Regence

Medical Policy Manual Surgery, Policy No. 231

Radiofrequency Ablation and Injection of Sacroiliac Joint Nerves

Effective: October 1, 2025

Next Review: August 2026
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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Radiofrequency ablation (RFA), also known as radiofrequency neurotomy, involves heating a portion of a pain-transmitting nerve to functionally denervate a designated joint (e.g., sacroiliac) and prevent the transmission of pain signals to the brain. A nerve block is injected prior to the RFA procedure for diagnostic purposes.

MEDICAL POLICY CRITERIA

Radiofrequency ablation (neurotomy) or injection (e.g., anesthetic agent, steroid) of the nerves innervating the sacroiliac joint is considered **investigational**.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Decompression of Intervertebral Discs Using Laser Energy (Laser Discectomy) or Radiofrequency Energy (Nucleoplasty), Surgery, Policy No. 131
2. Pulsed Radiofrequency for Chronic Spinal Pain, Surgery, Policy No. 156
3. Sacroiliac Joint Fusion, Surgery, Policy No. 193
4. Ablation of Peripheral Nerves to Treat Pain, Surgery, Policy No. 236

BACKGROUND

The sacroiliac joint (SIJ) is a joint between the sacrum and ilium of the pelvis. The SIJ is a strong weight bearing joint with a self-locking mechanism that provides stability with movement on the left and right side of the sacrum. Similar to other structures in the spine, it is assumed that the SIJ may be a source of low back pain.

Treatments being investigated for SIJ pain include prolotherapy, corticosteroid injection, radiofrequency ablation, stabilization, and arthrodesis. Radiofrequency ablation (denervation, neurotomy) involves destruction of the nerves using heat generated by a radiofrequency current. A catheter or electrode is placed near or in the target nerve. The position of the electrode is confirmed by fluoroscopy. Once the electrode is in place, a radiofrequency current is applied to heat and destroy the surrounding tissues, including the target nerve. Before the RFA procedure, a nerve block is injected into one or two of the nerves innervating the SIJ to locate the target nerve for ablation.

REGULATORY STATUS

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

FDA product codes: GXD, GXI.

EVIDENCE SUMMARY

The principal outcome for treatment of pain is symptom relief and improved functional level. Relief of pain can be subjective depending on the validity of the measurement tool used. Randomized controlled trials (RCTs) are desirable to control for the placebo effect and determine whether any treatment effect provides a significant advantage over the placebo. In addition, well-designed studies comparing radiofrequency ablation (RFA) treatment with conventional treatment are important to determine the overall effectiveness of this therapy for the treatment of sacroiliac joint (SIJ) pain. This evidence review includes both SIJ RFA and injections (e.g., anesthetic, steroid).

SACROILIAC JOINT INJECTION (E.G., ANESTHETIC, STEROID)

Systematic Reviews

Janapala (2023) published a systematic review (SR) evaluating the effectiveness of therapeutic sacroiliac joint injections (intraarticular).[1] The SR included a total of 11 studies. The authors were unable to complete the dual arm analysis due to limitations in the studies included. They reported that a single-arm meta-analysis demonstrated a difference of approximately 3 points on the Numeric Rating Scale (NRS) and 8 points on the Oswestry Disability Index (ODI). However, there were no studies that considered >= 50% relief as the criterion standard. The authors concluded that the qualitative and quantitative evidence combined shows Level III or fair evidence for therapeutic sacroiliac joint injections for managing low back pain of sacroiliac joint origin. However, there were several limitations to the studies available including variations in techniques and variable diagnostic standards.

Randomized Controlled Trials

Patel (2023) randomized 72 patients with SIJ pain and sacroiliac joint dysfunction to fluoroscopy-guided intra-articular injection of corticosteroid and local anesthesia or a sham group consisting of fluoroscopy-guided anesthetic injection and distilled water injection.[2] Diagnosis of sacroiliac joint dysfunction was based on the International Association for the Study of Pain criteria. All patients reported pain located over the SIJ. In a single-blinded assessment, pain (Numeric Rating Scale [NRS]) and disability (Oswestry Disability Index [ODI]) were significantly reduced at 4 weeks follow-up within each group ($p < 0.05$). The corticosteroid injection group had a greater magnitude for both outcomes ($p < 0.001$).

