NO. 91571

OSTEOARTHRITIS OF THE KNEE

Effective: 08/01/2026
Committee Review: 05/13/2026
Last Updated: 08/31/2026

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Policy scope: This policy addresses diagnostic and therapeutic interventions for osteoarthritis of the knee, including operative, interventional pain, and regenerative treatments.

Related policies:

- Computer Assisted Surgical Navigation No. 91641
- Neuroablation for Pain Management No. 91647
- Platelet Rich Plasma/Platelet Rich Fibrin Matrix/Autologous Blood-Derived Products/BMAC No. 91553

I. MEDICAL NECESSITY CRITERIA

Inclusions:

A. The following procedures are considered medically necessary when performed in accordance with applicable TurningPoint clinical criteria, where required:
1. Autologous chondrocyte implantation (e.g., *Carticel*®) for the repair of articular cartilage defects
2. Knee resurfacing procedures (e.g., MAKOplasty®)
3. Partial or total knee arthroplasty (knee replacement)

B. Conventional thermal or cooled genicular nerve radiofrequency ablation (RFA) for treatment of knee pain associated with osteoarthritis of the knee may be considered medically necessary when **ALL** of the following criteria are met:

1. Documented symptomatic knee osteoarthritis confirmed by imaging demonstrating Kellgren–Lawrence grade II–IV disease
2. Moderate to severe **chronic** knee pain that results in functional impairment
3. Failure of at least 6 months of conservative management, which may include but is not limited to:
    a. Physical therapy
    b. Pharmacologic management (e.g., NSAIDs)
    c. Intra-articular injections (e.g., corticosteroids)
4. The individual:
    a. Is not an appropriate candidate for partial or total knee arthroplasty; or
    b. Elects to defer arthroplasty
5. Diagnostic confirmation with a genicular nerve block demonstrating:
    a. At least 50% pain relief lasting a minimum of 24 hours

Limitations:

A. The MAKO® device may also be used for computer-assisted navigation; as with other similar devices, this is not separately payable (See Medical Policy Computer Assisted Surgical Navigation No. 91641).

Exclusions:

A. Not Medically Necessary

The following are considered not medically necessary for the treatment of knee pain associated with osteoarthritis:

1. Pulsed radiofrequency ablation (RFA) of the genicular nerves
2. Repeat genicular nerve radiofrequency ablation when there is **no** documented clinically meaningful benefit following a prior ablation
3. Genicular nerve radiofrequency ablation in individuals with end-stage knee osteoarthritis when knee arthroplasty is imminently planned

B. Not Medically Necessary as Considered Experimental and Investigational

The following treatments for osteoarthritis of the knee are considered experimental, investigational, or unproven due to insufficient evidence demonstrating clinically meaningful benefit and long-term safety:

1. Autologous and allogeneic Biologic injectable therapies, including but not limited to:
    a. Adipose-derived regenerative cell therapies (e.g., stromal vascular fraction, microfragmented adipose tissue [Lipogems®])
    b. Bone marrow aspirate concentrate (BMAC)
    c. Platelet-rich plasma (PRP)
    d. Mesenchymal stem/stromal cell injections
2. Peripheral nerve–targeted neuromodulation including:

    a. Transcutaneous electrical nerve stimulation (TENS)
3. Neuroablative therapies, including:
    a. Cryotherapy or cryoneurolysis of peripheral nerves (e.g., Iovera®)
4. Mechanical / External Off-Loading Interventions such as:
    a. Biomechanical shoe-based devices/footwear (e.g., AposHealth®)
    b. Orthotic interventions (e.g., Custom-made lateral wedge insoles)
5. Genicular artery embolization (GAE)
6. Medial knee implanted shock absorber devices (e.g., MISHA®)
7. Synthetic cartilage repair implants (e.g., CartiHeal Agili-C®)
8. Low-Level Laser Therapy (LLLT)
9. Prolotherapy

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
NCD - Prolotherapy, Joint Sclerotherapy, and Ligamentous Injections with Sclerosing Agents (150.7)	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	LCD - Platelet Rich Plasma Injections for Non-Wound Injections (L39023)
First Coast Service Options, Inc.	LCD - Platelet Rich Plasma (L39071) LCD - Peripheral Nerve Blocks (L33933)
Wellpoint Federal (formerly National Government Services, Inc.)	LCD - Platelet Rich Plasma (L38937) LCD - Peripheral Nerve Blocks (L36850)
Noridian Healthcare Solutions	LCD - Platelet Rich Plasma Injections for Non-Wound Injections (L39058)
Novitas Solutions, Inc.	LCD - Platelet Rich Plasma (L39068)
Palmetto GBA	LCD - Platelet Rich Plasma (L38745)

WPS Insurance Corporation	None Identified

III. BACKGROUND

Osteoarthritis (OA) is a degenerative joint disorder characterized by progressive deterioration of articular cartilage, subchondral bone remodeling, and variable degrees of synovial inflammation. Clinical symptoms of osteoarthritis of the knee commonly include activity-related joint pain, stiffness, swelling, and progressive functional limitation. Symptom severity often worsens over time and may ultimately result in disability (Hsu and Siwiec, 2023).

Radiographic severity of knee osteoarthritis is commonly classified using the Kellgren–Lawrence (KL) grading system, in which grades II–IV represent definitive to severe disease, characterized by osteophyte formation, joint-space narrowing, subchondral sclerosis, and, in advanced cases, joint deformity. This grading system is widely used to define disease severity and eligibility criteria in interventional clinical trials and professional society guidelines (Kellgren & Lawrence, 1957; Hunter et al., 2022).

Contemporary clinical practice guidelines emphasize core non-pharmacologic management as a foundation of knee OA, including structured therapeutic exercise, patient education and self-management strategies, and weight management when appropriate. Pharmacologic therapies are generally recommended as adjunctive treatments to support pain control and facilitate participation in physical activity and rehabilitation programs (Bannuru et al., 2019; National Institute for Health and Care Excellence [NICE], 2022).

Biologic Injectable Therapies for Knee Osteoarthritis
Biologic injectable therapies, including bone marrow aspirate concentrate (BMAC), mesenchymal stem/stromal cell (MSC)-based products, and platelet-rich plasma (PRP), have been investigated for the treatment of osteoarthritis due to proposed regenerative and anti-inflammatory effects. Despite growing clinical interest, the evidence base remains heterogeneous and methodologically limited, with substantial variability in product composition, preparation methods, dosing protocols, patient selection, comparators, and outcome measures.

