07.01.58 Radiofrequency Ablation and Alternative Ablative Methods for Chronic Facet Joint Mediated Neck, Back and Sacroiliac Joint Pain*

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Related Policies:

- 07.01.41 Pulsed Radiofrequency Ablation
- 07.01.66 Treatments for Occipital Neuralgia, Chronic Headaches and Persistent Idiopathic Facial Pain*
- 07.01.73 Ablative Procedures of the Peripheral Nerves to Treat Pain*

Summary

Description

For individuals who have chronic sacroiliac joint (SIJ) pain, treatment with radiofrequency ablation (RFA) has been explored.

For individuals with chronic facet joint mediated neck and back pain (cervical, thoracic and lumbar) or chronic SIJ pain, alternative ablative methods of treatment has been explored including but not limited to the following: laser denervation, chemical neurolysis (e.g., alcohol, phenol, glycerol, or hypertonic solution), cryodenervation (cryoablation), cooled radiofrequency ablation, pulsed radiofrequency (PRF) ablation and endoscopic radiofrequency ablation.

Summary of Evidence

For individuals who have chronic sacroiliac joint (SIJ) pain who receive radiofrequency ablation (RFA), the evidence includes 6 randomized controlled trials (RCTs) using different radiofrequency applications and case series. Relevant outcomes are symptoms, functional outcomes, quality of life (QOL), medication use, and treatment-related morbidity. Meta-analysis of available sham controlled RCTs suggests that there may be a small effect of RFA on SIJ pain at short-term (1 to 3 months) follow-up. However, the RCTs of RFA have methodologic limitations, and there is limited data on the duration of the treatment effect. The single RCT with 6 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. For RFA with a cooled probe, 3 small RCTs reported short-term benefits, but these are insufficient to determine the overall effect on health outcomes. An RCT on palisade RFA of the SIJ did not include a sham control. Another sham controlled RCT showed no benefit from RFA. Further high-quality controlled trials are needed to compare this procedure in defined populations with sham control and alternative treatments. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have chronic facet joint mediated neck and back pain (cervical, thoracic and lumbar) or chronic SIJ pain who receive alternative ablative methods including but not limited to the following: laser denervation, chemical neurolysis (e.g., alcohol, phenol, glycerol, or hypertonic solution), cryodenervation (cryoablation), cooled radiofrequency ablation, pulsed radiofrequency (PRF) ablation and endoscopic radiofrequency ablation, the evidence includes systematic reviews, RCTs, an AHRQ Comparative Effectiveness Review, observational studies, and case series. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. The current evidence is considered low-quality with common limitations including small sample sizes and short follow-up. While some studies may show promise in improving pain and function within the first 1-3 months and in improving treatment success at 6 months, further well-designed, RCTs with large sample sizes and long-term follow-up are needed to establish the impact on health outcomes. The evidence is insufficient that these alternative ablative methods for treating chronic facet joint pain (cervical, thoracic, lumbar) and chronic SIJ pain result in improvement in net health outcome.

Additional Information

2014 Input

In response to requests, input was received from 4 physician specialty societies and 4 academic medical centers (5 responses) while this policy was under review in 2014. Input was mixed on the use of arthrography, radiofrequency ablation, and fusion of the SIJ. Most reviewers considered injection for diagnostic purposes to be medically necessary when using controlled blocks with at least 75% pain relief, and for injection of corticosteroids for treatment purposes. Treatment with prolotherapy, periarticular corticosteroid, and periarticular botulinum toxin were considered investigational by most reviewers.

OBJECTIVE

The first objective of this evidence review is to determine whether the use of radiofrequency ablation (RFA) for the treatment of chronic sacroiliac joint (SIJ) pain improves net health outcomes.

The second objective of this evidence review is to determine whether the use of alternative ablative methods including but not limited to the following: laser denervation, chemical neurolysis (e.g., alcohol, phenol, glycerol, or hypertonic solution), cryodenervation (cryoablation), cooled radiofrequency ablation, pulsed radiofrequency (PRF) ablation and endoscopic radiofrequency ablation to treat individuals with chronic facet joint mediated neck and back pain (cervical, thoracic and lumbar) facet joint pain or chronic SIJ pain improves net health outcomes.

PRIOR APPROVAL

Prior approval is required.

POLICY

Radiofrequency Ablation (RFA) for the Treatment of Chronic Sacroiliac Joint Pain

Radiofrequency ablation (RFA) for the treatment of chronic sacroiliac joint (SIJ) pain is considered **investigational.** The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Alternative Ablative Methods

Alternative ablative methods including but not limited to the following for the treatment of chronic neck and spinal/back pain, including but not limited chronic facet joint pain (cervical, thoracic, and lumbar) and chronic SIJ pain is considered **investigational.** The evidence is insufficient to determine that the technology results in an improvement in the net health outcome:

- Chemical neurolysis (chemodenervation; e.g., alcohol, phenol, glycerol, or hypertonic solution)
- Cooled radiofrequency
- Cryodenervation (cryoablation)
- Endoscopic radiofrequency ablation
- Laser denervation
- Pulsed radiofrequency (PRF) ablation

POLICY GUIDELINES

Coding

See the Codes table for details.

BACKGROUND

Sacroiliac Joint Pain

Similar to other structures in the spine, it is assumed the SIJ may be a source of low back pain.

Research into SIJ pain has been plagued by a lack of a criterion standard to measure its prevalence and against which various clinical examinations can be validated. For example, SIJ pain typically presents without any consistent, demonstrable radiographic or laboratory features and most commonly exists in the setting of morphologically normal joints. Clinical tests for SIJ pain may include various movement tests, palpation to detect tenderness, and pain descriptions by the patient. Further confounding the study of the SIJ is that multiple structures, (e.g., posterior facet joints, lumbar discs) may refer pain to the area surrounding the SIJ.

Because of inconsistent information obtained from history and physical examination, some have proposed the use of image-guided anesthetic injection into the SIJ for the diagnosis of SIJ pain. Treatments being investigated for SIJ pain include RFA and alternative methods including but not limited to: laser denervation, chemical neurolysis (e.g., alcohol, phenol, glycerol, or hypertonic solution), cryodenervation (cryoablation), cooled radiofrequency ablation, pulsed radiofrequency (PRF) ablation and endoscopic radiofrequency ablation.

Alternative Ablative Methods in the Treatment of Cervical, Thoracic and Lumbar Chronic Facet Joint Pain and Chronic Sacroiliac Joint Pain

Chemical Neurolysis

Chemical neurolysis also referred to as chemodenervation involves an injection of neurolytic agent(s) such as phenol, alcohol, glycerol, or hypertonic solution to denervate a nerve(s). The use of chemical neurolysis (chemodenervation) has been proposed as an option for facet joint (cervical, thoracic, and lumbar) and SIJ pain relief. The chemical ablating agent is injected into the facet joint nerve or SIJ, the damage to the nerve tissue reduces its ability to transmit pain signals, thereby reducing pain sensation.

