DISCLAIMER

This Molina Clinical Policy (MCP) 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 medical coverage guidance (MCG) document and provide the directive for all Medicare members.1Molina Clinical Policy

FDA INDICATIONS

Sacroiliac injections (SIJ) and radiofrequency ablation (RFA) are a procedure which is not subject to regulation by the FDA. There are numerous devices listed in the FDA 510(k) Premarket Notification database that are cleared for radiofrequency ablation (RFA) therapy.39

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

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 medical coverage guidance (MCG) document and provide the directive for all Medicare members. The directives from this MCG document may be followed if there are no available NCD or LCD documents available and outlined below.

There is no National Coverage Determination (NCD) that addresses sacroiliac joint injections or radiofrequency ablation. A local coverage determination is available for sacroiliac joint injections and outlines that the injections are covered for both diagnostic and therapeutic interventions for low back pain.24 The pain must have been present for greater than 3 months. Maximum of two therapeutic injections are covered, one to two weeks apart. Therapeutic injections can be performed to each region once every two to three months if 50% or greater pain relief is achieved. A maximum of four therapeutic injections per region per year are allowed. Patients who have gained no symptom relief of functional improvement after two injections of the SI joint should not proceed with additional injections because the likelihood of pain relief after two failed attempts is low.37
INITIAL COVERAGE CRITERIA

1. Radiofrequency ablation and pulsed radiofrequency for diagnosing or 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. 39-53

2. Sacroiliac injections (local anesthetics with or without corticosteroids) with fluoroscopy 25-30 are considered medically necessary for chronic severely debilitating low back pain when all of the following criteria are met: [ALL]

- Adults who are age 18 years or older

- A comprehensive pain evaluation and treatment plan has been performed by a qualified practitioner with pain management expertise in conjunction with a comprehensive treatment plan (e.g., medications, rehabilitation and psychological evaluation and intervention); 21,22 and

- 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; 21,22 and
  - Intermittent or continuous pain causing functional disability; 21,22 and
  - Failure to respond to 3 to 6 months of conservative treatment management (e.g., physical therapy modalities with exercise, NSAIDS, etc) 21,22

Initiation of Treatment and Injection Frequency following Criteria Approval

- In the diagnostic phase:
  - A total of two injections for diagnosis may be given no less than one week apart, preferably two weeks apart. 21,22
  - If the patient does not experience 80% symptom or pain relief (using visual analog scale or verbal descriptor scale) for a minimum of 6 weeks following the second injection, no further injections should be given 21,22,54

- In the therapeutic phase all of the following criteria must be met:
  - The previous diagnostic or therapeutic injection provided pain relief of 80% documented through an objective assessment of pain using a standardized pain assessment tool (e.g., visual analog scale, verbal descriptor scale) for minimally 6 weeks before subsequent injections within the same region are authorized 21,22,54
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. 21,22 54

- Injections at different joints can be given 2 weeks apart but no sooner than 1 week following an injection in a different region. 21,22 54

- A maximum of 4 injections total per rolling calendar year may be given for local anesthetic and corticosteroid injections. 21,22 54

- 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 December 2013, the rolling calendar year would end in December 2014)

- 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. 24

- 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. 24

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**CONTINUATION OF THERAPY**

The frequency and scope of service is outlined under the ‘coverage criteria’ section of this document. Sacroiliac joint injections should only be performed with anesthetics and/or corticosteroids. Refer to the ‘Coverage Criteria section for the number of approved treatments.

**COVERAGE EXCLUSIONS**

1. **Lateral Nerve blocks and Radiofrequency ablation 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. 39-

2. Sacroiliac injections are excluded for the following:

- Members that do not meet the outlined “Coverage 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

**DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL**

**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 42C are transmitted to the nerve.  

Both RFA and PFRA are performed in the outpatient setting.

**SIJ pain**
SIJ pain is most commonly attributed to traumatic injury resulting from direct impact on the buttocks, trauma involving the lateral aspect of the pelvic ring, torsion force from lifting, pulling and twisting, and sudden gait
pattern changes from miscalculated stepping resulting in height variation changes.\textsuperscript{2,5} Pes planus (fallen arches) can also develop into sacroiliac pain. Pregnant women have a higher incidence of developing SI joint dysfunction as progesterone production may soften supporting ligaments causing hypermobility.

