Molina Clinical Policy
Genicular Artery Embolization of the Knee for Osteoarthritis
Policy No. 410

Last Approval: 12/10/2025
Next Review Due By: December 2026

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

Osteoarthritis (OA), also referred to as degenerative joint disease, is the most common form of arthritis worldwide and a leading cause of disability among older adults. OA of the knee is the result of cumulative stress and degeneration of the articular cartilage and the subchondral bone. As the cartilage wears down, there is a loss of joint space with increased shear forces and stress on the capsule. The synovial membrane becomes irritated and inflamed, with thickening and knee effusion resulting in a swollen and painful joint. Currently, there is no cure for OA. Existing treatments aim to reduce pain, alleviate symptoms, and improve and preserve range of motion, function, and health-related quality of life. Treatment options for knee OA are available depending on disease severity and commonly include a combination of nonpharmacologic and pharmacologic therapies. Nonpharmacologic interventions typically include weight management, exercise, physical therapy, and assistive devices (e.g., canes, walkers, braces). Pharmacologic therapies may include topical capsaicin, oral and topical nonsteroidal anti-inflammatory drugs, duloxetine, and intraarticular glucocorticoids. Surgical treatment, such as partial or total knee replacement, is reserved for severe joint disease, pain, and functional limitations refractory to both pharmacological and nonpharmacological treatment modalities. Interventional procedures targeting the genicular nerve, such as nerve blocks or ablations, may also be considered for select cases where surgery is not an option ([1-2]Deveza & Bennell 2025; Hayes 2025).

Genicular artery embolization (GAE) is an interventional radiology procedure used to treat knee pain due to OA by reducing hypervascularity to the lining of the knee, or synovium, as pain may be contributed by increased blood flow to the knee related to inflammation. The inflammatory component in the pathogenesis is thought to be associated with increased angiogenesis; therefore, small vessels can be temporarily or permanently obliterated by embolization. During the procedure, a vascular interventional radiologist inserts a small catheter, typically via the femoral artery under fluoroscopic guidance, and advances it to the genicular arteries supplying the knee. Embolic agents (e.g., hydrogel or trisacryl microspheres, polyvinyl alcohol particles, imipenem/cislastin, biodegradable spheres) are then injected to embolize, block, and reduce hypervascularity to the area of inflammation. GAE may provide a minimally invasive, nonsurgical treatment option for patients with symptomatic knee OA refractory to conservative therapy who are unwilling or unable to undergo surgery (Hayes 2025).

Regulatory Status

Embolic agents investigated for GAE in knee OA include both temporary and permanent agents, such as Embozene (Varian Medical Systems), Embosphere (Merit Medical), Contour PVA Embolization Particles (Boston Scientific), imipenem/cilastatin combinations, and resorbable microspheres. The FDA has granted Breakthrough Device Designation for both Embozene and Embosphere for investigation in GAE for symptomatic knee OA (Merit Medical 2022; Varian 2021). Additional devices, such as the Optisphere/Gel-Bead microspheres (Teleflex), are currently being evaluated in GAE for knee OA (ClinicalTrials.gov 2025). However, while many of these embolic agents have been FDA-cleared for indications such as hyper-vascular tumors, uterine fibroids, and benign prostatic hyperplasia, there are currently no embolic agents or devices that have received FDA 510(k) clearance, premarket approval, or de novo authorization for GAE in the treatment of knee OA.

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COVERAGE POLICY

Genicular artery embolization (GAE) for the treatment of knee osteoarthritis (OA) is considered **experimental, investigational, and unproven** 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

