Molina Clinical Policy
Sacroiliac Injections and Radiofrequency Ablation (RFA) for Sacroiliac Joint Pain: Policy No. 033

Last Approval: 4/13/2022
Next Review Due By: April 2023

OHIO MEDICAID: Do not exclude code 64625 as all requests are reviewed for medical necessity on individual basis

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Sacroiliac Joint (SIJ) Pain. The SIJ, the largest axial joint in humans, connects the sacrum to the ilium in the spine and serves more as a stabilizing than a moving joint. Numerous major ligaments and muscle groups contribute to the joint's stability. Pain may occur in this highly innervated joint or in the muscles and ligaments that surround it. The SIJ has been identified as a primary source of chronic low back pain (LBP). SIJ pain is defined as pain caused by an injury, disease, or surgery to the SIJ and/or its supporting ligamentous tissues (Wieczorek et al., 2021).

Sacroiliac (SI) injections are intraarticular injections performed for both diagnostic and therapeutic purposes. Diagnostic injections are performed to confirm the location of pain originating in the SIJ region. The current “gold standard” for SIJ diagnosis and treatment is performing injections with a corticosteroid or anesthetic drug under fluoroscopic guidance to obtain between 50 to 75% pain relief (Ou-Yang et al. 2017; Thawrani et al. 2019; Landi et al. 2016). The procedure is performed most commonly using fluoroscopy guidance for accurate needle placement. The needle is placed in the SIJ region and contrast media are injected for arthrogram viewing to confirm correct needle placement. An injection of a small amount of anesthetic is injected to determine the patient’s pain relief response.

Radiofrequency Ablation (RFA) for SIJ pain involves the use of radiofrequency (RF) current to generate heat and destroy sensory nerves to the SIJ. The goal of this therapy is to interrupt transmission of pain signals from the SIJ nerves to the brain in patients with refractory SIJ pain.

Pulsed Radiofrequency (PRFA) has been introduced as a non-ablative alternative to RFA. PRFA delivers short bursts of RF current, instead of the continuous flow of RF current produced by continuous RF generators. Tissue can cool between bursts, resulting in considerably lower maximum temperatures as compared with the continuous mode, and reduces the risk of neighboring tissue destruction. It does not destroy targeted nerves and surrounding tissue and therefore requires less precise electrodes placement. During PRFA, intermittent low temperature electric currents of 2 Hz at temperatures not exceeding 42°C are transmitted to the nerve.

Cooled Radiofrequency, similar to pulsed RFA, enables larger lesions to be created as adjacent tissue is cooled during the procedure. Cooling is regulated by an attached computer. Internally cooled electrodes can create lesions 8 to 10 millimeters (mm) in diameter, with the depth extending distal to the electrode tip.

Regulatory Status

SIJ injection with corticosteroids and/or local anesthetics is a procedure and therefore not subject to FDA regulation. However, any medical devices, drugs, biologics, or tests used as a part of this procedure may be subject to FDA regulation.

RFA for spinal pain is a procedure and is not regulated by the FDA. However, the FDA oversees RFA equipment, and there are various devices approved for use in conducting RFA for neurosurgical operations that are listed in the FDA 510(k) database. These devices are classified according to two product codes: radiofrequency lesion generators

(GXD), radiofrequency lesion probes (GXI).

RELATED POLICIES

Radiofrequency Ablation (RFA) for Chronic Back Pain Associated with the Facet Joint: Policy No. MCP-085

COVERAGE POLICY

A. RFA (including water cooled RFA) and PRFA is **considered experimental, investigational, or unproven** for the treatment of acute, subacute, or chronic SIJ pain and may NOT be authorized due to insufficient evidence in the peer-reviewed literature.

B. SI injections (local anesthetics with or without corticosteroids) with *fluoroscopy is **considered medically necessary** for chronic severely debilitating LBP in adults who are age 18 years or older as part of a comprehensive pain management treatment program when **ALL** of the following criteria are met:

1. Physical examination documentation reveals **ALL** of the following clinical characteristics of SIJ disease:

   a. Somatic or non-radicular low back pain and lower extremity pain (greater than 6 on scale 0-10) below the level of L5 vertebra for minimally three (3) months; **AND**

   b. Intermittent or continuous pain causing functional disability.

AND

2. Inadequate response to conservative therapy that includes **ALL** of the following:

   a. Physical therapy a minimum of four (4) weeks (3-4 times per week for a total of 12 sessions); **OR** Documentation of the basis for PT contraindication. If ANY of the following conditions exist, PT may be contraindicated
      - Pain worsened with physical therapy, **OR**
      - Physical therapy tried but was not able to be tolerated.