Cooled Radiofrequency

Cooled radiofrequency allows for higher power delivery and larger volume of treated tissues with decreased risk of adjacent tissue damage. Cooled radiofrequency (also referred to as cooled radiofrequency ablation or cooled radiofrequency neurotomy) uses a water-cooled radiofrequency probe to ablate a larger lesion size and treat a larger area than standard radiofrequency technology. Procedures utilizing this alternate treatment include sacroiliac joint denervation and denervation of the facet joints (cervical, thoracic, and lumbar).

One such cooled radiofrequency (RF) procedure is called COOLIEF. Per the manufacturer website for COOLIEF, Avanos, Inc., states the following: “COOLIEF Cooled RF is a minimally invasive procedure that ablates the nerves sending pain signals from the facet joint to the brain for up to 24 months. COOLIEF Cooled RF uses water-cooled technology that enables more RF energy to safely deactivate pain-transmitting sensory nerves which creates a larger, spherical lesion that distally projects 45% or greater beyond the probe’s tip.”

Cryodenervation (Cryoablation)

Cryodenervation (cryoablation) is a minimally invasive procedure that involves the use of extreme cold to destroy nerve(s) that transmit pain. It is utilized to treatment chronic pain such as chronic back and facet joint pain. Cryodenervation (cryoablation) involves inserting a slim, laminated, double-walled cryodenervation probe under local anesthesia. The cryodenervation probe is cooled to -170 degrees Celsius by carbon dioxide, thereby freezing and destroying the nerve(s) transmitting the pain. Cryoablation does not damage the surrounding tissue.

Endoscopic Radiofrequency Ablation

An endoscopic radiofrequency ablation is a minimally invasive procedure in which the nerves that innervate the facet joints are transected and then ablated through a small tube using small instruments. This procedure is an outpatient procedure usually performed under light sedation. The procedure offers another means of pain relief for facet joint related pain. This procedure is an alternative to percutaneous radiofrequency ablation, where either the patient has disease that may appear to not be amendable to the percutaneous approach, such has patients with severe facet joint disease, history of lumbar fusion, or severe scoliotic curvature and have had a positive response to the diagnostic medial branch block (MBB). The endoscopic radiofrequency is also an option for patients that have recurrent pain after 6-9 months of relief with the percutaneous radiofrequency ablation and do not wish to repeat the percutaneous approach.

Special equipment is used including fluoroscope and a monitor to view the spine through the scope, and small instruments are used to ablate the nerves. A small incision is made over the facet joint and after local anesthetic is administered, the port, which is the size of a small pen chamber, is passed onto the facet joint. A camera is inserted into the port along with instruments to transect and then ablate the medial branch nerves. Under direct visualization the nerve is localized and ablated. Once the nerve is ablated, the facet joint ineffectively transmits pain to the brain. When adequate nerve ablation has occurred, the tools are removed, a suture is placed under the skin and a bandage is placed.

Laser Denervation

Laser denervation involves the use of a high intensity laser to denervate or destroy the nerves related to chronic facet joint pain (cervical, thoracic, and lumbar) or chronic sacroiliac joint (SIJ) pain.

Pulsed Radiofrequency Ablation

Pulsed radiofrequency (PRF) ablation has been proposed as a possibly safer alternative to non-pulsed or continuous radiofrequency ablation (RFA) in the treatment of a variety pain syndromes to include chronic facet joint pain (cervical, thoracic, and lumbar) and chronic sacroiliac joint (SIJ) pain. Pulsed radiofrequency uses short bursts of radiofrequency current (heat is dissipated during the silent period), rather than the continuous current, which allows the needle to remain relatively cool so that the tissue cools slightly between each burst, reducing the risk of destroying nearby tissue. Pulsed radiofrequency causes the transmission across small unmyelinated nerve fibers to be disrupted, but not permanently damaged. This is because the temperature will not exceed 42 degrees Celsius, versus 80 degrees Celsius reached in non-pulsed or continuous radiofrequency ablation (RFA). *See medical policy 07.01.41 Pulsed Radiofrequency Ablation*

Regulatory Status

A number of radiofrequency (RF) generators and probes for the peripheral nervous system have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process, some examples are listed in the Table 1.

Table 1. Radiofrequency and Cryoneurolysis Devices

Device	Manufacturer	Date
SInergy®/Bayless Pain Management Probe	Kimberly-Clark/Baylis	2005
NeuroTherm® NT 2000	NeuroTherm	2011
iovera	Myoscience4	2014
COOLIEF® Cooled Radiofrequency Kit	Avanos, previously known as Halyard Health	2016
COOLIEF® Cooled RF Probe	Avanos, previously known as Halyard Health	2017
COOLIEF® Radiofrequency Generator (CRG) System	Avanos Medical Inc.	2020
COOLIEF® Cooled Radiofrequency Kit Advanced	Avanos Medical Inc.	2020
COOLIEF® Radiofrequency Generator	Avanos Medical Inc.	2024
Rulo(TM) Radiofrequency Lesion Probe	Epimed International	2019
Intracept Intraosseous Nerve Ablation System	Relievant Medsystems, Inc.	2022
Apex 6 Radiofrequency Lesion Generator	RF Innovations, Inc.	2023
cyroICE™, cryoFORM™ cryoablation probe cryoICE™ cryoablation probe (Cryo2), cryosphere cyroablation probe (CryoS, Cryo S-L)	AtriCure Inc.	2016 2020

Products for other types of spinal ablation therapies can be searched at the following website: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

RATIONALE

This evidence review was created in February 2002 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through January 2026.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, QOL, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The RCT is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Treatment of Sacroiliac Joint Pain: Radiofrequency Ablation

Clinical Context and Therapy Purpose

The purpose of radiofrequency ablation (RFA) is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with chronic sacroiliac joint (SIJ) pain.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with chronic SIJ pain.

Interventions

The therapy being considered is RFA, also known as radiofrequency neurotomy. RFA involves heating a portion of a pain-transmitting nerve to create a heat lesion. The goal of the heat lesion is to functionally denervate the SIJ and prevent the transmission of pain signals to the brain. Several variations of RFA are available, including water-cooled, pulsed, and conventional continuous RFA. Water-cooled RFA produces larger lesions than the other 2 modalities, however, lesion size is also dependent on temperature, needles size, and procedure duration. Lateral branch RFA targets the SIJ nerves.

Comparators

The following therapy is currently being used to treat chronic SIJ pain: conservative therapy.