Randomized Controlled Trials

van Zadelhoff et al. (2024) conducted a double-blind, single center, randomized controlled trial (RCT) to evaluate the efficacy of genicular artery embolization (GAE) for pain reduction in symptomatic mild-to-moderate knee osteoarthritis (OA) that has not improved with conservative treatment. The study enrolled 58 adult participants (n= 58), randomized evenly between the intervention and sham procedure. The primary outcome was the change in pain at 4 months, measured using the Knee Injury and Osteoarthritis Outcome Score (KOOS) pain scale. Secondary outcomes included KOOS subscales, Visual Analog Scale (VAS) pain scores, the Intermittent and Constant Osteoarthritis Pain (ICOAP) questionnaire, the painDETECT questionnaire, and the EuroQol five-dimension five-level questionnaire (EQ-5D-5L) for quality of life. After 4 months, the mean KOOS pain score improvement was 21.4 points in the GAE group (95% CI 13.9-28.8) and 18.4 points in the sham group (95% CI 11.6-25.1). The between-group difference was not statistically significant (mean difference 3.0, 95% CI -7.1 to 13.0, p = 0.31). After using the Bonferroni correction for Type I errors, secondary outcomes also did not show a statistically significant difference between the two groups. While both groups experienced pain reduction exceeding the minimal important difference of 12 points, the similar level of improvement in the sham group suggests a strong placebo effect. Adverse events were more frequent in the GAE group, with 23 mild AEs reported compared to 5 for the sham group, with the most common being transient skin erythema. Two patients in the GAE group experienced persistent paresthesia in the treated leg, which was deemed related to the procedure. No serious adverse events occurred in either group. The authors concluded that GAE did not demonstrate a clinically significant effect compared to sham GAE over 4 months. The observed pain reductions in both groups were likely influenced by a significant placebo effect. Further trials are needed to better understand the effectiveness of GAE for knee OA. (ClinicalTrials.gov NCT03884049).

Landers et al. (2023) conducted a triple-blind, single center, RCT to evaluate the efficacy of transcatheter arterial embolization (TAE) in treating early-stage, symptomatic knee OA. A total of 59 participants with Kellgren-Lawrence grade 1 knee OA were randomly assigned to receive either TAE (n = 29) or a sham procedure (n = 30). The sham procedure involved the same light sedation followed by local anesthetic, a small incision, simulated intervention by the physician, a pre-recorded video of an angiogram and embolization procedure displayed that the patient could see, and the same recovery, discharge, and adjunct treatments over 12 months as the intervention group. The primary outcome was knee pain at 12 months measure by the KOOS pain scale. Secondary outcomes included other KOOS subtypes such as function and quality of life, self-reported global improvement, the EQ-5D-5L, performance tests measured by the six-minute walk test and 30-second chair stand test, anxiety and depression scores, and adverse events. At 12 months, no statistically significant difference was observed between the two groups in the primary outcome of KOOS pain scores despite improvements in both groups. Notably, the intervention group improved pain by 41.3% while the control group improved pain by 29.4%, suggesting a significant placebo effect. Similarly, no significant differences were found in secondary outcomes across 12 months. While both groups showed functional and quality of life improvements, between group differences remained non-significant in the intention-to-treat analysis. However, subgroup analysis found that intervention group participants who received complete embolization of all genicular arteries (n = 17) showed statistically and clinically significant improvements over the control group in KOOS Quality of Life, KOOS Sports and Recreation, and self-reported global improvement. The authors cautioned that subgroup analysis carries a risk of Type I error, and these findings should be considered exploratory. No serious adverse events

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were reported, and no cases of osteonecrosis were found on MRI at 12 months. The authors concluded that TAE produced no significant benefit over placebo when comparing intervention to sham. However, subgroup analysis suggests that when complete embolization of all genicular arteries is performed, TAE may produce benefits over placebo. Further research is needed before definitive conclusions can be made regarding the effectiveness of TAE.

Systematic Reviews and Meta-Analyses
Ashraf et al. (2025) performed a systematic review to evaluate the safety and efficacy of GAE for managing knee OA-related pain. The review included 23 studies for a total of 657 participants and 704 knees. Of these studies, 15 were case series and 8 were clinical trials, including 5 pilot studies and 3 RCTs. Most of the studies focused on patients with mild-to-moderate OA (Kellgren-Lawrence grades 1-3), and some included severe OA (grade 4). Clinical improvement was most often measured using WOMAC, KOOS, and VAS. In general, among patients with lower OA severity, clinical improvement measures consistently demonstrated significant reductions in pain and improved function. However, among patients with severe OA, these response rates were significantly lower. The definition and measurement of clinical success also varied substantially between studies, which made study comparisons difficult and suggested significant heterogeneity in the data. Adverse events were generally minor and transient, with the most common being skin discoloration without ulceration (15.6%, n = 98), post-procedural knee pain (10.2%, n = 64), and access-site hematoma or subcutaneous hemorrhage (7.0%, n = 44). Other, less frequent adverse events included erythema, skin ulceration, plantar paresthesia, and rare complications such as foot drop. Adverse event rates also varied by embolic agent, with imipenem/cilastatin sodium being associated with fewer skin-related side effects compared to Embozene. Some evidence also suggested that embolization volumes above 3.0mL may increase the risk of adverse events. The authors concluded that GAE is a promising, minimally invasive intervention for knee OA -related pain. However, the current evidence remains limited in quality, and larger high-quality RCTs with longer follow-up, including standardized outcome definitions, are needed to establish GAE as a standard treatment option.

