Medical Policy

Subject:	Genicular Procedures for Treatment of Knee Pain		
Document #:	SURG.00142	**Publish Date:**	01/30/2025
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Description/Scope

This document addresses procedures of the genicular nerve for treatment of knee pain. These include nerve blocks, radiofrequency ablation (also called genicular neurotomy, genicular denervation, or cooled radiofrequency therapy), and artery embolization.

Note: This document does not apply to regional anesthetic blocks or acute surgical pain.

Note: This document does not apply to the use of peripheral nerve blocks (for example sciatic and/or femoral nerve blocks) as an adjunct to systemic analgesia in the perioperative period for major knee surgery.

Note: Please see the following related documents for additional information:

- DME.00011 Electrical Stimulation as a Treatment for Pain and Other Conditions: Surface and Percutaneous Devices
- SURG.00140 Peripheral Nerve Blocks for Treatment of Neuropathic Pain
- SURG.00155 Cryosurgery of Peripheral Nerves

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Position Statement

Investigational and Not Medically Necessary:

Genicular nerve blocks are considered **investigational and not medically necessary** as a treatment for knee pain.

Genicular nerve radiofrequency ablation is considered **investigational and not medically necessary** as a treatment for knee pain.

Genicular artery embolization is considered **investigational and not medically necessary** as a treatment for knee pain.

Rationale

Genicular Nerve Blocks

Genicular nerve blocks are accomplished by the injection of a local anesthetic agent into or in the vicinity of the genicular nerve, with the objective of blocking neural signals from the knee to the brain.

In a 2021 study by Yilmaz and colleagues, the authors reported on 40 participants with osteoarthritis of the knee who received either intra-articular steroid (IAS) injections (n=20) or IAS injections plus genicular nerve block (n=20). Severity of pain was assessed using a visual analog scale (VAS) (0-10) and the Leeds Assessment of Neuropathic Symptoms and Signs pain scale. Functional status was assessed using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). Quality of life was assessed by the Nottingham Health Profile. Participants were assessed at baseline, 1 month and 3 months following injections. In the IAS injection only

group, the baseline and 3-month VAS was 6.75 and 1.50 for the IAS group compared to 6.65 and 3.0 for the IAS + genicular nerve block group. Baseline and 3-months Leeds Assessment of Neuropathic Symptoms and Signs pain scales were 13.40 and 6.70 for the IAS group compared to 14.35 and 8.4 for the IAS + genicular nerve block group. For the WOMAC score, the baseline and 3-months scores were 51.57% and 35.06% for the IAS group and 54.26% and 48.74% for the IAS + genicular nerve block group. The baseline and 3-month Quality of Life scores were 27.69 and 21.90 for the IAS group compared to 28.15 and 25.63 for the IAS + genicular nerve block group. The Quality of Life score in the IAS injection plus genicular nerve block group only improved from baseline to 1 month evaluation. While both treatment groups showed improvements in pain and quality of life scores, the IAS injection only group showed greater improvements than the steroids plus genicular nerve block group. Limitations of this study include its small size and the lack of comparison between genicular nerve block to treatments other than IAS injection.

In a 2021 randomized trial of 64 participants, Elsaman and colleagues reported outcomes for individuals with osteoarthritis of the knee who received either genicular nerve block (n=33) or IAS injections (n=31). Follow-up was for 12 weeks. Assessment was done using sonography of large joints in Rheumatology (SOLAR) scoring, VAS, and Lysholm score. Pain improved in both treatment groups with no significant between-group differences.

A 2022 randomized trial by Ghai and colleagues reported results for 30 individuals with osteoarthritis of the knee who had either radiofrequency of the genicular nerves or genicular nerve block using local anesthetic and steroid. Follow-up assessments were made 12 weeks after the procedures using WOMAC scores and a verbal Numeric Rating Scale (NRS). The verbal NRS scores decreased in both groups and WOMAC scores improved in both groups. No significant outcome differences were observed between the 2 groups.

Another randomized trial in 2022 compared genicular nerve block to physical therapy in participants with knee osteoarthritis. Güler and colleagues reported on 51 participants who received genicular nerve block and 51

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participants who received physical therapy along with a standard home exercise program. Follow-up assessments were done after 12 weeks. These assessments were done using VAS, WOMAC score, and a 6-minute walk test. Both treatment groups improved during the course of the study with no significant differences between the treatment groups.

A placebo-controlled trial by Shanahan and colleagues in 2023 reported on the effectiveness of genicular nerve block in participants with longstanding knee osteoarthritis. In this 12-week trial, 33 participants received the intervention and 31 participants were allocated to placebo. Primary outcome was reduction of pain after 12 weeks, measured by VAS. In the active group, VAS score ranged from 6.2 at baseline to 4.6 after 12 weeks following treatment. In the placebo group, VAS score ranged from 5.3 at baseline to 5.1 after 12 weeks. There were 5 participants lost to follow-up and not included in the 12-week analysis (2 from the active group and 3 from the placebo group). The short-term follow-up of 12 weeks, lack of safety data, potential for inadequate blinding, and 5 participants lost to follow-up do not allow for generalizability.

Genicular Radiofrequency Ablation
Genicular nerve radiofrequency ablation involves the application of extreme heat or cold to the genicular nerves to interrupt the transmission of pain signals from the knee to the brain.

In a 2011 randomized controlled trial by Choi and colleagues, the authors investigated whether radiofrequency ablation applied to articular nerve branches (genicular nerves) was effective in treating osteoarthritic knee joint pain. The 38 study participants (who had severe knee osteoarthritis lasting longer than 3 months) were randomized to two treatment arms; radiofrequency ablation (n=19) or control group (n=19). Using the VAS, Oxford Knee Score (OKS), and Global Perceived Effect (GPE) on a 7-point scale, measurements were taken at baseline, and at 1, 4, and 12 weeks following the procedure. At the 4-week point, the VAS showed the radiofrequency group had less knee joint pain than the control group. Similar findings were noted in the OKS. There were no post-procedure

adverse events reported during the follow-up period. While this study showed pain reduction in those with osteoarthritic knee pain, the authors concluded that "further trials with larger sample size and longer follow-up are warranted."

