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

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DESCRIPTION

Radiofrequency Ablation (RFA)

Most back pain resolves with conservative treatment, but a significant number of individuals may develop chronic spinal pain. Facet joint pain has been attributed to chronic spinal pain and radiofrequency denervation or ablation of the facet joint(s) has been proposed and used with increased frequency to treat neck, upper/middle and lower back pain, and sacroiliac joint (SIJ) pain.

A variety of terms may be used to describe percutaneous radiofrequency denervation including radiofrequency ablation (RFA), non-pulsed radiofrequency, radiofrequency neuroablation, radiofrequency lesioning, radiofrequency neurotomy, radiofrequency facet rhizotomy and radiofrequency articular rhizolysis.

The facet joints, also known as apophyseal joints or zygapophyseal joints, are formed by the superior and inferior articular processes of sequential vertebrae. The facet joints are joints in the spine that make the back flexible and enable an individual to bend and twist. Nerves exit the spinal cord through these joints on their way to other parts of the body. Healthy facet joints have cartilage, which allows the vertebrae to move smoothly against each other without grinding. The nerves that communicate with these joints sometimes become inflamed or impinged, which leads to facet joint pain.

Percutaneous radiofrequency facet joint ablation/denervation is used to treat neck or back pain originating in the facet joints with degenerative changes and for the treatment of sacroiliac joint (SIJ) pain. The diagnosis of facet joint pain is confirmed by a positive response from at least two diagnostic blocks i.e., facet joint injections or medical branch blocks (MBB). Based on the American Society of Interventional Pain Physicians (ASIPP) 2013 evidence-based guidelines for interventional techniques in chronic spinal pain, states "based on the available evidence it appears the best response is obtained after confirmation of the diagnosis of facet joint pain with controlled diagnostic blocks preferably with 75% pain relief as the criterion standard with dual blocks." The goal of facet joint radiofrequency denervation is long-term pain relief. However, the nerve(s) may regenerate, and repeat procedures may be required.

Radiofrequency facet joint ablation/denervation is performed under local anesthetic with fluoroscopic guidance. Radiofrequency ablation (RFA) is a percutaneous treatment that uses radiowave-induced heat to create a lesion in a spinal sensory nerve. Following a prognostic blockade (MBB) to target the affected nerve(s), radiofrequency (RF) current is applied in a continuous manner for several minutes via a needle electrode to the targeted nerves under imaging guidance. Continuous radiofrequency ablation involves the constant application of energy via an image guided needle electrode inserted through the skin (percutaneously) to the affected nerve. Once the probe is placed, lesions or nerves are then targeted unilaterally or bilaterally for 40 to 90 seconds at temperatures of 60 to 90 degrees Celsius. The goal of RFA is to relieve pain and symptoms by interrupting pain signal transmission from the sensory nerve to the brain. A minimum of two levels must be addressed to ablate/denervate a single joint. Radiofrequency ablation (RFA)/denervation is directed at each of the levels to be lesioned. Destruction of the nerve may be permanent or temporary. In cases where the pain returns, the procedure can be repeated in the same joint(s) or spinal levels.

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

Similar to other structures in the spine, it is assumed that the sacroiliac joint (SIJ) may be a source of low back and/or buttock pain with or without lower extremity pain. Radiofrequency ablation/denervation has been used to manage sacroiliac joint (SIJ) pain.

The sacroiliac joint (SIJ) receives innervation from the lumbosacral nerve roots. There is no universally accepted gold standard for the diagnosis of low back pain stemming from sacroiliac joints.

Due to the inability to make the diagnosis of sacroiliac joint (SIJ) pain with non-invasive tests, sacroiliac joint blocks appear to be the evaluation of choice to provide appropriate diagnosis. A positive response is considered ≥ 75% relief or with ability to perform previous painful movements. Radiofrequency ablation/denervation has been used to manage pain of the sacroiliac joint, using thermal lesioning at 80 to 85 degrees Celsius. The mechanism of radiofrequency ablation/denervation is by denaturing of the nerves. Pain may return when the nerves regenerate requiring repeat procedures.

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

Populations
The relevant population of interest is individuals with chronic sacroiliac joint (SIJ) pain.

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

Comparators
The following therapy is currently being used to treat sacroiliac joint (SIJ) pain: conservative therapy.

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

Systematic Reviews
In 2022, Lowe et. al. performed and systematic review of randomized controlled trials regarding radiofrequency ablation as an effective long-term treatment for chronic sacroiliac joint pain. Radiofrequency ablation (RFA) has emerged as a popular intervention for chronic pain management, including pain originating in the sacroiliac joint. It offers a less invasive option than surgery but with better results than the previous standard treatment with steroid and anesthetic injections. Procedure volumes have enjoyed significant growth in the market in recent years. The evidence supporting this intervention, in the form of randomized controlled trials, however, is both thin and mixed. The purpose of this systematic review is to evaluate the body of randomized

controlled trials (RCTs) to determine the quality of support for and against the use of radiofrequency ablation to treat sacroiliac joint (SIJ) pain. Several important new papers have emerged since previous systematic reviews with similar objectives were published. Only RCTs were sought, and no other filters, such as a historical timeline cut-off, were used. Among 95 publications that returned in response to the query, 16 were ultimately accepted as meeting the inclusion/exclusion criteria. Among the included publications, 15 out of 16 publications featured positive results and conclusions that supported the use of RFA in treating chronic sacroiliac joint pain. The single negative study was also the largest trial (n=681), but it was identified as "High Risk" using the Cochrane risk-of-bias tool. It included several design flaws including neither operator nor patient blinding, missing information, use of inconsistent treatment modalities across groups, and disproportionate drop-out rates. Despite its flaws, we have included this study in the present review because of its sheer size. Taken in aggregate, the total body of research included in this review supports this intervention. Questions continue to exist around whether there are clinically significant benefits associated with different RFA modalities (for example, unipolar vs. bipolar), with convincing evidence supporting each of them. Finally, it can be concluded that while the benefits are reasonably and justifiably supported in this patient population for up to one year, there is a lack of evidence beyond a 12-month post-intervention follow-up.