Hernández-Yumar et al. (2025) performed a systematic review with a meta-analysis and cost analysis to evaluate the effectiveness, safety, and cost-effectiveness of GAE for mild-to-moderate knee OA unresponsive to standard treatment and for severe cases where surgery is not an option. While their initial database search identified many primary studies, only two RCTs met the eligibility criteria, giving the review a total of 80 participants. Primary outcomes included pain, function, health-related quality of life (HRQoL) and analgesic use, across time points up to 12 months. At 6 and 12 months, there was a moderate certainty of evidence suggesting little to no effect on pain. Functional outcomes, measured by Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and KOOS subscales, showed no significant differences between GAE and control groups at 1, 6, or 12 months. HRQoL, measured using KOOS and EQ-5D, also showed little to no difference, although one low-certainty measure (EQ-5D VAS at 6 months) suggested a modest benefit (mean difference of -10.00, 95% CI -19.45 to -0.55). At 12 months, the GAE group had a lower proportion of participants taking analgesics compared to the control group (24% and 48% respectively); however, this was not statistically significant (risk ratio of 0.52, 95% CI 0.24 to -1.10). No major adverse events were reported in either study, and MRI showed no osteonecrosis or ischemic complications for up to 2 years post-procedure. The authors conducted a cost-analysis from the perspective of the Spanish National Health System over a one-year time horizon. GAE would result in an incremental cost of €3,432.37 per patient and would need to provide a health improvement of at least 0.137 Quality-Adjusted Life Year (QALY) to be deemed a cost-effective technology. The authors concluded that based on moderate to low-certainty evidence, it remains inconclusive whether there is any difference between GAE and standard treatment for knee OA; however, the use of GAE would increase costs.

Milhem et al. (2025) performed a systematic review of sham-controlled RCTs to evaluate the efficacy and safety of GAE for symptomatic knee OA. Three RCTs met inclusion criteria, giving the review a total of 138 participants with mild-to-moderate knee OA. Primary outcomes were changes in pain, measured by KOOS and VAS. Secondary outcomes included function, measured by WOMAC, quality of life, measured by KOOS-QOL and EQ-5D-5L, and adverse events. Results showed that GAE may provide short term pain relief, with one trial supporting a statistically significant reduction in VAS scores at one month (-50.8 in the GAE group vs -0.5 in the sham group, $p < 0.01$). However, the other two studies reported more modest improvements with statistical significance. KOOS pain scores improved slightly but did not show significant between-group differences. Functional outcomes were mixed, where one study reported a significant 30-point improvement on the WOMAC function scale ($p < 0.05$) while another found better quality-of-life outcomes only in patients who underwent complete embolization. One study showed no clinically meaningful or statistically significant differences in either pain or function between GAE and sham groups. No serious adverse events were reported in any of the studies, and minor adverse events, such as catheter-site bruising, were infrequent. The authors concluded that GAE is a safe and minimally invasive option that may offer short-term symptom relief for some

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patients with knee OA. However, due to limited sample sizes, variability in methodology, and short follow-up periods, definitive conclusions on GAE are limited. Larger RCTs with longer follow-up are necessary to confirm the efficacy of GAE and optimize patient selection.