In a 2016 randomized study by Qudsi-Sinclair and colleagues, 28 participants with continued knee pain following total knee arthroplasty were evaluated after having received traditional radiofrequency (n=14) or local anesthetic and corticosteroid block of the genicular nerves in the knee (n=14). In this double-blind, randomized study, the participants were followed for 1 year. During the first 3 to 6 months, an improvement in joint function and a reduction in pain were shown, with the results being similar between the two treatment arms. While the study showed improvement in both groups, the authors noted that further studies should be done with larger sample sizes to determine if there are any long-term adverse effects.

Santana Pineda and colleagues (2017) reported on a prospective study in which 25 participants with osteoarthritis of the knee received radiofrequency ablation of genicular nerves. Follow-up evaluations were done at 1, 6, and 12 months after the procedure. The primary outcome measure was the change from baseline knee pain using VAS. Those who reported an improvement of 50% or greater in pretreatment VAS 1-, 6-, and 12-months following intervention were 22/25 (88%), 16/25 (64%) and 8/25 (32%), respectively. The study did not control for or assess post-procedural medication or physical therapy use. The observational, noncontrolled, unblinded design of this study allows the possibility that these subjectively reported results may have been influenced by placebo effects and reporter biases. While improvement was noted following the radiofrequency procedure, the authors stated that "Larger-scale studies are needed to confirm the results and address the safety aspects in other populations."

In a 2018 randomized study by El-Hakeim and colleagues, the authors reported on the efficacy of genicular radiofrequency neurotomy for pain due to knee osteoarthritis. There were 30 participants who received radiofrequency compared to 30 participants who received only conventional analgesics. Participants were followed

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for 6 months. Outcomes were measured by WOMAC, VAS, and a Likert scale to assess member satisfaction. Although the scores were reviewed by an investigator who was unaware of each participant's study group, the participants themselves were aware of whether they received radiofrequency ablation or not. VAS scores were lower in the radiofrequency group at all follow-up times. WOMAC scores were also reported as better in the radiofrequency group. The small cohorts, single-center design, potential placebo effects, and short-term follow-up limit the generalizability of these findings. Further study is needed to confirm these results.

A 2018 study by Davis and colleagues reported on the safety and efficacy of genicular cooled radiofrequency ablation (CRFA) compared to IAS injection for individuals with osteoarthritis of the knee. In this prospective, randomized, cross-over trial, study participants were included if they had a known diagnosis of osteoarthritis of the knee, complaints of knee pain for at least 6 months that was unresponsive to conservative treatment, NRS pain score of 6 or greater, OKS of 35 or less, positive diagnostic genicular nerve block (defined as a decrease of ≥ 50% in NRS score), and, if the participant was taking an opioid or other morphine-equivalent medication, the dose was clinically stable. Participants were allowed to use analgesics as needed during the study. A total of 138 participants proceeded to treatment; 67 participants received genicular CRFA, and 71 participants received IAS. Participants were assessed at baseline and at 1-, 3-, and 6-months following treatments. After 6 months of treatment, the participants randomized to the IAS cohort were allowed to crossover and receive CRFA. Using the 11-point NRS, the primary efficacy outcome was the proportion of participants whose knee pain was reduced by 50% or greater from baseline at 6 months after treatment. Secondary outcomes included change in knee function detected by OKS, participant perception of treatment effect as reflected by the GPE score, and opioid and nonopioid (nonsteroidal anti-inflammatory drugs) analgesic use measured by self-reported average daily dosage used. The mean baseline pain scores were 7.3 ± 1.2 for the 76 participants in the CRFA group and 7.2 ± 1 for the 75 participants in the IAS group. At the 6-month visit, the NRS score was 2.5 ± 2.3 in the CRFA group (n=58) and 5.9 ± 2.2 in the IAS group (n=68). A total of 43/58 (74%; 95% confidence interval [CI], 62.9–85.4%) participants in the CRFA and 11/68 (16%; 95% CI, 7.4–24.9%) participants in the IAS group had ≥ 50% reduction in NRS score at 6 months. The mean

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OKS in each study cohort did not significantly differ at baseline and improved at all end points in both study groups. The differences between mean OKS improvement (and 95% CIs) were significantly better for CRFA than for the IAS group at 1 month (4; 0.98–7, p=0.004), 3 months (10; 7.28–12.7, p<0.0001) and at 6 months (13.3; 10.28–16.4, p<0.0001). At 6 months, 53/58 participants (91%; 95% CI, 83.9–98.8) in the CRFA cohort reported improved GPE compared to the participants 16/67 (24%; 95% CI, 13.4–34.4) in the IAS. At baseline, 33 participants in the CRFA group required nonopioid medication and 34 participants in the IAS group required nonopioid medication. At 6 months, mean nonopioid drug dose use was −34.5 ± 128.9 mg in the CRFA group and 135.5 ± 391 mg in the IAS group. No procedure-related serious adverse events were reported. At 6 months, 74.1% of CRFA participants reported reduced index knee pain by at least 50% compared to 16.2% in participants treated with IAS injections. GPE improved in 91% of the CRFA group compared to 24% in the IAS group. Opioid analgesic use was not different between the two groups and remained similar to baseline use. While this study suggests that, when compared with a single IAS injection, CRFA provides a reduction in knee pain associated with improved knee function, the study has several limitations. The participants received only one IAS injection over a 6-month period, the study was not blinded, and the study questionnaires were self-administered. There was a lack of a true control group since IAS injections are considered analgesics. There was no formal recording of medication usage in this study. This allowed for the potential for error and/or inability to identify acute changes in medication dosage during the study. Since participants in both study groups used opioids for medical indications other than osteoarthritis-related knee pain, the effect of each treatment on opioid use could not be specifically measured. Further studies with a true control group and consistent tracking of additional medication usage are necessary to determine efficacy of genicular CRFA for osteoarthritis-related knee pain.