Outcomes

The general outcomes of interest are symptoms (e.g., reductions in pain), functional outcomes, QOL, reductions in medication use, and treatment-related morbidity. Follow-up at 3 and 15 months is of interest to monitor outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and AEs, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

De Salvatore et al (2024) performed a systematic review regarding the efficacy of interventional treatments in the management of low back pain (LBP) due to sacroiliac joint pain (SJP) dysfunction. The following databases were searched Medline, EMBASE, Scopus, CINAHL, Cochrane Library, and CENTRAL bibliographic. Fourteen studies (n=352 patients) were included for qualitative synthesis (3 RCTs. 7 case studies, 2 observational studies, 1 cohort study and 1 case control study). Five studies used the traditional radiofrequency approach (tRF), five studies used cooled radiofrequency approach (cRF), one study used botulinum toxin (BT), two studies used steroid injection, triamcinolone (TA) and local anesthetics injections, and one study used pulsed radiofrequency (PRF) denervation. Two studies used sham as a comparator. Various outcome scales were utilized: for pain assessment numeric rating scale (NRS), paid disability index (PDI) and visual analog score (VAS); for physical function Oswestry Disability Index (ODI), Patient Global Impression of Change scale (PGIC), Roland Morris Functional score (RMF), and Short-Form 12 and 36 (SF-12 and SF-36); and for other scores assessed included: Assessment of Quality of Life (AQoL), Functional Assessment of Chronic Illness Therapy (FACIT), Global Perceived Effect (GPE), Hospital Anxiety Scale (HADS-total), and MODI: Modified Oswestry Disability Index. Eleven studies reported pain and functional outcomes (3 RCTs, 6 case studies, 1 observational study and 1 cohort study). The majority of studies that reported pain outcomes follow-up was 6-months except one study reported a longer follow-up of 18 months (Romero et al 2015). All studies reported an improvement in pain after the first month of the interventions. In regards to physical function outcomes the maximum follow-up outcome was 12-months and all studies reported improvement in function at different times. The majority of studies included did not report any major adverse events. While studies may have shown promise outcomes were considered to be “short-term improvement and impossible to conclude

long-term results." Limitations included lack of high-quality literature, only included 3 RCTs and was not possible to establish significant conclusions regarding the effectiveness of the treatments included. There was high heterogeneity between studies regarding the type of treatments, and duration of follow-up. The authors concluded that "cRF seems to be the most effective treatment in improving pain and functionality, however, due to the lack of high-quality studies it was not possible to draw significant conclusions and further clinical trials are required to establish which nonsurgical treatment could be most effective in LBP by SI joint dysfunction."

Hayes health technology assessment updated December 2025 regarding conventional radiofrequency ablation (RFA) for sacroiliac joint (SIJ) denervation for chronic low back pain (CLBP) not responding to conventional, this assessment identified 2 newly published studies 1 comparison study (Chen 2023) and 1 single arm study (Boos 2024). The December 2022 assessment identified 10 studies that met inclusion criteria. There was no change in the assessment the overall quality of evidence was considered low-quality due to heterogeneity in procedural variables, small to moderate sample sizes, lack of consistency across the studies regarding functional outcomes, and lack of studies reporting outcomes other than function and pain. Also, patient selection criteria for RFA of SIJ to treat CLBP has not been established. While some studies may show promise in the reduction of SIJ pain following conventional RFA up to 6 months, uncertainty remains whether there is longer durability of effect. Further studies are needed regarding conventional RFA of SIJ designed with more than 12-months of follow-up to evaluate the effectiveness of pain relief to include the measures of quality of life (QOL), function and disability.

Tables 1 and 2 summarize the characteristics and results of systematic reviews below.

Ciaffi et al (2024) conducted a meta-analysis on minimally invasive interventional procedures for osteoarthritis and inflammatory arthritis, including SIJ RFA. A total of 52 studies of SIJ RFA were identified, of which 33 (8 RCTs, 25 non-randomized studies [NRS]) were included in the quantitative synthesis. At 1-month, pooled RCT data (n=340) showed a mean VAS reduction of -3.18 (95% CI: -3.96 to -2.39; p<.001; I^2=93%), while NRS data (n=804) showed a larger reduction of -4.93 (95% CI: -5.58 to -4.28, p<.001; I^2=97%). Improvements persisted across 3, 6, and 12 months, though the magnitude diminished slightly over time (RCTs, -2.51; I^2=93% vs. NRS, -3.73; I^2=99% at 12 months). Functional outcomes on the Oswestry Disability Index also improved, with RCTs showing a mean decrease of -11.8 points (p<.001; I^2=65%) at 1 month and NRS a larger decrease of -21.1 points (p<.001; (p<.001; I^2=96%), with benefits maintained to 12 months. Heterogeneity across studies was high, especially among observational cohorts. Overall certainty of evidence was rated moderate for RCT pain outcomes and low for NRS, due to risk of bias and inconsistency in results.

Janapala et al (2024) conducted a meta-analysis on the effectiveness of RFA for SIJ pain. The review included 8 RCTs and 12 observational studies meeting inclusion criteria. Qualitative analysis, after downgrading based on GRADE criteria, resulted in Level III evidence with fair recommendation for RFA in managing sacroiliac joint pain. The meta-analysis included both dual-arm and single-arm analyses. A single-arm meta-analysis of 12 studies (including both RCTs and observational studies) showed a mean pain score reduction of 3.848 points at 3 months follow-up (95% CI: -4.552 to -3.145, p<.0001). Dual-arm analysis comparing RFA to non-active controls at 3 months showed a statistically significant difference in pain levels (standardized mean difference [SMD] -0.96, 95% CI: -1.73 to -0.19; p=.02). Functional improvement was variable but generally showed significant improvement across different time points. The authors suggest that while the evidence supports a Level III recommendation for RFA in managing sacroiliac joint pain, further high-quality research is needed to strengthen these findings.

Chou et al (2021) conducted a systematic review 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. The systematic review identified 2 trials (N=79) on cooled RFA versus sham for SIJ pain with results at 3 months, and 1 trial (N=28) on cooled RFA versus sham with results at

1 month. Meta-analysis indicated that cooled RFA is probably more effective for pain and function compared to sham at 1 and 3 months with moderate to large benefits. The strength of evidence was rated moderate for pain and function at 3 months and low for function at 1 month. When comparing cooled RFA to conventional RFA, 1 trial (N=43) showed no differences at 1 or 3-month follow-up and a small, nonstatistically significant reduction in pain at 6 months. The strength of evidence was rated as low.

Chappel et al (2020) performed a meta-analysis of RFA for chronic back pain. The review included 5 RCTs comparing RFA to sham or medical treatment in patients with chronic SIJ pain with follow-up from 1 to 3 months, and 1 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 1 to 3-month follow-up, but there was no significant reduction in pain in the single RCT (n=228) that had 6- and 12-month follow-up. The RCT by Juch et al (2017) with 12-month follow-up is described in greater detail below.

Chen et al (2019) performed a meta-analysis of 5 RCTs comparing RFA to sham or medical treatment in patients with chronic SIJ pain. 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 2 studies utilizing cooled RFA. While studies showed no significant heterogeneity for disability outcomes, heterogeneity was high for pain outcomes.