Stem Cell–Based and Cell-Derived Therapies
Bone marrow aspirate concentrate (BMAC) is an autologous biologic derived from bone marrow, most commonly aspirated from the iliac crest and processed via centrifugation to concentrate cellular components, including low-frequency mesenchymal stromal cells and growth factors. Adipose-derived cellular therapies (e.g., stromal vascular fraction [SVF], microfragmented adipose tissue [MFAT] such as *Lipogems*®) involve minimally invasive fat harvesting followed by mechanical or enzymatic processing to yield cellular products containing MSCs and other bioactive components. These therapies are typically considered in patients who remain symptomatic despite conservative management and who may be poor candidates for or wish to defer joint replacement. Clinical evidence supporting these therapies is limited and inconsistent. A phase 2b, randomized, double-blind, placebo-controlled trial evaluating a single intra-articular injection of autologous adipose-derived ex vivo expanded mesenchymal stromal cells (ADSCs) in patients with mild-to-moderate knee OA found no significant difference

compared with placebo in pain, function, quality of life, or cartilage thickness through 12 months, and no difference in the proportion of OARSI/OMERACT strict responders at 6 months (Pers et al., 2025).

Systematic reviews of randomized controlled trials further indicate that while BMAC and other cell-based therapies may show improvements in pain and function compared with baseline, these benefits frequently do not exceed minimal clinically important difference (MCID) thresholds, and comparative superiority over standard intra-articular therapies (e.g., hyaluronic acid) has not been consistently demonstrated. Recent double-blind RCTs comparing BMAC with hyaluronic acid reported statistically greater pain reduction favoring BMAC at select time points—primarily in early OA (KL I–II)—but differences often failed to meet MCID thresholds and did not demonstrate disease modification (Boffa et al., 2022). A 2024 systematic review of eight RCTs (~900 patients) similarly found no clinically meaningful superiority of BMAC over other injectables when MCID thresholds were applied, and longer-term observational studies were limited by small sample sizes and lack of controls (Han et al., 2024; Kon et al., 2023).

Collectively, updated evidence supports at most short-term symptomatic improvement for some cell-based therapies but does not confirm durable benefit, disease modification, or consistent clinical superiority, reinforcing their investigational status for routine knee OA management.

Major professional societies advise against routine use of stem cell–based therapies for knee OA. The American College of Rheumatology/Arthritis Foundation (ACR/AF) conditionally recommends against stem cell injections for knee and hip OA due to insufficient evidence and lack of standardization (Kolasinski et al., 2019). The Osteoarthritis Research Society International (OARSI) strongly recommends against intra-articular stem cell therapies for knee, hip, and polyarticular OA, citing very low-quality evidence and non-standardized formulations (Bannuru et al., 2019). Similarly, the American Association of Hip and Knee Surgeons (AAHKS) states that biologic injections including PRP, BMAC, and stem cell–based therapies, cannot be recommended for routine treatment of advanced hip or knee OA outside of clinical trials due to inconsistent benefit and substantial variability in preparation and administration (AAHKS, 2025).

Platelet-Rich Plasma (PRP)
Among biologic injectables, PRP is the most extensively studied for knee OA. Recent systematic reviews and meta-analyses of randomized controlled trials indicate that PRP provides pain relief comparable to hyaluronic acid or corticosteroid injections, with greater functional improvement in some analyses, particularly in early-stage OA and when administered using higher platelet concentrations and multi-injection regimens (Pelluri et al., 2024; Wang & Yao, 2025). A large 2025 meta-analysis of 28 RCTs (3,246 patients) demonstrated that PRP achieved pain relief comparable to HA but greater functional improvement, with a dose-response relationship favoring three to five injection protocols over single-injection regimens (Khalilizad et al., 2025; Wang & Yao, 2025).

However, long-term durability beyond 12–24 months remains uncertain, and substantial heterogeneity persists across PRP studies with respect to preparation methods, leukocyte content, dosing frequency, and outcome assessment. As a result, professional society guidance remains cautious, and concerns regarding lack of standardization and

limited long-term data continue to preclude routine endorsement of PRP for knee OA management.

Biomechanical Shoe-Based Device (AposHealth®)
AposHealth® (Apos®) is a customized, noninvasive biomechanical shoe-based device marketed for the treatment of knee osteoarthritis (OA) and other musculoskeletal conditions. The system consists of footwear with adjustable external pods affixed to the outsole, which are calibrated by a physical therapist using computerized gait analysis. The pods are intended to modify the center of pressure during ambulation, introduce controlled perturbation, and alter gait mechanics with the goal of reducing joint loading and improving pain and function.

The published clinical evidence supporting AposHealth® consists predominantly of retrospective case series, prospective cohort studies, and nonrandomized trials, with limited randomized controlled trial (RCT) data. Observational studies have reported short- to mid-term improvements in pain, function (e.g., WOMAC, SF-36), and gait parameters, as well as reductions in use of analgesics and other nonpharmacologic therapies in some individuals with knee OA (Debbi et al., 2019; Shema-Shiratzky et al., 2017; Drew et al., 2022; Greene et al., 2023).

More recent retrospective analyses have evaluated progression to total knee replacement (TKR) following initiation of biomechanical gait therapy, reporting that a majority of treated patients did not undergo TKR over follow-up periods ranging from two to five years (Drew et al., 2022; Greene et al., 2023; Shema-Shiratzky et al., 2023). However, these studies are limited by retrospective design, absence of control groups, reliance on self-reported outcomes, inconsistent osteoarthritis confirmation methods, and limited information regarding device adherence and adjustment protocols. Consequently, these findings do not establish causality, disease modification, or true avoidance of surgical intervention.

Evidence from randomized trials remains limited. A 24-week randomized controlled trial comparing biomechanical footwear therapy with control footwear demonstrated statistically greater improvements in WOMAC pain and function scores in the intervention group; however, the clinical significance of these differences was uncertain. Noted limitations included lack of participant blinding, differences in shoe appearance, longer daily wear time in the intervention group, allowance of concomitant analgesic use, and absence of long-term outcome data (Reichenbach et al., 2020).
Although some studies suggest that AposHealth® may provide short-term symptomatic improvement in selected individuals, there is insufficient high-quality comparative evidence demonstrating durable, clinically meaningful benefit over established non-surgical treatments such as structured physical therapy, bracing or orthoses, or intra-articular injections.

Current professional society guidelines for knee osteoarthritis do not recommend biomechanical shoe-based devices such as AposHealth® for routine management. The American Academy of Orthopaedic Surgeons (AAOS) does not include or endorse perturbation-based biomechanical footwear in its evidence-based guideline for non-arthroplasty management of knee OA, citing insufficient evidence (AAOS, 2021). Similarly, the American College of Rheumatology and Arthritis Foundation (ACR/AF) guideline emphasizes exercise therapy, weight management, NSAIDs, and selected intra-articular injections and does not recommend customized biomechanical footwear

devices (Kolasinski et al., 2019). Osteoarthritis Research Society International (OARSI) guidelines also do not support biomechanical footwear beyond standard orthoses, citing lack of robust comparative and long-term data (Bannuru et al., 2019).