As a follow-up, Davis and colleagues (2019) reported on the proportion of individuals from the Davis 2018 cohort who had reduction in knee pain by ≥ 50% from baseline to 12 months. The focus of the Davis 2019 study was to describe the individual's experience through 12 months. Reduction in knee pain at 12 months was evaluated using the NRS. Secondary endpoints included change in knee function using the OKS, participant perception of treatment

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measured by the GPE score, and opioid analgesic use by self-reporting. At 12 months, 52 of the original 78 participants in the original CRFA group and 4 of the original 75 IAS group members completed the NRS assessment tool. The IAS cohort was significantly reduced in size because 58 of its participants crossed over to the CRFA group 6 months after their IAS injection. Twelve months after the study intervention, there were no significant differences between the CRFA group and the IAS group in the mean NRS score (3.1 for CRFA vs. 3.3 for IAS, p=0.99), OKS (34.3 for CRFA vs. 22 for IAS, p=0.11), or in the percentage of participants with improved (75 for CRFA vs. 50 for IAS, p=0.29) In the CRFA group, the mean total daily dose of opioid analgesic medication at 12 months was similar to baseline. Between 6 and 12 months, there were 81 adverse events that occurred in the CRFA group. These included pain in the index knee, pain in the non-index knee, musculoskeletal pain, and falls. This study shares the limitations outlined above for the original study. Significant cross-over led to severe attrition in the IAS group. This prevents reasonable conclusions from being drawn about the relative effects of CRFA and IAS at 12 months.

In another study using the original participants from the Davis 2018 cohort, Hunter and colleagues (2020) reported on outcomes of participants at 18 and 24 months after CRFA. This extended outcome study included 33 of the 151 participants from the 2018 cohorts (19 from the CRFA arm,14 from the crossover arm, and 0 from the ISA-only arm). At 18 months after CRFA, 25 participants were evaluated. The mean NRS pain score for these 25 participants was 3.1 with a mean OKS of 47.2. Only 18 participants remained at the 24 months evaluation. Using the NRS, mean pain score was 3.6 and OKS was 46.8. Perceived improvement of the GPE score was reported by 20 of the 25 participants remaining for evaluation at 18 months and by 12 of the 18 who remained at 24 months. No adverse events were reported at 18 and 24 months after CRFA. In addition to the limitations noted above for the original study, this follow-up is further limited by significant attrition in the studied population.

Chen and colleagues (2020a) reported the 6-month results of an industry-sponsored randomized, multicenter study comparing CRFA of the genicular nerve to a single injection of intra-articular hyaluronic acid. The authors

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acknowledged that the Food and Drug Administration (FDA) has questioned hyaluronic acid's mechanism of action in treatment of knee pain and that "clinical practice guidelines for orthopaedic surgeons do not currently recommend hyaluronic acid for the treatment of knee osteoarthritis pain." All participants received genicular nerve block. Pain was assessed using the NRS. The CRFA group had a mean NRS pain score at baseline of 6.5 and 0.6 following the block. The intra-articular hyaluronic acid group had a mean NRS pain score of 6.5 at baseline and 0.5 after the block. Following the blocks, those who experienced greater than or equal to 50% reduction in pain within 15 minutes after the block were randomized to the CRFA group (n=88) or to the single intra-articular hyaluronic acid injection group (n=87). The primary endpoint was the proportion of individuals who had knee pain reduced by greater than or equal to 50% from baseline to 6 months following treatment. Knee pain, function, and stiffness was assessed by WOMAC. Treatment effect was assessed by GPE and the EuroQol-5 Dimensions-5 Level (EQ-5D-5L) questionnaire. At the 6-month evaluation, 76 (87%) participants in the CRFA group and 82 (94%) in the intra-articular hyaluronic acid group were available for evaluation. The authors report a mean NRS score reduction of 4.1 in the CRFA group with 71% of participants reporting greater than or equal to 50% reduction in pain. In the intra-articular hyaluronic acid group, the mean NRS score reduction was 2.5 with 38% of participants reporting greater than or equal to 50% reduction in pain. Mean WOMAC score at baseline in the CRFA group was 66.1 compared to 67.7 in the intra-articular hyaluronic acid group. At the 6-month evaluation, the mean total WOMAC scores in the CRFA were 33.6 and 53.6 in the intra-articular hyaluronic acid group. Between-group differences were statistically significant at all follow-up intervals for the WOMAC total score as well as for the WOMAC pain, physical functioning scores. Differences for the WOMAC knee stiffness scores were significant at the 3- and 6-month follow-ups. In terms of GPE, 1 month after treatment, the CRFA group had 18 participants with 'not improved' or 'worse' condition and 69 participants who 'felt improvement' compared to 32 and 52 in the intra-articular hyaluronic acid group, respectively. At the 6-month evaluation, the CRFA group had 21 participants with 'not improved' or 'worse' condition and 55 participants who 'felt improved'. The intra-articular hyaluronic acid group had 49 participants with 'not improved' or 'worse' condition and 33 participants who 'felt improvement'. The mean EQ-5D-5L Index score at baseline in the CRFA group was 0.67 and 0.80 at 6 months following treatment. Mean