Chou et. al. (2021) conducted a systematic review and meta-analysis on interventional treatments for acute and chronic pain for the Agency for Healthcare Research and Quality for use by the Centers for Medicare and Medicaid Services. The systematic review identified 2 trials (N=79) on cooled RFA versus sham for SIJ pain with results at 3 months, and 1 trial (N=28) on cooled RFA versus sham with results at 1 month. Meta-analysis indicated that cooled RFA is probably more effective for pain and function compared to sham at 1 and 3 months with moderate to large benefits. The strength of evidence was rated moderate for pain and function at 3 months and low for function at 1 month. When comparing cooled RFA to conventional RFA, 1 trial (N=43) showed no differences at 1 or 3-month follow-up and a small, nonstatistically significant reduction in pain at 6 months. The strength of evidence was rated as low.

Yang et. al. (2021), reported on radiofrequency ablation for chronic posterior sacroiliac joint complex pain. The review discussed current diagnostic block paradigms and selection criteria for sacral lateral branch radiofrequency ablation, varying techniques and technologies utilized for sacral lateral branch radiofrequency ablation and updates on the clinical outcome literature. The current evidence suggests that sacral lateral branch radiofrequency ablation can provide relief for posterior sacroiliac joint complex pain, but the literature is limited by variability in selection criteria, the specific nerves targeted by radiofrequency ablation, and the types of radiofrequency ablation technology and techniques utilized in clinical outcome studies. Further studies are warranted.

In 2020, Chappel et. al. performed a meta-analysis of RFA for chronic back pain. The review included 5 RCTs comparing RFA to sham or medical treatment in patients with chronic SIJ pain with follow-up from 1 to 3 months, and 1 study that had a follow-up to

12 months. This meta-analysis did not include pulsed RFA. Low-quality evidence indicated that RFA led to a modest reduction in pain at 1 to 3-month follow-up, but there was no significant reduction in pain in the single RCT (n=228) that had 6- and 12-month follow-up. The RCT by Juch et. al. (2017) with 12-month follow-up is described in greater detail below, *see Randomized Controlled Trials*.

In 2019, Chen et. al. published a meta-analysis, and the objective of the review was to compare the effectiveness of radiofrequency neurotomy versus conservative nonsurgical approaches for the management of chronic lumbar and sacroiliac joint pain. The PICOS framework was adhered to (P [population]: patients with a history of chronic function-limiting lumbar and sacroiliac joint pain lasting at least 6 months; I [intervention]: RF neurotomy; C [comparator]: other nonsurgical treatments; O [outcomes]: the Oswestry Disability Index (ODI), measurement for pain, and a quality of life (QoL) questionnaire; S [study design]: meta-analysis). Two trained investigators systematically searched Medline, Cochrane, EMBASE, and ISI Web of Knowledge databases for relevant studies published in English through March 2019. Patients treated with RF neurotomy (n=528) had significantly greater improvement in ODI scores, pain scores and QoL measured by EQ-5D compared with controls (n=457); however, significant heterogeneity was observed when data were pooled from eligible studies. In subgroup analyses, patients who received RF neurotomy had a significantly greater improvement in ODI scores compared with those with sham treatment. Patients treated with RF achieved significantly greater improvement in pain scores compared with controls who received sham treatment or medical treatment. In a subgroup analysis of pain in the sacroiliac joint and in lumbar facet joints, the RF neurotomy group achieved a significantly greater improvement in ODI score and pain scores compared with the control group. The ODI score and pain score were improved after 2 months of follow up in the analyses stratified by follow-up duration. There were several study limitations worth noting. First, this systematic review lacked a pre-specified protocol and its preliminary registration; thus, biased post-hoc decisions during review of the methods may occur. Second, the current analysis included a small number of studies measuring QoL. In addition, heterogeneity was noted among both RF neurotomy and other conservative nonsurgical treatments. For example, cooled RF was used in certain studies, whereas others used conventional RF thermocoagulation. In addition, 3 groups compared RF neurotomy and steroid injections, and one study compared palisade sacroiliac joint RF neurotomy and celecoxib. Researchers in the11 remaining studies used sham neurotomy as the control. They performed additional subgroup analyses using similarly designed studies (such as separate analyses of studies that used RF versus sham treatment and studies that used RF versus steroid injections/celecoxib). Although the findings depended on the selection criteria and the designs of included studies, the criteria were not unreasonably strict. Third, some of the 2-arm studies included in the meta-analysis lacked blinding (to patients and/or physicians). Finally, others may have reported inflated results in their neurotomy groups due to pre-emptive joint injections of corticosteroids or local anesthetics; therefore, future studies using larger cohorts will be needed to confirm our results. The authors concluded Patients treated with RF neurotomy for chronic lumbar and sacroiliac joint pain had significantly greater improvement in pain and functional outcomes compared with those

who received conservative treatment or sham therapy. Larger, more directly comparable studies will be needed to confirm the current finding.