At present, there is insufficient evidence in the peer-reviewed medical literature to support the clinical efficacy or long-term benefit of AposHealth® for treatment of knee osteoarthritis. Available data are limited by methodological weaknesses, lack of appropriate comparators, and uncertainty regarding durability of effect. Consistent with current professional society guidance, biomechanical shoe-based devices remain investigational and are not recommended for routine clinical use in knee OA.

Cryotherapy / Cryoneurolysis
Cryotherapy-based interventions for knee osteoarthritis (OA) include local cryotherapy (e.g., ice or cooling devices) and cryoneurolysis, a minimally invasive technique that applies targeted freezing to peripheral sensory nerves—most commonly the anterior femoral cutaneous nerve or the infrapatellar branch of the saphenous nerve—to temporarily disrupt pain signal transmission. Cryoneurolysis devices (e.g., Iovera®) are intended to provide temporary analgesia without permanent nerve damage and do not address underlying joint degeneration.

Evidence from randomized controlled trials and systematic reviews indicates that cryoneurolysis may provide modest, short-term pain relief in some patients, but benefits are inconsistent, of low certainty, and of uncertain clinical relevance. In a randomized, double-blind, sham-controlled trial of 87 patients with chronic knee OA, cryoneurolysis did not demonstrate a clinically meaningful reduction in pain at the primary 14-day endpoint compared with sham treatment. Although a statistically greater reduction in pain was observed at 6-month follow-up, the magnitude of effect raised uncertainty regarding clinical significance, and both groups experienced notable short-term improvement, suggesting possible placebo or nonspecific effects (Nygaard et al., 2025).

Broader evidence syntheses consistently rate the certainty of evidence for cryoneurolysis as low to very low. A large 2025 systematic review and meta-analysis of 25 randomized controlled trials evaluating genicular nerve–targeting interventions—including radiofrequency ablation, genicular nerve blocks, and cryoneurolysis—found minimal short-term effects of cryoneurolysis on pain and function, no sustained benefit, and no consistent advantage over sham or placebo. The authors concluded that routine use of these interventions for knee OA is not supported by current evidence (Almeida et al., 2025). Similarly, a 2025 meta-analysis of seven randomized trials reported modest short-term pain reductions with cryoneurolysis but variable functional outcomes and no consistent improvements in quality of life, with interpretation limited by heterogeneity and small sample sizes (Antunes Júnior et al., 2025).

Evidence from postoperative settings further underscores limited durability. An updated Cochrane systematic review of 22 trials evaluating cryotherapy following total knee replacement found only small, short-term reductions in pain and swelling, with low to very low certainty of evidence and no consistent benefits for function, analgesic use, quality of life, or other patient-important outcomes (Aggarwal et al., 2025).

Major professional society guidelines do not endorse cryoneurolysis or cryotherapy as routine treatment for knee osteoarthritis. The Osteoarthritis Research Society

International (OARSI) does not recommend genicular nerve–targeting interventions due to low-certainty evidence and lack of sustained benefit. The American College of Rheumatology/Arthritis Foundation does not include cryoneurolysis among recommended OA therapies, emphasizing exercise, pharmacologic management, and selected intra-articular injections instead (Kolasinski et al., 2019). The American Academy of Orthopaedic Surgeons similarly does not support routine use of nerve-ablative or cryogenic techniques for knee OA due to insufficient high-quality evidence (AAOS, 2021).

Overall, although cryoneurolysis may provide temporary pain relief in selected individuals, available evidence does not demonstrate consistent, durable, or clinically meaningful benefit for pain, function, or quality of life. Consistent with current professional society guidance, cryoneurolysis is considered experimental, investigational, or unproven for routine management of knee osteoarthritis.

Custom Made Lateral Wedge Insoles

Custom-made lateral wedge insoles are orthotic devices designed to alter lower-limb biomechanics by reducing the knee adduction moment and unloading the medial tibiofemoral compartment. They may be fabricated with or without additional arch support and are primarily proposed for individuals with medial compartment knee osteoarthritis (KOA), particularly those with concomitant foot pronation. The intent is symptom relief through mechanical load redistribution rather than disease modification.

The clinical evidence supporting lateral wedge insoles for knee OA is mixed and generally limited, with reported benefits typically modest, short-term, and highly dependent on patient selection. In a randomized crossover study involving patients with medial tibiofemoral knee OA and pronated feet, lateral wedge insoles combined with custom arch support were associated with greater functional improvement and fewer adverse effects compared with lateral wedge insoles alone. Although both interventions improved pain and function from baseline, the addition of arch support resulted in better stair-climbing performance and higher patient preference, suggesting a potential role in a narrow subgroup. However, the authors emphasized the preliminary nature of the findings and the need for larger, longer-term trials (Hunt et al., 2017).

Broader evidence syntheses report inconsistent findings. A systematic review evaluating footwear and shoe inserts for lower-extremity osteoarthritis found that while some smaller studies suggested short-term pain relief with lateral wedge or shock-absorbing insoles, larger randomized controlled trials generally showed no significant advantage over flat or neutral insoles. The review concluded that high-quality evidence supporting durable benefit is lacking, and any effectiveness appears limited to select patient subsets (Wagner & Luna, 2018).

Professional society guidelines do not recommend lateral wedge insoles for routine management of knee osteoarthritis. The American College of Rheumatology/Arthritis Foundation conditionally recommends against their use due to limited and inconsistent clinical benefit (Kolasinski et al., 2019). The American Academy of Orthopaedic Surgeons does not recommend lateral wedge insoles in its knee OA clinical practice guideline, citing insufficient evidence of sustained or clinically meaningful improvement (American Academy of Orthopaedic Surgeons, 2021). Similarly, Osteoarthritis Research Society International guidelines emphasize exercise-based management and

pharmacologic therapies and do not support lateral wedge insoles as a recommended intervention for knee OA (Bannuru et al., 2019).

Overall, although custom-made lateral wedge insoles—particularly when combined with arch support—may provide short-term functional improvement in selected individuals with medial compartment knee osteoarthritis and pronated feet, available evidence is inconsistent and of limited quality. Benefits have not been shown to be durable or generalizable across broader KOA populations. Consistent with current professional society guidance, custom-made lateral wedge insoles are considered experimental, investigational, or unproven for routine treatment of knee osteoarthritis.

