Sacroiliac Joint Injections and Procedures

Medicare Advantage Medical Policy #MNG-029
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Applies to all products administered or underwritten by the Health Plan,, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Health Plan may consider sacroiliac joint injections and procedures to be eligible for **coverage**** as described in the coverage indications below.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Health Plan considers sacroiliac joint injections to be **investigational.***

The use of sacroiliac joint injections when patient selection criteria are not met is considered to be **investigational.***

Coverage Indications, Limitations, and/or Medical Necessity

Coverage Indications, Limitations, and/or Medical Necessity

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.1 The SIJ 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 ileum 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 SIJ goes through many age-related changes throughout life that will restrict motion significantly due to the surface of the ilium becoming rougher and coated with fibrous plaques. 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.2 The SIJ has variable joint capacity as the SIJ 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. 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.1 The spectrum of pain and dysfunction from SIJ pain is variable but can be debilitating.

Treatment for SIJ pain includes conservative, surgical and interventional procedures, including SIJ injections (SIJIs) and radiofrequency ablation (RFA) of the SIJ. Injections are typically intra-articular and contain anesthetic and corticosteroids. Ablation relies on RF-generated thermal energy to ablate the sensory nerve fibers of the SIJ, 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

- SIJIs will be considered medically reasonable and necessary when all the following requirements are met:
    - Moderate to severe LBP primarily experienced over the anatomical location of the SIJs between the upper level of the iliac crests and the gluteal fold, AND
    - LBP duration of at least 3 months, AND
    - LBP below L5 without radiculopathy, AND
    - 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
    - At least 3 positive findings with provocative maneuvers: FABER, Gaenslen, Thigh Thrust or Posterior Shear, SI Compression, SI Distraction and Yeoman Tests,3,4 AND
    - LBP persists despite a minimum of 4 weeks of conservative therapies.5

Diagnostic SIJIs

- Diagnostic SIJI is used to determine if the etiology of pain is from the SIJ complex.3
- Diagnostic SIJI are considered reasonable and necessary for patients who meet ALL the following criteria:
  - The patient must meet the above criteria for Covered Indications for SIJI, AND
  - The SIJIs must be performed under computed tomography (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,6 AND
  - SIJI are not performed with other musculoskeletal injections in the lumbosacral spine, AND
  - The documentation should show direct causal benefit from the SIJI and not from other musculoskeletal injections or treatments, AND
  - The diagnostic SIJI provided a minimum of 75% relief of primary (index) pain with the diagnostic SIJI (a positive diagnostic response is defined as ≥75% sustained and constant pain relief for the duration of the local anesthetic and ≥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 SIJI, 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 2 diagnostic joint sessions, unilateral or bilateral. To clarify, 2 unilateral sessions, if performed on 1 side at 1 session and on the opposite side at a different session, would meet the limitation of 2 diagnostic sessions.

Therapeutic SIJI

- Therapeutic SIJI will be considered medically reasonable and necessary for patients who meet ALL the following criteria:
  - The patient must meet the above criteria for Covered Indications for SIJI, AND
  - The diagnostic SIJI provided a minimum of 75% relief of primary (index) pain with the diagnostic SIJI (a positive diagnostic response is defined as ≥75% sustained and constant pain relief for the duration of the local anesthetic and ≥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 SIJI, 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, AND

- 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 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
- The SIJIs 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.

Limitation: No more than 4 therapeutic SIJI sessions, unilateral or bilateral, will be reimbursed per rolling 12 months. To clarify, a therapeutic SIJI session if performed on 1 side first and then on the opposite side at a different session would qualify as 2 sessions for the limitation of 4 therapeutic SIJ sessions per rolling 12 months.