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baseline score in the intra-articular hyaluronic acid group was 0.66 and 0.72 after 6 months. Overall, there were 94 adverse events in the CRFA group and 63 in the intra-articular hyaluronic acid group. The CRFA group had 18 adverse events deemed to have a relationship to treatment compared to 9 adverse events in the intra-articular hyaluronic acid cohort. This study has several limitations beginning with the selection of a questionably effective treatment (hyaluronic acid) as the comparison group. Potentials for bias exist due to industry sponsorship, the open-label design, and lack of blinding. Significantly more CRFA group members (11/87, 12.6%) were lost to follow-up compared to the intra-articular hyaluronic acid cohort (3/84, 3.6%). There were also only 8 participants in the CRFA group and 7 in the intra-articular hyaluronic acid group who reported taking opioid medication at baseline. With such low numbers, the authors reported difficulty measuring trends regarding opioid consumption following treatment. This study took place across several medical centers with imbalanced enrollment at several of the sites. Further well-designed, randomized controlled trials comparing CRFA to guideline-directed therapy are necessary to support reasonable conclusions about the effectiveness of genicular nerve CRFA.

Using the same cohort in the 2020a Chen study above, Chen and colleagues (2020b) reported on participants in the intra-articular hyaluronic acid group who were invited to "crossover" to receive CRFA treatment 6 months after their hyaluronic acid injection. These participants were then followed for an additional 6 months. The original CRFA group was also evaluated after the additional 6 months. Twelve months after the original study start date, 66 (75%) of the participants from the CRFA group were available for evaluation. In the original intra-articular injection group, 68 participants (78%) chose to cross over and receive CRFA. There were 62 crossover participants available for evaluation at 12 months. A total of 14 participants who received intra-articular injection did not crossover and 11 of them were available for evaluation at 12 months. In the original CRFA group, 43 participants (65%) reported pain reduction greater than or equal to 50% using the NRS pain scale. The mean NRS pain score was 2.8 at 12 months compared to the mean baseline score of 6.9. Mean total WOMAC score at 12 months was 33.2. Using GPE, 63.3% of participants reported improved knee condition. The mean EQ-5D-5L Index score was 0.81 compared to a mean baseline of 0.67. There were 47 adverse events reported and all were deemed unrelated or

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unlikely related to treatment. In the crossover group, 40/62 participants reported greater than or equal to 50% reduction in pain. The mean NRS score was 5.1 in this crossover group prior to receiving the CRFA. At 6 months after receiving CRFA, the mean NRS score was 3.0. Mean total WOMAC score at 12-months was 38.4. Using GPE, 62.9% reported improved knee condition. The mean EQ-5D-5L Index score was 0.79 compared to the mean baseline of 0.65. There were 68 adverse events with 62 unrelated to the treatment, 1 was unlikely to have been related, 2 were possibly related, and 3 were probably related to treatment. Of the 11 participants in the original intra-articular injection group available at the 12-month evaluation, 10 reported greater than or equal to 50% reduction in pain. The mean NRS score at baseline was 6.9 and 1.5 at 12 months. There were 8 adverse events reported and all were deemed unrelated or unlikely related to treatment. While this study suggests individuals who initially receive intra-articular hyaluronic acid injections can benefit from CRFA afterwards, this study has the same limitations noted above for the Chen 2020a study as well as an additional limitation from the nearly total elimination of the control group by the cross over intervention.

In a planned extension of the Chen study discussed above, Lyman and colleagues (2022) compared CRFA of genicular nerves to a single hyaluronic injection in 57 participants. Efficacy was assessed at 18 and 24 months by using NRS, WOMAC, the GPE scale, and the EQ-5D- 5L questionnaire. At 24 months, most participants reported pain relief and improvement in function and quality of life. However, only 27 participants were available for follow-up at 24 months. And those from the Chen study who received the hyaluronic injection were not followed out for 24 months. Therefore, there was no true comparison group.

Kwon and colleagues (2024) reported the results of a double-blind, randomized, controlled study that evaluated the efficacy of cooled RFA compared with a sham procedure. Participants with knee pain due to osteoarthritis were randomly assigned to receive either cooled RFA of the knee (n=17) or a sham procedure (n=18). The primary outcome was the number of successful responders after 3 months. Successful responders were defined as those who experienced at least a 50% or four-point reduction in NRS for pain in the affected knee. The secondary outcomes

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were the proportion of participants who achieved at least a 50% or a four-point reduction in knee pain at 1 and 6 months and in the pain intensity of the knee (NRS), WOMAC, Medication Quantification Scale III (MQS), and The Global Perceived Effect of Satisfaction (GPES) at 1, 3, and 6 months. For the primary outcome, after 3 months, 13 participants in the cooled RFA group (76.5%) obtained a successful response and 6 participants in the sham group (33.3%) obtained a successful response. For the secondary outcome, the number of successful responders was significantly higher in the cooled RFA group than in the sham group at 1 and 6 months after the procedure (p=0.041 and p=0.007, respectively). The mean pain intensity (NRS) in the sham group was improved after 1 month compared with the baseline (p=0.003) and the mean pain intensity (NRS) in the cooled RFA group was improved at all post-procedure assessment points (1, 3, and 6 months) compared with the baseline (p<0.001). There were no significant improvements in WOMAC, MQS, and GPES at all post-procedure assessment points compared with the baseline, except WOMAC at 1 month (p=0.047). There were no significant between-group differences observed in WOMAC, MQS, and GPES at any period during the follow-up. There was also no significant group-by-time interaction between the two groups over time in WOMAC, MQS, and GPES. The authors concluded that "Further prospective studies with longer follow-up periods are needed to better understand its efficacy and long-term effects, which may ascertain the usefulness of this new advanced treatment."

Two retrospective chart reviews (Innaccone, 2017; Konya, 2020) reported on individuals who received radiofrequency ablation of the genicular nerves due to knee osteoarthritis. Participants were evaluated for 6 months following treatment. While there was reported improvement in pain following radiofrequency ablation, the lack of a control group, high attrition rate and potential for selection bias limit the findings. Other retrospective reviews (Kapural, 2019; McCormick, 2017) reported on the efficacy of CRFA for knee osteoarthritis. Lack of a control group, lack of consistent treatments, and varying follow-up times make generalizability difficult.

