Subject: Sacroiliac Injections and Radiofrequency Ablation (RFA) for Sacroiliac Joint Pain	**Original Effective Date:** 7/5/07
Policy Number: MCR-033	**Revision Date(s):** 12/3/09, 8/23/12, 12/11/13, 6/25/14, 12/5/16, 2/9/17, 7/25/17 *This MCR is no longer scheduled for revisions*
Review Date: 6/25/14, 12/16/15, 6/15/16, 3/8/18, 6/19	
MCPC Approval Date: 7/25/17, 3/8/18	

DISCLAIMER

This Molina Clinical Review (MCR) is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina Clinical Review (MCR) and provide the directive for all Medicare members.[1]

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL [45-46]

Sacroiliac Joint Injections:

Intraarticular sacroiliac joint injections are performed for both diagnostic and therapeutic purposes. Diagnostic injections are performed to confirm the location of pain originating in the sacroiliac joint region. The procedure is performed most commonly using fluoroscopy guidance for accurate needle placement. The needle is placed in the sacroiliac joint region and contrast media is 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. If pain is reduced by 50% or removed, a therapeutic injection of anesthetic with or without corticosteroid would be provided to achieve long term pain relief.

Radiofrequency Ablation:

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

Pulsed Radiofrequency:

Pulsed RFA (PRFA) has been introduced as a nonablative alternative to RFA. PRFA delivers short bursts of radiofrequency (RF) current, instead of the continuous flow of RF current produced by continuous RF generators. This allows the tissue to 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, cooled 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.

SIJ pain

The sacroiliac joint (SI) joint, the largest axial joint in humans, connects the sacrum to the ilium in the spine The SI joint has been identified as a primary source of chronic low back pain (LBP). Pain in the SI joint may be caused by a wide variety of events, including infection; benign or malignant tumors; inflammatory arthritis; injuries caused by sudden impact during motor vehicle accidents; athletic injury; protracted lifting and bending; torsional strain; altered gait mechanics; and spine misalignment.

RECOMMENDATION [42 44]

1. Radiofrequency ablation (including water cooled RFA) and pulsed radiofrequency for treating acute, subacute, or chronic SI joint pain are considered experimental, investigational, or unproven and may NOT be authorized due to insufficient evidence in the peer reviewed literature.

2. Sacroiliac injections (local anesthetics with or without corticosteroids) with fluoroscpopy are considered medically necessary for chronic severely debilitating low back pain 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: [ALL]

   - ❑ Physical examination documentation reveals ***all*** of the following clinical characteristics of sacroiliac joint disease:
     - Somatic or nonradicular low back pain and lower extremity pain (greater than 6 on scale 0-10) below the level of L5 vertebra for minimally three months*; and*
     - Intermittent or continuous pain causing functional disability; *and*
   - ❑ Has tried and failed conservative therapy that includes: [ALL]
     - Physical therapy (PT) a minimum of 10-12 sessions over 8 weeks; or
     - There must be documentation submitted that explains why physical therapy is contraindicated:
       *<u>*Note:*</u> PT may be contraindicated if any of the following are present:
       - pain worsened with PT;
       - PT tried but was not able to be tolerated

       AND
     - Activity modification a minimum of 6 weeks; and
     - Drug therapy (i.e. NSAIDS, muscle relaxants, corticosteroids, antidepressants, anticonvulsants, or opiates)

<u>Initiation of Treatment and Injection Frequency following Criteria Approval</u>

- ❑ In the ***<u>diagnostic phase:</u>***

- A total of two injections for diagnosis may be given no less than one week apart, preferably two weeks apart.

- If the patient 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 2 months, no further injections should be given

- ❑ In the therapeutic phase ***all*** of the following criteria must be met:
  - 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 2 months before subsequent injections within the same region are authorized

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

  - Injections at different joints can be given 2 weeks apart but no sooner than 1 week following an injection in a different region.

  - A maximum of 4 injections total per rolling calendar year may be given for local anesthetic and corticosteroid injections.

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

Notes:

- ❑ *A rolling calendar year is twelve 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 2017, the rolling calendar year would end in June 2018)

- ❑ When sacroiliac joint 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-sacroiliac joint pain generators, as SI joint dysfunction may resolve once these pain generators have been successfully treated. If there is residual sacroiliac pain, it may be appropriate to perform SI joint 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.

COVERAGE EXCLUSIONS [42 44]

1. **Lateral Nerve blocks and Radiofrequency ablation (including water cooled RFA) and pulsed radiofrequency** for diagnosing or treating acute, subacute, or chronic SI joint pain procedures are considered experimental, investigational, or unproven and may NOT be authorized due to insufficient evidence in the peer reviewed literature.

