

Molina Clinical Policy

Genicular Radiofrequency Ablation and Genicular Nerve Blocks for Chronic Knee Pain: Policy No. 314

Last Approval: 2/8/2023

Next Review Due By: February 2024



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

Treatment for OA of the knee aims to alleviate pain and improve function. However, most treatments do not modify the natural history or progression of OA and are not considered curative. Evidence-based treatments for knee osteoarthritis (OA) include Nonsurgical modalities and surgical approaches aimed at alleviating pain, enhancing joint function, and decreasing disease progression risk factors. Nonsurgical modalities used include lifestyle modifications, exercise, weight loss, supportive devices; pharmacologic agents such as acetaminophen or nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen); nutritional supplements (glucosamine, chondroitin); and intra-articular viscosupplementation. Corticosteroid injection may be considered when relief from NSAIDs is insufficient, or the patient is at risk of gastrointestinal adverse events (AEs). If symptom relief is inadequate with conservative measures, invasive treatments may be considered. Surgical methods are recommended when conservative measures fail to relieve symptoms and include arthroscopy and knee replacement procedures. Neuroablative destruction of the genicular (and other nerves) has recently been proposed as a treatment method for knee pain and disability caused by OA of the knee. Because genicular nerves are anatomically close to genicular arteries, vascular injury is a potential complication of genicular nerve RF (Kim, et al., 2016). In addition to septic arthritis, pes anserine tendon rupture, third-degree skin burn, and clinically significant hematoma and/or hemarthrosis, other risks include septic arthritis (McCormick, et al., 2021).

Pain in OA can be transmitted by the genicular nerve, a sensory nerve that surrounds the knee and provides innervation for the joint. Genicular nerve block (GNB) procedures involve injection of anesthetics and/or chemicals such as glycerol into the tissue surrounding the nerve and are used as either a diagnostic or therapeutic modality to temporarily disrupt pain transmission. The procedure is used as a diagnostic modality to isolate the source of pain, and as a therapeutic modality to temporarily relieve pain. If the block is effective in relieving pain, ablation of the peripheral nerve has been proposed as the next step.

Genicular radiofrequency ablation (RFA), also called genicular neurotomy, genicular denervation, cooled radiofrequency therapy, and peripheral nerve ablation of the knee, is performed to relieve chronic pain associated with the knee. During RFA, radiofrequency (RF) energy delivers heat to the genicular nerves surrounding the knee creating a lesion that stops pain input to the central nervous system. Prior to planning the procedure, a diagnostic GNB is administered to ensure that there is adequate pain relief to indicate the patient is a suitable candidate for therapeutic neurotomy. RFA is performed in an outpatient setting, typically by a pain management specialist using fluoroscopic or ultrasonographic guidance to facilitate localization of the target nerves. After intradermal injection of a local anesthetic, an RF cannula is inserted and advanced until it contacts bone. Sensory stimulation is performed to identify the location of each target nerve. At this point, an anesthetic may be applied to the target nerve to relieve pain during the procedure. In conventional RFA, heat is delivered via probe to the target nerve at a temperature of 70°C to 80°C. Newer types of RFA, including pulsed and cooled RFA, deliver heat at lower temperatures and may cover a larger area. The pain relief afforded is temporary, as the peripheral nerves retain the ability to regrow and regenerate over time, thus allowing pain to return (Kidd et al., 2019).

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Regulatory

RFA is a procedure and, therefore, not regulated by the FDA. However, RFA utilizes medical devices that are regulated under the 510(K)-clearance process. The RF probes (FDA product code: GXI) and lesion generators (FDA product code: GXD) used for RFA are both Class II devices. ([510\(k\) Premarket Notification](#))

A GNB is a procedure and, as such, is not subject to FDA regulation. Any medical devices, drugs, biologics, or tests used as part of this procedure, on the other hand, may be subject to FDA regulation. Lidocaine, levobupivacaine, triamcinolone, and betamethasone are among the FDA-approved local anesthetics and corticosteroids used for nerve blocks.

COVERAGE POLICY

Genicular radiofrequency ablation and genicular nerve blocks **are considered experimental, investigational, and unproven** for the treatment of chronic knee pain, including but not limited to **ANY** of the following:

1. Degenerative joint disease or osteoarthritis of the knee; **OR**
2. As a treatment prior to or following a knee replacement; **OR**
3. As a treatment for individuals who are not candidates for knee replacement surgery.