Genicular Artery Embolization (GAE)
Genicular artery embolization (GAE) is a minimally invasive, image-guided interventional radiology procedure intended to reduce pain associated with knee osteoarthritis (OA) by targeting synovial hypervascularity. The procedure involves catheter-based embolization of pathologically hyperemic genicular arterial branches supplying the synovium, with the proposed goals of reducing inflammation, neovascularization, and nociceptive signaling. GAE is typically performed on an outpatient basis under moderate sedation (Ferreira-Dos-Santos et al., 2021; Kim et al., 2018). Procedural technique, including target vessel selection and embolic materials, has been described in detail in technical reviews (Sterbis & Casadaban, 2023).

Initial prospective and retrospective observational studies suggested that GAE may be associated with improvements in pain and function in patients with mild-to-moderate knee OA, with an acceptable short-term safety profile. These early studies, including orthopedic-focused feasibility reports, demonstrated symptom improvement following GAE but were limited by lack of control groups, small sample sizes, heterogeneous embolic agents, and variable outcome measures (Padia et al., 2021; Torkian et al., 2021). As a result, early evidence was insufficient to establish long-term outcomes or comparative effectiveness.

More recent evidence incorporating randomized data highlights continued uncertainty regarding clinical effectiveness. A meta-analysis of randomized controlled trials and prospective studies found that although open-label investigations reported clinically meaningful improvements in pain and function, evidence from sham-controlled trials was mixed, with some studies demonstrating no significant benefit over placebo at intermediate follow-up. Overall certainty of evidence was limited due to study heterogeneity, short follow-up duration, and inconsistent comparative benefit across trials (Abussa & Jeremic, 2025).

High-quality, sham-controlled randomized trials are currently underway to address existing evidence gaps. For example, the GENESIS-2 trial is a double-blind, randomized, sham-controlled study designed to evaluate the efficacy and safety of GAE for knee OA; however, outcome data are not yet available to inform routine clinical use (Little et al., 2023).

Professional society guidance reflects the investigational status of GAE. A consensus statement from the Society of Interventional Radiology (SIR) notes that although preliminary findings suggest GAE may reduce OA-related knee pain, the current evidence base is insufficient to support routine clinical use, emphasizing the need for additional high-quality, sham-controlled randomized trials to better define safety,

durability, optimal patient selection, and GAE's role within the knee osteoarthritis treatment algorithm (Society of Interventional Radiology, 2024).

In contrast, pain-specialty consensus guidance from the American Society of Pain and Neuroscience (ASPN) describes GAE as a potential option for selected patients with refractory knee pain, acknowledging promising early results but also recognizing the limited availability of high-quality comparative evidence (Hunter et al., 2022). This contrast reflects differing perspectives between professional society guidance documents regarding the clinical role of genicular artery embolization.

GAE represents a promising symptom-modifying intervention for select patients with knee osteoarthritis; however, current evidence demonstrates heterogeneous, largely short-term benefits with limited durability and uncertain comparative effectiveness. Early feasibility and safety studies, including orthopedic and interventional perspectives, support further investigation (Padia et al., 2021), but the absence of consistent sham-controlled efficacy, limited long-term data, and mixed guideline endorsement support continued classification of GAE as investigational. Routine clinical use is not supported pending further high-quality randomized evidence demonstrating durable benefit and clear clinical value.

Low-level laser therapy (LLLT)
Low-level laser therapy (LLLT), also referred to as photobiomodulation (PBM), is a noninvasive electrotherapeutic intervention that delivers low-intensity red or infrared light to periarticular tissues with the intent of reducing pain and inflammation and promoting tissue repair. While preclinical studies suggest potential modulation of inflammatory mediators and cellular processes, the clinical mechanisms by which LLLT improves outcomes in knee osteoarthritis (KOA) remain incompletely established (Zhao et al., 2025).

Evidence from recent systematic reviews and meta-analyses suggests that LLLT may provide short-term pain reduction, particularly when used as an adjunct to exercise therapy; however, consistent improvements in physical function, muscle strength, or range of motion have not been demonstrated, and the overall certainty of evidence is low to very low. A 2023 systematic review of randomized controlled trials found statistically significant short-term pain reduction with LLLT plus exercise but no meaningful benefit for non-pain outcomes compared with placebo (Malik et al., 2023). A subsequent meta-analysis reported moderate reductions in pain at rest but no significant improvement in functional performance measures, with conclusions limited by high risk of bias and small study sizes (Oliveira et al., 2024).

Major professional society guidelines do not recommend LLLT for routine management of knee osteoarthritis. The American College of Rheumatology/Arthritis Foundation conditionally recommends against laser therapy for knee OA due to inconsistent benefit and limited quality evidence (Kolasinski et al., 2019). The American Academy of Orthopaedic Surgeons similarly does not recommend electrotherapeutic modalities, including LLLT, citing insufficient and inconsistent evidence of clinically meaningful outcomes (American Academy of Orthopaedic Surgeons, 2021). Osteoarthritis Research Society International guidelines emphasize exercise-based and pharmacologic therapies and do not support laser therapy for KOA due to weak and heterogeneous evidence (Bannuru et al., 2019). The National Institute for Health and Care Excellence advises

against offering electrotherapy treatments, including laser therapy, for osteoarthritis because of insufficient demonstrated benefit (NICE, 2022).

Overall, although LLLT may provide short-term symptomatic pain relief in selected patients, the available evidence does not demonstrate durable, clinically meaningful improvements in function or structural outcomes. Consistent with current professional society guidance, low-level laser therapy is considered experimental, investigational, or unproven for routine treatment of knee osteoarthritis.

Medial Knee Implanted Shock Absorber (MISHA®)
The medial knee implanted shock absorber (MISHA®) is a surgically implanted, extra-articular load-absorbing device designed to reduce medial compartment joint loading in patients with symptomatic medial tibiofemoral knee osteoarthritis who have failed conservative therapy and are not yet candidates for arthroplasty. The device is implanted subcutaneously along the medial aspect of the knee, spanning the distal femur to the proximal tibia, where it functions to offload the medial compartment during weight-bearing and gait without altering native joint anatomy. Unlike high tibial osteotomy (HTO), MISHA does not involve bone cutting or joint surface modification and preserves future surgical options, including knee arthroplasty.

Evidence supporting MISHA and related implantable shock absorber (ISA) devices remains limited and primarily nonrandomized. A PRISMA-based systematic review of 17 studies involving approximately 400 patients found that ISA and knee joint distraction (KJD) were associated with short- to mid-term improvements in pain and function; however, overall certainty of evidence was low to moderate due to small sample sizes, heterogeneous study designs, and overlapping cohorts. ISA studies demonstrated improvements in validated pain and functional scores and higher two-year arthroplasty-free survival compared with HTO or nonoperative care, while KJD showed arthroplasty-free survival rates of approximately 75%–85% at 5–9 years in selected cohorts. The authors concluded that while these interventions may delay arthroplasty in carefully selected patients, larger, standardized randomized trials are needed before widespread adoption (Anzillotti et al., 2026).