In 2018, Sun et. al. conducted a meta-analysis to systematically assess the efficacy and safety of using cooled radiofrequency in treatment patients with chronic sacroiliac joint (SIJ) pain in terms of pain and disability relief, patients' satisfaction degree as well as complications. Studies of using cooled radiofrequency procedure in managing SIJ pain were retrieved from Medline and Web of Science according to inclusion and exclusion criteria. Quality evaluation was conducted using Cochrane collaboration tool for randomized controlled trials and MINORS quality assessment for noncomparative trials. Statistics were managed using Review Manager 5.3. Totally 7 studies with 240 eligible patients were enrolled. The overall pooled results demonstrated that pain intensity decreased significantly after cooled radiofrequency procedure compared with that measured before treatment. The mean difference (MD) was 3.81 [95% confidence intervals (95% CIs): 3.29–4.33, P<.001] and 3.78 (95% CIs: 3.31–4.25, P<.001) as measured by the Numerical Rating Scale (NRS) and Visual Analog Scale (VAS), respectively. Disability also relieved significantly after treatment compared with that measured before treatment. The MD was 18.2 (95% CIs: 12.22–24.17, P<.001) as measured by the Oswestry Disability Index (ODI). Seventy-two percent of the patients presented positive results as measured by the Global Perceived Effect (GPE). The OR was 0.01 (95% CIs: 0.00–0.05, P<.001). Only mild complications were observed in the 7 studies, including transient hip pain, soreness, and numbness. Limitations of this study include the sample size of the included studies was small and various heterogeneity existed. The authors concluded cooled radiofrequency procedure can significantly relieve pain and disability with no severe complications, and majority of patients are satisfied with this technique. Thus, it is safe and effective to use this procedure in managing patients with chronic SIJ pain. More high-quality and large-scale randomized controlled trials (RCTs) are required to validate our findings.

Randomized Controlled Trials

In 2018, Mehta et. al. performed and reported on the effects of radiofrequency neurotomy using a strip-lesioning device on patients with sacroiliac joint (SIJ) pain. This was a prospective, double-blind, randomized, sham-controlled trial with 6-month follow-up. The setting was a tertiary care interventional pain management center in the UK. Patients with SIJ pain with positive diagnostic local anesthetic blocks were randomly assigned (2:1) to either the sham (no RF lesions performed) or the active group (RF lesions performed). The primary endpoint was improvement of pain using the Numeric Rating Scale (NRS-11) at 3 months. Results were analyzed using nonparametric tests. Safety, secondary, and long-term outcome data were also collected. Seventeen of 30 enrolled patients were randomly assigned to active treatment (n = 11) or sham treatment (n = 6). At 3 months, the mean NRS-11 score for the active group had decreased significantly, from 8.1 (± 0.8) at baseline to 3.4 (± 2.0) (P < 0.001). The sham group did not experience a statistically or clinically meaningful decrease in mean NRS-11 score from baseline (7.3 ± 0.8) to 3 months (7.0 ± 1.7). On average, patients in the active group moved from borderline anxiety at baseline (9.4 ± 5.9) to no anxiety (6.6 ± 6.3) at 3 months. Results

were similar at 6 months. Limitations of this study included the following: Recruitment was stopped at 30 enrolled patients, only 17 of whom were randomly assigned to active or sham treatment, after the interim analysis indicated a statistically significant (P < 0.001) difference in the pain outcome between the treatment and the sham groups.

In 2017, Juch et. al. reported on a non-blinded multicenter randomized controlled trial (RCT) of radiofrequency denervation in patients with suspected sacroiliac joint pain unresponsive to conservative care who were asked to participate in the trial. All participants received a 3-month standardized exercise program and psychological support if needed. Participants in the intervention group received radiofrequency denervation as well. This is usually a one-time procedure, but the maximum number of treatments in the trial was three. The primary outcome was pain intensity (numeric rating scale, 0-10; whereby 0 indicated no pain and 10 indicated worst pain imaginable) measured 3 months after the intervention. The prespecified minimal clinically important difference was defined as 2 points or more. Final follow-up was at 12 months, ending October 2015. Among 681 participants who were randomized (mean age, 52.2 years; 421 women [61.8%], mean baseline pain intensity, 7.1), 599 (88%) completed the 3-month follow-up, and 521 (77%) completed the 12-month follow-up. The mean difference in pain intensity between the radiofrequency denervation and control groups at 3 months was -0.18 (95% CI, -0.76 to 0.40) in the facet joint trial; -0.71 (95% CI, -1.35 to -0.06) in the sacroiliac joint trial; and -0.99 (95% CI, -1.73 to -0.25) in the combination trial. The authors concluded, in 3 randomized clinical trials of participants with chronic low back pain originating in the facet joints, sacroiliac joints, or a combination of facet joints, sacroiliac joints, or intervertebral disks, radiofrequency denervation combined with a standardized exercise program resulted in either no improvement or no clinically important improvement in chronic low back pain compared with a standardized exercise program alone. The findings do not support the use of radiofrequency denervation to treat chronic low back pain from these sources.