**Summary of Medical Evidence**

**Radiofrequency Ablation**

12 studies that focused on radiofrequency ablation (RFA) for the treatment of sacroiliac (SI) joint pain have been identified. Five studies each assessed conventional RFA in patients with SI joint pain\textsuperscript{43-47} or cooled RFA\textsuperscript{41,42,48-50} while one assessed the use of pulsed RFA\textsuperscript{51}. One study compared conventional and cooled RFA and it did not reveal evidence that cooled RFA of the lateral branches provides longer relief of sacroiliac joint pain as compared with traditional RFA.\textsuperscript{52} The overall quality of evidence of all studies was very low. The best available evidence was in the form of two patient-blinded, randomized, placebo-controlled studies.\textsuperscript{41,42} In both of these studies, the control was a sham procedure. The remaining studies were case series: four were prospective and six were retrospective.\textsuperscript{43-52} One meta-analysis demonstrated that RFA is an effective treatment for SI joint pain at 3 months and 6 months but this study is limited by the available literature and lack of randomized controlled trials.\textsuperscript{53}

Patel et al. (2012) prospectively enrolled 51 adults into a partially blinded, randomized, placebo-controlled study to evaluate the impact of cooled RFA (neurotomy) on patients with chronic SI joint pain. The treatment group of 34 patients received RFA at 60°C for 150 seconds to the L5 dorsal rams and S1 to S3 lateral branches. The control group of 17 patients received placebo treatment in which no RF current was applied but the patient was subjected to sounds typical of the procedure, injections, and placement of electrodes. Patients in both groups were blinded up to 3 months after treatment. Patients in the placebo group were offered crossover to treatment after the 3-month follow-up. Sixteen of seventeen patients accepted the offer to crossover; results presented here do not include those from the crossover group. This study did not disclose the proportion of patients with pain relief, making it challenging to compare results with those from other studies. The mean decrease in NRS pain score was significantly higher in the treatment group at 2.4 compared with the control group at 0.8 (P=0.035) 3 months after treatment. The difference was not significant 1 month after treatment (P=0.16). The mean decrease in ODI score was significantly higher in the treatment group at 12 versus 4 (P=0.046) 1 month after treatment and 11 versus 2 (P=0.011) 3 months after treatment. A larger proportion of patients in the treatment group were considered to have a successful outcome compared with those in the control group (47% versus 12%; P=0.015) 3 months after treatment. Similarly, a larger percentage of patients in the treatment group (47% versus 8%; P=0.017) reported a positive GPE 3 months after treatment. Quality of life (QOL) was marginally better in the treatment group at 0.69 – 0.21 versus 0.56 – 0.21 (P=0.048). Patients reported soreness or numbness at the treatment entry site for up to 2 weeks after treatment. No serious complications were reported. This study took place at three pain management centers in the United States and was sponsored by Baylis Medical, the manufacturer of the RF generator.\textsuperscript{42}
Cohen et al. (2008) enrolled 28 patients between the ages of 27 and 75 years into treatment and control groups. Fourteen of the patients made up the treatment group and received RF stimulation of ≤0.5 V at 75°C for 150 seconds at the S1-S3 joints and at 80°C for 90 seconds at the L4 and L5 joints. All patients were blinded up to 3 months following the procedure. Results presented here do not include those from the crossover group. The control group was subjected to the same procedures, with the exception that RF electrodes were not energized. Three months after the placebo procedure, 11 of 14 patients in the placebo group accepted the offer to cross over to treatment. Several outcome measures were reported. The differences in NRS pain score, GPE, and reduction in medication use were statistically significant between the treatment and placebo groups. For the treatment group compared with the control group, mean pain score was reported as 2.4 – 2.0 versus 6.3 – 2.4 (P<0.001), respectively; the proportion of patients with positive GPE was 93% versus 21% (P<0.001), respectively; reduction in medication was 77% (10 of 14) versus 8% (1 of 11) (P<0.001), respectively. The difference in ODI score was not statistically significant, while the differences in success rate and duration of pain relief between the two groups were not reported. Mean ODI score was lower in the treatment group at 20.9 – 10.9 compared with 43.6 – 14.0 in the control group (P<0.03). Successful outcome rate was 79% (11 of 14) in the treatment group compared with 14.3% (2 of 14) (P value not reported) and duration of pain relief was 5.8 – 4.2 months in the treatment group compared with 0.7 – 1.6 months in the placebo group (P value not reported). One case of transient nonpainful buttock paresthesia was resolved without treatment. The majority of patients experienced worsening pain 5 to 10 days after treatment.