Additional evidence includes a pooled analysis of three prospective, multicenter, single-arm trials in 171 working-age patients with mild to moderate medial compartment knee osteoarthritis, which reported substantial improvements in WOMAC pain and function and arthroplasty-free survival of approximately 90% at three years and 85% at five years. Interpretation of these findings is limited by the lack of randomized comparators (Gomoll et al., 2023). A prospective cohort study with a propensity-matched historical control demonstrated superior composite outcomes for ISA compared with HTO at 24 months, including faster recovery and earlier return to full weight-bearing; however, conclusions are constrained by the nonrandomized design and use of historical controls (Diduch et al., 2023).

At present, major professional society guidelines do not recommend implantable medial knee shock absorbers for routine management of knee osteoarthritis. Guidelines from the American Academy of Orthopaedic Surgeons, the American College of Rheumatology/Arthritis Foundation, and the Osteoarthritis Research Society International emphasize exercise-based, pharmacologic, and selected intra-articular therapies and do not include implantable load-absorbing devices due to insufficient high-quality randomized comparative evidence. As a result, MISHA and related ISA

technologies are considered emerging or investigational pending further evidence demonstrating durable benefit, long-term safety, and comparative effectiveness.

Osteochondral Implant (e.g.; CartiHeal Agili-C® (Smith+Nephew))
CartiHeal Agili-C® is a resorbable, biphasic osteochondral implant composed of calcium carbonate–based aragonite, designed for the treatment of focal articular cartilage and osteochondral defects of the knee. The implant supports infiltration of bone marrow–derived cells and regeneration of both subchondral bone and overlying cartilage. Agili-C is intended as a joint-preserving, lesion-specific intervention and is not designed as a disease-modifying therapy for generalized knee osteoarthritis (OA) (U.S. Food and Drug Administration [FDA], 2022).

Evidence supporting Agili-C primarily derives from controlled clinical trials in patients with discrete cartilage or osteochondral lesions, including select individuals with mild-to-moderate degenerative changes. The pivotal randomized controlled trial comparing Agili-C with standard cartilage repair techniques (microfracture or mosaicplasty) demonstrated statistically and clinically meaningful improvements in pain and function at two years, with durability reported in extension studies; however, outcomes were not evaluated for advanced or diffuse OA (Daniels et al., 2022; Gomoll et al., 2023). Subsequent follow-up and post-approval observational studies support durable lesion-level repair and symptom improvement in appropriately selected patients but do not establish benefit for global OA progression or arthroplasty avoidance in generalized disease (Gomoll et al., 2023).

Contemporary narrative and systematic reviews of cartilage repair technologies consistently categorize Agili-C as a focal osteochondral repair option, appropriate for contained defects and select early OA cases, while emphasizing that available evidence does not support extrapolation to generalized knee OA. Reviews further note that outcomes are highly dependent on patient selection, lesion characteristics, and absence of advanced degenerative disease (Filardo et al., 2023; Makris et al., 2024).

Major professional society guidelines for knee osteoarthritis do not include or recommend Agili-C as a standard OA treatment, reflecting its lesion-specific indication rather than whole-joint disease management. Guidelines from the American Academy of Orthopaedic Surgeons (AAOS), American College of Rheumatology/Arthritis Foundation (ACR/AF), and Osteoarthritis Research Society International (OARSI) emphasize nonpharmacologic and pharmacologic management for knee OA and do not address focal cartilage implants such as Agili-C within OA treatment algorithms (AAOS, 2021; Kolasinski et al., 2019; Bannuru et al., 2019).

Overall, CartiHeal Agili-C® is FDA-approved for focal cartilage and osteochondral knee lesions, including select patients with mild to moderate degenerative changes, but it is not indicated or supported by evidence for routine treatment of generalized knee osteoarthritis. Consistent with regulatory labeling and current professional society guidance, Agili-C is considered experimental, investigational, or unproven for generalized knee OA.

Prolotherapy
Prolotherapy is an injection-based therapy in which an irritant solution, most commonly hypertonic dextrose is injected into periarticular or intra-articular tissues with the goal of stimulating a localized inflammatory response and promoting tissue repair. In knee

osteoarthritis, prolotherapy has been proposed to improve pain and function by inducing ligamentous strengthening or cartilage repair mechanisms. However, treatment protocols vary widely with respect to injectate concentration, injection sites (intra-articular vs periarticular), dosing frequency, and use of imaging guidance.

Evidence from recent systematic reviews and meta-analyses indicates that prolotherapy may provide short-term improvements in pain and function compared with baseline and, in some analyses, compared with placebo or conservative care. However, the certainty of evidence is variable and limited by substantial heterogeneity across studies, including differences in prolotherapy techniques, comparator interventions, outcome measures, and follow-up duration (Rabago et al., 2019; Sit et al., 2022). Although some trials report statistically significant improvements in WOMAC or VAS pain scores, these benefits are inconsistently durable and often do not clearly exceed minimal clinically important difference thresholds.

Methodological limitations commonly identified include small sample sizes, lack of standardized treatment regimens, inconsistent blinding, and risk of performance and detection bias. Consequently, systematic reviewers conclude that while prolotherapy may be associated with temporary symptomatic improvement in select patients, current evidence is insufficient to support routine clinical use or to establish superiority over standard non-surgical OA therapies (Rabago et al., 2019; Sit et al., 2022).

Professional society guidelines do not support prolotherapy as a standard treatment for knee osteoarthritis. The American College of Rheumatology/Arthritis Foundation conditionally recommends against prolotherapy for knee OA due to limited and inconsistent evidence and uncertainty regarding clinically meaningful benefit (Kolasinski et al., 2019). Similarly, the American Academy of Orthopaedic Surgeons does not recommend prolotherapy in its knee OA clinical practice guideline, emphasizing reliance on treatments with reproducible evidence of benefit (AAOS, 2021). The Osteoarthritis Research Society International also does not include prolotherapy among recommended non-surgical treatments, citing insufficient high-quality supporting evidence (Bannuru et al., 2019).

Overall, although prolotherapy may offer short-term pain relief in some individuals with knee osteoarthritis, available evidence is heterogeneous and does not demonstrate consistent, durable, or clinically meaningful benefit. Consistent with ACR/AF, AAOS, and OARSI guidance, prolotherapy is considered experimental, investigational, or unproven for routine treatment of knee osteoarthritis.

Transcutaneous Electrical Stimulation (TENS)
Transcutaneous electrical nerve stimulation (TENS) is an electrotherapeutic modality that delivers cutaneous electrical stimulation to peripheral nerves with the intent of reducing pain. Multiple related modalities, including conventional TENS, interferential current, and neuromuscular electrical stimulation (NMES), have been proposed for symptom management in knee osteoarthritis (OA); however, evidence supporting clinically meaningful and durable benefits remain inconsistent.