Section Summary

Evidence for injections of the nerves that innervate the SIJ include one small RCT comparing steroid injection to sham control and a systematic review. The evidence is limited by small sample size, lack of studies, inconsistencies among available studies for the SR and variations in techniques. The evidence is insufficient to support injections of the nerves that innervate the sacroiliac joint to treat pain.

RADIOFREQUENCY ABLATION (RFA)

Systematic Reviews

Janapala (2024) published a SR with meta-analysis evaluating the effectiveness of radiofrequency neurotomy (ablation) of the SIJ.[3] The authors report methodological disparities in the included studies. They suggest level III evidence and provide a fair recommendation for RFA as a treatment option. Limitations included variations in criteria and technical factors. The authors conclude that further high-quality studies and real-world scenarios are needed.

Maccagnano (2022) published a systematic review (SR) comparing clinical outcomes of thermal (RFT) versus cooled radiofrequency ablation (RFC) in patients (n=276) with SIJ pain.[4] The analysis revealed a small and non-significant difference in pain reduction and an improvement in quality of life in RFT subgroup (pain measured in Visual Analogic Scale: RFT subgroups standardized mean difference (SMD) =-3.643 (95% confidence interval [CI] -4.478 to 2.807), RFC subgroup SMD = -3.285 (95% confidence interval [CI] -4.428 to -2.141), p=0.587; Quality of Life measured in Oswestry Disability Index: RFT subgroup SMD=-35.969 (95% CI -53.993 to -17.945), RFC subgroup SMD=-20.589% (95% CI -33.424 to -7.754), p=0.123). Publication bias was found in quality-of-life assessment due to the low number and high heterogeneity of studies. Two techniques showed no major complications.

Chou (2021) conducted a SR and meta-analysis on interventional treatments for acute and chronic pain for the Agency for Healthcare Research and Quality for use by the Centers for Medicare and Medicaid Services.[5] The systematic review identified two trials (n=79) on cooled RFA versus sham for SIJ pain with results at three months, and one trial (n=28) on cooled RFA versus sham with results at one month. Meta-analysis indicated that cooled RFA is probably more effective for pain and function compared to sham at one and three months with moderate to large benefits. The strength of evidence was rated moderate for pain and function at three months and low for function at one month. When comparing cooled RFA to conventional RFA, one trial (n=43) showed no differences at one or three-month follow-up and a small, nonstatistically significant reduction in pain at six months. The strength of evidence was rated as low.

Chappel (2020) performed a meta-analysis of RFA for chronic back pain.[6] The review included five RCTs comparing RFA to sham or medical treatment in patients with chronic SIJ pain with follow-up from one to three months, and one study that had a follow-up to 12 months. This meta-analysis did not include pulsed RFA. Low-quality evidence indicated that RFA led to a modest reduction in pain at one to three-month follow-up, but there was no significant reduction in pain in the single RCT (n=228) that had six- and 12-month follow-up. The RCT by Juch (2017) with 12-month follow-up is described in greater detail below.[7]

Chen (2019) published a meta-analysis of five RCTs comparing RFA to sham or medical treatment in patients with chronic SIJ pain.[8] Various RFA procedures were represented, including percutaneous, cooled, and palisade SIJ radiofrequency neurotomy. Pain outcomes from all RCTs were pooled for the meta-analysis. Disability outcomes were only available for two studies utilizing cooled RFA. While studies showed no significant heterogeneity for disability outcomes, heterogeneity was high for pain outcomes.