- **SIJ Denervation (also called 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 LBP 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.
- 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.
  - The SIJ procedure(s) should be performed in conjunction with conservative treatments.
  - Patient should be actively participating in an ongoing rehabilitation program, home exercise program or functional restoration program.
  - 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 SIJI 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 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 ADLs it is insufficient to provide a vague or nonspecific statement regarding the improvement of previously painful movements and 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

- Injections performed without radiographic image guidance are not considered reasonable and necessary.
- 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.
- It is not considered medically reasonable and necessary to perform multiple blocks (epidural steroid injection (ESI), sympathetic blocks, facet blocks, trigger point injections, etc.) during the same session as SIJIs and during the post SIJI efficacy assessment period.
- Use of Moderate or Deep Sedation, General Anesthesia, and Monitored Anesthesia Care (MAC) is usually unnecessary or rarely indicated for SIJIs, and therefore, not considered medically reasonable and necessary.10 Even in patients with a needle phobia and anxiety, typically oral anxiolytics suffice.
- SIJIs to treat non-specific LBP, axial spine pain primary above the level of L5, complex regional pain syndrome (CRPS), widespread diffuse pain, chronic pain syndrome, and pain from neuropathy are considered investigational, and therefore, are not considered medically reasonable and necessary.
- SIJIs used as part of a series of lumbar spine and musculoskeletal injections to treat nonspecific or chronic LBP is not considered reasonable and necessary.
- 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.
- Patients with coexisting psychological conditions or depression related illness should be treated and stabilized prior to proceeding with interventional procedures.11 Multidisciplinary biopsychosocial rehabilitation (MBR) principles should be provided to these patients.

- It generally would not be considered medically reasonable and necessary for treatment with SIJIs to extend beyond 12 months. Frequent continuation of SIJIs over 12 months may trigger a focused medical review. Use beyond 12 months requires the following:
    - 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.
    - 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 3 months.
    - Rationale for the continuation of SIJIs, including but not limited to, patients 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 3 months.
    - 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 MBR.
- A subsequent diagnostic SIJI is not reasonable and necessary when the initial diagnostic block does not produce a positive response of ≥ 75% pain reduction.
- 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 ADLs for at least 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.

It is mandated that healthcare professionals who perform SIJIs/procedures for chronic pain 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 guidance. Credentialing or privileges are required for procedures performed in both inpatient and outpatient settings.

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 (MRI), ultrasound). At a minimum, training must cover and accomplish 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, limitations, and general requirements for medical necessity as stated in all existing CMS LCDs, NCDs,CMS payment policy manuals, and all Medicare payment rules.

Summary of Evidence

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 SIJIs 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 LBP which is worse after prolonged sitting, bending forward and going from sitting to standing. Pain also may be worsened by weight bearing exercises, climbing stairs or prolonged walking. Gait pattern changes and referred pain to the buttocks, groin, thigh and sometimes behind the knee are common. Physical exams and provocative tests are essential to determining SIJ disorders.3 One meta-analysis (MA) showed that the thigh thrust test, the compression test, and 3 or more positive stressing test have discriminative power for diagnosing SIJ pain.4 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.

Imaging of the SIJ 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 LBP, 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.21,22 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.22 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.3 The diagnosis of spondylarthritis is characterized by sacroiliitis on plain radiographs; however, early in disease there may not be

radiographic findings and MRI may detect changes earlier than plain film.23 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, SIJIs, 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 radiofrequency ablation, 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 = 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.

Their literature includes diagnosis of sacroiliitis, spondylosis, and inflammatory spondyloarthropathies. Inflammatory arthritis as well as axial and peripheral spondyloarthropathies may affect the SIJ. The subject matter experts (SMEs) confirm that inflammatory back pain may be due to inflammation at the site of tendon attachments throughout the spine, with SIJ being 1 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.24 Early disease may not have radiographic findings with MRI being the most sensitive for detection of SIJ inflammation leading to the Assessment of Spondylarthritis International Society (ASAS) criteria to strongly recommend MRI of the SIJs for determination of sacroiliitis.