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

GNB and genicular RFA are under evaluation for the treatment of chronic knee pain for patients that have not been effectively managed by pharmacologic or other therapies. Overall, there is a low-quality body of evidence proposing that GNBs and genicular RFA safely relieve pain and improve function in patients with OA-related knee pain lasting more than 3 months that is refractory to conservative treatment. Currently, there are limitations of these published studies such as small sample size, lack of a control or comparison group, lack of randomization, lack of objective outcome measures, methodology or procedures not clearly reported, and baseline differences in disease severity between groups. Therefore, there is currently insufficient evidence to support the use of GNBs and genicular RFA for the treatment of knee pain and OA.

Randomized Controlled Trials (RCTs)

A RCT (Choi et al., 2011) examined whether RF neurotomy applied to genicular nerve branches was effective in providing relief to 38 patients from chronic osteoarthritis (OA) knee joint pain. Patients were randomly assigned to receive percutaneous RF genicular neurotomy under fluoroscopic guidance (RF group; n = 19) or the same procedure without effective neurotomy (control group; n = 19). Measurements were taken at baseline, 1, 4, and 12 weeks after the procedure using a visual analog scale (VAS), an Oxford Knee Score (OKS), and a Global Perceived Effect (GPE) on a 7-point scale. The VAS results at 4-week showed that the radiofrequency group had less knee joint pain than the control group. The OKS revealed similar results. Study limitations include a small sample size, a lack of long-term follow-up, and a lack of objective outcome measures.

Sari et al. (2016) conducted an RCT that compared RFA with intra-articular steroid injection in 73 patients with chronic OA knee joint pain. The results suggest that RFA was associated with significantly greater improvements in knee pain, stiffness, and function compared with intra-articular injections of steroid. Benefits began to decline by 3 months for both treatment types across outcomes. There were no AEs in either treatment group. Study limitations include a lack of power analysis, blinding, long-term follow-up, monitoring of analgesic use, and objective outcome measures, and significant differences in disease severity between groups at baseline.

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A fair-quality RCT compared RFA plus intra-articular injection with platelet-rich plasma and sodium hyaluronate with injections alone in 54 patients with chronic OA knee joint pain (Shen et al., 2016). The results suggest that the addition of RFA to intra-articular injection therapy improves knee pain and function in patients with OA compared with intra-articular injections alone. Both treatments were associated with significant improvements from baseline to 3 months for all outcomes. AEs were not reported. Study limitations include small sample size, lack of power analysis, randomization method was not reported, assessor blinding unknown, lack of objective outcome measures, no long-term follow-up, and RFA group treatment procedures were not reported thoroughly.

Qudsi-Sinclair et al. (2017) published the findings of a double-blind RCT comparing traditional RF neurolysis (n = 14) to genicular nerve local anesthetic and corticosteroid block (n = 14) for the treatment of persistent pain in patients who had total knee arthroplasty but still experienced pain. Following treatment, subjects were followed for a year. At three and six months, both groups showed a reduction in pain and significant improvement in joint function, as well as an improvement in quality of life and disability and a reduced need for analgesics. The study is limited by its small sample size and short-term results; additional clinical trials are required to establish safety and efficacy.

Systematic Reviews

Several systematic reviews and meta-analyses evaluating the use of RFA and GNBs for the treatment of knee OA have been published. Due to the variability in process and assessment procedures, varying follow-up durations, and the use of multiple comparable therapies in these studies, thus definitive evidenced-based conclusions regarding the effects of the technology on health outcomes cannot be established.

Chen et al. (2021) performed a systematic review to compare the efficacy and safety of nerve RFA to other non-surgical treatments for symptomatic knee OA. The inclusion criteria of symptomatic knee OA, comparative design, and quantitative patient-reported outcome data were met by seven RCTs. Comparators included intra-articular corticosteroids, intra-articular hyaluronic acid, NSAIDs, acetaminophen (paracetamol), and control/sham procedures. Pain, function, and composite patient-reported outcomes varied in measurement tools used and included the following: VAS, numerical rating scale (NRS), WOMAC, Short Form-36, Lysholm knee score, Oxford Knee Score (OKS), and Global Perceived Effect. Length of follow up varied between the studies from three months to one year. Outcome measures were varied, however all RCTs showed favorable results for geniculate nerve thermal RFA. The results showed consistent agreement across all RCTs in favor of geniculate nerve thermal RFA use for nonsurgical treatment of knee OA and no RCTs reported any serious AEs related to geniculate nerve RFA. The duration of the studies ranged from three months to one year. None of the studies reported long-term outcomes, with the longest outcome timeframe being one year. However, there remains a lack of standardization in terms of administration technique and control group treatment and a lack of long-term safety data, the effectiveness of RFA remains questionable.