In 2016, van Tilburg et. al. reported a sham-controlled randomized trial of percutaneous radiofrequency ablation (RFA) in 60 patients with sacroiliac joint (SIJ) pain. Patients selected had clinically suspected SIJ pain and a decrease of 2 or more points on a 10-point pain scale with a diagnostic sacroiliac block. Treatment group: percutaneous radiofrequency (RF) heat lesion at the lateral branches of S1, S2, S3, and S4 nerve roots and the posterior ramus dorsalis of L5; sham group: same procedure as the treatment group except for the radiofrequency (RF) heat lesion. No statistically significant differences in pain level over time between the groups (Group×Period) ($F_{1,58}=0.353$; $P=0.56$) nor within the treatment Group ($F_{1,58}=0.212$; $P=0.65$) were found. The Period factor, however, yielded a significant difference ($F_{1,58}=61.67$; $P<0.001$), that is, when pooled together the mean pain level of the patients was significantly reduced at T1 compared with T0. In the crossover group, 42.1% experienced a reduction in NRS of 2 or more at 1 month ($P=0.65$). No statistically significant difference in satisfaction over time between the groups was found ($F_{1,50}=2.1$; $P=0.15$). The independent factors Group ($F_{1,50}=2.02$; $P=0.16$) and Period ($F_{1,50}=0.95$; $P=0.33$) also showed no statistically significant difference. The same applies to recovery: no statistically significant

Group×Period effect (F1,51=0.09; P=0.77) was found, neither an effect of Group (F1,51=0.004; P=0.95) nor of Period (F1,51=0.27; P=0.60). The authors concluded the hypothesis of no difference in pain reduction or in Global Preceived Effect between the treatment and sham group cannot be rejected.

In 2014, Zheng et. al. reported a randomized controlled trial (RCT) of palisade sacroiliac radiofrequency ablation (RFA) in 155 patients with ankylosing spondylitis. Palisade RFA uses a row of radiofrequency cannula perpendicular to the dorsal sacrum. Inclusion criteria were ages 18 to 75 years; diagnosis of ankylosing spondylitis; chronic low back pain for at least 3 months; axial pain below L5; no peripheral involvement; pain aggravation on manual pressing of the sacroiliac joint (SIJ) area; and at least 50% pain relief following fluoroscopically guided anesthetic injection into the joint. Patients who met the inclusion criteria were randomized to palisade RFA or celecoxib. Blinded evaluation to 24 weeks found that RFA (2.8) resulted in lower global VAS (visual analog) scores than celecoxib (5.0; $p<0.001$) as well improved scores for secondary outcome measures. This study lacked a sham control.

In 2012, Patel et. al. reported a randomized, double-blind, placebo-controlled trial of lateral branch neurotomy with a cooled radiofrequency probe. Twelve-month follow-up was reported in 2016 (Patel et. al.). Fifty-one patients who had a positive response to 2 lateral branch blocks were randomized 2:1 to lateral branch radiofrequency or to sham. At 3-month follow-up, significant improvements were observed in pain levels (-2.4 vs -0.8), physical function (14 vs 3), disability (-11 vs 2), and quality of life (0.09 vs 0.02) for radiofrequency treatment compared with controls (all respectively). With treatment success defined as a 50% or greater reduction in numeric rating scale score, 47% of radiofrequency-treated patients and 12% of sham-treated patients achieved treatment success. The treatment response was durable to 12 months in the 25 of 34 patients who completed all follow-up visits.15 Of the 9 patients who terminated study participation, 4 (12%) of 34 were considered treatment failures.

Summary of Evidence

For individuals who have chronic sacroiliac joint (SIJ) pain who received radiofrequency ablation (RFA), the overall quality of the evidence is low. Meta-analysis of available sham-controlled randomized controlled trials (RCTs) suggests that there may be a small effect of RFA on SIJ pain at short-term (1-3 months) follow-up. However, the RCTs of RFA have methodologic limitations, and there is limited data on the duration of the treatment effect. The single RCT with 6 and 12-month follow-up showed no significant benefit of RFA compared to an exercise control group at these time points. In addition, heterogeneity of RFA treatment techniques precludes generalizing results across different studies. For RFA with a cooled probe, 2 small RCTs reported short-term benefits, but these are insufficient to determine the overall effect on health outcomes. An RCT on palisade RFA of the SIJ did not include a sham control. Another sham-controlled RCT showed no benefit from RFA. Also, the lack of a standard RFA technique for SI joint RFA prevents definitive conclusions regarding the efficacy and safety of the procedure. An inherent challenge to the efficacy of RFA is the variable anatomy of targeted lateral

branch nerves in the SI joint. Questions remain regarding patient selection criteria, long-term outcomes, and the comparative efficacy versus alternative therapies. Further high quality comparative randomized controlled trials (RCTs) with sham control and alternative treatments are required to confirm results and to determine the optimal candidates and treatment parameters regarding the use of radiofrequency ablation (RFA) for the treatment of chronic SI joint pain. The evidence is insufficient to determine the effects of the technology on net health outcomes.

Alternative Methods of Ablation/Denervation in the Treatment of Cervical, Thoracic and Lumbar Chronic Facet Joint Pain and Chronic Sacroiliac Joint Pain
Alternative methods of ablation/denervation in the treatment of chronic cervical, thoracic, and lumbar facet joint pain and chronic sacroiliac joint (SIJ) pain include but are not limited to the following: laser denervation, chemical neurolysis (chemodenervation) (e.g., alcohol, phenol, glycerol, or hypertonic saline) cryodenervation (cryoablation), cooled radiofrequency denervation/ablation, pulsed radiofrequency ablation and endoscopic radiofrequency ablation.