Conservative Management

A significant portion of the patient population would be expected to improve with time with or without intervention.26 Therefore, a trial of conservative management is an accepted standard despite limited 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.27,28 There was evidence to support physical therapy (PT) with a systematic review (SR) finding benefit of PT to reduce pain and dysfunction. SME review concludes low quality, but existing, data to support PT, manual therapies, and exercise interventions as potentially beneficial.

Diagnostic Injections

Due to 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 SIJ 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% verses 87%).3 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.3 The SIJ 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.6,31-33 Diagnostic and therapeutic intraarticular injections placed directly into the SIJ cavity anesthetizing the articular nerves and potentially the surrounding ligaments but does not access the posterior sacral network.

A single double blinded randomized control trial (RCT) with 20 subjects reported on the effectiveness of multi-site, multi-depth sacral lateral branch (SLB) 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.

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%.

In a 2015 systematic review, 10 reviewers assessed 45 publications on diagnostic validity or effectiveness of fluoroscopically guided interarticular SIJIs.6 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 1 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% verses >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.35 Limitations included the paucity of literature, and variations in technique and criteria for diagnosis of SIJ pain. The authors rate the evidence for diagnostic accuracy for SIJIs as good; however, that was based largely on observational studies with only 1 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 1 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 SIJ interventions.36 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 heterogenicity 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 verses sacral lateral branch blocks (SLBB) and the need to target the portion of the joint that is the pain generator.37 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.34 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.37 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.

Regarding the use of SIJI for axial SpA, the Medicare Administrative Contractors' (MACs) 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.39 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.

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 1 month for 5/6 that received steroids compared to 0/7 for those that received placebo.42 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 spondyloarthropathy 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.
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-spondyloarthropathic patients with chronic pain.44 Clinical assessment at the onset of the study and after 1 month included VAS score and pain index. At 1 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.45 conducted a systematic review to evaluate the accuracy of imaged guided therapeutic SIJ interventions in patients with back pain for at least 3 months. The primary outcome measures were short term (<6 months) and long term (>6 months) pain relief, and secondary outcome measures were improvement in functional status, psychological status, return to work, and reduction in opioid intake.

The authors conclude the evidence was fair in favor of cooled RF 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 RF, and conventional RF 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.17 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 2 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 (± 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 entheseal injections seemed safe and effective.

A systematic review was done to evaluate evidence on the comparative effectiveness of surgery versus SIJIs for injection confirmed non-traumatic SIJ pain.46 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 VAS or NRS 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 SIJIs.46 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 1 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.

A retrospective review concluded that extra-articular sources for SI region pain exists, and intra-articular anesthetic blockade may underestimate the true prevalence of SI 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=0.025). 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=0.037).48 Limitations include study design, self-reported patient outcomes, and short follow up.

In a single blinded randomized trial by Visser et al.,7 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 SIJs 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 conclude that manual therapy appears to be the treatment of choice for SIJ related leg pain with second line therapy being injection. Limitations include the lack of control group, small sample size, and short-term follow-up.

A prospective randomized control trial comparing patients with SIJ pain confirmed by diagnostic block of local anesthetic with 50% improvement lasting 3 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 SIJ 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.

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 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.4,34,50,51 It is proposed that SLBBs would better identify candidates for SLBRFA; however, there are no placebo controlled trials of sacral nerve blocks to confirm this theory.51 In a 2009 double blinded RCT by Dreyfuss et al., multi-site multi-depth SLBBs were evaluated in asymptomatic volunteers. Seventy percent of the active group achieved loss of sensation within the interosseous and dorsal SI 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. The authors predicted this could be a potential tool to identify patients who may benefit from SLBRFA.34 However, there are no studies that evaluate multi-site, multi depth or any other form of SLBBs to predict success with SLBRFA.4 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, RFA 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 RF neurotomy including monopolar, bipolar, cooled and palisade (strip) lesions have been utilized. There is not sufficient evidence to state 1 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 SIJs. A different procedure called cryoanalgesia has been proposed for SIJ pain. There is minimal literature on the role of cryoanalgesia for SIJ pain and the SMEs agree there is not sufficient evidence to support cryoanalgesia of SIJ.

