < .001). Hematoma was reported without serious adverse events. Limitations of this study include inconsistent diagnostic/patient selection criteria (not all patients received diagnostic blocks), lack of control group, small numbers, lack of blinding introducing risk of bias and mean age was lower than the average Medicare recipient.

A 2015 prospective, observational study, with data collection over 5 years, was conducted at the authors' private practice to obtain a real-world view of RFA treatment outcomes for SIJ pain.<sup>70</sup> A cohort of 215 patients with SIJ pain confirmed with dual diagnostic SIJIs with unknown cut-off for pain relief underwent fluoroscopically guided SIJ RFA of the dorsal and lateral branches of S1-S3 and the descending branch of L5. They reported an average pain reduction of  $2.3 \pm 2.1$  NRS points following RFA (baseline pain score of  $6.9 \pm 1.7$  to a follow-up average of  $4.6 \pm 2.7$  NRS points; p = 0.01). Using a Likert scale at a mean follow-up period of  $14.9 \pm 10.9$  months (range 6 - 49 months), an overall 42.2% of patients reduced their analgesic use, 67% of patients were satisfied with RFA outcome and 21/82 reported an improvement in employment capacity leading to conclusion that RFA is a safe and effective treatment for pain confirmed to originate from the sacroiliac joint. Limitations include this was an observational study without a control group, single study site, no pre-treatment improvement from procedure reported, type of RFA not reported, risk of selection bias, unclear criteria for inclusion (percentage of pain relief required from diagnostic blocks) and non-consecutive enrollment.

### Other studies

Cohen et al.<sup>71</sup> conducted a retrospective review seeking outcome predictors to determine whether any demographic or clinical variables can be used to predict SI joint RF denervation success. Pre-procedure pain intensity, age older than 65 years, and pain radiating below the knee were predictors of failure. Regular opioid therapy showed a trend

towards negative outcome. The use of cooled, rather than conventional RF, was associated with a higher percentage of positive outcomes. The authors conclude several factors were found to influence outcomes including lack of a single clinical variable that reliably predicted treatment results and the use of more stringent selection criteria was not associated with better outcomes.

A prospective observational study evaluated 31 patients to which a new technique for RFA that applied multiple electrodes simultaneously to the L5 dorsal rami and lateral branch blocks of the S1, S2 and S3 by creating a stripped lesion from the lateral border of the base of the sacral superior articular process to the lateral border of the S3 sacral foramen was used. There was no sham group nor comparison to other RFA techniques however the authors concluded the technique reduced operating time, X ray exposure and cost as well as offered significant clinical improvement.<sup>72</sup>

A retrospective observational comparative study attempted to address if cooled RFA is superior to traditional RFA in providing longer pain relief. They did not determine there was a significant difference between the procedures and both procedures reduced pain by >50% pain reduction for 3-6 months in majority of the patients.<sup>73</sup>

A retrospective study was done to evaluate records from 126 patients with physical examination and positive response ( $\geq 50\%$  pain relief) to an intra-articular SIJ block who underwent cooled RF lateral branch neurotomy (LBN) of S1-S3 and L5 dorsal rami to treat chronic SIJ-mediated low back pain. Visual analog scale (VAS) pain scores, quality of life, medication usage, and satisfaction were collected before the procedure, at 3–4 weeks post procedure (N = 97), and once again between 4 and 20 months post procedure (N = 105).<sup>74</sup> When stratified by time to final follow-up (4–6, 6–12, and >12 months, respectively): 86%, 71%, and 48% of subjects experienced  $\geq 50\%$  reduction in VAS pain scores, 96%, 93%, and 85% reported their quality of life as much improved or improved, and 100%, 62%, and 67% of opioid users stopped or decreased use of opioids. Limitations include a retrospective study design and lack of control group to account for confounders, risk of recall bias and missing data due to difficulty in contacting certain subjects.