Randomized Controlled Trials

Cohen (2023) published the results from a multicenter, randomized comparative effectiveness study to assess cooled RFA with standard medical management for chronic SIJ pain.[9] Patients (n=210) with clinically suspected sacroiliac joint pain who obtained short-term benefit from diagnostic sacroiliac joint injections and prognostic lateral branch blocks were randomly assigned to receive cooled radiofrequency ablation (cRFA) of the L5 dorsal ramus and S1-S3 lateral branches or standard medical management (SMM) consisting of pharmacotherapy, injections and integrative therapies. The primary outcome measure was mean reduction in low back pain score on a 0-10 Numeric Rating Scale (NRS) at three months. Secondary outcomes included measures of quality of life (QOL) and function. The mean NRS pain score for the cRFA group was 3.8 ± 2.4 (mean reduction 2.5±2.5) compared with 5.9 ±1.7 (mean reduction 0.4±1.7) in the SMM group ($p<0.0001$). More than half (52.3%) of subjects in the cooled radiofrequency ablation group experienced > 2.0 points (30%) pain relief and were deemed responders versus 4.3% of standard medical management patients ($p<0.0001$). Comparable improvements favoring cooled radiofrequency ablation were noted in Oswestry Disability Index score (mean 29.7 ± 15.2 vs 41.5 ± 13.6; $p<0.0001$) and QOL (mean EuroQoL-5 score 0.68 ± 0.22 vs 0.47 ± 0.29; $p<0.0001$). Long term outcomes are lacking and there is potential bias as each of the authors are consultants for the RFA device company. Mehta (2018) published results from a double-blind, randomized, sham-controlled trial assessing the efficacy of radiofrequency neurotomy with a strip-lesioning device in patients with chronic SIJ pain.[10] Seventeen of 30 enrolled patients were randomized to active (n=11) or sham (n=6) treatment. Recruitment was terminated after an interim analysis indicated a statistically significant difference in the pain outcome between groups. After the three-month study endpoint, patients receiving sham treatment were allowed to crossover. While a statistically significant reduction in pain scores was reported at three months, there was no significant difference in functional outcome as measured by the Physical Component Score at three months. Due to the crossover design, it is difficult to gauge long-term outcomes and durability of the treatment.

Dutta (2018) published a randomized prospective study comparing RFA with depo-methylprednisolone (DMP) injection for SIJ pain.[11] Patients (n=30) were randomly assigned to RFA or DMP injection of the L4 medial branch and L5 dorsal rami and the lateral sacral branches. Both groups reported a reduction in pain as measured by the Numeric Rating Scale (NRS) at one month. At six months the NRS score began to rise for the DMP group while the RFA group remained the same (since the last visit). Both groups had improvement in the

Oswestery Disability Index (ODI) score at three and six months with the RFA group having a lower score at both time points. This study is limited by a small sample size.

Juch (2017) reported a nonblinded multicenter RCT of radiofrequency denervation in 228 of 2498 patients with suspected sacroiliac pain who were asked to participate in the trial.[7] Patient selection criteria included body mass index (<35 kg/m^2), age (<70 years old), and pain reduction of at least 50% within 30 to 90 minutes of receiving a diagnostic sacroiliac block (n=228). An additional 202 patients had a negative diagnostic sacroiliac block; 1666 patients declined to participate in the trial. Patients meeting criteria were randomized to exercise plus radiofrequency denervation (n=116) or an exercise program alone (n=112) and were followed for a year. The RFA group had a modest improvement for the primary outcome at 3 months (-0.71; 95% CI: -1.35 to -0.06), but the control group improved over time and there were no statistically significant differences between the groups for pain intensity score (p=.09) or in the number of patients who had more than a 30% reduction in pain intensity (p=0.48) at 12 months. Limitations included the use of several techniques to achieve radiofrequency denervation, self-selection, lack of blinding, and a high dropout rate (31%) in the control group.

Van Tilburg (2016) reported a sham-controlled randomized trial of percutaneous RFA in 60 patients with SIJ pain.[12] Patients selected had clinically suspected SIJ pain and a decrease of two or more points on a 10-point pain scale with a diagnostic sacroiliac block. At three-month follow-up, there was no statistically significant difference in pain level over time between groups (group by period interaction, p=0.56). Both groups improved over time (≥ 2.0 points out of 10; p-value for time, p<.001). In their discussion, trialists mentioned the criteria and method used for diagnosing SIJ pain might have resulted in the selection of some patients without SIJ pain.

Canovas (2016) published a randomized, prospective study comparing blockade injection, bipolar thermal RFA (needle distance 1 cm) and a modified bipolar RFA (needle distance > 1.0 cm) in 60 patients.[13] One month after the treatment, pain reduction was >50% in the three groups p<0.001. Three and 12 months after the technique, the patients of the group A did not have a significant reduction in pain. At three months, almost 50% patients of the group B referred to improvement of the pain (p=0.03), and <25% at 12 months, and those results were statistically significant (p=0.01) compared to the baseline. Group C showed an improvement of 50% at three and 12 months (p<.001). All patients completed the study.

