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

Last Approval: 12/11/2024
Next Review Due By: December 2025

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

Knee osteoarthritis (OA) is a degenerative joint condition characterized by the gradual breakdown of cartilage in the knee, leading to pain, stiffness, and reduced mobility. Evidence-based treatments for knee OA include non-surgical modalities and surgical approaches aimed at alleviating pain, enhancing joint function, and decreasing disease progression risk factors. Non-surgical modalities include lifestyle modifications, exercise, weight loss, supportive devices; pharmacologic agents such as acetaminophen or nonsteroidal anti-inflammatory drugs (NSAIDs), supplements (glucosamine, chondroitin), and intra-articular viscosupplementation. Corticosteroid injections may be considered when relief from NSAIDs is insufficient or if the patient is at risk of gastrointestinal adverse events. Surgical methods are recommended when conservative measures fail to relieve symptoms and include arthroscopy and knee replacement procedures.

Genicular nerve block (GNB) procedures involve injection of anesthetics and/or chemicals such as glycerol into the tissue surrounding the genicular 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. RFA is performed in an outpatient setting 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. 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. Vascular injury is a potential complication of genicular nerve RFA because genicular nerves are anatomically close to genicular arteries (Kim et al. 2016). Other risks associated with the procedure include septic arthritis, pes anserine tendon rupture, third-degree skin burn, and clinically significant hematoma and/or hemarthrosis (McCormick et al. 2021). 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).

Regulatory Status

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 (FDA date unknown).

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.

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COVERAGE POLICY

Genicular radiofrequency ablation and/or genicular nerve blocks are considered **experimental, investigational, and unproven** for the treatment of chronic knee pain due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes.

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

Genicular Nerve Block (GNB) and genicular radiofrequency ablation (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 osteoarthritis (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

Lyman et al. (2022) conducted randomized controlled trial to assess the outcomes of cooled radiofrequency ablation (CRFA) of genicular nerves for chronic knee patient due to osteoarthritis. Patients were part of a 12-month clinical trial comparing CRFA to a single hyaluronic injection for treatment of chronic OA knee pain. This study is an extension of those patients who agreed to visits at 18- and 24-months post CRFA and had not undergone additional knee procedures since. Outcomes reported included pain using the Numeric Rating Scale (NRS), function using the Western Ontario McMaster Universities Osteoarthritis Index (WOMAC), and quality of life using the EuroQol-5-Dimensions-5 Level (EQ-5D-5L) questionnaire. NRS pain scores were significantly decreased ($p < 0.0001$) from 6.8 at baseline to 2.4 at 18-months and 3.4 at 24-months. After 24-months 63% of patients post CRFS continued to experience at least 50% reduction in pain. WOMAC scores improved from baseline at 64.4 to 29.3 at 18-months post CRFA and then increased at 24-months post CRFA to 41.39 but continued to reflect significant improvement relative to baseline ($p = 0.0007$). Improvement in general health and quality of life following CRFA based on EQ-5D-5L. Points increased from baseline by 0.15 points ($p < 0.0001$) at 18 months and by 0.07 points ($p = 0.0146$) at 24 months post CRFA. Limitations of this study included the small sample size and protocol deviations due to patients reporting data outside the predetermined follow-up period. The lack of blinding due to study design allowed opportunities for bias. The study concluded that genicular CRFA for chronic OA knee pain resulted in pain relief, improvements in functional ability and quality life after a 24-month.

Güler et al. (2022) conducted a single-blinded, prospective, randomized study to compare the effectiveness of ultrasound-guided genicular nerve block (GNB) and physical therapy (PT) in patients with chronic knee osteoarthritis. Patients were excluded if they had received a glucocorticoid or hyaluronic acid injection or oral glucosamine or had received PT for knee pain within the last 6 months. Overall, 102 patients were included (mean age 55.88), 51 patients received ultra-sound guided GNB, and 51 patients received PT with a standard home exercise program. Scores for pain were measured by VAS and the WOMAC; physical capacity was measured by a 6-minute walking test (6MWT). All measurements were assessed pre-treatment, 2 and 12 weeks. There was no statistically significant difference in VAS and WOMAC scores between the two groups. Increase in the 6MWT test at the 2-week follow up was similar for both groups ($p=0.073$) and the increase in walking distance was greater in the ultrasound-guided GNB group at 12 weeks ($p=0.046$). Limitations of the study include the lack of a control group, exercise compliance was only measured by verbal confirmation from patient, and a short follow-up period.