Clinical Context and Therapy Purpose
Alternative methods of denervation (laser denervation, chemical neurolysis, cryodenervation (cryoablation), cooled radiofrequency ablation, pulsed radiofrequency ablation and endoscopic radiofrequency ablation) in individuals who have chronic facet joint pain or chronic sacroiliac joint (SIJ) pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations
The relevant population of interest is individuals with chronic facet joint pain and chronic sacroiliac joint (SIJ) pain.

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

Comparators
The following therapies and practices are currently being used to treat confirmed facet joint pain or sacroiliac joint (SIJ) pain: intra-articular nerve blocks and conservative therapy.

Outcomes
The general outcomes of interest are symptoms reduction in pain, functional outcomes, quality of life (QOL), reductions in medication use, and treatment related morbidity. Follow-up may be required up to 12 months to monitor for symptom recurrence and the need for additional treatments.

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

In 2007, Iwatsuki et. al. reported laser denervation to the dorsal surface of the facet capsule in 21 patients who had a positive response to a diagnostic medial branch block. One year after laser denervation, 17 patients (81%) experienced greater than 70% pain reduction. In 4 patients (19%) who had previously undergone spinal surgery, the response to laser denervation was not successful. There also was no control group in this study. There are no comparative studies for the use of laser denervation to treat facet joint (cervical, thoracic, and lumbar) pain or sacroiliac joint pain.

Summary of Evidence
Based on review of the peer reviewed medical literature the evidence is limited. Additional research is needed to assess the effectiveness of this alternative treatment method, laser denervation in the treatment of chronic facet joint pain (cervical, thoracic, and lumbar) and chronic sacroiliac joint (SIJ) pain. The evidence is insufficient to determine the effects of the technology on net health outcomes.

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

Joo et. al. (2013), compared alcohol ablation with radiofrequency ablation in a randomized study of 40 patients with recurrent thoracolumbar facet joint pain following an initial successful radiofrequency ablation. At 24-month follow-up, three patients in the alcohol ablation group had recurring pain compared to 19 in the radiofrequency group. The median effective periods were 10.7 months (range 5.4 to 24) for radiofrequency and 24 months (range 16.8 to 24) for alcohol ablation. No significant complications were identified.

Summary of Evidence
There is lack of published data regarding chemical neurolysis in the treatment of chronic facet joint pain (cervical, thoracic, and lumbar) or for chronic sacroiliac joint (SIJ) pain, only one small randomized controlled trial (RCT) was found comparing alcohol ablation with radiofrequency ablation for the treatment of recurrent thoracolumbar facet joint pain. Additional studies are needed to assess the safety and effectiveness of this alternative method to treat chronic facet joint pain (cervical, thoracic, and lumbar) or sacroiliac joint

(SIJ) pain. The evidence is insufficient to determine the effects of the technology on net health outcomes.

Cryodenervation (Cryoablation)
Cryodenervation (cryoablation) is a minimally invasive procedure that involves the use of extreme cold to destroy abnormal tissue. Cryodenervation (cryoablation) involves inserting a slim, laminated, double-walled cryodenervation probe under local anesthesia. The cryodenervation probe has been cooled to -70 degrees Celsius by carbon dioxide, thereby freezing the pain causing nerves.

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

Summary of Evidence
There is lack of published data to support the safety and efficacy of cryodenervation (cryoablation) for the treatment of chronic facet joint pain (cervical, thoracic, and lumbar) or for chronic sacroiliac joint (SIJ) pain, only one case series was found. Additional studies are needed to assess the safety and effectiveness of this alternative method to treat chronic facet joint pain or sacroiliac joint (SIJ) pain. The evidence is insufficient to determine the effects of the technology on net health outcomes.

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

One such cooled radiofrequency denervation/ablation procedure is called COOLIEF which is a non-surgical pain relief option for those suffering from chronic back pain. This procedure uses cooled radiofrequency energy to target the sensory nerves causing pain. Radiofrequency (RF) energy heats and cools tissue at the site of pain. COOLIEF circulates water through the area that is larger than conventional RF treatments. This

combination targets the pain-causing nerves without excessive heating, leading to pain relief. The patient should feel pain relief within one to two weeks. In some patients, the pain relief can be relatively long lasting and in others additional treatments may be required.

- COOLIEF Cervical Cooled Radiofrequency
- COOLIEF Lumbar Cooled Radiofrequency
- COOLIEF Thoracic Cooled Radiofrequency
- COOLIEF Sinergy Sacroiliac Cooled Radiofrequency

