

Molina Clinical Policy

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

Last Approval: 4/13/2023
Next Review Due By: April 2024



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 is a condition in which pain is caused by the joint connecting the sacrum and the pelvis, and its prevalence ranges between 18% and 30% (Sun et al., 2018). The SIJ, the largest axial joint in humans, connects the sacrum to the ilium in the spine and functions 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 to administer injections of a corticosteroid or anesthetic drug under fluoroscopic guidance to achieve pain relief of 50 to 75% pain relief (Ou-Yang et al. 2017; Thawrani et al. 2019; Landi et al. 2016). Fluoroscopy guidance is most used for accurate needle placement during the procedure. The needle is inserted into the SIJ region, and contrast media is injected for arthrogram viewing to confirm proper needle placement. A small amount of anesthetic is injected to assess the patient's pain relief response.

Radiofrequency Ablation (RFA) is a treatment for SIJ pain that utilizes radiofrequency current to generate heat and destroy SIJ sensory nerves. In patients with refractory SIJ pain, the goal of this therapy is to disrupt pain signal transmission from the SIJ nerves to the brain. RFA is also referred to as RF neurolysis, RF neurotomy, RF coagulation, RF lesioning, and RF denervation (Manchikanti et al., 2016; Lee et al., 2021). Alternatives to conventional (consistent, thermal) RFA include **cooled radiofrequency ablation (CRFA)** and **pulsed radiofrequency ablation (PRFA)**. CRFA and PRF are both percutaneous procedures that use radiofrequency energy. Typically, both procedures are performed on an outpatient basis and are guided by fluoroscopy.

CRFA uses radiofrequency energy to heat tissue to the point of ablation, preventing pain signals from reaching the central nervous system (Lee et al., 2021; Wray et al., 2022). CRFA probes differ from standard RFA probes in that water circulated through the CRFA probe tip draws heat away from the tissue-tip interface. The continuous flow of water cools the multichannel electrode, preventing it from reaching high tissue temperatures, allowing a continuous flow of RF current to produce a larger ablation zone, or lesion, which is thought to improve the chances of successful interventional capture of the target nerve within the lesion zone. As a result, this has been proposed to help achieve better or equal results when compared to conventional radiofrequency. CRFA, like PRFA, allows for larger lesions to be created by cooling the adjacent tissue during the procedure.

PRFA has been introduced as a non-ablative alternative to RFA. Unlike traditional RFA and CRFA, the goal of PRF is not to create a thermal lesion, and the precise mechanism by which PRF relieves pain is unknown. PRFA provides radiofrequency current in short bursts instead of continuous current, allowing the tissue to cool between bursts. Tissue

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can cool between bursts results in significantly lower maximum temperatures compared to the continuous mode and reducing the risk of tissue damage to neighboring tissue. It does not destroy targeted nerves and surrounding tissue, therefore requiring less precise electrode placement. Evidence suggests, however, that the electrical fields produced during PRF may disrupt the pain signal to the brain (Hayes, 2022). During PRF, the energy signal is delivered in short (20-millisecond) high-voltage pulses every half second for 120 seconds, keeping the probe temperature between 39 and 42 degrees Celsius.

Regulatory Status

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

RFA (e.g., CRFA, PRFA) for spinal pain is a procedure and is not regulated by the FDA. However, the FDA regulates RFA equipment, and various devices approved for use in RFA for neurosurgical operations are listed in the FDA 510(k) database that have been cleared as class II devices by the FDA. These devices are classified into two product codes: radiofrequency lesion generators (GXD) and radiofrequency lesion probes (GXI).

RELATED POLICIES

MCP-085: Radiofrequency Ablation (RFA) for Chronic Back Pain Associated with the Facet Joint

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** the following criteria are met:
 1. Physical examination documentation reveals **ALL** 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** 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).*

Limitations and Exclusions

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The following are considered **experimental, investigational, and unproven** based on insufficient evidence:

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. Any indications other than those listed above.

SI injections are considered **contraindications/exclusions** based on insufficient evidence:

Exclusions to receiving SI injections include:

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

Contraindications to receiving SI injections include:

1. Allergy to the medication to be administered
2. Anticoagulation therapy
3. Bleeding disorder
4. Localized infection in the region to be injected
5. Systemic infection
6. Other comorbidities that could exacerbate the procedure/steroid use (e.g., diabetes, congestive heart failure, poorly controlled hypertension)
7. Pregnancy: Fluoroscopy use is contraindicated for members that are pregnant

QUANTITY LIMITATION

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** 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**

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- 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 each session so that the effectiveness of its treatment can be assessed prior to attempting another type of spinal block or injection.

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 (RFA)

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 the precise innervation of the joint. Studies assessed in published systematic reviews, Cochrane reviews, and technology assessments overlap. 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 RCTs comparing CRFA to conventional radiofrequency (Cheng, et al., 2013) and CRFA to a new bipolar radiofrequency 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.

CRFA for SIJ. There is insufficient published evidence to support the use of CRFA for the treatment of facet joint or sacroiliac pain. Additional randomized controlled clinical trials (RCTs) with longer follow up and larger patient populations are required. The evidence is insufficient to determine the effects of this technology on net health outcomes.

A Cochrane review evaluated the evidence for radiofrequency 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 radiofrequency 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 radiofrequency denervation relieves back pain.

A randomized multicenter study (Mint Study) evaluating the effectiveness of radiofrequency 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 to 3 treatments were allowed). The primary outcome was pain intensity 3 months after treatment, with a

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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, radiofrequency 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 CRFA 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, CRFA 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, analysis supported the safety and efficacy of CRFA for SIJ pain.