Randomized Controlled Trials with Placebo Arm

Our SME reported 5 sham-controlled studies regarding the efficacy of SIJ RFA.52-55 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. 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. performed a randomized placebo-controlled study to determine whether SIJ denervation is a viable treatment for patients with chronic, intractable SIJ pain. Participants included 28 patients with injection-diagnosed SIJ pain using 75% or greater improvement after a single diagnostic SIJI. Under local anesthetic block, 14 patients received L4–L5 primary dorsal rami and S1–S3 lateral branch RF 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%) RF-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 RF 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 SIJ 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. 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 12-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.

van Tilburg 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.55 Thirty patients underwent percutaneous RFA 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 2 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 RF 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 17 reporting improvement.56 Eleven subjects were treated with the RFA 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 (± 0.8) at baseline to 3.4 (± 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 ± 0.8) to 3 months (7.0 ± 1.7). Subjects who had RFA moved from borderline anxiety at baseline (9.4 ± 5.9) to no anxiety (6.6 ± 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 1 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 SIJ trial.58 Diagnosis was made by history and physical exam and 1 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 RFA 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 the 1 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 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 1 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 3 months was reported by the authors which was used to calculate a sum of difference between baseline and 3 months. These values where 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. 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. The study by van Tilburg was a placebo-controlled study, in which cross-over occurred at 3 months 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.

Systematic review (SR)/Meta-Analysis (MA)

The Agency for Healthcare Research and Quality (AHRQ) SR/MA included evaluation of cooled RFA procedures for SIJ pain. Evaluation of the Cohen and Patel 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 which is below the Medicare population.

Chen et al. conducted a MA to compare the clinical effectiveness of RF neurotomy versus conservative nonsurgical approaches for the management of chronic lumbar and SIJ pain. Five of 15 studies included reported SIJ pain with the rest on lumbar facet joint pain. In the pooled data authors conclude patients treated with RF 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 SLBRFA and reported that the targeted nerve branches treated in the 32 studies varied with 5 studies targeting the L4 medial branch, 1 study targeting the S4 SLB, 24/32 studies included the L5 dorsal ramis, and all studies included the S1 to S3 SLBs except for 2.31 Most studies were observational and uncontrolled and only 2 placebo-controlled trials were available. The type of RFA 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 Simopoulous et al. SR 14 therapeutic studies were reviewed using a modified grading approach described in the paper. The authors conclude the evidence for cooled RF neurotomy is level II-III. The evidence for conventional RF 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 SLBBs and the effectiveness of SLB thermal RF neurotomy for SI complex pain. 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. In consideration of 15 studies on RFA the authors find moderate evidence for SLB thermal RF neurotomy; however, evidence shows relief is limited in extent and duration and the indication for the procedure is 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 SLB pain. While this SR utilized GRADE criteria, the only included RCT accessing the validity of SLBBs was challenged by small sample size with only 20 patients enrolled (10 in active arm) and did not evaluate the role of SLBBs in predicting SLBRFA success.

In a 2010 MA to assess the effectiveness of RFA of the SIJ for reduction of pain by >50% post-RFA procedure at 3 and 6 months included 10 articles (1 RCT, 4 prospective observational and 5 retrospective studies). They conclude the MA demonstrated that RFA is an effective treatment for SIJ pain at 3 months and 6 months. This was limited by lack of RCTs, and the lack of standardization among the studies for diagnostic criteria, RFA lesion techniques, pain scale and outcome measures resulting in high heterogenicity which reduces the reliability of the MA.

A 2018 SR/MA on cooled RFA included 240 subjects from retrospective, observational and 2 small RCTs.1 Due to pooling of studies with different designs, high heterogenicity and small samples sizes the results may not be valid. The author's acknowledge additional studies are needed to confirm their conclusion that cooled RFA is safe and effective for SIJ pain.