A 2013 retrospective study of 20 charts of patients who had undergone cooled RFA were reviewed 2 years after the procedure. 15/20 patients reported significant reduction in pain based on a decrease of at least three points on numerical rating scale. The authors conclude cooled radiofrequency denervation shows long term efficacy for up to two years. Patients in this study were diagnosed by a single positive diagnostic intraarticular SIJ injection<sup>75</sup>. Another retrospective review included 41 consecutive patients who underwent cold radiofrequency ablation after clinical diagnosis and greater than 50% pain relief from a single intraarticular block. The authors report pain relief lasted on average 5.5 months after the first radiofrequency ablation and nine months after repeat radiofrequency ablation with the longest duration of pain relief has 26 months.<sup>76</sup> Both studies are limited by the study design without any placebo-controlled or sham controlled group, no comparison to conventional radiofrequency ablation, no accounting for other interventions during this time, limitations in patient selection with single intra-articular SIJ block and small sample size.

A 2015 prospective longitudinal cohort study including 32 patients diagnosed with sacroiliac joint pain and confirmed with single positive diagnostic intraarticular sacroiliac joint injection underwent conventional radiofrequency ablation. Authors report an overall decrease in mean NRS pain score decreasing from  $7.7 \pm 1.8$  at baseline to  $2.8 \pm 1.2$  at one month and to  $3.1 \pm 1.9$  at six months post-procedure ( $p < 0.001$ ) with 27/32 reporting satisfaction. Long-term pain relief was sustained at twelve- and eighteen-months post-procedure, with NRS pain remaining at  $3.4 \pm 2.1$  and  $4.0 \pm 2.7$ , respectively. Mean age was below Medicare population at 58.3.<sup>77</sup>

While these studies suggest some potential long-term benefits there are too many variables to draw a reliable conclusion. Without a comparison to placebo, it is uncertain if the benefit is a result of the disease course improving overtime, additional interventions the patient received throughout this time period, a result of the radiofrequency ablation or placebo effect. Further investigation would be necessary to delineate these factors.

2020 retrospective study 27 patients with SIJ pain refractory to conservative treatment and on opioids with a single intra-articular diagnostic block underwent cooled radiofrequency ablation. The authors report a decrease in numerical rating score as well as a decrease in opioid use up to 12 months post intervention reporting a 44.4% success rate in the RFA defined by baseline NRS reduced by 50%. 18.5% did not use opioids during the follow-up up to 12 months.<sup>78</sup> While this is promising it is limited by the challenges with the selection criteria, retrospective study design, potential influence of physician prescribing practices, comorbidities including previous back surgery in the patient population, considerable variation in the opioid use outcomes and small sample size.

## **Frequency and Laterality**

Sacroiliac joint pain is typically unilateral. Bilateral joint pain is less common representing less than 10% of patients with SI joint disease. The highest reported incidence of bilateral pain is in those with ankylosing spondylitis and reactive psoriatic arthritis where bilateral sacroiliitis is more common. The SME panelists stated that bilateral involvement is also more common in the cases of elderly patients with degenerative disease. They also expressed that in patients who have had a fusion bilateral pain is more common and in patients who have relief on one side recurrence of pain on the opposite side is not uncommon.

There is a lack of strong evidence in the literature to support exact frequency or timing of SIJ injections. Subject matter experts found that utilizing the existing literature, current guidelines, and similar types of injections that no more than 2 injections per 6 months or 4 within a 12 months periods were reasonable limitations. The current literature and guidelines support at least a 50% relief in pain and/or function lasting a minimum of 8 to 12 weeks before repeating injections. This aligns with NASS Guidelines for SIJ injections recommendation of =50% relief for =3 months.<sup>22</sup> The QALY for SI joint RFA following physical therapy and steroid injections is 2.52.<sup>78</sup>

There is also little data in terms of long-term treatment with therapeutic injections. The subject matter experts advocated a progressive approach to management. If a patient had relief from therapeutic injection(s) it may provide sustained relief or it may reoccur. It is important to reevaluate and assess for response and then have the patient return if pain reoccurs. The panel felt that a very small proportion of patients should receive three or four therapeutic injections in a year.