Chou et al. (2021) recommended against radiofrequency denervation for the management of chronic LBP in an evidence-based peer-review on nonsurgical interventional treatment for LBP (UpToDate, 2021). The available data are inconclusive and suggest that, when compared to placebo, radiofrequency denervation may reduce pain in the short term; however, there does not appear to be any long-term benefit. Radiofrequency denervation adds little to a treatment regimen that includes a regular exercise program and psychologic support (Juch et al. 2017). Discogenic LBP, radicular pain, and chronic SIJ pain have all shown no efficacy or only modest, mostly short-term benefit in small clinical trials.

A Health Technology Assessment (December 2022) assessed the effectiveness and safety of CRFA and PRF for the treatment of chronic LBP that originates from the SIJ.

- The use of CRFA in adults for chronic LBP caused by SIJ is regarded as potentially beneficial but unproven. This rating reflects an overall low-quality body of evidence indicating that SIJ CRFA is safe and may be effective for 6 to 12 months in reducing the intensity of chronic LBP and improving physical function. This rating also reflects significant uncertainty about the long-term durability, impact on quality of life, and effectiveness of CRFA in comparison to most treatment alternatives.
- The use of PRFA to treat chronic LBP arising from the SIJ in adults is rated as insufficient evidence due to the 'very small and limited body of published evidence' to assess the safety and/or impact on health outcomes or patient management. This HTA based the rating on an overall very low-quality body of evidence that is insufficient to allow any conclusions regarding the efficacy and safety of PRF for treatment of chronic LBP arising from the SIJ.

SIJ Injections

The current peer-reviewed published literature for SIJ injections with corticosteroids and local anesthetic for treatment of chronic LBP consists of RCTs prospective cohort studies and retrospective reviews. There are no randomized trials of intraarticular SIJ steroid injection versus a sham procedure in patients without spondyloarthritis (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. There were no reported side effects from the treatment. The limitations of

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this study include a small sample size and lack of power analysis, a single-blind design, a short 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 LBP as opposed to SIJ pathology.

Jee et al. (2014), in a RCT of 120 patients (n = 120) with noninflammatory SI arthritis, ultrasound (US)-guided SIJ injections, compared to fluoroscopic (FL)-guided SIJ injections to evaluate the short-term efficacy and safety of US and FL-guided SIJ injections. Patients were not blinded, but an investigator who was blinded assessed their pain, disability, and satisfaction. The FL-guided SIJ approach was more accurate than the US-guided approach (98.2% versus 87.2%). The function and pain relief of both groups improved without significant differences. The US-guided strategy is just as effective as the FL-guided strategy; however, the SIJ's lower diagnostic accuracy rate may limit its diagnostic utility.

National and Specialty Organizations

Agency for Healthcare Research and Quality (AHRQ) conducted a comparative effectiveness review on CRFA for the treatment of sacroiliac and facet joint pain (Chou et al., 2021). At 1-month, CRFA for sacroiliac pain was associated with a moderate to large reduction in pain and a small to large improvement in function when compared to sham radiofrequency. At three months, pain and function had improved moderately. There is insufficient evidence beyond 6 months. Furthermore, the trials used a variety of techniques, with insufficient evidence to determine the best method. CRFA for presumed facet joint pain was associated with a small, non-statistically significant reduction in pain and no difference in function at 6 months compared to conventional RFA. At the 1- and 3-month follow-ups, there were no differences. There is insufficient evidence beyond 6 months. All studies had small sample sizes and short follow-up periods. Longer-term studies with larger sample sizes are required to confirm these findings.

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.

American Society of Interventional Pain Physicians (ASIPP)

'An Update of Comprehensive Evidence-Based Guidelines for Interventional Techniques in Chronic Spinal Pain. Part II: Guidance and Recommendations' (Manchikanti, et al., 2013) indicates:

- There was fair-quality evidence of the efficacy of CRFA for SIJ pain.
- The evidence of effectiveness of PRF of the SIJ was considered limited.
- The evidence for intraarticular injections as an intervention for SIJ indications is limited (Manchikanti, 2013).

Institute for Clinical Systems Improvement (ICSI)

- ICSI guideline 'Pain: Assessment, Non-Opioid Treatment Approaches and Opioid Management Care for Adults' issued in 2019 indicate that conflicting evidence exists regarding the efficacy of SIJ injections for management of LBP.
- The guideline (2019) also notes that mixed evidence exists regarding the efficacy of RF neurotomy (Maas, 2015; Manchikanti, 2015a).

North American Spine Society (NASS)

The 'Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis and Treatment of Low Back Pain,' published in 2020, assigned a grade of C to the following recommendations, indicating poor quality evidence (Level IV or V studies) for or against recommending intervention:

- Intraarticular SIJ injections with steroid may be considered in patients with suspected SIJ pain, and
- CRFA 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.

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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

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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

4/13/2023	Policy reviewed and updated. No changes to intent of policy or coverage criteria. Added updated literature to the 'Summary of Evidence' section. Updated references.
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	Policy reviewed, no changes to criteria.
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	Policy reviewed, no changes to criteria.
8/23/2012	Policy reviewed, no changes to criteria.
12/11/2013	Policy reviewed, no changes to criteria.
6/25/2014	Policy reviewed, no changes to criteria.
12/16/2015	Policy reviewed, no changes to criteria.
6/15/2016	Policy reviewed, no changes to criteria.
7/5/2007	New policy.

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

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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.