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

In 2018, Sun et. al. conducted a meta-analysis to systematically assess the efficacy and safety of using cooled radiofrequency in treating patients with chronic sacroiliac joint (SIJ) pain in terms of pain and disability relief, patients' satisfaction degree as well as complications. Seven studies with 240 eligible patients were enrolled. The overall pooled results demonstrated that pain intensity decreased significantly after cooled radiofrequency procedure compared with that measured before treatment. The mean difference (MD) was 3.81 [95% confidence intervals (95% CIs): 3.29-4.33, P<.001] and 3.78 (95% CIs: 3.31-4.25, P<.001) as measured by the Numerical Rating Scale (NRS) and Visual Analog Scale (VAS), respectively. Disability also relieved significantly after treatment compared with that measured before treatment. The MD was 18.2 (95% CIs: 12.22-24.17, P<.001) as measured by the Oswestry Disability Index (ODI). Seventy-two percent of the patients presented positive results as measured by the Global Perceived Effect (GPE). The OR was 0.01 (95% CIs: 0.00-0.05, P<.001). Only mild complications were observed in the 7 studies, including transient hip pain, soreness, and numbness. The

limitation of this analysis was the sample size included in the studies was small and various heterogeneity existed. The authors concluded, cooled radiofrequency procedure can relieve pain and disability with no severe complications. It is safe and effective to use this procedure in managing patients with chronic SIJ pain. However, more high-quality and large-scale randomized controlled trials (RCTs) are required to validate our findings.

In 2016, Patel et. al. reported on the twelve-month follow-up of a randomized trial assessing cooled radiofrequency (CRF) lateral branch neurotomy (LBN) as a treatment for sacroiliac (SI) region pain. This study originally included 51 subjects who were randomized 2:1 to receive CRF/LBN treatment or a sham intervention, respectively, for SI region pain. Subjects and assessors were blinded for 3 months. At that time, sham participants were permitted to receive CRF/LBN, designated as "crossover" study subjects, and followed for 6 additional months. For the purpose of this evaluation, the original CRF/LBN-treated study subjects were followed for a total of 12 months. Study participants were 18 to 88 years of age and had chronic (symptomatic for >6 months) axial back pain. All subjects were qualified for study inclusion following positive responses to dual lateral branch blocks. Lateral branch neurotomy was performed by CRF to ablate the S1 to S3 lateral branches and the L5 dorsal ramus. Pain was measured by a numerical rating scale (NRS) and Short Form 36-bodily pain (SF36-BP) scores. The Oswestry disability index and Short Form 36-physical functioning (SF36-PF) assessment each served to evaluate subject disability. Treatment successes ("responders") in the originally treated CRF/LBN group at 12 months, and in the crossover group at 6 months, were also determined. In the original CRF/LBN treatment group, 12-month outcomes compared to baseline were favorable, with a mean 2.7 point drop in the NRS score, a 13.9 decrease in the ODI, and a 15.8 increase in SF-36BP. In the crossover study group, 6-month outcomes were also favorable, with a mean NRS score decrease of 2.5 points, a reduction in ODI of 8.8, and an increase in SF36-BP of 11.9. The authors concluded; these favorable 12-month results illustrate the durability of effective CRF/LBN-mediated treatment of SI region pain for selected patients. Furthermore, successful CRF/LBN treatments in unblinded crossover study subjects demonstrate the unlikelihood that such positive outcomes are attributable to a "placebo" effect and suggest that CRF/LBN is an effective therapeutic option for alleviating pain, and improving physical function and quality of life, with few complications.

Summary of Evidence

Based on review of the peer reviewed medical literature there is a limited number of studies regarding the use of cooled radiofrequency ablation for chronic sacroiliac joint (SIJ) pain and chronic cervical, thoracic, and lumbar facet joint pain. Most studies in the literature are based on the traditional radiofrequency ablation (TRFA) procedure which has been proven to be safe and effective in pain management for certain indications. Cooled radiofrequency is a newer technique and the limited data regarding the use of cooled radiofrequency ablation in the treatment of chronic pain related to cervical, thoracic, and lumbar facet joints and chronic sacroiliac joint (SIJ) pain suggests some patients may obtain short term relief from the use of this ablative treatment along with the reduction of pain, however, the long-term efficacy remains unknown. Limitations also include no comparison with conventional radiofrequency treatment for sacroiliac joint

(SIJ) pain. Additional long term comparative-controlled studies are needed to determine the safety and efficacy of cooled radiofrequency ablation for the treatment of chronic facet joint pain and sacroiliac joint (SIJ) pain. The evidence is insufficient to determine the effects of the technology on net health outcomes.

Pulsed Radiofrequency

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

Pulsed radiofrequency (RF) denervation was compared with steroid injection in a randomized trial of 80 patients (Hashemi et. al. 2014). Patients were randomly assigned to one of two groups: group one received pulsed RF, and group 2 received injection by steroids (triamcinolone) and bupivacaine. Multiple outcome measures were utilized which included the numeric rating scale (NRS), the Oswestry Disability Index (ODI), satisfaction status, and analgesic intake with assessment at 3-, 6-, and 12-months post-treatment. Significant pain relief was defined as 50% or more, whereas significant improvement in disability score was defined as reduction of 40% or more. Eighty patients were enrolled in the study and were divided into the two groups of study. PRF significantly reduced NRS at 6-month follow-up compared to steroid + bupivacaine. 75.6 ± 14.3% at pre-treatment and 19.3 ± 9.5% at 6 months ($p = 0.001$) in PRF group. The mean ODI is depicted in two groups of study (Fig. 1). Interestingly, ODI% was significantly lower in PRF group at 12 weeks and 6 months compare to steroid + bupivacaine group ($p = 0.022$ and 0.03, respectively), but it was not significantly different at 6 weeks ($p = 0.31$). Proportion of patients who did not require analgesics were significantly higher in PRF group compared to other group ($p = 0.001$) in Log-rank (Mantel-Cox) test. The authors concluded, our results demonstrated that the application of pulsed radiofrequency might be more effective then steroid and bupivacaine injection in decreasing back pain due to degenerative facet pain and improvement in function of patients.