Table 2. Characteristics of Systematic Reviews

Study	Dates	Trials	Participants	N (Range)	Design	Duration, mo
Janapala et al (2024)	Inception-2023	8 RCTs, 12 observation studies	Patients with chronic SIJ pain treated by various RFA procedures with or without sham control groups.	(17 to 228)	RCTs and single-arm studies	**3**
Chou et al (2021)	2007-2021	3	Patients with chronic SIJ pain treated by various RFA procedures compared to sham.	122 (28 to 51)	RCTs	1 to 3
Chappel et al (2020)	2008-2019	5	Patients with chronic SIJ pain treated by various RFA procedures compared to sham or medical treatment. One trial with 12 mo follow-up had 228 participants.	384	RCTs	3 to 12
Chen et al (2019)	2012-2018	5	Patients with chronic SIJ pain treated by various RFA procedures compared to sham or medical treatment	311 (28 to 155)	RCTs	3 to 6

SIJ: sacroiliac joint; RCT: randomized controlled trial; RFA: radiofrequency ablation

Table 3. Results of Systematic Reviews

Study	Pain Score	Pain Score	ODI Score	GPE Score
Janapala et al (2024)	3 mo (NRS)	6 mo (NRS)	3 mo	6 mo (ODI)
Chou et al (2021)	3 mo vs sham RFA	6 mo vs conventional RFA		
Total N	79			
Cooled RFA	-2.4	-3.8		
Sham or conventional RFA	-0.8	-3.0		
p	.04	.041		
Chappel et al (2020)	1 to 3 mo	6 mo		

Study	Pain Score	Pain Score	ODI Score	GPE Score
Total N	5 studies[1]; n=384	1 study[1]; n=228		
MD (95% CI)	-1.53 (-2.62 to 0.45)	-0.28 (-1.00 to 0.44)		
p	.02			
I^2 (p)	83%	NA		
Chen et al (2019) Various RFA				
Total N	5 studies[1]; n=311	See NRS Score[1]	2 studies; n=79	1 study; n=60
MD (95% CI)	-2.13 (-3.4 to -0.87)		-8.91 (-16.44 to -1.38)	0.60 (-0.09 to 1.29)
p	.001		.020	.090
I^2 (p)	82.3% (NR)		44.8% (NR)	NR

CI: confidence interval; GPE: Global Perceived Effect; MD: mean difference; NA: not applicable; NR: not reported; NRS: numerical rating scale; ODI: Oswestry Disability Index; RFA: radiofrequency ablation; VAS: visual analog score.
[1] All pain scores (NRS, VAS) utilizing an 11-point scoring system were pooled together for the meta-analysis.

Randomized Controlled Trials

Tables 4 and 5 summarize the characteristics and results of randomized controlled trials (RCTs).

Table 4. Characteristics of Key RCTs Assessing Radiofrequency Ablation

Study	Countries	Sites	Dates	Participants	Interventions	
Cohen et al (2023)	U.S.	15	2018-2019	Patients with SIJ pain lasting 3 or more mos	Cooled RFA (n=105)	Medical management (n=105)
Mehta et al (2018)	UK	1	2012-2015	Patients with SIJ pain confirmed by diagnostic intra-articular injection; only 17 of 30 enrolled patients were randomized due to results of interim analysis	Multi-probe strip lesion RFA (n=11)	Sham (n=6) 4 patients crossed over to active group after 3-month endpoint
Juch et al (2017)	Netherlands	16	2013-2014	Patients with chronic low back pain related to the SIJ	RFA + exercise program (n=116) 110 received RFA 81 received Palisade radiofrequency treatment 23 received cooled RFA 6 received multi-probe strip lesion RFA	Exercise program (n=112) 69 completed program 18 did not complete program 25 with unknown completion
Van Tilburg et al (2016)	Netherlands	NR	2012-2014	Patients with SIJ pain	Percutaneous RFA to lateral branch and dorsal root primary ramus (n=30)	Sham (n=30)

Zheng et al (2014)	China	1	2010-2012	Patients with ankylosing spondylitis and SIJ pain	PSRN with computed tomography guidance (n=82)	Celecoxib treatment (n=73)
Patel et al (2012; 2016)	U.S.	NR	2008-2010	Patients with SIJ pain	Lateral branch cooled RFA (n=34)	Sham (n=17)

NR: not reported; PSRN: palisade sacroiliac joint radiofrequency neurotomy; RFA: radiofrequency ablation; RCT: randomized controlled trial: SIJ: sacroiliac joint.

Table 5. Results of Key RCTs Assessing Radiofrequency Ablation

Study	Pain Outcomes		Functional Outcomes		Treatment Success	
Cohen et al (2023)	NRS at Baseline (SD)	NRS at Month 3 (SD)	ODI at Baseline (SD)	ODI at Month 3 (SD)	At Month 3 (%)	
Cooled RFA	6.3 (1.4)	3.8 (2.4)	40.7 (13.8)	29.7 (15.2)	52.3%	
Medical management	6.3 (1.4)	5.9 (1.7)	43.7 (13.9)	41.5 (13.6)	4.3%	
p Value	NR	<.0001	.27	<.0001	<.0001	
Mehta et al (2018)	NRS at Baseline (SD)	NRS at Month 3 (SD)	PCS[1] at Baseline (SD)	PCS at Month 3 (SD)	Treatment Success	
Strip lesion RFA	8.1 (0.8)	3.4 (2.0)	28.4 (7.1)	34.7 (10.8)	NR	
Sham	6.5 (2.0)	7.3 (0.8)	28.6 (5.0)	29.6 (5.6)	NR	
p Value	NR	<.001	NR	.0645	NR	
Juch et al (2017)	NRS at Month 3 (95% CI)	NRS at Month 12 (95% CI)	ODI at Month 3 (95% CI)	ODI at Month 12 (95% CI)	At Month 3, n/N (%)	At Month 12, n/N (%)
RFA + exercise program	4.77 (4.31 to 5.24)	4.65 (4.16 to 5.13)	27.72 (24.50 to 30.95)	27.29 (23.89 to 30.69)	43/110 (39.10)	49/102 (48.03)
Exercise program	5.45 (4.94 to 5.95)	4.84 (4.30 to 5.38)	29.09 (25.47 to 2.71)	24.49 (20.74 to 28.23)	19/88 (21.59)	24/76 (31.78)
MD/RR (95% CI)	-0.71 (-1.35 to -0.06)	-0.07 (-0.74 to 0.60)	-4.20 (-8.39 to -0.00)	2.11 (-2.25 to 6.47)	1.87 (1.13 to 2.71)	1.46 (0.92 to 2.02)
p Value	.03	.83	.05	.34	.02	.10
Van Tilburg et al (2016)	Mean NRS at Baseline (SD)	Mean NRS at Month 1 (SD)	Mean GPE at Month 1 (SD)	Mean GPE at Month 3 (SD)	Treatment Success	
Percutaneous RFA	7.2 (1.4)	5.4 (1.7)	3.2 (1.1)	3.4 (1.6)	NR	