A meta-analysis was conducted by Advin et al. (2010) to assess the effectiveness of RFA of the SI joint for pain relief at 3 and 6 months after an RFA procedure. Articles that addressed RFA of the SI joint were reviewed. Ten articles ranging from inception to January 1, 2010, were found. The main outcome measure was a reduction of pain by ≥50% post-RFA procedure. At 3 months, 7 groups met the criteria and at 6 months, 6 groups met the criteria. A meta-analysis with a forest plot was done at the 3- and 6-month patient follow-up intervals. The associated standard error was calculated for each study group. An overall weighted average with respective standard error was also obtained. A calculation of 95% confidence intervals (95% CI) was then derived. A test for heterogeneity, publication bias, and file drawer effect was also done at the 3- and 6-month intervals. At 3 months, a range of 0.538-0.693 was found to have a 95% CI, with a pooled mean of 0.616. At 6 months, a 95% CI of 0.423-0.576 was found, with a pooled mean of 0.499. The meta-analysis demonstrated that RFA is an effective treatment for SI joint pain at 3 months and 6 months. This study is limited by the available literature and lack of randomized controlled trials. Further standardization of RFA lesion techniques needs to be established, coupled with prospective randomized controlled trials.

SIJ Injections

There is some evidence that intra-articular injections of the sacroiliac joint with corticosteroids and an anesthetic provide relief of symptoms in 33% to 93% of people for a period of 1 month to up to 12 months. The studies (n=14) were small, three studies were controlled studies n=10 to 24), and the indications for treatment varied. All patients had failed conservative drug therapy or physical therapy in one study. The two randomized, double blind studies evaluating periarticular injections demonstrated significant improvements in pain at 1 and 2 months in patients with noninflammatory or inflammatory disorders of the Sacroiliac joint.
There are no randomised controlled trials evaluating the use of epidural corticosteroid injections in the pediatric population.

Twelve studies investigated intra-articular injections. One double-blind, randomized showed very good or good results in 83.3% corticosteroid injections versus 14.3% placebo injections (p<0.05).\(^4\) A six-month follow-up showed 58% of joints remained improved. Long term efficacy was evaluated in eleven of the twelve studies (6 to 22 months) with some degree of improvement (33% to 93%) in 9 of the eleven.\(^4,6-8,11-13\) No improvement was seen in two studies.\(^14,15\) Evaluation of short term response was evaluated in three of the twelve studies with improvement suggested in two studies\(^4,5\) and no improvement in the third.\(^14\)

The majority of studies evaluated patients with spondyloarthropathy and five studies involved patients with noninflammatory conditions. According to Hayes\(^1\), the weight of evidence suggests that corticosteroid sacroiliac injections may improve symptoms short and long term but the data is not conclusive. Sacroiliac injections should be used as a component of a pain management program following ineffective conservative treatment and not as a replacement for conventional therapy. These injections may lessen the demand for the need for more invasive treatments\(^1\)