A 2020 SR with MA designed to compare different RFA techniques used for treatment of lumbar facet joint and SIJ pain was conducted. A MA was performed despite high heterogenicity which limits the analysis with I2 =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 heterogenicity and that "our results may not be reliable". They report a comparison of cooled RFA, thermal RF and pulsed RF results in improvement for lumbar facet joint and SIJ pain for up to 6 months. However, the authors acknowledge that a comparison of the efficacy among 3 RF techniques in the treatment of LBP has not been well investigated, and acknowledge the results lack a high level of evidence and more high-quality trials are needed.

A 2022 SR pairing thermal versus cooled RFA in patients with SIJ pain included 9 studies with a total of 276 patients. The MA reported overall pain reduction from the random effects model was -3.485 (95% CI -4.144, -2.286) for VAS scores with high heterogenicity (I2=75.65%, P<0.001). There was also reported improvement in OID scores of -29.809 (-42.906, -16.713) with high heterogenicity (I2=97.02%, P<0.001) The MA 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 2 techniques examined and the literature is currently lacking calling for additional studies period.65 This MA is limited by pooling data from multiple study types and very high heterogenicity. While MA has been conducted the results must

be interpreted with caution in light of this degree of heterogenicity, multiple different types of literature pooled together, small sample sizes and high risk of bias which limits reliability of MA and calls for further investigation as stated by the study authors.

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.66 The author acknowledges the studies in Figure 1 above as the only sham-controlled studies specific to SNRFA population. MA was not conducted which was appropriate given the high heterogenicity 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.

RCTs with comparative arm (non-placebo)

A randomized blinded study with 30 patients with chronic LBP requiring regular analgesia and single positive diagnostic SIJ block requiring 75% or greater pain relief.67 Fifteen underwent RF 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 1 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.68 In the steroid group NRS scores decreased from baseline (7.133 ± 1.060) at 15 days (3.333 ± 0.4880) and 1 month (3.333 ± 0.4880) post-procedure with increase at 3 months (4.400 ± 0.9856). In the RFA group NRS scores also decreased from baseline (7.067 ± 1.033) to 15 days (3.200 ± 0.4140) with further decrease at 1 month (2.933 ± 0.5936) and stable at 3 months (3.067 ± 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 RF with SIJ block compared SIJI to bipolar thermal RF.70 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 3 groups (n=20 in each group): ultrasound guided SIJI with local anesthetic/corticosteroid, conventional or modified (needle distance >1cm) bipolar RF ‘‘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 ($p<0.001$). 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 ($p<0.001$). 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.70 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 ± 2.1 NRS points following RFA (baseline pain score of 6.9 ± 1.7 to a follow-up average of 4.6 ± 2.7 NRS points; $p=0.01$). Using a Likert scale at a mean follow-up period of 14.9 ± 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 SIJ. Limitations include this was an observational study without a control group, single study site, no precent 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.

Frequency and Laterality

SIJ 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 AS 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 1 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 SIJIs. SMEs 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 month period 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 SIJIs recommendation of ≥50% relief for ≥3 months.22 The QALY for SIJ RFA following physical therapy and steroid injections is 2.52.

There is also little data in terms of long-term treatment with therapeutic injections. The SMEs 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 3 or 4 therapeutic injections in a year.

Safety

The cumulative literature has shown few significant adverse events associated with SIJIs 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.80,81 Several studies reported worsening pain shortly after the procedure and 1 study reported transient non-painful buttock paresthesia, and hematomas.

Image guidance reduces risk of injection outside of the joint. One study found in patients who underwent blind SIJIs, intra-articular needle placement was confirmed on subsequent CT scans in only 22%, and another study of blind injections, only 5 of 60 needles closely approximated the joint without any successful proper intra-articular placement. 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.6 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).83 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 SIJIs, 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.