Study	Pain Outcomes		Functional Outcomes		Treatment Success	
Sham	7.5 (1.2)	5.4 (1.9)	3.3 (1.0)	3.4 (1.5)	NR	
p Value	NR	NR	NR	NR	NR	
Zheng et al (2014)	VAS at Week 12 (95% CI)	VAS at Week 24 (95% CI)	Mean BASFI[2] at Baseline (95% CI)	BASFI at Week 24 (95% CI)	Treatment Success	
PSRN	2.5 (2.2 to 3.0)	2.8 (2.5 to 3.2)	5.4 (5.0 to 5.8)	3.1 (2.7 to 3.6)	NR	
Celecoxib	4.4 (4.0 to 4.9)	5.0 (4.6 to 5.3)	5.3 (4.8 to 5.8)	5.0 (4.5 to 5.5)	NR	
MD (95% CI)	-1.9 (-2.4 to -1.4)	-2.2 (-2.6 to -1.6)	NR	-1.9 (-2.5 to -1.2)	NR	
p Value	<.0001	<.0001	NR	<.0001	NR	
Patel et al (2012; 2016)	NRS at Baseline (SD)	NRS at Month 3 (SD)	ODI at Baseline (SD)	ODI at Month 9 (SD)	At Month 3, n/N (%)	At Month 6, n/N (%)
Cooled RFA	6.1 (1.3)	-2.4 (2.7)	37 (14)	-11 (17)	16/34 (47)	13/34 (38)
Sham	5.8 (1.3)	-0.8 (2.4)	35 (10)	2 (6)	2/17 (12)	7/16 (44)[3]
p Value	.370	.035	.639	.011	.015	NR

BASFI: Bath Ankylosing Spondylitis Functional Index; CI; confidence interval; GPE: Global Perceived Effect; MD: mean difference; NR: not reported; NRS; Numeric Rating Scale; ODI: Oswestry Disability Index; PCS: Physical Component Score; RCT: randomized control trial; RFA: radiofrequency ablation; RR: relative risk; SD: standard deviation; VAS; Visual Analog Scale.
[1] Higher scores on the SF-12 Physical Component Score (PCS) indicate improved outcomes.
[2] The Bath Ankylosing Spondylitis Functional Index (BASFI) measures overall functional outcomes on a scale from 0 to 10 with 0 indicating best possible functioning.
[3] Patients assigned to the sham group were allowed to crossover to active treatment after the 3-month study endpoint.

Cohen et al (2023) reported results from a multi-center, single-blind, randomized, controlled trial assessing the efficacy of cooled RFA in patients with chronic SIJ pain compared to a control group of medical management alone. 210 enrolled patients were randomized to active (n=105) or control (n=105) treatment. Outcome assessors were blinded to treatment assignment. After the 3-month study endpoint, patients in the active group had significant improvements in the primary outcome of change in NRS score, and significantly more patients who reported ≥50% pain relief on the NRS (41.9% vs 6.5%; p<.0001) (Table 9). The secondary outcome ODI scores at 3 months significantly favored the cooled RFA group (p<.0001), as did SF-36 Physical component scores (40.2 vs 33 p<.0001), 5-level EuroQol-5D (EQ-5D-5L) scores (0.68 vs. 0.47; p<.0001), and the number of patients reporting improved Patient Global Impression of Change (PGIC) scores (65.5% vs 6.5%; p<.0001). Procedure-related adverse events were reported in 16 (15%) individuals who received cooled RFA, but none were considered severe. This study is limited by the short duration of follow-up as well as the single-blinded nature of the study, which could influence many of the self-reported outcomes. Additionally, participants continued their medical management during the study period, which may affect quality and functional outcome measurements.

Mehta et al (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. 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 3-month study endpoint, patients receiving sham treatment were allowed to crossover. While a statistically significant reduction in pain scores was reported at 3 months, there was no significant difference in functional outcome as measured by the Physical Component Score at 3 months. Due to the crossover design, it is difficult to gauge long-term outcomes and durability of the treatment.

Juch et al (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. 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% confidence interval [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=.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 et al (2016) reported a sham-controlled randomized trial of percutaneous RFA in 60 patients with SIJ pain. Patients selected had clinically suspected SIJ pain and a decrease of 2 or more points on a 10-point pain scale with a diagnostic sacroiliac block. At 3-month follow-up, there was no statistically significant difference in pain level over time between groups (group by period interaction, p=.56). Both groups improved over time (≥2 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.

Zheng et al (2014) reported on an RCT of palisade sacroiliac RFA in 155 patients with ankylosing spondylitis. Palisade RFA uses a row of radiofrequency cannula perpendicular to the dorsal sacrum. Inclusion criteria were ages 18 to 75 years; diagnosis of ankylosing spondylitis; chronic low back pain for at least 3 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 et al (2012) reported a randomized, double-blind, placebo-controlled trial of lateral branch neurotomy with a cooled radiofrequency probe. Twelve-month follow-up was reported in 2016. Fifty-one patients who had a positive response to 2 lateral branch blocks were randomized 2:1 to lateral branch radiofrequency or to sham. At a 3-month follow-up, significant improvements were observed in pain levels (-2.4 vs -0.8), physical function (14 vs 3), disability (-11 vs 2), 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. Of the 9 patients who terminated study participation, 4 (12%) of 34 were considered treatment failures.

Tables 6 and 7 display notable relevance, design, and conduct limitations identified in each study.

Table 6. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Cohen et al 2023			2. Not a sham control.		1.Not sufficient duration for benefit. Limited to 3 months follow-up.
Mehta et al (2019)				1. Disability outcomes were not reported.	
Juch et al (2017)	4. Patients older than 70 years were excluded.		2. Not a sham control.		
Van Tilburg et al (2016)					
Zheng et al (2014)	1. Patients were required to have a diagnosis of ankylosing spondylitis in addition to chronic low back pain related to the SIJ.		2. Not a sham control.		
Patel et al (2012)					

SIJ: sacroiliac joint.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not established and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 7. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Cohen et al 2023		1.Not blinded to treatment assignment.		1.18% of the cooled RFA group and 13% of control group patients missed 3 mo follow-up,		
Mehta et al (2019)				3. 66.6% of sham group patients crossed over to treatment group at 3 mo	Other: Small study size due to interim analysis	
Juch et al (2017)		1-2. Study was not blinded.				
Van Tilburg et al (2016)				3. 63.3% of sham group patients crossed over to the treatment group		

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Zheng et al (2014)						
Patel et al (2012)				3. Patients in the sham group could cross over at 3 mo		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Section Summary: Treatment of Sacroiliac Joint Pain Radiofrequency Ablation

Meta-analysis of available sham controlled RCTs suggests that there may be a small effect of RFA on SIJ pain at short-term (1 to 3 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 6 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.