In 2008, Kroll et. al. compared the efficacy of continuous radiofrequency (CRF) with pulsed radiofrequency (PRF) in the treatment of lumbar facet syndrome. The study design was prospective, randomized, double blinded study with 50 patients. Target facet joints were identified with oblique radiographic views. Continuous radiofrequency thermocoagulation was delivered at 80 degrees C for 75 seconds, while PRF was

delivered at 42 degrees C with a pulse duration of 20 months and pulse rate of two Hz for 120 seconds. Visual analog scale (VAS) pain assessment and Oswestry Low Back Pain and Disability Questionnaire (OSW) were administered at baseline and then at three months. Comparisons between groups and within groups were made of the relative percentage improvement in VAS and OSW scores. No significant differences in the relative percentage improvement were noted between groups in either VAS (P = 0.46) or OSW scores (P = 0.35). Within the PRF group, comparisons of the relative change over time for both VAS (P = 0.21) and OSW scores (P = 0.61) were not significant. However, within the CRF group, VAS (P = 0.02) and OSW scores (P = 0.03) showed significant improvement. The authors concluded, although there was no significant difference between CRF and PRF therapy in long-term outcome in the treatment of lumbar facet syndrome, there was a greater improvement over time noted within the CRF group.

In 2007, Van Zundert et. al. randomized 23 patients (of 256 screened) with chronic cervical radicular pain to pulsed radiofrequency (RF) or sham treatment. Success was defined as 50% or more improvement on global perceived effect (GPE), 20% or more reduction in VAS (visual analogue scale) pain, and reduced pain medication use measured 3 months after treatment. Eighty-two percent of patients in the treatment arm and 33% in the sham arm showed at least 50% improvement on GPE (p=0.03) and 82% in the treatment group and 27% in the sham group achieved at least 20% reduction in VAS pain (p=0.02).

Summary of Evidence
For individuals with chronic facet joint pain (cervical, thoracic, and lumbar), or chronic sacroiliac joint (SIJ) pain using pulsed radiofrequency ablation, the evidenced is limited and based on the current peer reviewed medical literature pulsed radiofrequency ablation does not appear to be as effective as conventional radiofrequency ablation, and there is insufficient evidence to evaluate the safety and efficacy of this alternative method for the treatment of chronic facet joint pain and chronic sacroiliac joint pain. Additional well-designed, longer term randomized controlled clinical trials (RCTs) are required to evaluate the safety and efficacy of this alternative denervation/ablation treatment methods. The evidence is insufficient to determine the effects of the technology on net health outcomes.

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

for patients that have recurrent pain after 6-9 months of relief with the percutaneous radiofrequency ablation and do not wish to repeat the percutaneous approach.

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

A search of the medical peer reviewed literature did not identify any clinical studies that evaluated endoscopic radiofrequency ablation for the treatment of spinal pain (facet joint pain) or sacroiliac joint pain. The clinical outcomes from a pilot study evaluating this technology were presented as a professional society conference abstract, Yueng et. al. 2011. There is insufficient evidence in the published medical literature to determine the safety and efficacy of this emerging alternative modality or approach compared to percutaneous radiofrequency ablation for the treatment of spinal pain.

In 2014, Li et. al. evaluated the effectiveness of surgical dorsal endoscopic rhizotomy in 58 patients with lumbar facetogenic chronic low back pain. Forty-five patients who experienced >80% relief of pain with two comparative lumbar medial branch blocks received dorsal endoscopic rhizotomy. The remaining 13 patients received conservative treatment. The authors reported that percentage of pain relief in the operation group at any time point postoperatively were significantly higher than that in the conservative group. Further studies with larger sample sizes and longer follow-up are needed to further validate the efficacy of this technique.

Summary of Evidence
Based on review of the peer reviewed medical literature there is insufficient evidence in the published medical literature of this emerging alternative treatment modality or approach using endoscopic radiofrequency ablation compared to percutaneous radiofrequency ablation (RFA) for the treatment of the chronic facet joint pain (cervical, thoracic, and lumbar) and chronic sacroiliac joint (SIJ) pain. Additional well-designed, longer term randomized controlled clinical trials (RCTs) are required to evaluate the safety and efficacy of this alternative denervation/ablation treatment methods. The evidence is insufficient to determine the effects of the technology on net health outcomes.

Practice Guidelines and Position Statements

American Society of Anesthesiologists Task Force and American Society of Regional Anesthesia and Pain Medicine

In 2010, the American Society of Anesthesiologists Task Force and American Society of Regional Anesthesia and Pain Medicine issued a practice guideline for chronic pain management which included the following:

Ablative techniques include chemical denervation, cryoneurolysis or cryoablation, thermal intradiscal procedures (i.e., intervertebral disc annuloplasty (IDET), transdiscal bioaculopathy), and radiofrequency ablation.