   AND

   b. Activity modification a minimum of six (6) weeks; **AND**

   c. Drug therapy (e.g., NSAIDS, muscle relaxants, corticosteroids, antidepressants, anticonvulsants, or opiates).

   ** Imaging guidance with fluoroscopy is required for SIJ injections to ensure proper needle placement (this is considered integral to the primary procedure and not separately reimbursable).*

Initiation of Treatment and Injection Frequency following Criteria Approval

1. In the diagnostic phase:

   a. Two (2) total injections for diagnosis may be given no less than one (1) week apart, preferably two (2) weeks apart.

   b. If the member does not experience significant functional pain relief of 50% measured by a decrease in pain medications and increase in physical function for a minimum of two (2) months, no further injections should be given.

2. In the therapeutic phase **ALL** of the following criteria must be met:

   a. The previous diagnostic or therapeutic injection provided symptom or significant functional pain relief of 50% measured by a decrease in pain medications and increase in physical function for a minimum of two (2) months before subsequent injections within the same region are authorized; **AND**

   b. The frequency should be two (2) months or longer between each injection in the same joint not to exceed a **total of four (4) injections in one region per year.** The injections should only be repeated as necessary if the medical necessity criteria above are achieved; **AND**

   c. Injections at different joints can be given two (2) weeks apart but no sooner than one (1) week following an injection in a different region; **AND**

   d. A maximum of four (4) injections total per rolling calendar year may be given for local anesthetic and corticosteroid injections; **AND**

   e. A member must be experiencing a return of pain or deterioration in function to receive a therapeutic injection.

      - A rolling calendar year is 12 months after the event, beginning and ending in the same month the initial event took place; (e.g., first diagnostic injection is given in June 2022, the rolling calendar year would end in June 2023).
      - When SIJ dysfunction is present in conjunction with other primary pain generators (such as lumbar radiculitis secondary to degenerative disc disease or lumbar facet arthropathy secondary to lumbar facet arthritis, treatment should first address the non-SIJ pain generators, as SI joint dysfunction may resolve once these pain generators have been successfully treated. If there is residual SI pain, it may be appropriate to perform SIJ injections to address the remaining pain.
      - Only one type of a block or injection (e.g., sacroiliac, epidural) should be performed in a given session so that the effectiveness of its treatment can be assessed prior to attempting another type of spinal block or injection.

Limitations and Exclusions

1. **Lateral nerve blocks and RFA (including water cooled RFA) and PRFA** for diagnosing or treating acute, subacute, or chronic SIJ pain procedures are considered experimental, investigational, or unproven and may NOT be authorized due to insufficient evidence in the peer-reviewed literature.

2. SI injections are **excluded** for the following:
   - Members that do not meet the outlined criteria listed above.
   - Use of agents other than local anesthetic agents with or without corticosteroids.
   - SIJ injections performed without imaging guidance.
   - Requests for SI injections exceeding the limits outlined above.
   - Treatment of patients with acute low back and acute pain syndromes.

3. Contraindications to receiving SI injections include, but are not limited to, the following:
   - Allergy to the medication to be administered
   - Anticoagulation therapy
   - Bleeding disorder
   - Localized infection in the region to be injected
   - Systemic infection
   - Other comorbidities that could exacerbate the procedure/steroid use (e.g., diabetes, congestive heart failure, poorly controlled hypertension)
   - Pregnancy: Fluoroscopy use is contraindicated for members that are pregnant

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Radiofrequency Ablation

The therapeutic efficacy and duration of impact of RFA in SIJ have not been reliably demonstrated in well-designed studies. RCT evidence is limited, comprises small sample sizes, and assesses primarily short-term results following RFA treatment. The medical literature does not provide sufficient evidence to establish the safety and efficacy of SIJ RFA or dorsal lumbar or sacral rami ablation for the treatment of SIJ and other lumbar-related pain. Studies assessed in published systematic reviews, Cochrane reviews, and technology assessments overlap. Furthermore, there is inadequate data in the peer-reviewed scientific literature to establish the safety and efficacy of various ablative modalities (e.g., laser, chemical, or electrical) when used to treat SIJ and other related types of pain.