## **Safety**

The cumulative literature has shown few significant adverse events associated with SI JIs and RFA procedures. Risk reported in the literature associated with the injections include possibility of septic arthritis and sciatic nerve palsy. There are also concerns about the risk of corticosteroids impact on cartilage and articular cartilage and a SR confirmed higher doses (greater than 3 milligrams/dose or 18 to 24 milligrams cumulative total/dose) for longer treatment duration with corticosteroids were associated with chondrotoxicity suggesting the importance of limiting use of corticosteroids to 3 to 4 IA injections annually into any given joint and using minimal steroid dosage possible.<sup>80,81</sup> Several studies reported worsening pain shortly after the procedure and one study reported transient non painful buttock paresthesia, and hematomas.<sup>52,56,57,62,69</sup>

Image guidance reduces risk of injection outside of the joint. One study found in patients who underwent blind SIJ injections, intra-articular needle placement was confirmed on subsequent computed tomography (CT) scans in only 22%<sup>82</sup>, and another study of blind injections, only 5 of 60 needles closely approximated the joint without any successful proper intra-articular placement.<sup>83</sup> The article also explains ultrasound cannot verify intra-articular placement and CT is less effective than fluoroscopy at capturing the escape of injected to the adjacent structures therefore fluoroscopy is the preferred imaging modality.<sup>6</sup> On the contrary, a study that compared fluoroscopically guided injections into the joint capsule to blind injections to the point of maximal tenderness using sham radiographs determined there was no significant difference in pain score at 1 month, and modestly decreased in the



fluoroscopically guided group as compared to the blind injection group at 3 months. The authors concluded that fluoroscopic guided injections provided greater intermediate benefits in some patients the differences were modest, and costs were increased. Adverse outcomes were reported in 6% of fluoroscopically guided group compared to 12% of landmark-guided ( $p=0.36$ ).<sup>83</sup> While this was not statistically significant, 61 patients receiving blind injections is not sufficient to assess the safety of this technique. In a prospective randomized study that compared ultrasound guided to fluoroscopically guided SIJ injections the authors concluded that function and pain relief were significantly improved in both groups. Ultrasound guidance was limited as 87.5% (US) verses 98.2% (fluoroscopy) were successful. However, when successful it offered good visualization of the vasculature and concluded that it was as effective as fluoroscopic guidance for treatment approach.<sup>84</sup>

The American Society of Anesthesiologists provides definitions on the continuum of the depth of sedation. Minimal sedation anxiolysis is defined as a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected. Progressing depth of sedation beyond minimal is moderate or “conscious”, deep and general. Monitored Anesthesia Care or “MAC” is not a depth of sedation, but a specific anesthetic service allowing a deeper level of analgesia than can be provided by moderate sedation.<sup>10</sup>

The American Society of Anesthesiologist also provides guidelines for anesthetic care during interventional pain procedures for adults stating that when sedation is provided during the performance of pain procedures it is important that the patient can be responsive during critical portions of the procedure to report potential procedure related paresthesia, acute changes in pain intensity or function for potential toxicity. The committee opinion states that interventional pain procedures generally only require local anesthetic however patients may elect to also receive supplemental sedation but must remain conscious. Examples of procedures that typically do not require moderate sedation and/or an anesthesia care team include sacroiliac joint injections. They also state that significant patient anxiety, medical comorbidities, procedures that require the patient to remain motionless for prolonged periods of time or remain in a painful position may require moderate sedation or anesthesia care team and an example of such a procedure is radiofrequency ablation.<sup>10</sup>

The subject matter expert panel agreed that sedation is not necessary for injections but may be appropriate in select cases of RFA. The panel also expressed concerns that sedation could increase risk as well as the validity of diagnosis.

## **Societal Guidance**

### *North American Spine Society (NASS)*

*2020 NASS Diagnosis and Treatment of Low Back Pain Guidelines<sup>22</sup> the following recommendations pertain to SIJs:*

- There was insufficient evidence to recommend non-specific physical exam maneuvers for assessment of SIJ pain or for or against obtaining laboratory tests to assess for inflammatory disease in patients with SIJ pain. Regarding efficacy of fluoroscopic guided SIJI the panel concludes intra-articular steroid joint injections may be considered in patients with suspected SIJ pain: Grade of Recommendation: C based on Level IV evidence. Statistically significant improvement in disability, pain and work status overtime was found in patients who had an 80% improvement from diagnostic sacroiliac joint injection followed by an intra-articular steroid injection. The average number of injections was 2.1.
- The panel concluded that in patients with temporary pain relief provided by SIJIs cooled radiofrequency ablation of the sacral lateral branch nerves and the dorsal ramis of L5 may be considered in patients with SIJ pain diagnosed with dual diagnostic blocks: Grade of Recommendation: C based on Level IV evidence. The reviewed studies required 50% and 75% dual diagnostic blocks prior to RFA.

