



Subject: Genicular Procedures for Treatment of Knee Pain

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Description/Scope

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

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

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 injection of a local anesthetic into the nerves.

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-month VAS was 6.75 and 1.50 for the IAS group compared to 1.43 sace 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 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 radiofrequency ablation involves using heat or a cooling agent 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 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 score 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, 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 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% Cls) 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 \geq 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 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 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 intraarticular 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 intraarticular 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 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 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

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.

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

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. During genicular artery embolization, a catheter is inserted through the femoral artery to the genicular arteries in the knee. An embolic agent is injected, followed by intraarterial contrast to confirm the cessation of flow. The procedure can be performed under moderate sedation or local anesthesia.

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 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 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. 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.

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, 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. 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, 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.

Several systematic reviews and meta-analyses have been published (Casadaban, 2021; Chen, 2021; Gupta, 2017; Hong, 2019; Jamison, 2018; Liu, 2022; Tan, 2022; Taslakian, 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

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 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.

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.

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.

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:

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

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

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

References

Peer Reviewed Publications:

- Bagla S, Piechowiak R, Hartman T, et al. Genicular artery embolization for the treatment of knee pain secondary to osteoarthritis. J Vasc Interv Radiol. 2020; 31(7):1096-1102.
- 2. Bagla S, Piechowiak R, Sajan A, et al. Multicenter randomized sham controlled study of genicular artery embolization for knee pain secondary to osteoarthritis. J Vasc Interv Radiol. 2022; 33 (1):2-10.e2.
- 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.
- 4. Chen AF, Khalouf F, Zora K, et al. Cooled radiofrequency ablation compared with a single injection of hyaluronic acid for chronic knee pain: a multicenter, randomized clinical trial demonstrating greater efficacy and equivalent safety for cooled radiofrequency ablation. J Bone Joint Surg Am. 2020a; 102(17):1501-1510.
- Chen AF, Khalouf F, Zora K, et al. Cooled radiofrequency ablation provides extended clinical utility in the management of knee osteoarthritis: 12-month results from a prospective, multi-center, randomized, cross-over trial comparing cooled radiofrequency ablation to a single hyaluronic acid injection. BMC Musculoskelet Disord. Jun 09 2020b; 21(1): 363.
- Chen AF, Mullen K, Casambre F, et al. Thermal nerve radiofrequency ablation for the nonsurgical treatment of knee osteoarthritis: a systematic literature review. J Am Acad Orthop Surg. 2021; 29(9):387-396.
- 7. Choi WJ, Hwang SJ, Song JG, et al. Radiofrequency treatment relieves chronic knee osteoarthritis pain: a double-blind randomized controlled trial. Pain. 2011; 152(3):481-487.
- 8. Davis T, Loudermilk E, DePalma M et al. Prospective, multicenter, randomized, crossover clinical trial comparing the safety and effectiveness of cooled radiofrequency ablation with corticosteroid injection in the management of knee pain from osteoarthritis. Reg Anesth Pain Med. 2018; 43(1):84-91.
- Davis T, Loudermilk E, DePalma M, et al. Twelve-month analgesia and rescue, by cooled radiofrequency ablation treatment of osteoarthritic knee pain: results from a prospective, multicenter, randomized, cross-over trial. Reg Anesth Pain Med. 2019; 44:499-506.
- 10. El-Hakeim EH, Elawamy A, Kamel EZ, et al. Fluoroscopic guided radiofrequency of genicular nerves for pain alleviation in