RFA as a treatment for SIJ pain has been studied in several pilot studies, retrospective case series, and prospective case series (Bellini and Barbieri, 2016; Romero, et al., 2015; Ho, et al., 2013; Karaman, et al., 2011). Furthermore, two randomized controlled trials comparing cooled RF to conventional RF (Cheng, et al., 2013) and cooled RF to a new bipolar RF approach (Cheng, et al., 2016) for the treatment of SI joint pain have been published. However, sample numbers are small in these trials, follow-up varies from 12 weeks to 2 years, patient selection criteria vary, procedure varies, and controls are insufficient.

A Cochrane review evaluated the evidence for RF denervation as a treatment for chronic LBP and concluded that while the results were inconsistent for disc pain, low-quality evidence revealed no differences in pain and function between RF denervation and placebo in the short-term for SIJ pain (Maas et al., 2015). One trial indicated a minor improvement on pain and function for SIJ discomfort, but there is no high-quality data that RF denervation relieves back pain.

A randomized multicenter study (Mint Study) evaluating the effectiveness of RF denervation added to a standardized exercise program for subjects with chronic LBP (n=681) was published by (Juch et al. 2017). Subjects with chronic LBP, a positive past diagnostic block of the facet (n=251), sacroiliac (n=228), or a combination of joints (n=202), and an inability to respond to conservative therapy were included. All subjects got a 3-month conventional exercise regimen and, if necessary, psychological support; the experimental group also received radiofrequency denervation (1 to3 treatments were allowed). The primary outcome was pain intensity 3 months after treatment, with a 12-month follow-up: 599 subjects (88%) completed the 3-month follow-up and 521 subjects (77%). The authors concluded that when compared to a conventional exercise program alone, RF denervation combined with a standard exercise program resulted in either no improvement or no clinically significant improvement in LBP.

Sun et al. (2018) conducted a meta-analysis on the efficacy and safety of cooled RF for SI joint pain. Seven studies (4 retrospective observational, 2 RCTs, and one prospective observational) with 240 patients (n=240) met the criteria for inclusion: persistent SI joint pain, cooled RF as the intervention, and three-month results. The overall pooled results showed decreased pain intensity compared to pre-treatment pain using VAS and NRS (3.78, 3.81), reduced disability scores using Oswestry Disability Index (ODI), and 72% of individuals had good results utilizing Global Perceived Effect. The studies found no serious side effects. The authors point out that small sample sizes within studies, observational studies, and discrepancies in diagnostic block cutoff values (50% versus 75%) all contribute to the potential for placebo effect. The authors found that despite study variances, the analysis supported the safety and efficacy of cooled RF for SIJ pain.

In an UpToDate peer-review on nonsurgical interventional treatment for LBP, Chou (2021) noted that small clinical trials testing RF denervation for facet joint pain found no efficacy or only modest, generally short-term, improvement. Discogenic LBP, radicular pain, and chronic SIJ pain (Cohen et al. 2008) have also shown limited effect.

SIJ Injections

The current peer-reviewed published literature for SIJ injections with corticosteroids and local anesthetic for treatment of chronic low back pain consists of randomized controlled trials (RCT) prospective cohort studies and retrospective reviews. There are no randomized trials of intraarticular SIJ steroid injection versus a sham procedure in patients without spondyloarthropathy (Chou 2021; UpToDate).

One RCT compared the long-term efficacy of SIJ injection of triamcinolone and levobupivacaine with intra-articular prolotherapy (dextrose water with local anesthetic) in 48 patients (n=48) with refractory SIJ pain confirmed by diagnostic injections (Kim et al., 2010). At 2 weeks, both groups' pain and disability scores decreased dramatically, with no differences between them. However, at 6 months, prolotherapy patients reported 50% less pain than steroid injection patients (64% versus 27% of patients at 6 months; 59% versus 10 percent at 15 months). The study had disadvantages such as early enrollment termination, small sample size and statistical power, no long-term follow-up, and no intention-to-treat analysis.

Another RCT compared the short-term efficacy of 3 treatments in 51 patients (n=51) with chronic SIJ-related leg pain: fluoroscopically guided SIJ injection with lidocaine plus triamcinolone, PT, and manual therapy (Visser et al., 2013). SIJ-related pain was not confirmed by diagnostic injection. The findings indicate that treatment effectiveness rates (as measured by pain relief) between the SIJ injection (50%), manual therapy (72%) or PT groups (20%). Manual therapy was substantially more effective than PT. No adverse effects associated with the treatment were documented. The limitations of this study include a small sample size and lack of power analysis, a single-blind design, a brief duration of follow-up, a lack of diagnostic injections to confirm the diagnosis of SIJ pain, possible selection bias during patient recruitment, and a failure to rule out discogenic causes of lower back pain as opposed to SIJ pathology.