Recommendations for Ablative Techniques:

- Chemical denervation: (e.g., alcohol, phenol, or high concentration local anesthetic) should not be used in the routine care of patients with chronic non-cancer pain.
- Cryoablation: may be used in the care of selected patients (e.g., post-thoracotomy pain syndrome, low back pain (medial branch), and peripheral nerve pain)
- Radiofrequency ablation: conventional (e.g., 80 degrees Celsius) or thermal (e.g., 67 degrees Celsius) radiofrequency ablation of the medical branch nerves to the facet joint should be performed for low back (medial branch) pain when previous diagnostic or therapeutic injections of the joint or medial branch nerve have temporary relief. Conventional radiofrequency ablation may be performed for neck pain, and water-cooled radiofrequency ablation may be used for chronic sacroiliac joint pain. Conventional or thermal radiofrequency ablation of the dorsal root ganglion should not be routinely used for the treatment of radicular pain.

Guideline does not address or indicate the use of radiofrequency ablation for thoracic facet joint pain and for sacroiliac joint pain.

The American Society of Interventional Pain Physicians (ASIPP)
In 2020, the American Society of Interventional Pain Physicians (ASIPP) updated the guideline on use of facet joint interventions for management of chronic spinal pain. Radiofrequency ablation is recommended for treatment of pain:

- In the lumbar spine (moderate strength recommendation; evidence level II), **and**
- In the cervical spine (moderate strength recommendation; evidence level II), **and**
- In the rhoracic spine (weak to moderate strength recommendation; evidence level III).

Regulatory Status
A number of radiofrequency generators and probes have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process.

PRIOR APPROVAL

Prior approval is required.

POLICY

See Related Medical Policies

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

Radiofrequency Ablation (RFA) for the Treatment of Chronic Sacroiliac Joint Pain
Radiofrequency ablation (RFA) using thermal non-pulsed radiofrequency ablation technology is considered **investigational** for the treatment of chronic sacroiliac joint (SIJ) pain.

Overall quality of the evidence regarding the use of radiofrequency ablation (RFA) using thermal non-pulsed radiofrequency ablation technology for treatment of chronic sacroiliac joint (SIJ) pain is low. There is positive but inconsistent evidence suggesting that traditional thermal non-pulsed radiofrequency ablation of the sacroiliac joint (SIJ) is safe and may improve symptoms of pain over the short to intermediate term compared with sham therapy or alternative therapies. The lack of a standard radiofrequency ablation techniques for sacroiliac joint (SIJ) prevents definitive conclusions regarding the efficacy and safety of the procedure. An inherent challenge to the efficacy of traditional thermal non-pulsed radiofrequency ablation technology is the variable anatomy of targeted lateral branch nerves in the SI joint. Questions remain regarding patient selection criteria, long-term outcomes, and the comparative efficacy versus alternative therapies. More high quality randomized controlled trials (RCTs) are required to confirm results and to determine the optimal candidates and treatment parameters regarding the use of traditional thermal non-pulsed radiofrequency ablation (RFA) for the treatment of chronic sacroiliac joint (SIJ) pain. The evidence is insufficient to determine the effects of the technology on net health outcomes.

Alternative Methods of Denervation/Ablation in the Treatment of Cervical, Thoracic and Lumbar Chronic Facet Joint Pain and Chronic Sacroiliac Joint Pain
All other methods of ablation/denervation for the treatment of chronic neck and spinal/back pain, including but not limited to chronic facet joint pain (cervical, thoracic, and lumbar) or chronic sacroiliac joint (SIJ) pain is considered **investigational** (not an all-inclusive list):

- Laser denervation
- Chemical neurolysis (chemodenervation) (e.g., alcohol, phenol, glycerol, or hypertonic saline)
- Cryodenervation (cryoablation)
- Cooled radiofrequency (includes but is not limited to COOLIEF radiofrequency e.g., cooled radiofrequency for cervical, lumbar, and thoracic, Sinergy sacroiliac cooled radiofrequency)

- Pulsed radiofrequency ablation *(See also medical policy 07.01.41 Pulsed Radiofrequency Ablation)*
- Endoscopic radiofrequency ablation

Based on review of the peer reviewed medical literature there is insufficient evidence in the published medical literature of these emerging alternative ablative treatment modalities regarding the use of these alternative denervation/ablative treatment methods for the treatment of chronic neck and spinal/back pain, including but not limited to cervical, thoracic, and lumbar chronic facet joint pain or chronic sacroiliac joint (SIJ) pain. While some studies may have shown promise, additional, well-designed, longer term randomized controlled clinical trials (RCTs) are required to evaluate the safety and efficacy of these alternative denervation/ablative treatment methods in comparison of these techniques with other medical (alternative therapies) and surgical therapies. The evidence is insufficient to determine the effects of the technologies on net health outcomes.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 64625 Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (i.e., fluoroscopy or computed tomography)
- 64633 Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
- 64635 Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint

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POLICY HISTORY

Date	Reason	Action
August 2022	Annual Review	Policy Revised
March 2022	Interim Review	Policy Revised
August 2021	Annual Review	Policy Renewed
August 2020	Annual Review	Policy Revised
August 2019	Annual Review	Policy Renewed
August 2018	Annual Review	Policy Revised
August 2017	Annual Review	Policy Revised
August 2016	Annual Review	Policy Revised
May 2016	Annual Review	Policy Revised
November 2015	Interim Review	Policy Revised
September 2015	Interim Review	Policy Revised
June 2015	Annual Review	Policy Revised
July 2014	Annual Review	Policy Renewed
September 2013		New Policy
		Policy was retired September 1, 2012
April 2012	Annual Review	Policy Renewed
May 2011	Annual Review	Policy Renewed

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

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
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