2. Sacroiliac 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
- ❑ Requests for sacroiliac injections exceeding the limits outlined above
- ❑ Treatment of patients with acute low back and acute pain syndromes

Contraindications to receiving sacroiliac joint 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)
- ❑ Fluoroscopy use is contraindicated for members that are pregnant

SUMMARY OF MEDICAL EVIDENCE [4-38]

Radiofrequency Ablation

The peer reviewed published literature for RFA as a treatment for SIJ pain is limited to case series or uncontrolled studies, and small randomized and placebo-controlled studies. Overall the quality of the evidence regarding RFA was low, limited by the small number of studies, small size of the study populations, lack of placebo control in all except two of the studies, variation in technique and patient characteristics, and short duration of follow-up. Efficacy of conventional, pulsed, and cooled RFA is limited and suggests that conventional RFA can provide short-term (3 to 6 months) pain relief in patients with SI joint pain. The percentage of patients who achieved at least 50% reduction in pain ranged from 47% to 89% at 3 months after RFA, with a mean of 68% across studies. This effect decreased over time, with 38% to 80% of patients still reporting ≥ 50% pain relief at 6 months. Results were similar for cooled and pulsed RFA, although there was only one small study on pulsed RFA. One study provided a direct comparison of conventional and cooled RFA, reporting comparable findings with both techniques. One of the two randomized placebo-controlled studies reported that 93% of patients had a positive GPE at 1 month after RFA, compared with 21% of control patients; by 3 months follow up, 71% of patients still had a positive GPE. The other placebo-controlled study did not report the proportion of patients with pain relief at follow-up. Instead, the authors compared outcome measures for patients treated with RFA and patients who underwent a placebo procedure. Three months after treatment, RFA was considered to be successful in a larger proportion of patients in the treatment group compared with those in the placebo control group (47% versus 12%). Similarly, a larger percentage of patients in the treatment group (47% versus 8%) reported a positive GPE during the same follow-up time frame. [4 6 7-10 15 16 22 26 27 29 30-36 46]

SIJ Injections [5 11-14 17-21 23-25 28 37 38]

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. One RCT compared the long-term efficacy of SIJ injection of triamcinolone and levobupivacaine with intra-articular prolotherapy in 48 patients with chronic SIJ pain confirmed by diagnostic injections. At 2 weeks, pain (≥ 50% reduction) and disability scores were significantly improved in both groups ($P<0.001$ for each) with no difference between the groups. However, the proportion of patients whose

improvement was ≥ 50% at 6 months was lower in the SIJ injection group than in the prolotherapy group (27.2% versus 63.6%; P<0.01) and at 15 months (10.2% versus 58.7%; P<0.005). Another RCT compared the short-term efficacy of 3 treatments in 51 patients with chronic SIJ-related leg pain: fluoroscopically guided SIJ injection with lidocaine plus triamcinolone, PT, and manual therapy. SIJ-related pain was not confirmed by diagnostic injection. Rates of treatment success, defined as complete relief of symptoms at 6- or 12-week follow-up or reduced VAS scores for pain at the final visit compared with baseline, were 50% in the SIJ injection group, 20% in the PT group, and 72% in the manual therapy group; the difference between the groups was significant (P=0.011). Manual therapy was significantly more efficacious than PT (P=0.003) although no differences were found between SIJ injection and manual therapy (P=0.17) or between SIJ injection and PT (P=0.07). Only patients in the manual therapy group had a significant improvement in pain between baseline and either follow-up visit (P=0.014). Another small RCT compared the short-term efficacy of US-guided SIJ injections versus fluoroscopic guidance in 120 patients with noninflammatory sacroiliac arthritis. Patients were not blinded, but pain, disability, and satisfaction scores were evaluated by a blinded investigator. Pain and disability scores improved at 2 and 12 weeks in both groups (P<0.025 for each), and patient satisfaction at 12 weeks was similar between the groups. [14 17 28]

A prospective study of SIJ injection of steroids in 39 consecutive patients found that 26 patients (66.7%) had significantly reduced pain for > 6 weeks. Mean scores for pain and disability were significantly decreased at a mean of 27.9 months (P<0.0001 for each). In a prospective cohort study evaluating the efficacy of CT-guided SIJ of triamcinolone and bupivacaine in 51 patients with low back pain, VAS scores were significantly lower at all postinjection time points from day 1 to > 6 months (P<0.05 for all time points). The overall initial success rate was 89.2%; however, the success rate at final follow-up at a mean of 26.7 months was lower (69.5%). Five patients (10.8%) had little improvement in pain and were considered treatment failures. The study excluded patients who did not have 2 years of follow-up, possibly biasing results in favor of SIJ injection. [19 25]

Professional Organizations [39-43]

American Society of Interventional Pain Physicians (ASIPP): Updated 2013 guidelines suggest that for sacroiliac joint 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.

American Society of Anesthesiologists (ASA): The practice guidelines for chronic pain management indicate that Sacroiliac joint injections may be considered for symptomatic relief of sacroiliac joint pain.

American Society of Anesthesiologists (ASA) / American Society of Regional Anesthesia and Pain Medicine (ASRA): In their Practice Guidelines for Chronic Pain Management, the ASA Task Force on Chronic Pain Management and ASRA in conjunction with consultants state that conventional or thermal RFA of the medial branch nerves should be performed for low back (medial branch) pain only after diagnostic or therapeutic injections of the joint or medial branch nerve have provided temporary relief. The task force recommends the use of water-cooled RFA for chronic SI joint pain, although the members of ASA and ASRA were equivocal on its use for this application. The Task Force recommends that neuroablative procedures should be used as part of a comprehensive pain management regimen, performed only as a last resort when pain is refractory to other therapies.

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
27096	Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography when performed
64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint (List separately in addition to code for primary procedure)
HCPCS	**Description**
G0260	Injection procedure for sacroiliac joint; provision of anesthetic, steroid and/or other therapeutic agent, with or without arthrography

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Revision/Review History

7/17: 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.
3/8/18 & 6/19: Policy reviewed, no changes to criteria.