In an RCT of 120 patients (n=120) with noninflammatory SI arthritis, ultrasound (US)-guided SIJ injections were compared to fluoroscopic (FL)-guided SIJ injections to assess the short-term benefits and safety of US/FL guided SIJ injections. Patients were not blinded, but a blinded investigator assessed pain, disability, and satisfaction. The FL-guided SIJ approach exhibited a greater accuracy (98.2%) than the US-guided approach (87.3%). Both groups' function and pain alleviation improved, with no significant differences between them. The US-guided strategy is as effective as the FL-guided approach; however, the SIJ's lower diagnostic accuracy rate may limit diagnostic use.

National and Specialty Organizations

The **American Society of Interventional Pain Physicians (ASIPP)** updated guidelines suggest that for SIJ interventions, the evidence for cooled radiofrequency neurotomy is fair; limited for intraarticular injections and periarticular injections; and limited for both pulsed radiofrequency and conventional radiofrequency neurotomy.

The **American Society of Anesthesiologists (ASA) / American Society of Regional Anesthesia and Pain Medicine (ASRA)** published *Practice Guidelines for Chronic Pain Management* (2010) with the following:

- The medical literature is insufficient to evaluate the efficacy of RFA for SIJ pain, although the guideline states that water-cooled RFA may be used for chronic SIJ pain. The task force recommended that neuroablative procedures be used as part of a comprehensive pain management regimen, and that they be used only as a last resort when other treatments have failed. There has been no update to the report located.
- SIJ injections may be considered for symptomatic relief of SIJ pain.

The **American Society of Interventional Pain Physicians (ASIPP)** updated guidelines, 'Interventional Pain Management' for the diagnosis and treatment of chronic spinal pain, suggest that the evidence for cooled radiofrequency neurotomy for SIJ interventions, is fair (based on two RCTS, 2 observational trials and one case report) and limited for both PRFA and conventional RF neurotomy (based on two observational studies) (Manchikanti, et al., 2013). An update to the report has not been located.

The **Institute for Clinical Systems Improvement (ICSI)** guidelines on 'Pain: Assessment, Non-Opioid Treatment Approaches and Opioid Management,' noted that there is conflicting evidence about the efficiency of percutaneous RF neurotomy on medial and lateral branch nerves supplying the target joints. (ICSI 2017).

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
27096	Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography when performed
64451	Injection(s), anesthetic agent(s) and/or steroid; nerves innervating the sacroiliac joint, with image guidance (i.e., fluoroscopy or computed tomography)
64625	Radiofrequency ablation, nerves innervating the sacroiliac joint, with imaging guidance (e.g. fluoroscopy or computed tomography)

HCPCS Codes

HCPCS	Description
G0259	Injection procedure for sacroiliac joint; arthrography
G0260	Injection procedure for sacroiliac joint; provision of anesthetic, steroid and/or other therapeutic agent, with or without arthrography

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

4/13/2022	Policy reviewed and updated; no changes in coverage criteria (revised verbiage and language for clarity but no changes in intent); updated Overview, Summary of Evidence, and References section.
4/5/2021	Policy reviewed, no changes to the criteria. Added CPT 64451 & 64625.
4/23/2020	Policy reviewed, changed PT requirement to a minimum of 4 weeks to be consistent with other guidelines and Molina pain management MCRs. Updated coding table: Added HCPCS code G0259 and removed CPT codes 64635 & 64636.
3/8/2018, 6/19/2019	Policy reviewed, no changes to criteria.
7/2017	Reduced PT requirement from 20 sessions to 10-12 sessions over 8 weeks, changed improvement scales from significant functional improvement of 80% improvement in 6 weeks to significant functional pain relief of 50% measured by a decrease in pain medication and increase in functional ability for a minimum of 2 months. Coding tables updated. Changes are based on 2017 ODG Guidelines per AMR review.
12/3/2009, 8/23/2012, 12/11/2013, 6/25/2014, 12/16/2015, 6/15/2016	Policy reviewed, no changes to criteria.
7/5/2007	New policy.

* IRO Peer Review (August 2021, April 2017, February 2020) by practicing, board-certified physician in the areas of Pain Management and Physical Medicine and Rehabilitation.

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Government Agency

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Peer Reviewed Publications

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

OHIO MEDICAID: Do not exclude code 64625 as all requests are reviewed for medical necessity on individual basis