Taslakian et al. (2023) performed a systematic review and meta-analysis to analyze GAE for the treatment of knee OA. Nine studies were included with 270 patients (339 knees), 69% of patients were female, median age of 65 years, and median BMI of 28 kg/m2. At baseline, OA characteristics included a median Kellgren-Lawrence score of 2.5, knee pain VAS of 69, and WOMAC score of 54. Studies were excluded if the sample size was less than 10, patients were treated with concomitant surgeries, or if they did not report any outcomes prespecified in the review. Outcomes measured included VAS score for knee pain and WOMAC score. Data was analyzed to determine the minimal clinically important difference (MCID), substantial clinical benefit (SCB), and weighted mean difference (WMD) of scores. The WMD for knee pain VAS score was -37 at 1 month (8 cohorts), -34 at 3 months (7 cohorts), -39 at 6 months (6 cohorts), and -36 at 12 months (5 cohorts) (all $p < 0.001$ vs. baseline). The WMD for WOMAC Total Score was -28 at 1 month (5 cohorts), -29 at 3 months (4 cohorts), -30 at 6 months (4 cohorts), and -34 at 12 months (2 cohorts) (all $p < 0.001$ vs. baseline). The improvement in knee OA symptoms ranged from 1.7 to 2.0 MCID units for knee pain and 1.7 to 2.0 units for WOMAC scores. The percentage of patients achieving the MCID was 76%, 78%, 87%, and 78% for knee pain VAS score at 1, 3, 6, and 12 months. The percentage of patients achieving clinical benefit for WOMAC score at 1, 3, 6, and 12 months was 68%, 83%, 86%, and 92% when using MCID and 44%, 60%, 66%, and 78% when using SCB. Adverse events were minimal with 2.0% of patients requiring medication and 0.3% of patients requiring hospitalization. The most common adverse events reported were skin discoloration (11.6%), knee pain (1.2%), access site hematoma (0.6%), and focal skin ulcers (0.3%). Limitation of this review and meta-analysis include heterogeneity in study design, treatments, and outcomes among studies and variation in completeness of data reported. Safety and effectiveness of GAE compared to other knee OA treatments is still unclear. Currently there is limited evidence suggesting GAE is a safe and effective procedure to improve knee OA symptoms.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Hayes (2025) conducted a review of the evolving evidence of GAE for the treatment of knee OA. A review of clinical studies and systematic reviews suggests minimal support for use of this treatment. The authors note that while in most studies and for most outcomes, improvements were clinically and statistically significant, sham-controlled trials observed a significant placebo effect, with very few statistically significant differences in outcome measures, suggesting that GAE may not be superior to sham. GAE appears to be a reasonably safe procedure, with most adverse events being mild and self-limiting, such as bruising or temporary skin discoloration. A review of clinical practice guidelines and position statements suggests no support or unclear support for the use of GAE for knee OA. For patients whose symptoms have not responded to conservative management (e.g., pharmacotherapy, physical therapy, biomechanical intervention), clinical alternatives to GAE include intra-articular injections (e.g., corticosteroids, hyaluronic acid), genicular nerve blocks, radiofrequency nerve ablation, cryoneurolysis, and stem cell and/or platelet-rich plasma therapies.

Padia et al. (2021) evaluated the safety and efficacy of GAE for the treatment of symptomatic knee OA in 40 patients aged 40 to 80 years (median age 69) with moderate to severe knee OA (based on the Kellgren-Lawrence score) who had previously failed conservative therapies and were ineligible for or declined surgery in a prospective open-label study. Knee OA severity was grade 2 in 18% of patients, grade 3 in 43%, and grade 4 in 40%. Embolization of the knee was conducted with 100-µm Embozene particles and technical success was reported in 100% of the participants with a median procedure time of 79 minutes. The baseline severity of knee pain was assessed by a VAS score and the baseline symptoms related to knee OA were quantified using WOMAC. The primary efficacy endpoint was the change in WOMAC score from baseline to 12 months after GAE with clinical success defined as a 50% reduction in WOMAC score. The WOMAC total decreased by 61% and the VAS pain scores decreased by 67% at 12 months. A reduction of ≥ 50% in both WOMAC total and VAS pain scores was reported in 68% of patients (27 patients), while 43% patients were reported to experience a ≥ 75% reduction at 12 months. The median WOMAC score decreased from 52 to 19 at 12 months. Of thirteen patients with < 50% improvement in the WOMAC score, 5 patients subsequently underwent total knee arthroplasty. The authors noted that the adverse events occurring at the knee included focal epidermal layer skin ulceration in 7 patients (18%) occurring 7 to 10 days after GAE and resolving within 3 days, 2 cases of clinically asymptomatic bone infarct in the tibia and patella, and 1 case of focal fat necrosis of the lower thigh.