Zheng (2014) reported on an RCT of palisade sacroiliac RFA in 155 patients with ankylosing spondylitis.[14] Palisade RFA uses a row of radiofrequency cannulae perpendicular to the dorsal sacrum. Inclusion criteria were ages 18 to 75 years; diagnosis of ankylosing spondylitis; chronic low back pain for at least three months; axial pain below L5; no peripheral involvement; pain aggravation on manual pressing of the SIJ area; and at least 50% pain relief following fluoroscopically guided anesthetic injection into the joint. Patients who met the inclusion criteria were randomized to palisade RFA or celecoxib. Blinded evaluation to 24 weeks found that RFA (2.8) resulted in lower global VAS scores than celecoxib (5.0; p<.001) as well as improved scores for secondary outcome measures. This study lacked a sham control.

Patel (2012) reported a randomized, double-blind, placebo-controlled trial of lateral branch neurotomy with a cooled radiofrequency probe.[15] Twelve-month follow-up was reported in 2016.[16] Fifty-one patients who had a positive response to two lateral branch blocks were randomized 2:1 to lateral branch radiofrequency or to sham. At a three-month follow-up, significant improvements were observed in pain levels (-2.4 vs -0.8), physical function (14.0 vs

3.0), disability (-11.0 vs 2.0), and QOL (0.09 vs 0.02) for radiofrequency treatment compared with controls (all respectively). With treatment success defined as a 50% or greater reduction in numeric rating scale score, 47% of radiofrequency-treated patients and 12% of sham-treated patients achieved treatment success. The treatment response was durable to 12 months in the 25 of 34 patients who completed all follow-up visits.[16] Of the nine patients who terminated study participation, four of 34 (12%) were considered treatment failures.

Section Summary

Meta-analysis of available sham controlled RCTs suggests that there may be a small effect of RFA on SIJ pain at short-term (one- to three-months) follow-up. However, the randomized trials of RFA have methodologic limitations, and there is limited data on the duration of the treatment effect. The single RCT with six and 12-month follow-up showed no significant benefit of RFA compared to an exercise control group at these time points. In addition, heterogeneity of RFA treatment techniques precludes generalizing results across different studies.

PRACTICE GUIDELINE SUMMARY

AMERICAN SOCIETY OF PAIN AND NEUROSCIENCE (ASPN)

In the 2024 updated ASPN published guidance on the treatment of sacroiliac disorders the following best practice statement was provided regarding sacroiliac radiofrequency ablation: RFA of the SIJ should be performed by an established and researched method and repeated no more than at six-month intervals when an improvement of 50% pain relief and functional improvement is seen.[17] American Society of Anesthesiologists & American Society of Regional Anesthesia and Pain Medicine

The American Society of Anesthesiologists and the American Society of Regional Anesthesia and Pain Medicine have a 2010 guideline for chronic pain management.[18] The guideline recommends that “Diagnostic sacroiliac joint injections or lateral branch blocks may be considered for the evaluation of patients with suspected sacroiliac joint pain.” Based on the opinions of consultants and society members, the guideline recommends that “Water-cooled radiofrequency ablation may be used for chronic sacroiliac joint pain.”

SUMMARY

There is not enough research to show that radiofrequency ablation (RFA) or injection (e.g., anesthetic agent, steroid) of the nerves innervating the sacroiliac joint (SIJ) improves net health outcomes in patients with sacroiliac joint pain. High quality data from randomized controlled trials are needed to compare RFA and injections to the nerves innervating the SIJ with the currently accepted treatments for SIJ pain. Therefore, the use of radiofrequency ablation (RFA) or injection (e.g., anesthetic agent, steroid) of the nerves innervating the sacroiliac joint for the treatment of sacroiliac joint pain is considered investigational.

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CODES

Codes	Number	Description
CPT	64451	Injection(s), anesthetic agent(s) and/or steroid; nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)
	64625	Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)
HCPCS	None	

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