Recent high-quality randomized evidence does not support clinical efficacy. In a 2025 randomized, placebo-controlled clinical trial involving 100 individuals with knee OA, NMES delivered via TENS, interferential current, or Aussie current over four weeks did not result in clinically meaningful improvements in pain, disability, or functional outcomes

compared with placebo stimulation. Although a statistically significant interaction was observed for WOMAC disability scores, improvements were also present in the placebo group, and no electrotherapy modality demonstrated superiority, suggesting nonspecific or placebo effects rather than treatment-specific benefit (de Almeida et al., 2025).

Earlier trials and systematic reviews similarly report variable short-term pain outcomes, frequent methodological limitations (including inadequate blinding and heterogeneous protocols), and lack of sustained clinical benefit, contributing to inconsistent adoption of TENS in clinical practice (Bennell et al., 2017; American Academy of Orthopaedic Surgeons [AAOS], 2021).

Major professional society guidelines consistently advise against routine use of electrotherapy for knee OA. The National Institute for Health and Care Excellence (NICE) recommends not offering electrotherapy treatments, including TENS, due to insufficient evidence of benefit (NICE, 2022). The American College of Rheumatology/Arthritis Foundation (ACR/AF) strongly recommends against TENS for knee OA, citing lack of clinically meaningful benefit and low-quality supporting evidence (Kolasinski et al., 2019). The AAOS does not recommend TENS in its knee OA clinical practice guideline, noting inconsistent results and absence of durable functional improvement (AAOS, 2021). Similarly, Osteoarthritis Research Society International (OARSI) guidelines emphasize exercise-based therapies and do not support electrotherapeutic modalities such as TENS because of limited efficacy data (Bannuru et al., 2019).

Overall, current randomized clinical trial evidence and major professional society guidance do not support the use of TENS or related electrotherapy modalities for the management of knee osteoarthritis. Available data fail to demonstrate benefit beyond placebo or durable clinical improvement. Consistent with ACR/AF, NICE, AAOS, and OARSI recommendations, TENS is considered experimental, investigational, or unproven for routine knee OA management.

Radiofrequency Ablation (RFA)/Cooled RFA/ Genicular Nerve RFA (e.g., Coolief®)
Genicular nerve radiofrequency ablation (RFA) is a minimally invasive procedure intended to reduce pain associated with knee osteoarthritis (KOA) by disrupting afferent sensory nerve transmission from the knee joint. Conventional thermal RFA delivers continuous heat at approximately 70–90 °C, resulting in localized thermocoagulation of sensory nerve fibers, while cooled RFA operates at lower temperatures (~60 °C) and creates larger, more uniform lesions through heat dispersion (Gupta et al., 2017; Lee & Epelboym, 2023; Alomari & Bhatia, 2024). Pulsed RFA, which operates at approximately 42 °C without causing nerve destruction, is mechanistically distinct and has demonstrated inferior clinical effectiveness compared with thermal approaches. Advances in probe design and electrode configurations allow broader ablation zones and simultaneous targeting of multiple nerves. Standard targets include the superomedial (SM), superolateral (SL), and inferomedial (IM) genicular nerves, which are primarily sensory branches.

Genicular nerve RFA is not intended to replace definitive surgical management in patients who are appropriate and imminent candidates for knee arthroplasty. To optimize patient selection and reduce exposure to ineffective intervention, a diagnostic genicular nerve block (GNB) is used as a required prognostic step prior to genicular nerve ablation. A clinically meaningful response—commonly defined as ≥50% pain relief

following anesthetic injection—has been associated with a greater likelihood of subsequent RFA benefit and is therefore used to identify appropriate candidates (Gupta et al., 2017; Anwar et al., 2025).

Recent meta-analyses of randomized controlled trials demonstrate that genicular nerve RFA may provide short-term pain reduction in a subset of patients with KOA, with response rates of approximately 30%–74% at 6 months. However, overall certainty of evidence is low to very low, durability beyond 6–12 months is inconsistent, and functional improvements are variable. Comparative analyses yield contradictory findings, with some reviews suggesting short-term benefit over intra-articular corticosteroid or hyaluronic acid injections, while others show no significant differences compared with intra-articular therapies or genicular artery embolization (Almeida et al., 2025; Antunes Júnior et al., 2025).

A large 2025 systematic review and meta-analysis of sham-controlled RCTs (8 trials; n=627) found that genicular nerve ablative procedures, predominantly conventional monopolar RFA, produced statistically and clinically significant reductions in pain scores and improvements in WOMAC functional outcomes at 12–24 weeks compared with sham procedures. Trial sequential analysis confirmed that evidence for short-term pain and functional improvement was conclusive, although heterogeneity and limited long-term data were noted (Barreto et al., 2025).

Comparisons among radiofrequency ablation modalities indicate that conventional thermal RFA is superior to pulsed RFA, a finding consistent with outcomes observed in other joints. Cooled RFA may offer modest incremental benefit through the creation of larger and more uniform lesions; however, randomized trials have not demonstrated consistently meaningful clinical superiority over conventional thermal RFA, and higher cost and resource utilization remain important considerations (Hunter et al., 2022; Almeida et al., 2025). Additional randomized controlled trials comparing cooled versus conventional RFA, including the multicenter COCOGEN trial, demonstrate that both modalities are associated with clinically meaningful pain reduction and functional improvement, with no clear superiority of one technique over the other at intermediate follow-up. (Belba et al., 2025).

Orthopedic and rheumatologic organizations—including NICE, AAOS, and the ACR/Arthritis Foundation—acknowledge potential short-term benefit but emphasize heterogeneity of techniques, inconsistent findings, and limited long-term or comparative evidence (NICE, 2023; Brophy & Fillingham, 2022; Kolasinski et al., 2020). In contrast, pain-specialty societies such as the American Society of Pain and Neuroscience (ASPN) and the World Institute of Pain (WIP) provide stronger consensus support for thermal or cooled genicular nerve RFA in therapy-resistant KOA, particularly in patients with moderate to severe pain and Kellgren–Lawrence grade II–IV disease (Hunter et al., 2022; Vanneste et al., 2025).

When synthesized across randomized trials, meta-analyses, and guideline positions, genicular nerve RFA demonstrates potential short-term pain relief in carefully selected patients, but benefits are modest, and variably durable; however, evidence from sham-controlled trials demonstrates clinically meaningful short-term improvement in well-selected patients. Accordingly, genicular nerve RFA is most appropriately utilized as a selective, criteria-based intervention rather than routine therapy, with candidate selection informed by response to diagnostic nerve block.