Genicular Artery Embolization

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Genicular artery embolization has been proposed as a treatment of mild to moderate symptomatic knee osteoarthritis when conservative management has failed. Osteoarthritic inflammation is accompanied by angiogenesis, the growth of new blood vessels from existing ones. Sensory nerves grow along the new blood vessels. The chemical and mechanical stimulation of these nerves may contribute to osteoarthritic pain. The embolization procedure is intended to cause the death of the nerves via denial of blood flow. During the procedure a catheter is inserted through the femoral artery to the genicular arteries in the knee. An embolic agent is injected to block those vessels, followed by intraarterial contrast to confirm the cessation of blood flow. The procedure can be performed under moderate sedation or local anesthesia.

In 2017 Okuno reported the results of a prospective, single-center, single-arm study that evaluated the safety and efficacy of transcatheter arterial embolization for individuals with mild to moderate osteoarthritis of the knee that was resistant to conservative management. Previous conservative therapies received by the participants included oral nonsteroidal anti inflammatory drugs, oral opioid agents, physical therapy, stretching, muscle strengthening, or intraarticular injection of hyaluronic acid. All participants received percutaneous angiography to identify eight arteries supplying the knee. This was followed by injection of embolic material into areas showing abnormal angiogenesis. There were 72 participants included. No major adverse events were reported. WOMAC scores decreased from baseline of 12.1 to 6.2 at 1 month, 4.4 at 4 months, 3.7 at 6 months, 3.0 at 12 months, and 2.6 at 24 months (all P<.001). While improvement was noted, the lack of a comparison group does not permit comparison to other established treatments. The lack of blinding of study participants in this study reporting subjective pain relief allows for the possibility that observed improvements may have been due to the placebo effect.

In a 2020 single-arm, prospective pilot study, Lander and colleagues reported the results for 10 participants with knee osteoarthritis who underwent genicular artery embolization. The primary outcome was the number of responders 12 months after treatment. The study defined a responder as an individual with at least 2 of the following 3 criteria: (a) pain improved > 20% from baseline with an absolute change > 10 points on a 0–100

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interval scale; (b) function improved > 20% from baseline with an absolute change > 10 points on a 0–100 interval scale; (c) patient's global assessment of "moderately better" or "much better." Pain and function were assessed using the Knee Injury and Osteoarthritis Outcome Score (KOOS) and the Pain scale and Function in Daily Living scale. There were 10 participants who underwent genicular artery embolization and were analyzed at 12 months following treatment. At 12 months, 2 participants withdrew from the study and 6 participants demonstrated a response to treatment. A secondary outcome was the response at 24 months following treatment. There were 3 participants who were responders at 24 months, with 2 participants who had repeat embolization between 12 and 24 months. There were no major adverse events reported. The authors also note there were little change in the use of analgesia over the 24-month period. Study limitations include the single-arm design with lack of control group or comparison to other treatment modalities. The authors note "more advanced study designs, such as randomized controlled trials, is warranted to produce higher-quality evidence."

Another study in 2020 reported the results of a prospective trial which evaluated the safety and efficacy of genicular artery embolization for participants with knee osteoarthritis (Bagla, 2020). Assessments were done at baseline, 1 month, 3 months, and 6 months using WOMAC and VAS. There were 20 participants. Baseline mean VAS was 76 points. The mean score fell to 22 at 1 month, 34 at 3 months, and 31 at 6 months. The mean WOMAC scores were 61 at baseline, 24 at 1 month, 31 at 3 months, and 31 at 6 months. Adverse events included skin discoloration that resolved on its own, small access site hematoma, and great toe numbness that resolved following treatment. This study's short-term follow-up and lack of control group do not permit firm conclusions about the efficacy of genicular artery embolization for treatment of knee osteoarthritis.

A single-center, single-arm prospective trial by Padia and colleagues in 2021 reported safety and efficacy results of genicular artery embolization for individuals with symptomatic moderate or severe osteoarthritis of the knee who were not candidates for total knee arthroplasty. The study's primary endpoint was a tabulation of adverse events related to the procedure. The secondary endpoint was efficacy of treatment (measured by total WOMAC score from

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baseline to 12 months following the procedure). In this study clinical success was defined as a reduction of at least 50% in WOMAC score from baseline to 12 months. There were 40 participants enrolled with assessments done at 1 week, 1 month, 3 months, 6 months, and 12 months after genicular artery embolization. Adverse effects included 1 participant with a groin hematoma from the femoral arterial access site, 7 participants with a focal epidermal layer skin ulceration, 2 individuals with clinically asymptomatic focal bone infarct, and 1 case of focal fat necrosis in the lower thigh. There were 27 participants (68%) who achieved clinical success and 17 participants (43%) who had reduction of ≥ 75% in WOMAC score at 12 months. Median WOMAC score decreased from 52 at baseline to 19 at 12 months. VAS pain scores were also reported. Median VAS score was 8 at baseline and 3 at each assessment thereafter. Although the study showed improvements in WOMAC and VAS scores at 12 months, the lack of a control group prevents conclusions about the effects of arterial embolization compared to more established treatments.