- The panel concluded insufficient evidence to determine if SIJ fusion compared to medical intervention improved pain and function.

#### *2020 NASS Coverage Policy Recommendations for Sacroiliac Joint Injections & Radiofrequency Ablation:<sup>5</sup>*

- Diagnostic blocks for evaluation for SIJ pain is appropriate if the following criteria are met:
  - a. Patient's report of nonradicular, typically unilateral, pain that is maximal below the L5 vertebrae, localized over the posterior SIJ, and consistent with SIJ pain.
  - b. A physical examination typically 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) or the absence of tenderness elsewhere (e.g., greater trochanter, lumbar spine, coccyx) that would explain the patient's symptoms.
  - c. Positive response to a cluster of at least three provocative tests (1. Patrick's or FABER, 2. Gaenslen, 3. Thigh thrust, 4. Sacral thrust, 5. Distraction, 6. Compression).
- Blocks should be performed with image guidance and injectant limited to 2mL.
- The guidelines distinguish between intra-articular injections and diagnostic blocks. Intra-articular injections target the SIJ intra-articular surfaces and capsule and are recommended for diagnosis of SIJ pain. Diagnostic blocks of the L5 primary dorsal ramus and sacral dorsal rami lateral branches (S1-S3) are aimed at the dorsal and interosseous ligaments and aid in the diagnostic work-up of low back pain. According to these guidelines diagnostic blocks should be performed prior to RFA using small volume (<0.5mL per nerve) image-guided anesthetic blocks. For either block a positive response is at least 75% reduction in pain for the expected duration of the anesthetic used on two separate occasions.
- Therapeutic injections:

Image-guided intra-articular SIJ injections of corticosteroid with or without local anesthetic are indicated for the treatment of sacroiliac pain when = 1 of the listed criteria are met:

- a. Clinical criteria for diagnostic SIJ injection are met (as above) AND pain has been present for at least 1 month AND pain is  $\geq 4/10$  with functional limitation OR any pain level with functional limitation despite other conservative treatment.
- b. SIJ pain has been confirmed with diagnostic intra-articular SIJ injections.
- c. SIJ pain has recurred following a previous therapeutic SIJ injection which resulted in >50% pain relief for  $\geq 3$  months.
- d. Advanced imaging (bone scan or MRI) demonstrates uptake or inflammation in the SIJ.
- e. Patients with spondyloarthropathies such as ankylosing spondylitis.

- Radiofrequency neurotomy:

Image-guided thermal radiofrequency neurotomy of the L5 primary dorsal ramus and sacral dorsal rami lateral branches at S1, S2 and S3 are indicated for the treatment of sacroiliac pain when either of the listed criteria are met:

- a. Clinical criteria for positive diagnostic anesthetic blocks of the L5 primary dorsal ramus and sacral dorsal rami lateral branches (as above) are met AND pain has been present for at least 3 months AND pain is severe enough to cause some degree of functional deficit despite other conservative treatment.

- b. Posterior sacroiliac ligament complex pain has recurred after = 50% improvement for  $\geq 6$  months from prior radiofrequency neurotomy of the L5 primary dorsal ramus and sacral dorsal rami lateral branches.

*Spine Intervention Society (SIS) Appropriate Use Criteria for Fluoroscopically Guided Diagnostic and Therapeutic Sacroiliac Interventions: Results from the Spine Intervention Society Convened Multispecialty Collaborative:*<sup>85</sup>