- chronic knee osteoarthritis: a single-blind randomized controlled trial. Pain Physician. 2018; 21(2):169-177.
- Elsaman AM, Maaty A, Hamed A. Genicular nerve block in rheumatoid arthritis: a randomized clinical trial. Clin Rheumatol. 2021; 40(11):4501-4509.
- Ghai B, Kumar M, Makkar JK, Goni V. Comparison of ultrasound guided pulsed radiofrequency of genicular nerve with local anesthetic and steroid block for management of osteoarthritis knee pain. Korean J Pain. 2022; 35(2):183-190.
- 13. Güler T, Yurdakul FG, Önder ME, et al. Ultrasound-guided genicular nerve block versus physical therapy for chronic knee osteoarthritis: a prospective randomised study. Rheumatol Int. 2022; 42(4):591-600.
- Gupta A, Huettner DP, Dukewich M. Comparative effectiveness review of cooled versus pulsed radiofrequency ablation for the treatment of knee osteoarthritis: a systematic review. Pain Physician. 2017; 20(3):155-171.
- 15. Hong T, Wang H, Li G, et al. Systematic review and meta-analysis of 12 randomized controlled trials evaluating the efficacy of invasive radiofrequency treatment for knee pain and function. BioMed Res Int. 2019; 2019:9037510.
- Hunter C, Davis T, Loudermilk E, et al. Cooled radiofrequency ablation treatment of the genicular nerves in the treatment of osteoarthritic knee pain: 18- and 24-month results. Pain Pract. 2020; 20(3):238-246.
- Iannaccone F, Dixon S, Kaufman A. A review of long-term pain relief after genicular nerve radiofrequency ablation in chronic knee osteoarthritis. Pain Physician. 2017; 20(3):E437-E444.
- Jamison DE, Cohen SP. Radiofrequency techniques to treat chronic knee pain: a comprehensive review of anatomy, effectiveness, treatment parameters, and patient selection. J Pain Res. 2018; 11:1879-1888.
- 19. Kapural L, Lee N, Neal K, Burchell M. Long-term retrospective assessment of clinical efficacy of radiofrequency ablation of the knee using a cooled radiofrequency system. Pain Physician. 2019; 22(5):489-494.
- 20. Konya ZY, Akin Takmaz S, Başar H, et al. Results of genicular nerve ablation by radiofrequency in osteoarthritis-related chronic refractory knee pain. Turk J Med Sci. 2020; 50(1):86-95.
- 21. Landers S, Hely R, Page R, et al. Genicular artery embolization to improve pain and function in early-stage knee osteoarthritis-24-month pilot study results. J Vasc Interv Radiol. 2020; 31(9):1453-1458.
- 22. Little MW, Gibson M, Briggs J, et al. Genicular artery embolization in patients with osteoarthritis of the knee (GENESIS) using permanent microspheres: interim analysis. Cardiovasc Intervent Radiol. 2021; 44(6):931-940.
- 23. Liu J, Wang T, Zhu ZH. Efficacy and safety of radiofrequency treatment for improving knee pain and function in knee osteoarthritis: a meta-analysis of randomized controlled trials. J Orthop Surg Res. 2022; 17(1):21.
- 24. Lyman J, Khalouf F, Zora K, et al. Cooled radiofrequency ablation of genicular nerves provides 24-Month durability in the management of osteoarthritic knee pain: outcomes from a prospective, multicenter, randomized trial. Pain Pract. 2022; 22(6):571-581.
- 25. McCormick ZL, Korn M, Reddy R, et al. Cooled radiofrequency ablation of the genicular nerves for chronic pain due to knee osteoarthritis: six-month outcomes. Pain Med. 2017; 18(9):1631-1641.
- 26. Padia SA, Genshaft S, Blumstein G, et al. Genicular artery embolization for the treatment of symptomatic knee osteoarthritis. JB JS Open Access. 2021; 6(4): e21.00085.
- 27. Qudsi-Sinclair S, Borrás-Rubio E, Abellan-Guillén JF, et al. A comparison of genicular nerve treatment using either radiofrequency or analgesic block with corticosteroid for pain after a total knee arthroplasty: a double-blind, randomized clinical study. Pain Pract. 2017; 17(5):578-588.
- 28. Santana Pineda MM, Vanlinthout LE, Moreno Martín A, et al. Analgesic effect and functional improvement caused by radiofrequency treatment of genicular nerves in patients with advanced osteoarthritis of the knee until 1 year following treatment. Reg Anesth Pain Med. 2017; 42(1):62-68.
- 29. Shanahan EM, Robinson L, Lyne S, et al. Genicular nerve block for pain management in patients with knee osteoarthritis: a randomized placebo-controlled trial. Arthritis Rheumatol. 2023; 75(2):201-209.
- 30. Tan YL, Neo EJR, Wee TC. Ultrasound-guided genicular nerve blockade with pharmacological agents for chronic knee osteoarthritis: a systematic review. Pain Physician. 2022; 25(4):E489-E502.
- 31. Taslakian B, Miller LE, Mabud TS, et al. Genicular artery embolization for treatment of knee osteoarthritis pain: Systematic review and meta-analysis. Osteoarthr Cartil Open. 2023; 5(2):100342.
- 32. Wang B, Tai TW, Liang KW, et al. Short-term effects of genicular artery embolization on symptoms and bone marrow abnormalities in patients with refractory knee osteoarthritis. J Vasc Interv Radiol. 2023.
- 33. Wu L, Li Y, Si H, et al. Radiofrequency ablation in cooled monopolar or conventional bipolar modality yields more beneficial short-term clinical outcomes versus other treatments for knee osteoarthritis: a systematic review and network meta-analysis of randomized controlled trials. Arthroscopy. 2022; 38(7): 2287-2302.
- 34. Yilmaz V, Umay E, Gundogdu I, Aras B. The comparison of efficacy of single intraarticular steroid injection versus the combination of genicular nerve block and intraarticular steroid injection in patients with knee osteoarthritis: a randomised study. Musculoskelet Surg. 2021; 105(1):89-96.

Websites for Additional Information

- American Academy of Orthopaedic Surgeons. Osteoarthritis. Available at: http://orthoinfo.aaos.org/topic.cfm?topic=a00227.
 Accessed on October 4, 2023.
- American College of Rheumatology. Osteoarthritis. Available at: http://www.rheumatology.org/l-Am-A/Patient-Caregiver/Diseases-Conditions/Osteoarthritis. Accessed on October 4, 2023.
- Centers for Disease Control. Osteoarthritis. Available at: http://www.CDC.gov/arthritis/osteoarthritis.htm. Accessed on October 4, 2023.

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Document History

Status	Date	Action
Revised	11/09/2023	Medical Policy & Technology Assessment Committee (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 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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