A 2021 prospective pilot study by Little and colleagues reported a planned interim analysis of outcomes for participants with knee osteoarthritis treated with genicular artery embolization. In this study evaluating genicular artery embolization in individuals with osteoarthritis of the knee (GENESIS), assessments were done at baseline, 6 weeks, 3 months, and 1 year using KOOS and VAS. There were 38 participants enrolled of whom 6 were unable to be embolized. The mean VAS score was 60 at baseline, 32 at 6 weeks, 36 at 3 months, and 45 at 12 months. Mean KOOS daily living score was 52.62 at baseline and 59.83 at 12 months. The mean KOOS sports and recreational activities score at baseline was 20.16 rising to 27.19 at 12 months. Mean pain score at baseline was 45.46 and 57.47 at 12 months. Mean quality of life score was 21.48 at baseline and 36.97 at 12 months. Mean symptoms and stiffness score was 47.21 at baseline and 56.92 at 12 months. There were four reports of mild self-limiting skin discoloration and one small self-limiting groin hematoma. Further randomized study is necessary to understand the effects of arterial embolization relative to more established treatments.

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In 2024, Little and colleagues reported 2-year outcomes for the GENESIS study discussed above. Out of the original 38 participants, 28 completed the 2-year follow-up. Nine (9) participants underwent knee replacement surgery, and 3 participants were lost to follow-up. The mean VAS decreased from a mean of 58.63 (SD = 20.57, 95% CI, 52.7–65.5) at baseline to 37.7 at 2 years (SD=26.3, 95% CI, 27.0–47.5). Adverse events included self-limiting skin discoloration in 4 participants, self-limiting groin hematoma in 1 participant, and 1 case of deep-vein thrombosis due to immobilization. The authors concluded that lack of an experimental control group creates a need for further trials to assess the placebo effect with genicular artery embolization.

In 2022, Bagla and colleagues reported the results of a multicenter, single-blinded randomized trial which evaluated genicular artery embolization compared to a sham procedure for individuals with knee osteoarthritis. There were 21 participants enrolled with 14 randomized to receive genicular artery embolization and 7 randomized to sham. After 1 month of treatment, if an individual in the sham group didn't report minimal clinically relevant improvement by WOMAC and VAS measurements, they were unblinded and allowed to crossover to treatment. At the 1-month follow-up time, none of the participants in the sham group demonstrated minimal clinically relevant improvement and all opted to undergo genicular artery embolization. One participant from the treatment group withdrew from the trial due to increased pain prior to the 1-month follow-up. Comparing genicular artery embolization to the sham group, in the genicular artery embolization group, mean VAS at baseline was 81.3 and 30.5 at 1 month. Mean WOMAC was 64.9 at baseline and 34.7 at 1 month. In the sham group, mean VAS at baseline was 78.9 and 78.4 at 1 month. Mean WOMAC was 70.9 at baseline and 65.9 at 1 month. Comparing the crossover group to sham, the 1-month mean VAS in the crossover group was 39.8 and the mean WOMAC was 46.3. At the 12-month follow-up, mean VAS in the genicular artery embolization group was 54.59 and mean WOMAC was 46.96. In the crossover group, mean VAS was 75.61 and mean WOMAC was 45.36. There were 3 total adverse events in the sham group compared to 11 in the genicular artery embolization group including knee pain, purpura, nausea/vomiting, skin change, skin ischemia, and pruritus. Significant limitations of this study include the very small sample size,

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elimination of the control group after 1 month, and lack of comparison to treatments known to be effective for osteoarthritic pain.

In a 2023 prospective observational pilot study, Wang and colleagues reported on the outcome of genicular artery embolization in participants with refractory mild to moderate knee osteoarthritis. Genicular artery embolization was performed on 24 knees of 22 participants (8 knees without bone marrow lesion, 13 knees with bone marrow lesion, and 3 knees with bone marrow lesion and subchondral insufficiency fracture of the knee). Knee pain was assessed using VAS at baseline and at 3 and 6 months following the procedure. WOMAC was also used to assess knee function at baseline and 3 months following the procedure. For those without a bone marrow lesion, median VAS scores were 7.0, 3.0, and 2.0 at the baseline, 3 months, and 6 months evaluations after genicular artery embolization, respectively. Median WOMAC scores were 40.5 and 24.0 at baseline and 3 months after the procedure, respectively. For those with a bone marrow lesion, the median VAS scores were 8.0, 3.0, and 3.0 at baseline and at 3 months and 6 months after genicular artery embolization, respectively. Median WOMAC scores were 54.0 and 32.0 at baseline and 3 months after procedure, respectively. For those with both a bone marrow lesion and a subchondral insufficiency fracture of the knee, median VAS scores were 7.0, 6.0, and 5.0 at baseline, 3 months after genicular artery embolization, and 6 months after genicular artery embolization, respectively. Median WOMAC scores were 67.0 and 53.0 at baseline and 3 months, respectively. There were no serious adverse events reported. The lack of a control group in this study prevents firm conclusions about the relative effectiveness of genicular artery embolization compared to other knee pain treatments.

In a single-center, single-arm, prospective trial published in 2024, Cusumano reported 2-year safety and effectiveness outcomes following genicular artery embolization in the treatment of symptomatic osteoarthritis of the knee. There were 40 participants initially included. The study's primary endpoint was the effectiveness of treatment measured by WOMAC scores. At 12 months, 27/40 participants (67.5%) were deemed to have clinical success. At the 24-month assessment, 38 participants available for analysis and 18/38 participants (47.4%)

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demonstrated ≥50% reduction in WOMAC scores. Adverse events occurred in the first 12 months following treatment and included groin hematoma (n=1), self-resolving focal skin ulceration (n=7), asymptomatic small bone infarct on MRI (n=2). Results from this single-center study might not be generalizable to other settings. The single-arm study design prevents comparison of this study's results to other more established treatments. The authors note "Further investigation with larger cohorts, further study into patients with severe OA, and randomized controlled studies are warranted to validate these findings and to refine patient selection criteria."