- SIS guidelines were developed in collaboration with the American Academy of Orthopaedic Surgeons, American Society of Anesthesiologists, American College of Radiology, American Academy of Physical Medicine and Rehabilitation, American Academy of Pain Medicine, and North American Spine Society and evidence quality evaluated with GRADE. The panel concluded no high-quality evidence therefore the guidelines are largely based on clinical expertise utilizing a rating scale of more than 10,000 clinical scenarios each evaluated twice.
- Brings up the conundrum that while 50% of patients receive pain relief with radiofrequency neurotomy of the lateral branches of the sacral dorsal rami most of the studies selected were based on their response to intra-articular sacroiliac joint injections rather than diagnostic blocks of the sacral lateral branches which are the target of the therapeutic procedure.
- The panel felt clinical exam and provocation maneuvers should be required and that maximal pain above the L5 vertebrae negatively correlated with a recommendation for SIJ injection, while 3 or more positive provocation tests were a positive correlation. There was no requirement for imaging. The panel preferred injection with local anesthetic and steroids rather than local anesthetic alone for the potential additional pain relief and the panel did not feel it was appropriate to perform lateral branch blocks as the first intervention.
- The panel recommendations were to not withhold anticoagulation or antiplatelet medication prior to injection of the SIJ or lateral branches based on lack of bleeding complications reported in the literature. Additionally, lack of sensitive neural structures that could be damaged by hematoma was not an issue in this region. Holding anticoagulation places the patient at greater risk from the underlying condition for which they are being treated.
- The panel felt that SIJ injections were appropriate for the patient who has had pain for more than 1 month, intensity greater than 4/10 and causing functional limitations regardless of whether conservative therapy has been provided. There was also discussion that by giving the first injection with local anesthetic and steroids they are providing a therapeutic agent to a patient who has yet to be diagnosed with sacroiliac pain. While this benefits the patient with a positive response to the local anesthetic it risks administering steroids to someone who may not benefit. It was the opinion of the panel that injection of steroid with local anesthetic, injection of steroid alone or lateral branch blocks would be appropriate following an initial diagnostic injection of local anesthetic that provided greater than 75% pain relief. Injections of local anesthetic and steroid were considered appropriate if there was at least 50% pain and repeat injections required at least 50% pain relief from the initial therapeutic injection. Additionally, they went on to say that if the patient had an injection of steroid alone that they should have at least 75% relief for 2 months.
- Two key factors, duration of symptoms and degree of pain relief obtained during the block, were identified for evaluation of indications for RFA. The panel felt the symptoms should be present for at least 2 months prior to the procedure and that a minimum of 50% pain relief from diagnostic injections was insufficient to proceed with RFA. The panel agreed that pain relief needed to be at least 75% to proceed with procedure. For repeat RFA, they felt that the first RFA had to result in at least 50% pain relief and the effects last at least 3 months. They concluded the type and sequence of blocks obtained intra-articular versus lateral branch block had minimal effect on the outcome and were most relevant for those with 50 to 75% pain relief and in those with only 2-3 months of symptoms.

*The American Society of Interventional Pain Physicians (ASIPP) Comprehensive Evidence-Based Guidelines for Interventional Techniques in Chronic Spinal Pain Part II: Guidelines and Recommendations:*<sup>86</sup>

- Evidence for diagnostic sacroiliac intra-articular injections is good with 75% to 100% pain relief as criterion standard with controlled local anesthetic or placebo blocks leading to recommendation for diagnostic SIJIs in

individuals suspicious of SIJ pain with  $\geq 75\%$  improvement in pain or ability to perform previously painful movements.

- For sacroiliac joint interventions, the evidence for cooled radiofrequency neurotomy is fair; limited for intra-articular injections and periarticular injections; and limited for both pulsed radiofrequency and conventional radiofrequency neurotomy.

*International Society for the Advancement of Spine Surgery (ISASS) Policy 2020 Update- Minimally Invasive Surgical Sacroiliac Joint Fusion (for Chronic Sacroiliac Joint Pain): Coverage, Indications, Limitations and Medical Necessity<sup>26</sup>*

- Imaging may be beneficial for inflammatory sacroiliitis and acute trauma but no imaging modality has acceptable sensitivity and specificity for non-inflammatory, non-traumatic SIJ pain.
- ISASS state intra-articular SIJI may be considered but not required due to a lack of high-quality evidence supporting short- or long-term effectiveness of the treatment and three randomized control trials comparing injection to radiofrequency ablation have been published without demonstration of improvement in pain or function in 1 month after the injections. They do not recommend repeat SIJI with steroids and state concern regarding accelerated cartilage degeneration in the hip and knee and lack of cost effectiveness data.
- ISASS concludes SIJ RFA may be considered but not required and there is modest evidence to support safety and effectiveness. They report while there are randomized control trials to support this technology, there is no standardized patient selection algorithms, no standardized technology or techniques and the literature has mixed results. They conclude treatment with repeat RFA is not recommended.
- ISASS recommend diagnostic blocks to confirm the diagnosis of SIJ with a small volume of local anesthetic. There is concern that extravasation of injectant can compromise diagnostic capabilities. Regarding use of SIJ to selection patients for fusion. ISASS states that injection of the intra-articular portion of the joint does not predict outcomes to fusion and there is not sufficient evidence to support this practice. They expressed concern that an overly stringent selection criteria such as 75% has no basis in evidence and is likely to result in withholding a beneficial procedure from a substantial number of patients with significant pain and functional impairment.