Alternative Ablative Methods in the Treatment of Cervical, Thoracic and Lumbar Chronic Facet joint Pain and Chronic Sacroiliac Joint Pain

Clinical Context and Therapy Purpose

The purpose of the use of alternative ablative methods is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with chronic facet joint pain (cervical, thoracic, lumbar) and individuals with chronic sacroiliac joint (SIJ) pain.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with chronic facet joint pain (cervical, thoracic, lumbar) and chronic sacroiliac joint (SIJ) pain.

Interventions

The alternative ablative methods being considered are laser denervation, chemical neurolysis, cryodenervation (cryoablation), cooled radiofrequency ablation, pulsed radiofrequency ablation and endoscopic radiofrequency ablation.

Comparators

The following therapies and practices are currently being used to treat confirmed facet joint pain: intra-articular injection and standard medical therapy to include radiofrequency ablation (RFA).

The following therapy is currently being used to treat chronic SIJ pain: conservative therapy and radiofrequency ablation (RFA).

Outcomes

The general outcomes of interest are reductions in symptoms and medication use, quality of life (QOL), and improvements in functional outcomes.

Follow-up after the use alternative ablative methods may be required from 6 to 12 months to monitor for symptom recurrence and the need for additional treatments.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies
- To assess long-term outcomes, single-arm studies that capture longer periods of follow-up and/or larger populations were sought
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Chemical Neurolysis

Randomized Controlled Trial

Joo et al. (2013), compared alcohol ablation with RFA in a randomized study of 40 patients with recurrent thoracolumbar facet joint pain after thermal RFA treatment. Patients were randomly allocated to two groups, receiving either the same repeated RFA (n = 20) or alcohol ablation (n = 20). At 24-month follow-up, three patients in the alcohol ablation group had recurring pain compared to 19 in the RFA group. The median effective periods were 10.7 months (range 5.4 to 24) for RFA and 24 months (range 16.8 to 24) for alcohol ablation. No significant complications were observed. This study is limited by small sample size and short-term follow-up.

Cooled Radiofrequency Ablation

Chou et. al. 2021, in an AHRQ comparative effectiveness review evaluated cooled RFA for treating sacroiliac and facet joint pain. Cooled RFA for sacroiliac pain was associated with a moderate to large

reduction in pain and small to large improvement in function versus sham radiofrequency at 1 month. Improvements in pain and function at 3 months were moderate. Evidence beyond 6 months is lacking. Additionally, the trials utilized different techniques, with insufficient evidence to determine the optimal method. Cooled RFA for presumed facet joint pain was associated with a small, no statistically significant reduction in pain versus conventional RFA at 6 months and no difference in function. There were no differences at 1- and 3-month follow-ups. Evidence beyond 6 months is lacking. All studies were limited by small sample size and short-term follow-up. Larger, long-term studies are needed to confirm these findings.

Randomized Controlled Trial

In 2019, McCormick et.al. performed the only randomized prospective comparative study comparing traditional radiofrequency ablation (TRFA) versus cooled radiofrequency ablation (CRFA) in the lumber spine. In this study they targeted to 6-month outcomes of pain and improvement of physical function in 43 low back pain patients who underwent randomized trial of TRFA versus CRFA. The primary outcome was the proportion of “responders” (≥50% NRS reduction) at 6-months. Therefore, the aim of the study was to determine whether the results of CRFA or TRFA were superior in treatment outcomes for individuals with lumbar facet joint pain. According to outcomes of this study, no significant differences were observed between the two RFA modalities. A greater proportion of participants reported a clinically significant improvement in physical function at 6-month follow-up in the CRFA group, but this difference was not statistically significant. When comparing procedure time for two RFA modalities, it was shorter in the CRFA group, but similarly, this difference also was not statistically significant. In this study, McCormick et al reported that with using a single diagnostic block with a threshold of >75% pain reduction, CRFA resulted in a treatment success rate >50% when defined by pain reduction, and greater that 60% when defined by improvement in physical function, at 6-month follow-up. The authors did not report any serious adverse events in both RFA treatment group. This study was the first trial that compared the clinical outcomes for the two RFA modalities for the treatment of lumbar facet joint mediated pain. This study had the limitations of including relatively low number of patients and short follow-up of outcome for only 6 months.

Cryodenervation (Cryoablation)

Observational Studies

Birkenmaier et al. (2007) conducted a prospective clinical case series to examine the effects of medial branch cryodenervation (cryoablation) in the treatment of lumbar facet joint pain. Patient selection was based on medical history, physical examination and positive medial branch blocks. Percutaneous medial branch cryodenervation was performed using a Lloyd Neurostat 2000. Target parameters were low back pain (by means of VAS, limitation of activity (McNab) and overall satisfaction. A total of 50 patients were recruited, and 46 completed the study. The follow-up time was 1 year. At 6 weeks, 33 patients (72 %) were pain free or had major improvement of low back pain; 13 (28 %) had no or little improvement. Including failures, mean low back pain decreased significantly from 7.7 pre-operatively to 3.2 at 6 weeks, 3.3 at 3 months, 3.0 at 6 months and 4.2 at 12 months. However, the authors noted that at the 12-month follow-up period the failure rate rose to 43%. The findings are limited by lack of a comparison group.

A prospective study by Staender et al. (2005) evaluated the therapeutic effect of computerized tomography (CT)–guided cryorhizotomy in the treatment of 76 patients with lumbar facet joint syndrome (LFJS). All of the patients received one treatment after confirmation with a medial branch block using a 1.3cm size needle. Twenty-six patients required 2-4 additional treatments and a 2.0cm needle was used. The VAS was used as an evaluation tool along with reports of return to work and pain med use. Success

was determined to be 50% reduction in VAS scores. Pre-treatment the median score was 6.7 and post-treatment was 3.2 for up to 6 months. Patients without prior back surgery had a better result than post-surgical patients. The authors concluded the CT-guided treatment was effective. The intervening variable of the medial branch blocks has to be taken into account as part of the pain relief response which the authors acknowledge. Fifty percent of patients had 50% pain relief for at least up to a year in the reported aggregate data. Six percent of patients failed treatment. Although the results are promising, further study is needed to identify the placebo effect of the medial branch blocks. The findings are limited by lack of a comparison group.

Endoscopic Radiofrequency Ablation

Randomized Controlled Trial

Li et al. (2014) evaluated the effectiveness of surgical dorsal endoscopic rhizotomy in 58 patients with lumbar facetogenic chronic low back pain in a randomized controlled trial. Forty-five patients who experienced > 80% relief of pain with two comparative lumbar medial branch blocks received dorsal endoscopic rhizotomy. The remaining 13 patients received conservative treatment. Patients' preoperative and postoperative VAS score, percentage of pain relief and the MacNab score were analyzed and compared. In the operation group, VAS scores of pain (low back/referred) at any time point postoperatively were significantly lower than that before MBB ($P<0.05$), which, however, showed no significant difference as compared to the scores after MBB ($P>0.05$). In the conservative group, VAS scores of pain (low back/referred) at any time point postoperatively with conservative treatment decreased significantly compared with that before MBB ($P<0.05$) and were significantly higher than that after MBB ($P<0.05$). Percentage of pain relief in the operation group at any time point postoperatively were significantly higher than that in the conservative group ($P<0.01$). The MacNab scores of 1 year follow-up in the operation group were higher than that in the conservative group. Further studies with a comparison group allowing masking to the intervention and larger sample sizes are needed to further validate the efficacy of this technique.