Several systematic reviews and meta-analyses have been published (Casadaban, 2021; Chen, 2021; Chen, 2023; Epelboym, 2023; Gupta, 2017; Hong, 2019; Jamison, 2018; Liu, 2022; Tan, 2022; Taslakian, 2023; Vilchez-Cavazos, 2023; Wu, 2022) evaluating the use of genicular nerve blocks, CRFA or genicular artery embolization for treatment of pain due to knee osteoarthritis. The heterogeneous procedural and assessment methods, inconsistent follow-up periods, and differing comparison treatments used in these studies does not permit formation of reasonable conclusions about the benefits of these procedures.

At this time published studies on the analgesic effects of genicular nerve blocks and genicular artery embolization lack true control groups or have serious methodologic problems that prevent reasonable conclusions about net health outcomes or formation of treatment-guiding conclusions from their results.

Background/Overview

Osteoarthritis of the knee is one of the most common diseases of advanced age. With up to 20 million adults in the United States suffering from osteoarthritis of the knee, close to 700,000 cases progress to total knee joint replacement. Many individuals with joint pain are not candidates for invasive procedures due to body mass index, age and other comorbidities. Alternative therapies including arthroscopic debridement or injections are associated with less than optimal clinical outcomes. In addition to osteoarthritis, adults can experience knee pain due to a

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number of other causes, and an estimated 10-34 % of individuals experience long-term pain after a total knee replacement.

When an individual exhibits knee pain, the pain signals can be generated from the peripheral nerves innervating the knee including several branches of the genicular nerve. A diagnostic genicular nerve block consists of placing a small amount of local anesthetic, on the genicular nerves to determine if there is sufficient pain relief in the knee to justify performing a therapeutic neurotomy.

Therapeutic genicular nerve block has been proposed as a treatment for a variety of painful conditions including degenerative joint disease, osteoarthritis of the knee, prophylactic pain treatment prior to knee replacement, adjunctive pain treatment following knee replacement, and as a pain treatment for individuals who are not a candidate for knee replacement.

Radiofrequency ablation of the genicular nerves is then performed to restore function and alleviate knee pain. Genicular artery embolization involves the injection of an agent into the genicular artery to prevent the flow of blood.

Definitions

Cooled Radiofrequency Ablation (CRFA): a modification of conventional radiofrequency ablation (see below) that uses a flow of water to draw heat away from the radiofrequency ablation probe tip. This reduces damage to collateral tissues.

Embolization: A procedure that uses particles or an embolic agent to block blood vessels.

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EuroQol-5 Dimensions-5 Level (EQ-5D-5L) Index: A standardized questionnaire-based tool developed by the EuroQol Group that assesses quality of life (QoL) in 5 dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression). Each dimension is assessed at 5 levels of severity. Higher scores indicate greater degrees of pain, anxiety, or limited function. The scores for the separate dimensions can be combined into a single measure of the individuals QoL at the time the tool is administered. EQ-5D has been validated in a wide variety of populations.

Numeric Rating Scale (NRS): A pain measurement tool in which the individual says or marks a discrete number within a range. Commonly used ranges are 0 – 10 (1, 2, 3, - 10), 0 -20, and 0 – 100 in which 0 represents "no pain" and the upper limit represents "the worst pain I have ever had". NRS is similar to VAS but is not continuous. It does not recognize responses between integers. It is thus less granular than VAS but can be used when VAS cannot be used, for example with vision-impaired individuals and during telephone interviews. Results are considered generally comparable to VAS.

Likert Scale: a psychometric tool used in questionnaires to assess an individual's subjective state. Participants are asked to choose a value from a set arranged from strongly positive to strongly negative (or vice versa). A typical example would be to rate your level of agreement to a statement as: strongly disagree, somewhat disagree, neutral, somewhat agree, or strongly agree.

Lysholm Score: A questionnaire developed to an individual's condition after knee ligament surgery. The tool assesses pain, swelling, limping, use of canes or crutches, locking or giving way of the knee, and the ability to climb stairs and to squat. Possible Lysholm scores range from 0 – 100 with higher scores indicating less pain, swelling and dysfunction.

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Osteoarthritis: A degenerative condition of the joints that causes destruction of the material in the joints that absorbs shock and allows proper movement.

Oxford Knee Score (OKS): A 12-question tool used to assess pain and function of the knee. Items are given a score between 1 and 5, with higher scores indicating higher levels of pain or dysfunction. The test has been shown to have good evidence of validity and strong inter-test reliability.

Patient Global Impression of Change (PGIC) score: a single-question assessment tool that asks an individual to describe the amount of change in activity limitation, symptoms, emotions, and quality of life. The 7 possible responses range from "No change (or condition is worse)", scored as 1 point, to "considerable improvement" scored as 7 points.

Radiofrequency ablation (also known as conventional radiofrequency ablation): A surgical procedure where diseased cells are destroyed using heat produced by high-frequency radio waves.

Visual Analog Scale (VAS): A pain measurement tool in which an individual indicates their level of pain by placing a mark along a continuous line between end points that represent "no pain" and "the worst pain I have ever had". The scale commonly uses a 10cm line on which the position of the mark can be reported in centimeters (0.0 – 10.0) or millimeters (0 – 100). VAS is widely used in clinical medicine and research and is considered a valid measure of a subjective phenomenon.

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC): A set of validated questionnaires used objectively to assess the condition of individuals with osteoarthritis of the knee or hip. The result is reported as a total score, pain score, stiffness score, and physical functioning score. Higher scores indicate worse pain, stiffness or physical functioning.