Genicular Nerve Block (GNB)
Genicular nerve radiofrequency ablation (RFA), including conventional thermal and cooled techniques, is a minimally invasive procedure intended to reduce pain associated with knee osteoarthritis (KOA) by disrupting afferent sensory nerve transmission from the knee joint. The procedure targets primarily sensory branches, most commonly the superomedial, superolateral, and inferomedial genicular nerves, which innervate the anterior knee capsule. Conventional thermal RFA delivers continuous heat typically between 70–90 °C, producing localized thermocoagulation of nerve fibers, whereas cooled RFA circulates internal coolant to maintain probe temperatures of approximately 60 °C while generating larger and more uniform lesions through heat dispersion. Pulsed RFA is mechanistically distinct and has demonstrated inferior and less durable clinical outcomes compared with thermal approaches (Lee et al., 2021; Barreto et al., 2025).

Patient selection is a key determinant of clinical response to genicular nerve ablation. Contemporary randomized controlled trials consistently incorporate diagnostic genicular nerve block (GNB) as a required prognostic step prior to radiofrequency ablation to confirm genicular-mediated pain and to reduce expose to ineffective intervention. Diagnostic GNB is performed using image-guided injection of local anesthetic adjacent to the targeted genicular nerves, with candidacy for ablation typically defined by achievement of ≥50% short-term pain relief, a threshold associate with improved likelihood of subsequent RFA benefit.

The multicenter COCOGEN randomized controlled trial required participants to demonstrate clinically meaningful pain relief following diagnostic genicular nerve block prior to randomization to cooled versus conventional thermal RFA. Among patients with Kellgren–Lawrence grade II–IV KOA or persistent post-arthroplasty knee pain, both ablation techniques produced statistically and clinically meaningful improvements in pain and function, with no consistent superiority of one modality over the other at intermediate or 12-month follow-up (Belba et al., 2024). The authors emphasized block-based enrichment as an important strategy to align treatment with likelihood of benefit.

Similarly, a 2024 double-blind, sham-controlled randomized trial evaluating cooled genicular nerve RFA required confirmation of genicular-mediated pain prior to enrollment. Patients undergoing cooled RFA demonstrated significantly higher responder rates and sustained pain reduction through six months compared with sham procedures, supporting the prognostic value of diagnostic nerve blocks (Kwon et al., 2024). Additional randomized comparative trials evaluating genicular nerve targeting strategies have also incorporated diagnostic block response before ablation, reinforcing its role in contemporary interventional protocols (Guven Kose et al., 2023).

Evidence synthesis from recent sham-controlled randomized trials and meta-analyses indicates that genicular nerve RFA provides statistically and clinically meaningful short-term pain reduction and modest functional improvement, particularly within 3–6 months following treatment. However, treatment effects are heterogeneous, durability beyond 6–12 months is inconsistent, and response rates vary in unselected populations. These limitations underscore the importance of enriched patient selection strategies, including diagnostic genicular nerve block response, to mitigate uncertainty and improve treatment yield (Barreto et al., 2025).

Professional society guidance reflects this evidence base. Pain-focused specialty organizations, including the American Society of Pain and Neuroscience (ASPN) and the World Institute of Pain (WIP), support thermal or cooled genicular nerve RFA for patients with moderate to severe KOA who have failed conservative therapy and recommend the use of diagnostic nerve blocks to confirm nociceptive source and guide candidacy (Lee et al., 2021; Hunter et al., 2022). In contrast, orthopedic and rheumatologic organizations such as NICE, AAOS, and the ACR/Arthritis Foundation acknowledge potential short-term benefit but emphasize heterogeneity of techniques, inconsistent long-term outcomes, and the need for careful patient selection rather than routine use. NICE guidance permits selective use of genicular denervation with appropriate governance and outcome monitoring, noting that most supporting studies utilize diagnostic confirmation prior to ablation (NICE, 2023).

When synthesized across randomized trials, systematic reviews, and guideline positions, genicular nerve RFA demonstrates potential benefit in carefully selected patients, with diagnostic genicular nerve block serving as a key prognostic tool to identify individuals most likely to respond. Accordingly, genicular nerve RFA is most appropriately positioned as a criteria-based intervention contingent on documented positive **diagnostic block response**, rather than as a routine treatment for knee osteoarthritis.

MAKOplasty/ Robotic-Assisted Unicompartmental Knee Arthroplasty
MAKOplasty ® (Stryker) is a robotic-assisted, computer-navigated surgical technique used to facilitate partial resurfacing of the knee (PKR) or unicompartmental knee arthroplasty (UKA). PKR involves selective removal and replacement of diseased articular surfaces with the intent of preserving surrounding healthy bone and soft tissue and potentially reducing surgical trauma compared with conventional techniques.

Early clinical evidence evaluating robotic-assisted UKA primarily focused on technical accuracy. In a pilot study, Lonner et al. (2010) reported improved postoperative alignment of the tibial component relative to preoperative planning in patients undergoing robotic arm–assisted UKA compared with conventional instrumentation; however, the study was limited by small sample size, short-term follow-up, and absence of patient-centered clinical endpoints.

Subsequent comparative observational studies synthesized in a 2019 systematic review reported that robotic-assisted UKA was associated with more accurate implant positioning, fewer alignment outliers, and lower early revision rates compared with conventional unicompartmental knee arthroplasty; however, the authors noted substantial heterogeneity across studies and limited long-term outcome data (Batailler et al., 2019).

A 2019 systematic review published in *The Bone & Joint Journal* evaluated 38 studies of robotic-assisted UKA across multiple robotic platforms, including MAKO (Stryker), Navio, Sculptor RGA, and Acrobot systems. The majority of studies (84%) utilized the MAKO platform. Robotic-assisted UKA demonstrated more accurate and reproducible implant positioning compared with manual techniques, and some studies suggested potential short-term functional improvement. Pooled survivorship was reported at 96% at six years; however, survivorship varied significantly by implant design, and the authors highlighted substantial heterogeneity, limited reporting of implant selection, predominance of non-randomized designs, and insufficient evidence to determine

whether improved alignment translates into superior mid- to long-term clinical outcomes or implant survival (Robinson et al., 2019).

More recently, a 2020 systematic review and meta-analysis of 16 case-control studies involving over 50,000 patients compared robotic-assisted UKA with conventional UKA. The analysis suggested that robotic-assisted UKA was associated with lower overall complication rates and lower revision rates compared with conventional surgery, while no significant differences were observed in non-implant-specific complications. However, the authors emphasized important methodological limitations, including reliance on observational case-control data, heterogeneity in surgical techniques and implant types, potential confounding related to surgeon experience and center volume, and variability in outcome definitions. As a result, the authors concluded that, despite statistically favorable findings, the reliability of the results is limited and that higher-quality comparative studies are needed to confirm clinical benefit (Sun et al., 2021).