Observational Study

Tseng et. al. (2023) in a retrospective study reported on the use of biportal endoscopic radiofrequency ablation (BERA) in the treatment of chronic low back pain. Sixteen patients were included and underwent BERA of the lateral branches of the S1-S3 foramina and L5 dorsal ramus which were the sources of the sacroiliac joint (SIJ) pain. Clinical results were assessed preoperatively and at 1-, 6- and 12-month time points postoperatively using outpatient clinic or phone call questionnaires using VAS and Oswestry Disability index (ODI) scores as the primary outcome assessments. At 6-months patient satisfaction survey was administered post procedure. The mean preoperative VAS score was 7 (range 6-8) and mean preoperative ODI score was 33 (range 25-48). At the 12-month follow-up the median VAS score improved to 1.0 (range 0-3), and the ODI score improved to 10 (range 5-22), which was statistically significant for both scores ($p < 0.001$). The 6-month post procedure patient satisfaction survey found an overall patient satisfaction score was 89.1%. Limitations related to this study included that it was a retrospective study with a limited number of cases and only 12-months of follow-up data. Also, they did not directly compare the clinical results and perioperative parameters of BERA with those of a single-port endoscopic ablation technique or other methods. The authors conclude: “We cannot make the conclusion that BERA is superior to other treatments in terms of pain control. In the future, we plan to conduct a meta-analysis to compare the different strategy in treating SIJ pain.”

Woiciechowsky et. al. (2021) conducted a retrospective study regarding endoscopic radiofrequency treatment of sacroiliac joint syndrome/sacroiliac joint pain (SIJ) that included 23 patients with duration of pain more than 12 months and a 50% reduction in pain based on the Numeric Rating System (NRS) following diagnostic block. All the patients received an endoscopic ablation of the medial branch L5/S1 and the lateral branches exiting the sacral foramina on S1/S2 and S2/S3 on both sides. Post procedure telephone interviews were conducted will all patients. The outcome was determined using Odom's criteria, percent reduction NRS, subjective assessment of the patient and duration of the effect. According to the Odom's criteria 79% of the patients showed acceptable results and confirmed that denervation helped manage their daily lives better. The average pain reduction in the responder group was 57% with an average duration of 13.4 months, The authors concluded "In this retrospective study, we could demonstrate the practicability and effectiveness of endoscopic SIJ denervation in the treatment of SIJ pain. Further studies should investigate if this procedure is more effective than percutaneous RF."

Meloncelli et al. (2020) conducted a prospective cohort study to assess the effectiveness of endoscopic rhizotomy for denervation of lumbar facet joints in patients with chronic low back pain due to facet joint syndrome. The study included 40 out of 50 screened patients divided into two equal groups: group A patients were previously treated with percutaneous RFA (n = 20) and group B patients were having their first interventional treatment (n = 20). NRS and ODI scores were assessed before and after the procedure. All patients had a reduction in NRS and an improvement in ODI. NRS was reduced significantly after 1 month and remained the same until the end of the study. ODI was significantly improved from 1 month after surgery up to the end of the study. The improvements did not differ whether already treated with percutaneous rhizotomy. Patients less than 60 years or with 1-2 joints treated had better improvement compared with the others. The authors concluded that patients treated with endoscopic rhizotomy achieved pain relief through follow-up at two years. Study limitations include lack of randomization and control and small sample size. Larger randomized studies are needed to confirm these results.

Laser Denervation

Case Series

Iwatsuki (2007) reported treatment of facet syndrome by laser neurolysis in a case series of 21 participants including 5 who had undergone previous spinal surgery. One year after laser denervation, 17 participants experienced pain reduction of at least 70%. Of the 5 individuals who had previously undergone spinal surgery, 4 did not have a successful outcome from laser denervation at 1-year follow-up. This study is limited by small sample size, short-term follow-up and lack of a control group.

See medical policy 07.01.41 Pulsed Radiofrequency Ablation

See Hayes Inc, health technology assessment above under Cooled Radiofrequency Ablation regarding the use of cooled or pulsed radiofrequency for the treatment of chronic low back pain arising from the SIJ.

Moussa et al (2020) evaluated pulsed RF in patients diagnosed with chronic lower back pain of facet origin. Patients were randomized into 3 groups: percutaneous pulsed RF treatment of the dorsal root ganglia (n=50), percutaneous RF denervation of the medial dorsal branch (n=50), and a control group that didn't receive any RF treatment (n=50). By 3 months post procedure, the pulsed RF group had better incidence of VAS improvement when compared to the other 2 groups (p=.014). At 2-year follow-up, the

pulsed RF group maintained significant VAS improvement (p=.041), and this continued to the end of the study duration at 3 years (p=.044). An important limitation of this study is the lack of a sham control group.

Pulsed RF denervation was compared with steroid injection in a randomized trial of 80 patients reported by Hashemi et al (2014). The patients were selected based on a single medial branch block; outcomes included a numeric rating scale for pain, ODI, and analgesic intake assessment. Radiofrequency and steroid injection to the medial branch reduced pain to a similar extent at 6 weeks; however, pain relief with pulsed RF remained low at 6 months (from 7.4 at baseline to 2.4 at 6 months) but had returned to near baseline levels in the steroid group pain by 6 months.

Kroll et al (2008) compared the efficacy of continuous RF with pulsed RF in the treatment of lumbar facet syndrome in an RCT with 50 patients. No significant differences in the relative percentage improvement were noted between groups in VAS (p=.46) or ODI (p=.35) scores. Within the pulsed RF group, comparisons of the relative change over time for both VAS (p=.21) and ODI (p=.61) scores were not significant. However, within the continuous RF group, VAS (p=.02) and ODI (p=.03) score changes were significant. The trial concluded that, although there was no significant difference between continuous RF and pulsed RF in the long-term outcomes, there was greater improvement over time in the continuous RF group.

Van Zundert et al (2007) randomized 23 patients (of 256 screened) with chronic cervical radicular pain to pulsed RF or sham treatment. Success was defined as a 50% or more improvement in GPE score, 20% or more reduction in VAS score for pain, and reduced pain medication use measured 3 months after treatment. Eighty-two percent of patients in the treatment arm and 33% in the sham arm showed at least 50% improvement in GPE score (p=.03) and 82% in the treatment group and 27% in the sham group achieved at least 20% reduction in VAS pain score (p=.02).