Bagla et al. (2020) conducted a pilot study of 20 patients to evaluate the efficacy and safety of embolization of hyperemic synovial tissue for the treatment of knee pain secondary to OA in a prospective, 2-site pilot study. The

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participants were between 49 and 84 years (mean age 59.4 years) and had radiographic knee OA with moderate-to-severe pain refractory to conservative therapy for at least 3 months. All patients underwent MRI before GAE and at 1 month after GAE. OA symptoms were assessed using WOMAC scores, and pain was assessed using VAS score. Adverse events were recorded at all time points. GAE was performed with 75- or 100-µm micrometer Embozene Microspheres. The primary endpoint of clinical success was defined as a 20% change in VAS or 16% change in WOMAC score at 6 months without an increase in pain medication use or intra-articular injection. Embolization of at least one genicular artery was achieved in 20 of 20 patients. The mean GAE procedure time was 81 minutes. The decreases in VAS and WOMAC scores from baseline to 6 months were significant. VAS scores decreased from a mean of 76 mm at baseline to 22 mm at 1 month, 34 mm at 3 months, and 21 mm at 6 months. WOMAC scores decreased from 61 at baseline to 24 at 1 month, 31 at 3 months, and 31 at 6 months. No patients increased their pain medications from baseline during the study and 65% of patients reported a decrease in daily analgesic medication use. At 6 months, 80% of patients met the primary WOMAC endpoint and 85% of patients met the primary VAS endpoint. Adverse events included skin discoloration at the knee in 13 cases that resolved within 3 months and great toe plantar numbness in 2 patients that resolved within 2 weeks. The authors concluded that GAE to treat knee pain secondary to OA can be performed safely and demonstrates potential efficacy; however, further randomized comparative studies are needed to determine the true treatment effect versus the placebo effect.

National and Specialty Organizations

The **Society of Interventional Radiology (SIR) Foundation** convened a research consensus panel for the development of a research agenda on the percutaneous management of knee OA. The panel was composed of a multidisciplinary group of experts from orthopedic surgery, rheumatology, anesthesiology/pain management, sports medicine, and interventional radiology. A statement on percutaneous management of knee OA issued by the panel on June 2021 noted that "limited published data available suggest that GAE is effective in reducing knee pain from OA" and that GAE will require additional safety and efficacy data to confirm its role in the management algorithm for knee OA (Ahmed et al. 2021).

The **SIR Foundation** also published research reporting standards regarding GAE for knee OA. The authors note that GAE has demonstrated symptomatic benefit mainly for patients with mild-to-moderate OA, and that while short- and mid-term safety and efficacy have been validated through many single-arm studies, more definitive sham and comparative studies are underway to evaluate placebo effects and better define safety and durability (Ahmed et al. 2024).

The **National Institute for Health and Clinical Excellence (NICE)** (2021) concluded that the evidence on the safety of GAE for pain from knee OA shows no major safety concerns in the short term; however, evidence on its efficacy and long-term safety is inadequate in quality and quantity. The procedure should only be used in the context of research and should only be performed by interventional radiologists with specific training in this technique. NICE recommended that the research includes randomized controlled trials versus shams, as well as current best practices. In addition, the research should report details of patient selection and identify those who would most benefit from this procedure. It should also report details of the technique used, long-term safety, and patient-reported outcomes.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
37242	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural road mapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (e.g., congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms)

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APPROVAL HISTORY

12/10/2025	Policy reviewed. No change to coverage criteria. IRO peer reviewed on October 17, 2025 by a practicing physician board certified in diagnostic radiology.
12/11/2024	Policy reviewed. No changes to coverage criteria. Updated References.
02/14/2024	Policy reviewed. No changes to coverage criteria. Updated References and Summary of Medical Evidence.
02/08/2023	Policy reviewed. Updated content. Revised verbiage and wording for clarity with no changes in intent or coverage position. Updated references.
02/09/2022	New policy. IRO Peer Review 12/23/2021. Reviewed by practicing physician board-certified in Interventional Radiology.

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