Huang et al. (2020) published a meta-analysis and systematic review to assess the efficacy and safety of ultrasound-guided RF treatment for chronic pain in patients with knee OA. The meta-analysis included eight publications and 256 patients (n = 256). The findings indicate that targeting the genicular nerve achieved better pain relief than targeting the intra-articular or sciatic nerve; however, the small number of relevant studies limited the confidence level of the meta-analysis. The inability to analyze the long-term effectiveness of the treatment is a significant limitation of the review, as most studies only provided short follow-up times.

Hong et al. (2019) conducted a systematic review and meta-analysis of 12 RCTs (n = 841) to assess the efficacy of invasive RF treatment for knee pain and function in patients with OA. The patient populations ranged from 33 to 151 individuals. Studies were included if they were RCTs that reported on the clinical efficacy of invasive radiofrequency treatment for OA. Excluded were studies on patients who had undergone knee arthroplasty or arthroscopic surgery. The interventions were RFA on the genicular nerve (n = 7 studies), intra-articular pulsed RFA (n = 4 studies), and cooled RFA (n = 1 study). Weight loss, physical therapy, oral NSAIDs, or intra-articular injections of hyaluronic acid or corticosteroids were used as comparators. The primary outcomes measured were pain improvement using the VAS/NRS and knee function improvement using the OKS/WOMAC. Following up was done after one week, one month, three months, and six months. Pain levels were reported to be lower in the RF treatment group (at one week, one month, and three months). OKS at one week, one month, or three months or WOMAC at one week, one month, or three months revealed no significant improvement in knee function. There were no AEs reported in the other studies. The author mentioned study limitations such as study heterogeneity and small patient populations with short-term follow-ups. RCTs with larger patient populations and long-term follow-ups are required to establish the safety and efficacy of invasive RF treatment for knee pain and function.

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Orhurhu et al. (2019) conducted a systematic review of the treatment of chronic knee pain that included 19 studies, only four of which were randomized, and found short- and long-term pain reductions, as well as that genicular nerve ablation improved average VAS and WOMAC scores. The authors noted that genicular nerve ablation improved average VAS and WOMAC scores; however, they cited limitations such as the lack of a standardized protocol, making it difficult to compare with standard care treatment protocols, and the absence of long-term follow-up are cited as limitations by the authors.

Gupta et al. (2017) published a systematic review that analyzed RF by conventional, pulsed, or cooled RF technique to relieve chronic knee pain. Seventeen total publications were included with most of them primarily treating the genicular nerves or alternatively employed in an intra-articular approach. Different therapeutic approaches to targeting the genicular nerve or an intra-articular approach produced no certain advantage. Different therapeutic technologies (conventional, pulsed, or cooled) to targeting the genicular nerve produced no certain advantage. Ongoing concerns on RF regarding the quality, procedural aspects, and monitoring of outcomes remain.

Bhatia et al. (2016) conducted a systematic review that included 13 reports on ablative or pulsed RF treatments of innervation of the knee joint. A high success rate of these procedures in relieving chronic pain of the knee joint was reported at 1 to 12 months after the procedures; however, only two of the publications were randomized controlled trials. There was evidence for improvement in function and a lack of serious AEs of RF treatments. RCTs of high methodological quality are required to further elaborate on the role of these interventions in this population.

Deveza and Bennell (2022), in an evidence-based peer review on management of knee osteoarthritis, states that “there are several approaches that have been used to treat patients with knee OA that we generally do not routinely use or recommend due to lack of sufficient evidence base for widespread dissemination such as nerve blocks, nerve ablation, stem cell injections, and joint distraction. In addition, there are other therapies in which the benefit remains uncertain” (UpToDate, 2022).