*Assessment of Spondyloarthritis International Society- European League Against Rheumatism:<sup>87</sup>*

- ASAS-EU recommendations include glucocorticoid injections directed to the local site of musculoskeletal inflammation may be considered. Patients with axial disease should not receive long term treatment with systemic glucocorticoids.

*American College of Radiology (ACR), Spondylitis Association of America (SAA), and Spondyloarthritis Research and Treatment Network (SPARTAN):<sup>39,41</sup>*

ARC/SAA/SPARTAN guidelines give a conditional recommendation for SIJIs for patients as an option for patients with isolated active sacroiliitis despite the use of NSAID acknowledging this recommendation was supported by very low-quality evidence. They recommend avoiding peri-tendon injections and acknowledged the recommendation was extrapolated from experience in other diseases and feel this option is best for patients who prefer local over systemic treatment and when only one to two joints are inflamed. The 2016 update of the Assessment of Spondyloarthritis International Society/European League Against Rheumatism management recommendation for SpA, states glucocorticoid injections directly into the local site of musculoskeletal inflammation may be considered and is preferred over treatment with systemic glucocorticoids offering a level of evidence of II and a grade of recommendation of B on the GRADE scale.

*American Society of Pain and Neuroscience (ASPN) Best Practice Guidelines:<sup>51</sup>*

- Lateral sacral branch radiofrequency neurotomy may be used for treatment of posterior sacral ligament and joint pain following positive response to appropriately placed diagnostic blocks. GRADE II-I (Well, designed controlled, nonrandomized clinical trials) B (USPSTF recommends the practice/ moderate benefit).
- The authors recommend lateral sacral branch blocks prior to performing RFA even in cases where previous SIJ injections with the intra articular approach were performed using a 50% or greater reduction in pain prior to advancing to RF.

## **Analysis of Evidence (Rationale for Determination)**

The literature for sacroiliac joint pain is limited by few placebo-controlled randomized trials, lack of long-term data, inconsistencies in diagnostic criteria, assessment of outcomes, and techniques of procedures resulting in high heterogeneity between the studies. The overall quality of the literature is low, leading to many unanswered questions on best practices and the true effectiveness of the procedures. However, there is a consistent trend to improvements in pain after the SIJ injections in a subset of patients suggesting there is benefit and offers a viable treatment option that may improve pain and quality of life and function in some sufferers. SIJIs may provide relief for those suffering from inflammatory spondyloarthropathies while awaiting systemic therapy to become effective. The optimal patient selection, treatment and algorithm for care has yet to be clearly defined in the literature.

SIJ pain is based on clinical evaluation and physical exam with three positive provocative maneuvers increasing the likelihood of SIJ as the source of pain. Exclusion of other etiologies is important and may require imaging depending on the presenting symptoms and examination. Due to inconsistencies in the diagnostic criteria, confirmation with diagnostic injection(s) is indicated based on the current literature. The percent improvement in pain is controversial, however, most studies utilized a 75% or higher cutoff for pain. While some argue a less stringent cutoff should be utilized, there is not sufficient data to support this approach. Given that many of these patients will progress to repeat injections or surgical management correct diagnosis is necessary, so the more stringent criteria are indicated. This is consistently supported by the literature and societal guidelines.

The literature is unclear on the long-term effectiveness of therapeutic sacroiliac joint injections. Repetitive injections of corticosteroids do involve risk therefore long-term management with this approach should include a multidisciplinary team and notification of the primary care provider to assess impact on other health conditions. Guidelines suggest the mean number of injections is two. Repetitive injections are typically less common as patients with persistent pain will often move to surgery for long-term management. After the initial diagnostic injection, the first therapeutic injection can serve as a confirmatory diagnostic injection as well as a treatment. Pain relief of greater than 50% for at least two to three months would be expected based on the current evidence for a positive result.