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Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:

CPT

	For the following procedure **when specified as embolization of the genicular artery:**
37242	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (eg, congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms) [*when specified as genicular artery embolization*]
	For the following **nerve procedures**:
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
64999	Unlisted procedure, nervous system [when specified as cooled or pulsed RF therapy (not destruction) to genicular nerve(s)]

ICD-10 Diagnosis

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M08.861-M08.869	Other juvenile arthritis, knee
M08.961-M08.969	Juvenile arthritis, unspecified, knee
M12.561-M12.569	Traumatic arthropathy, knee
M12.861-M12.869	Other specific arthropathies, not elsewhere classified, knee
M13.161-M13.169	Monoarthritis, not elsewhere classified, knee
M13.861-M13.869	Other specified arthritis, knee
M17.0-M17.9	Osteoarthritis of knee
M21.061-M21.069	Valgus deformity, not elsewhere classified, knee
M21.161-M21.169	Varus deformity, not elsewhere classified, knee
M21.261-M21.269	Flexion deformity, knee
M22.00-M22.92	Disorder of patella
M23.000-M23.92	Internal derangement of knee
M24.361-M24.369	Pathological dislocation of knee, not elsewhere classified
M24.461-M24.469	Recurrent dislocation, knee
M24.561-M24.569	Contracture, knee
M24.661-M24.669	Ankylosis, knee
M25.361-M25.369	Other instability, knee
M25.561-M25.569	Pain in knee
M25.661-M25.669	Stiffness of knee, not elsewhere classified
M25.761-M25.769	Osteophyte, knee
M25.861-M25.869	Other specified joint disorders, knee
M66.0	Rupture of popliteal cyst
M67.361-M67.369	Transient synovitis, knee
M67.461-M67.469	Ganglion, knee
M67.50-M67.52	Plica syndrome

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M67.861-M67.869	Other specified disorders of synovium and tendon, knee
M70.40-M70.42	Prepatellar bursitis
M70.50-M70.52	Other bursitis of knee
M71.20-M71.22	Synovial cyst of popliteal space
M71.561-M71.569	Other bursitis, not elsewhere classified, knee
M92.40-M92.42	Juvenile osteochondrosis of patella
M92.501-M92.529	Juvenile osteochondrosis of tibia and fibula
M94.261-M94.269	Chondromalacia, knee
S80.00XA-S80.02XS	Contusion of knee
S83.101A-S83.196S	Subluxation and dislocation of knee
S83.401A-S83.92XS	Sprain of knee
S87.00XA-S87.02XS	Crushing injury of knee
T84.84XA-T84.84XS	Pain due to internal orthopedic prosthetic devices, implants and grafts
Z96.651-Z96.659	Presence of artificial knee joint

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Peer Reviewed Publications:

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3. Casadaban LC, Mandell JC, Epelboym Y. Genicular artery embolization for osteoarthritis related knee pain: a systematic review and qualitative analysis of clinical outcomes. Cardiovasc Intervent Radiol. 2021; 44(1):1-9.

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- **A. Submit the rationale used to preliminarily indicate the service is experimental/investigational**
  - **1. Include peer-reviewed journal articles in PDF format with links to the online articles**
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1. American Academy of Orthopaedic Surgeons. Osteoarthritis. Available at: http://orthoinfo.aaos.org/topic.cfm?topic=a00227. Accessed on September 23, 2024.
2. American College of Rheumatology. Osteoarthritis. Available at: http://www.rheumatology.org/I-Am-A/Patient-Caregiver/Diseases-Conditions/Osteoarthritis. Accessed on September 23, 2024.
3. Centers for Disease Control. Osteoarthritis. Available at: https://www.cdc.gov/arthritis/osteoarthritis/index.html. Accessed on September 23, 2024.

Index

Document History

Status	Date	Action
Reviewed	11/14/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised Description/Scope, Rationale, References, and Websites for Additional Information sections.
Revised	11/09/2023	MPTAC review. Revised title to Genicular Procedures for Treatment of Knee Pain. Added genicular artery embolization to the scope of document. Revised Position Statement to add genicular artery embolization as INV/NMN. Updated

The requirements below are specific to the Florida Medicaid Managed Care Plan and are not a part of the Medical Policy or Clinical UM guideline approved by Elevance Health's Medical Policy and Technology Assessment Committee.

If the Florida Medicaid Managed Care Plan intends to deny coverage on the basis that a diagnostic test, therapeutic procedure, or medical device or technology is experimental or investigational, the Managed Care Plan shall submit a request for coverage determination to the Agency in accordance with rule 59G-1.035, F.A.C and Core SMMC Contract, Attachment II, Section VI.G.4.d.

Below is a list of the materials the plans are required to submit when they deny coverage as experimental/investigational:

- **A. Include the CPT or HCPCS code(s)**
- **B. Include a list of other state Medicaid agencies and private insurers who cover the service**
- **C. Include information about the health service from the U.S. Food and Drug Administration**
- **D. Include known risks of the service and health outcomes of others who have received it**
- **E. Include a list of covered alternative services, if any, that could be used to treat the condition**
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		Description/Scope, Rationale, Background/Overview, Definitions, References and Index sections. Updated Coding section to add CPT code 37242.
Reviewed	11/10/2022	MPTAC review. Updated Rationale, Definitions, References, and Index sections.
Reviewed	11/11/2021	MPTAC review. Updated Rationale and References sections.
Reviewed	11/05/2020	MPTAC review. Updated Rationale and References sections.
	10/01/2020	Updated Coding section with 10/01/2020 ICD-10-CM changes; added M92.501-M92.529 replacing M92.50-M92.52 deleted 09/30/2020.
	07/01/2020	Added cross reference to SURG.00155 Cryoneurolysis for Treatment of Peripheral Nerve Pain.
Reviewed	11/07/2019	MPTAC review. Updated Rationale and References sections. Updated Coding section with 01/01/2020 CPT changes; added 64454, 64624 replacing 64450, 64640.
	04/24/2019	Updated Description/Scope section.
Reviewed	11/08/2018	MPTAC review. Updated Rationale and References sections.
Reviewed	02/27/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Updated Rationale and References sections.
Reviewed	02/02/2017	MPTAC review. Updated Rationale and References sections.
New	02/04/2016	MPTAC review. Initial document development.

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