A health technology assessment (HTA) addressing RFA of the genicular nerves for the treatment of chronic, treatment-refractory pain associated with OA of the knee summarizes the body of evidence as being of low quality and suggests that RFA may safely relieve pain and improve function in patients with chronic OA of the knee (Hayes, 2021). Individual studies’ small sample sizes, lack of power analysis, lack of randomization, lack of reporting of outcome data, retrospective design, unknown assessor blinding, methodology or procedures not clearly reported, and baseline differences in disease severity between groups are among the limitations of the evidence. The HTA acknowledges that RFA of the genicular nerves is a promising technology for relieving pain and improving joint dysfunction in chronic OA of the knee, but it also concludes that there is significant uncertainty due to a lack of standardization in procedural techniques. Additionally, the assessment also states that there are currently no established treatment guidelines that recommend RFA for knee OA and that there is insufficient comparative evidence to determine the superiority of one RF modality over another (Ajrawat et al., 2020). Furthermore, the effects of RFA are temporary, and the studies have been generally limited to one year, as pain signal transmission will return with peripheral nerve regrowth and regeneration. There is also insufficient evidence to establish definitive patient selection criteria for the use of RFA for the treatment of pain associated with OA of the knee (Hayes, 2021).

An HTA (updated May 2022) concluded that there was insufficient published evidence to support the use of genicular nerve blocks alone or in combination with a corticosteroid for the treatment of pain and function loss associated with osteoarthritis of the knee or persistent chronic pain following total knee arthroplasty. The assessment identified a body of evidence of very low quality that does not consistently provide proof of benefit. The HTA stated that while short-term results frequently showed clinically and statistically significant improvements from baseline, these results were not maintained at the last follow-up (Qudsi-Sinclair et al., 2017; Kim et al., 2018; Kim et al., 2019; Yilmaz et al., 2019). Three of the four RCTs found statistically significant improvement from baseline; however, none of these improvements were clinically significant. In comparison, no statistically significant difference was found between GNB combined with a corticosteroid and RFA or GNB alone. Due to conflicting evidence and limited follow-up, the HTA deemed that the procedure remains subject to significant uncertainty.

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The **American College of Rheumatology/Arthritis Foundation (2019)** Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee (Kolasinski, 2020) states that RFA is conditionally recommended for treatment of knee OA. The recommendation remains conditional due to the fact that although some studies have demonstrated potential analgesic benefits with various ablation techniques, the available studies lack a standardized technique and controls were not uniform. There is also a lack of evidence showing long-term safety data.

The **American Academy of Orthopedic Surgeons (2021)** Guidelines for treating Osteoarthritis of the Knee classify RFA as “denervation therapy,” along with chemical ablation. The guideline states that “Denervation therapy may reduce pain and improve function in patients with symptomatic osteoarthritis of the knee.” The strength of this recommendation is noted to be limited due to inconsistent evidence and bias. Future research in the area should utilize clinically relevant outcomes and controls for bias.

The **Osteoarthritis Research Society International (OARSI)** guidelines do not include RFA in their Level IA, IB, or Level 2 recommendations for treatment of knee OA (Bannuru et al., 2019).

**Several organizations have issued recommendations for the treatment of OA of the knee, but none have addressed treatment with GNB.*

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed
64624	Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed

HCPCS Codes – N/A

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

02/08/2023	Policy reviewed. No change to coverage position. Updated Summary of Evidence and references.
02/09/2022	Policy reviewed. Updated ‘Summary of Evidence’ and references.
06/20/2021	IRO Peer Review: Policy reviewed by IRO practicing physician Board certified in Physical Med & Rehab, Pain Management. According to the reviewer: “...There are no CMS LCD’s that apply to GNBs or RFA. The coverage criteria and exclusions are appropriate. The genicular blocks and RFA are all considered experimental/investigational...”
02/08/2021	Policy reviewed. New literature and guideline; No change to coverage position; procedure remains experimental, investigational, and unproven. Added updated literature search to references and one new guideline (Kolasinski et al, 2020).
04/23/2020	Policy reviewed. No change to coverage position. Added two new 2020 CPT codes: 64454, 64624; removed old codes 64450, 64640, 64999.
09/18/2019	Policy reviewed. No change to coverage position.
09/13/2018	New policy. IRO peer review. July 23, 2018. Practicing, board-certified physician in the area of Physical Medicine, Rehabilitation and Pain Management.

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Government Agencies

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2. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (search: genicular nerve block; nerve block; genicular radiofrequency ablation). No national coverage determination was identified for use of RFA or for the use of genicular nerve blocks for pain associated with knee OA. Available from [CMS](#). Accessed January 2023.

Evidence Based Reviews and Publications

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2. Hayes. Available from Registration and login required. Accessed January 2023.
 - a. Health Technology Assessment. Radiofrequency Nerve Ablation for the Management of Osteoarthritis of the Knee. December 22, 2020. Updated December 23, 2021.
 - b. Health Technology Assessment. Genicular Nerve Block for the Management of Knee Pain. June 24, 2020. Updated May 23, 2022.

Peer Reviewed Publications

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