The frequency and duration between treatment is also not clear in the literature, however guidelines address this topic. There was consistency in the guidelines and SME input that therapeutic injections should be given at a minimum of two months and more typically  $\geq 3$  months apart leading to a frequency limit of a maximum of 4 injections in a rolling 12 months, understanding that use of more than 2 SIJI is not standard.<sup>22,74</sup> Bilateral administration, while may be appropriate in some cases, is also not standard.

Multiple guidelines, SME input and one paper suggest that intra-articular injections may not be optimal for selection for radiofrequency ablation. Because radiofrequency ablation focuses on the posterior nerves, they recommend lateral sacral branch blocks (targeting dorsal and interosseous ligaments) to better select appropriate patient for RFA of SIJ, however there is insufficient evidence for this recommendation. It is possible that spread of the anesthetic and steroids out of the intra-articular space may be responsible for some of the positive results for patients who have been selected utilizing the intra-articular approach. This presents a conundrum as the diagnostic injections used to

confirm the presences of SIJ pain are not targeting the nerve which is being ablated during SLBRFA. Dreyfuss et al.<sup>34</sup> provides support that multi-site, multi-depth lateral branch blocks do not effectively block the intra-articular portion of the SIJ and suggest lateral branch blocks may serve as a better predictive tool, but that is not used in a single study on RFA all of which use the intra-articular approach with variable results. While guidelines recommend the use of lateral sacral branch blocks to predict optimal candidates for RFA this is not validated in any studies.

The literature shows a positive trend for SIJ RFA pain improvement and most subject matter experts on our panel support this as a treatment option. While meta-analysis that have been done in attempt to reconcile the small sample size, extremely high heterogeneity in these studies is problematic. Some meta-analysis attempt to pool data from various procedures including facet RFAs<sup>66</sup> or combine multiple study types into a single MA<sup>1</sup> which does not yield reliable. The AHRQ SR/MA includes only cooled RFA to reduce the heterogeneity and concluded the evidence was fair quality with moderate strength of evidence at 3 months for RFA for pain and function but was limited by a small sample size (n=79).<sup>60</sup> There are no studies to determine if one technique of RFA is superior to the others. To further evaluate the literature evidence analysis using GRADE was conducted with primary outcome of change in NRS at baseline and three months after RFA (Figure 1). NRS was selected as it was the only consistent measurement among the RCTs. This analysis concludes very low-quality evidence for RFA compared to placebo for SIJ pain. Additional studies are challenged by methodological flaws, small sample sizes, cross-over design, inconsistency, incomplete data and variability in patient selection and procedures performed.

For a service to be considered “reasonable and necessary” under §1862(a) (1) (A) of the Act it must be furnished in accordance with acceptable standard medical practice for the diagnosis or treatment of the condition.<sup>12</sup> To meet this requirement, an acceptable standard must be established and supported by the medical literature. There is insufficient evidence to determine a diagnostic criterion for identifying patients who may benefit from RFA. The existing studies report effectiveness outcomes that are based on selection criteria (intraarticular SIJ) that have been refuted within the literature and by experts creating a conundrum. Despite expert opinion suggesting SLBB criteria this lacks both evidence and clarity leading to tremendous variability within current practices and in patient outcomes (ranging from 32-89%). The lack of established practice standards, patient selection assessment criteria, frequency of treatment and long-term outcomes in the existing literature necessitates additional investigation to develop appropriate use criteria that can establish optimal patient selection and confirm effectiveness in properly selected patients to meet criteria for reasonable and necessary.

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## General Information

### Associated Information

N/A

### Sources of Information

N/A

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## Revision History Information

N/A

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## Associated Documents

### Attachments

N/A

### Related Local Coverage Documents

### Articles

[A59154 - Billing and Coding: Sacroiliac Joint Injections and Procedures](#)

[A59301 - Response to Comments: Sacroiliac Joint Injections and Procedures](#)

### LCDs

[DL39383 - Sacroiliac Joint Injections and Procedures](#)

### Related National Coverage Documents

N/A

### Public Versions

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