In a study by Tekin et al (2007), patients were randomized 20 each to conventional RF, pulsed RF, or a control group (local anesthetic only). Outcome measures were pain measured on a VAS and the ODI. Mean VAS and ODI scores were lower in both treatment groups than in controls posttreatment; however, reductions in pain were maintained at 6- and 12-month follow-ups only in the conventional RF group. The number of patients not using analgesics and patient satisfaction were highest in the conventional RF group.

Section Summary: Alternative Ablative Methods

There is insufficient evidence to establish the safety and efficacy of these alternative ablative methods for treating chronic facet joint pain (cervical, thoracic, lumbar) and chronic sacroiliac joint (SIJ) pain. The current evidence is considered low-quality in addition to small sample sizes and short follow-up. While some studies may show promise further well-designed, randomized controlled trials (RCTs) with large sample sizes and long-term follow-up are needed to establish the impact on health outcomes.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input from Physician Specialty Societies and Academic Medical Centers

2014 Input

In response to requests, input was received from 4 physician specialty societies and 4 academic medical centers (5 responses) while this policy was under review in 2014. Input was mixed on the use of arthrography, radiofrequency ablation, and fusion of the SIJ. Most reviewers considered injection for diagnostic purposes to be medically necessary when using controlled blocks with at least 75% pain relief, and for injection of corticosteroids for treatment purposes. Treatment with prolotherapy, periarticular corticosteroid, and periarticular botulinum toxin were considered investigational by most reviewers.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Society of Anesthesiologists and 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. 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.”

American Society of Interventional Pain Physicians

In 2013, the American Society of Interventional Pain Physicians guideline recommended the use of controlled SIJ blocks with placebo or controlled comparative local anesthetic block when indications are satisfied with suspicion of SIJ pain. A positive response to a joint block is considered to be at least a 75% improvement in pain or in the ability to perform previously painful movements. For therapeutic interventions, the only effective modality with fair evidence was cooled radiofrequency neurotomy, when used after the appropriate diagnosis was confirmed by diagnostic SIJ injections.

American Society of Pain and Neuroscience

In 2024 the American Society of Pain and Neuroscience (ASPN) published best practice guideline for the treatment of sacroiliac disorders. “These recommendations should not be construed as a standard of care but instead represent best practices. This guidance is based on several factors and peer-reviewed evidence, and regardless of the strength of evidence, requires interpretation for clinical application.”

“Studies comparing radiofrequency ablation (RFA) modalities for sacroiliac joint (SIJ) pain are lacking. High-quality evidence is limited to two randomized controlled trials, sham controlled. Limitations include heterogeneity in selection criteria and radiofrequency technique utilized. Studies comparing RFA modalities are lacking. Some studies may show that cooled radiofrequency may show higher efficacy in pain outcomes, however, other radiofrequency modalities showed no difference.”

Best Practice Statement on Neuroablative Technique and Approach for SI Pain

“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.”

In 2021, ASPN published latest evidence-based application for radiofrequency neurotomy (LEARN): Best practice guidelines from the American Society of Pain and Neuroscience (ASPN) which provided the following regarding radiofrequency neurotomy lateral sacral branch:

Treatment Gaps and Future Research

“The main limitation found within the literature is the heterogeneity of the studies involved. Most studies utilized intra-articular joint injections to select patients for sacral lateral branch radiofrequency neurotomy (RFN). As identified by Dreyfuss et al, the use of diagnostic nerve blocks in the posterior sacral nerve supply is more appropriate and prognostic for outcomes of RF. Not only is further research needed for the use of diagnostic sacral nerve blocks but also with neurotomy itself. Studies used conventional RF, pulsed RF, and cooled RF, with variable parameters and procedural times. The present literature suggests the clinical efficacy of unipolar, bipolar, cooled and pulsed RF; however, studies are limited and are of fair quality at best.”

Consensus Statement:

- “Lateral sacral branch radiofrequency neurotomy may be used for the treatment of posterior sacral ligament and joint pain following positive response to appropriately placed diagnostic blocks. GRADE II-1 B.”
- “Contraindications for RFN include sacral fracture, tumor, radiculopathy, infection and coagulopathy”
- “A diagnostic block for the lateral sacral branches is highly recommended prior to performing RF, even in cases when previous sacroiliac joint injection was performed. While limited evidence exists regarding diagnostic cutoff, recommendation is for 50% or greater reduction in pain prior to advancing to RF. Multisite and multi-depth technique is recommended to appropriately select RF candidates.”

International Society for Advancement of Spine Surgery

In 2020, the International Society for the Advancement of Spine Surgery provided guidance which included the following: “It was recommended that intra-articular SIJ steroid injection and radiofrequency ablation (RFA) of the SIJ lateral branch nerves may be considered but are not required.”

Specifically, not recommended were:

- Minimally invasive posterior (dorsal) SIJ fusion
- Repeat intra-articular steroid injection
- Repeat SIJ radiofrequency ablation

North American Spine Society (NASS)

In 2020 the North American Spine Society (NASS) clinical guidelines provided the following recommendations regarding ablative treatments for adults with low back pain:

- "Thermal RFA is suggested as a treatment for patients with low (lumbar) back pain from the zygapophyseal joints. The outcomes of this procedure become more reliable when more stringent diagnostic criteria are used. The relief from these ablations is durable for at least six months following the procedure. Grade of recommendation: B - fair evidence (Level II or III studies with consistent findings) for or against recommending intervention."
- "Cooled RFA of the sacral lateral branch nerves and dorsal ramus of L5 may be considered in patients with sacroiliac joint pain diagnosed with dual diagnostic blocks. Grade of recommendation: C - poor quality evidence (Level IV or V studies) for or against recommending intervention."
- 'There is insufficient evidence to make a recommendation for or against the use of cryodenervation for the treatment of zygapophyseal joint pain. Grade of recommendation: I - insufficient or conflicting evidence not allowing a recommendation for or against intervention."

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	64625	Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (i.e., fluoroscopy or computed tomography)
	64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
	64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
HCPCS		
	None	
Type of Service	Surgery	
Place of Service	Outpatient/Inpatient	

POLICY HISTORY

Date	Action	Action
January 2026	Annual Review	Policy Renewed
January 2025	Annual Review	Policy Renewed

Date	Action	Action
August 2024	Annual Review	Policy Renewed
August 2023	Annual Review	Policy Revised
August 2022	Annual Review	Policy Revised
March 2022	Interim Review	Policy Revised
August 2021	Annual Review	Policy Renewed
August 2020	Annual Review	Policy Revised
August 2019	Annual Review	Policy Renewed
August 2018	Annual Review	Policy Revised
August 2017	Annual Review	Policy Revised
August 2016	Annual Review	Policy Revised
May 2016	Annual Review	Policy Revised
November 2015	Interim Review	Policy Revised
September 2015	Interim Review	Policy Revised
June 2015	Annual Review	Policy Revised
July 2014	Annual Review	Policy Renewed
September 2013		New Policy Created
September 2012	Annual Review	Policy Retired
April 2012	Annual Review	Policy Renewed
May 2011	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

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