Two systematic reviews of sacroiliac injections concluded there was moderate evidence to support the diagnostic utility of sacroiliac injections and limited evidence for therapeutic injections.\(^18,19\) The sacroiliac joint is highly innervated and has been shown to be a significant source for both low back and referred pain. There is controversy regarding the diagnostic and therapeutic standards for identifying and treating sacroiliac joint pain due to limited research in this area. There is no scientific evidence that history or physical examination can accurately identify the sacroiliac joint as a source of pain, controlled sacroiliac intra-articular injections appear to be the evaluation of choice to provide appropriate diagnosis of sacroiliac joint pain.\(^20,21,23\) Treatment of sacroiliac joint dysfunction typically consists of non-surgical conservative management (e.g., physical therapy, NSAIDS and other modalities) for three to six months trying to restore normal joint motion.\(^21\) Pain management guidelines have been developed for therapeutic sacroiliac injections for chronic pain unresolved by conservative treatment measures.\(^21,22\)

Another systematic review of diagnostic and therapeutic sacroiliac injections indicated level of evidence of II-2 (evidence was obtained from at least one properly designed small diagnostic accuracy study) for the diagnosis of sacroiliac joint pain utilizing comparative, controlled local anesthetic blocks.\(^32\)

### Fluoroscopy

False-positive rates are reported to be approximately 20% for single uncontrolled sacroiliac joint injections.\(^25\) A false-positive injection may occur with extravasation of anesthetic agent out of the joint secondary to defects in the joint capsule. False negative results may occur from intravascular injection, faulty needle placement, or inability of the local anesthetic agent to reach the painful portion of the joint due to loculations. A low success rate between 12% and 22% has been reported in sacroiliac injections performed without fluoroscopy. Blind injections are unlikely to reach a joint space.\(^16\) Epidural spread was seen in 24% of the patients with foraminal filing noted in 44% of the patients.\(^25,26\) A range of approximately 95% success rate been reported by several authors with the use of fluoroscopically guided sacroiliac joint injections.\(^27-30\)
Hayes, Cochrane, UpToDate

A Hayes Medical Technology Directory report on RFA for SIJ pain indicates that the data is insufficient to draw any definitive conclusions about the efficacy and safety of radiofrequency ablation (RFA) in patients with sacroiliac (SI) joint pain but there is some limited evidence that conventional RFA can provide short-term (3 to 6 months) pain relief in patients who have SI joint pain that is responsive to injection of local anesthetic. Several studies suggest that cooled RFA may have a pain-relieving effect that is comparable to that of conventional RFA, although the evidence is too sparse to support conclusions about the relative efficacy of the two techniques. Data from a single study of pulsed RFA are insufficient to evaluate the efficacy of this technique. 39

UpToDate: In a recent report on the nonsurgical intervention for subacute and chronic low back pain, sacroiliac injections are mentioned as a method of treatment for sacroiliac joint pain however, the evidence was limited. The same report indicated that the evidence for radiofrequency denervation for presumed facet joint pain is inconsistent. 35

Professional Organizations

American Society of Interventional Pain Physicians (ASIPP): 1, 2, 11 ASIPP guidelines updated in 2009 suggest that sacroiliac joint injections are indicated for patients with the following:

- Somatic or nonradicular low back and lower extremity pain below the level of L5 vertebra
- Duration of pain of at least 3 months.
- Average pain levels of ≥6 on a scale of 0 to 10
- Intermittent or continuous pain causing functional disability
- Failure to respond to more conservative management, including physical therapy modalities with exercises, chiropractic management, and non-steroidal anti-inflammatory agents.
- No disc-related or facet joint pain
- No contraindications with understanding of consent, nature of the procedure, needle placement, or sedation
- No history of allergy to contrast administration, local anesthetics, steroids, Sarapin, or other drugs potentially utilized
- Contraindications or inability to undergo physical therapy, chiropractic management, or inability to tolerate nonsteroidal anti-inflammatory drugs.
- For therapeutic sacroiliac joint interventions with intraarticular injections or radiofrequency neurotomy, the joint should have been positive utilizing controlled diagnostic blocks

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. 1, 31

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.

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RESOURCES REFERENCES


May 2012 Update:
37. CMS First Coast Service Options. LCD #L29274 for Sacroiliac Joint Injections. Updated Jan 2012. Accessed at: http://www.cms.gov/medicare-coverage-database/search/search-results.aspx?CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=sacroiliac&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAAAAAAAAA&=&
2013 Update
Policy reviewed and approved by Dr. Gary Call, MD, MHI 12/11/13

2014 Update