Shanahan et al. (2022) conducted a randomized controlled trial to evaluate the effectiveness of ultrasound-guided genicular nerve block (GNB) in managing pain for patients with knee osteoarthritis (OA). The study included 59 patients (36 female, 23 male) with an average age of 68.2. Eligible participants were at least 18 years old, had a confirmed diagnosis of knee OA, and experienced chronic knee pain with a visual analog scale (VAS) score of 4 or higher on most days for more than three months. Exclusion criteria included any history of inflammatory joint disease, allergy to the injection agents, pregnancy, or having received a glucocorticoid injection in the affected knee(s) within the previous three months. VAS pain scores in the treatment versus placebo groups were as follows: baseline (6.2 vs. 5.3; P = 0.294), week 2 (2.7 vs. 4.7; P < 0.001), week 4 (3.2 vs. 5.1; P < 0.001), week 8 (3.9 vs. 4.9; P < 0.001), and week 12 (4.6 vs. 5.1; P = 0.055). WOMAC scores in the treatment versus placebo groups were as follows: baseline (54.5 vs. 48.1; P = 0.177), week 2 (32.9 vs. 44.4; P < 0.001), week 4 (33.7 vs. 45.8; P < 0.001), week 8 (39.2 vs. 44.8; P = 0.001), and week 12 (42.65 vs. 45.1; P = 0.012). While the study's limitations include a small sample size, limited blinding, and loss of participants to follow-up, it suggests that GNB may offer short-term pain relief for knee OA patients.

Sari et al. (2016) conducted a randomized controlled trial (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 adverse events (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.

Systematic Reviews and Meta-Analyses

Chen et al. (2021) performed a systematic review to compare the efficacy and safety of geniculate nerve thermal 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), Western Ontario and McMaster Universities Osteoarthritis Index (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 non-surgical treatment of knee OA and no RCTs reported any serious AEs related to geniculate nerve RFA. Due to the 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.

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. 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, intra-articular pulsed RFA, and cooled RFA. 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. Follow-ups were 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. No significant improvement in knee function was reported with OKS or WOMAC scores. Study limitations included 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.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Hayes (2023) published a health technology assessment to assess the effectiveness and safety of genicular nerve block for treatment of knee osteoarthritis in adults. A very low-quality body of evidence suggested that GNB is considered safe, but evidence regarding clinically significant improvements in pain and function scores to baseline is inconsistent. It has not been established whether GNB given with corticosteroids improves pain and function compared to other alternative therapies including pulsed radiofrequency, physical therapy, intra-articular corticosteroid injection, or genicular nerve alcoholic neurolysis. There is uncertainty regarding the long-term effectiveness of GNB and the effectiveness of treatment compared to other standard therapies.

Hayes (2020) published a health technology assessment addressing RFA of the genicular nerves for the treatment of chronic, treatment-refractory pain associated with OA of the knee suggests that RFA may safely relieve pain and improve function in patients with chronic OA of the knee (Hayes 2020). The assessment 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 the current body of evidence is of low quality. There is currently no established treatment guidelines that recommend RFA for knee OA and there is insufficient comparative evidence to determine the superiority of one RFA modality over another. 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.

National and Specialty Organizations

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

The **American College of Rheumatology/Arthritis Foundation** 2019 Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee states that RFA is conditionally recommended for treatment of knee OA. The recommendation remains conditional because although 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 (Kolasinski 2020).

The **American Academy of Orthopedic Surgeons (2021)** guideline for Management of Osteoarthritis of the Knee (Non-Arthroplasty) 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).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	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

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

12/11/2024	Policy reviewed. No changes to coverage position. Updated Summary of Medical Evidence and References.
02/14/2024	Policy reviewed. No change to coverage position. IRO Peer Review. Practicing, board-certified physician in Physical Medicine, Rehabilitation and Pain Management. Updated Summary of Medical Evidence and references.
02/08/2023	Policy reviewed. No change to coverage position. Updated Summary of Medical Evidence and references.
02/09/2022	Policy reviewed. No change to coverage position. Updated Summary of Medical Evidence and references.
06/20/2021	Policy reviewed. No change to coverage position. IRO Peer Review. Practicing physician board certified in Physical Medicine, Rehabilitation, and Pain Management.
02/08/2021	Policy reviewed. No change to coverage position. Updated Summary of Medical Evidence and references.

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 Physical Medicine, Rehabilitation and Pain Management.

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