Overall, although robotic-assisted UKA, including MAKOplasty, demonstrates improved implant positioning accuracy and may be associated with lower complication or revision rates in observational analyses, the current evidence base is largely derived from non-randomized studies with inherent risk of bias and limited long-term comparative data. There remains insufficient high-quality evidence to establish consistent improvements in long-term functional outcomes, durability, or patient management compared with conventional unicompartmental knee arthroplasty. Accordingly, the safety and effectiveness of MAKOplasty for the treatment of knee osteoarthritis have not been conclusively established.

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
American Academy of Orthopaedic Surgeons (AAOS)	AAOS Management of Osteoarthritis of the knee 2021
American College of Rheumatology (ACR)/Arthritis Foundation (AF)	Osteoarthritis Clinical Practice Guidelines | American College of Rheumatology (2020)
Osteoarthritis Research Society International (OARSI)	OARSI guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis (2019)
National Institute for Health Care and Excellence (NICE)	Osteoarthritis in over 16s: diagnosis and management (2020) Radiofrequency Denervation for Osteoarthritic Knee Pain (2023)
VA/DOD	VA/DoD_Clinical_Practice_Guideline_(CPG)_for_the_Non-surgical_Management_of_Hip_and_Knee_Osteoarthritis (2020)

American Association of Hip and Knee Surgeons	AAHKS-Position-Statement-on-Biologics-2025
World Institute of Pain (WIP)	9. Chronic Knee Pain (2025)
Society of Interventional Radiology	Society of Interventional Radiology Research Reporting Standards for Genicular Artery Embolization (2024) Percutaneous Management of Osteoarthritis in the Knee: Proceedings from the Society of Interventional Radiology Research Consensus Panel - Journal of Vascular and Interventional Radiology (2021)
American Society of Pain and Neuroscience	Consensus Guidelines on Interventional Therapies for Knee Pain (STEP Guidelines) (2022)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration (FDA) Medical Device Databases for the most current information.

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Notice date
AposTherapy System (APOS Medical Assets Ltd., now AposHealth)	K182090	11/16/2018
Erchonia FX-405 (Erchonia Corp.)	K231409	08/11/2023
Theralase TLC-2000 (Theralase Inc.)	K151816	11/19/2015
Lightstream Low Level Laser (Solica Corp.)	K081166	04/03/2009
MISHA Knee System	DEN220033	04/10/2023
Iovera	K243677	12/26/2024

VI. CODING

CPT/HCPCS Codes

27438 Arthroplasty, patella; with prosthesis
27446 Arthroplasty, knee, condyle and plateau; medial OR lateral compartment
27447 Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)

27486 Revision of total knee arthroplasty, with or without allograft; 1 component
27487 Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component

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
27412	Autologous chondrocyte implantation, knee
J7330	Autologous cultured chondrocytes, implant

Codes considered not medically necessary for the indications in the policy:

0232T	Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed
0481T	Injection(s), autologous white blood cell concentrate (autologous protein solution), any site, including image guidance, harvesting and preparation, when performed
0552T	Low-level laser therapy, dynamic photonic and dynamic thermokinetic energies, provided by a physician or other qualified health care professional
0565T	Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; tissue harvesting and cellular implant creation
0566T	Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; injection of cellular implant into knee joint including ultrasound guidance, unilateral
0737T	Xenograft implantation into the articular surface
20999	Unlisted procedure, musculoskeletal system, general
27599	Unlisted procedure, femur or knee
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)
64640	Destruction by neurolytic agent; other peripheral nerve or branch (e.g., lovera)
C8003	Implantation of medial knee extraarticular implantable shock absorber spanning the knee joint from distal femur to proximal tibia, open, includes measurements, positioning and adjustments, with imaging guidance (e.g., fluoroscopy)
C9809	Cryoneurolysis needle (e.g., iovera system), including needle/tip and all

	disposable system components, non-opioid medical device (must be a qualifying medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the caa, 2023)
E0720	Transcutaneous electrical nerve stimulation (TENS) device, two-lead, localized stimulation
E0730	Transcutaneous electrical nerve stimulation (TENS) device, four or more leads, for multiple nerve stimulation
L2999	Lower extremity orthoses, not otherwise specified- *when billed for biomechanical shoe-based devices*
L3649	Orthopedic shoe, modification, addition or transfer, not otherwise specified- *when billed for biomechanical shoe-based devices*
L3000	Foot insert, removable, molded to patient model, UCB type, Berkeley shell, each
M0076	Prolotherapy

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the Priority Health Provider Manual.

To access TurningPoint guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

- **HMO/EPO**: This policy applies to insured HMO/EPO plans.
- **POS**: This policy applies to insured POS plans.
- **PPO**: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO**: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.

- **INDIVIDUAL**: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE**: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN**: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IX. REFERENCES

For references on procedures reviewed according to TurningPoint guidelines see the applicable policy.

Professional and Society Guidelines

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Radiofrequency Ablation (RFA)/Cooled RFA/ Genicular Nerve RFA

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Transcutaneous Electrical Stimulation (TENS)

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SUMMARY OF CHANGES

Deletions:

- Removed a related policy that was retired (Autologous Chondrocyte Implant/Meniscal Allograft).
- Removed outdated references.

Additions:

- New Policy scope section
- New Medical/Professional Society Guidelines section
- New Government Regulations section listing applicable CMS NCDs or LCDs
- New FDA/Regulatory sections
- Added partial and total knee arthroplasty as medically necessary treatment for knee OA when Turning Point criteria is met.

- Added additional not medically necessary treatments, including Transcutaneous electrical nerve stimulation (TENS), Neuroablative therapies (e.g.,cryoneurolysis), biomechanical shoe-based devices, implanted shock absorbers (e.g., MISHA®), synthetic cartilage implants, low-level laser therapy, and prolotherapy.

Changes:

- Genicular nerve radiofrequency ablation moved from not medically necessary to medically necessary when strict criteria are met. Prior Authorization required.
- Updated background and reference sections to reflect recent RCTs, meta-analyses, and consensus guidelines among interventional pain procedures, and emerging technologies.

Clarifications:

- Policy Language was added/removed/changed to better or more fully explain criteria.

Past committee review dates: 02/2010, 02/2011, 02/2012, 02/2013, 02/2014, 02/2015, 02/2016, 02/2017, 02/2018, 02/2019, 02/2020, 05/2020, 08/2020, 08/2021, 08/2022, 08/2023, 11/2023, 05/2024, 05/2025, 05/2026

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The name "Priority Health" and the term "plan" mean Priority Health, Priority Health Managed Benefits, Inc., Priority Health Insurance Company and Priority Health Government Programs, Inc.