The American Society of Anesthesiologists 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 SIJIs. 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 RFA.

The SME 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 LBP Guidelines22 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 SIJI 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 RFA of the SLB 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 functon.

2020 NASS Coverage Policy Recommendations for SIJIs & RFA5:

- Diagnostic blocks for evaluation for SIJ pain is appropriate if the following criteria are met:
    - Patient's report of non-radicular, typically unilateral, pain that is maximal below the L5 vertebrae, localized over the posterior SIJ, and consistent with SIJ pain.
    - 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.
    - Positive response to a cluster of at least 3 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 IO ligaments and aid in the diagnostic work-up of LBP. 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 2 separate occasions.
- Therapeutic injections:
  Image-guided intra-articular SIJIs of corticosteroid with or without local anesthetic are indicated for the treatment of SI pain when = 1 of the listed criteria are met:
    - Clinical criteria for diagnostic SIJI are met (as above) AND pain has been present for at least 1 month AND pain is ≥ 4/10 with functional limitation OR any pain level with functional limitation despite other conservative treatment.
    - SIJ pain has been confirmed with diagnostic intra-articular SIJIs.
    - SIJ pain has recurred following a previous therapeutic SIJI which resulted in >50% pain relief for ≥ 3 months.
    - Advanced imaging (bone scan or MRI) demonstrates uptake or inflammation in the SIJ.
    - Patients with spondyloarthropathies such as AS.
- RF neurotomy:
  Image-guided thermal RF neurotomy of the L5 primary dorsal ramus and sacral dorsal rami lateral branches at S1, S2 and S3 are indicated for the treatment of SI pain when either of the listed criteria are met:
    - 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.
    - Posterior SI ligament complex pain has recurred after = 50% improvement for ≥ 6 months from prior RF 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 SI Interventions: Results from the Spine Intervention Society Convened Multispecialty Collaborative:

- 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 RF neurotomy of the lateral branches of the sacral dorsal rami most of the studies selected were based on their response to intra-articular SIJIs rather than diagnostic blocks of the SLBs 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 SIJI, 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 SIJIs 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 SI 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:

- Evidence for diagnostic SI 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 ≥ 75% improvement in pain or ability to perform previously painful movements.
- For SIJ interventions, the evidence for cooled RF neurotomy is fair; limited for intra-articular injections and periarticular injections; and limited for both pulsed RF and conventional RF 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:

- 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 3 RCTs comparing injection to RFA 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 RCTs 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:

- 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):

- 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 1 to 2 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 Guidelines51:

- Lateral sacral branch RF 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 SIJIs 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 SIJ 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 SIJIs 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 3 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 SIJIs. 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 2. 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 2 to 3 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 2 months and more typically ≥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 SIJIs is not standard. Bilateral administration, while may be appropriate in some cases, is also not standard.

Multiple guidelines, SME input and 1 paper suggest that intra-articular injections may not be optimal for selection for RFA. Because RFA focuses on the posterior nerves, they recommend lateral sacral branch blocks (targeting dorsal and IO 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.34 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 SMEs on our panel support this as a treatment option. While MA that have been done in attempt to reconcile the small sample size, extremely high heterogenicity in these studies is problematic. Some MA attempt to pool data from various procedures including facet RFAs or combine multiple study types into a single MA1 which does not yield reliable results. The AHRQ SR/MA includes only cooled RFA to reduce the heterogenicity 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). There are no studies to determine if 1 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 3 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.12 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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Policy History

Original Effective Date: 01/01/2025
Current Effective Date: 01/01/2025
09/26/2024 Medical Policy Committee review
09/26/2024 Medical Policy Implementation Committee approval. New policy.

Coding

The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of the Health Plan Medical Policy Coverage Guidelines is with the Health Plan and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in the Health Plan Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of the Health Plan Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	27096, 64451
HCPCS	G0260
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally

recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

Medicare Advantage Members

Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-bene-help.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.