Cohere Medicare Advantage Policy - Knee Arthroplasty

Clinical Guidelines for Medical Necessity Review

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This policy was reviewed by the American Association of Orthopaedic Surgeons (AAOS) prior to publication.

Important Notices

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Table of Contents

Medical Necessity Criteria

Service: Knee Arthroplasty

Benefit Category

Not applicable.

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.[1-7]

- Local Coverage Determination. Total Joint Arthroplasty (L36039)
- Local Coverage Determination. Major Joint Replacement (Hip and Knee). (L33618)
- Local Coverage Determination. Total Knee Arthroplasty. (L36575)
- Local Coverage Determination. Total Joint Arthroplasty. (L33456)
- Local Coverage Determination. Lower Extremity Major Joint Replacement (Hip and Knee). (L36007)
- Local Coverage Determination. Total Knee Arthroplasty. (L36577)
- Local Coverage Determination. Total Joint Arthroplasty. (L39911)

Recommended Clinical Approach

Total knee arthroplasty (TKA) is the most commonly performed joint replacement procedure in the United States and is expected to increase in frequency in the coming years. During the operation, the damaged bone and cartilage are replaced with a metal and plastic-based prosthesis that can tolerate repetitive motion and wear as the patient ages. TKA can relieve pain, restore function, and improve a patient's quality of life. It may be performed on one or both knees. Opinions differ as to whether bilateral TKA should be performed simultaneously in the same operation, replacing both knees at once, or staged, wherein the knees are replaced during separate procedures. The majority of staged bilateral procedures occur between six months to a year apart.[8-10] Unicompartmental knee arthroplasty (UKA) is an alternative to TKA, which is used to partially replace the knee for individuals whose disease is limited to only one area. Patellofemoral arthroplasty is another type of partial knee arthroplasty, reserved for patients with isolated patellofemoral

disease. During partial knee replacements, the healthy parts of the knee are retained, potentially resulting in more natural-feeling motion and function. Importantly, the primary risk of a partial knee replacement is the possibility of eventual total knee arthroplasty, should additional joint and cartilage disease develop in other areas of the knee in the future. Revision or repeat TKA is performed when an initial knee arthroplasty fails or has suboptimal results. This may occur when the components of the knee prosthesis loosen or break, or become infected. A prior TKA may also be revised when bone loss progresses around the prosthetic. In some cases, only a portion of the prosthesis will be replaced, while in others, the entire prosthesis must be removed and replaced, often with specialized implants that provide extra durability and support.[11]

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of knee arthroplasty procedures. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, adverse reactions, and infection.

The potential clinical harms of using these criteria may include:

- Adverse effects from delayed or denied treatment, such as increased pain and decreased mobility, can worsen patient outcomes. According to Katz, patients with knee osteoarthritis are more sedentary and have more comorbidities than those patients without knee arthritis, resulting in a 20% higher age-adjusted mortality.[12] Therefore, inadequate management of severe knee conditions due to inappropriate denials can result in comorbidities or mortality.
- Risks with inappropriate surgical procedures include infection, bleeding requiring a transfusion, injury to neurovascular structures, anesthetic risk, and need for repeat or additional procedures due to implant failure, periprosthetic fracture, and ongoing pain. Bin et al. reviewed the literature and reported that the risk for postoperative complications, revisions, and reoperations is highest with knee joint distraction and lowest with unicompartmental knee arthroplasty and total knee arthroplasty.[13] Papakostidis et al. described the most serious adverse events (SAEs) for joint arthroplasty, including repeat operative intervention, death, coma, venous thromboembolism, deep infection,

cerebrovascular accident, or pneumonia.[14] For total knee arthroplasty, the most common SAEs were venous thromboembolism and urinary complications.
- Increased healthcare costs and complications from the inappropriate use of emergency services, and any additional treatments.

The clinical benefits of using these criteria include:
- Improved patient outcomes by ensuring timely and appropriate access to knee arthroplasty. The goal of total knee arthroplasty is to alleviate pain and improve patient function and mobility.
- Unicompartmental knee arthroplasty is an option for patients with isolated unicompartmental arthritis due to osteonecrosis. It is not appropriate for arthritis in more than one compartment of the knee. Careful patient selection is needed to ensure optimal outcomes. According to Chalmers et al., the unicompartmental knee survivorship was 89% at 5 years and 76% at 10 years.[15] The most common reason to convert to a total knee arthroplasty was progressive knee degeneration.
- Patellofemoral knee arthroplasty is a surgical option for isolated patellofemoral arthritis. The most common reason for failure is due to progression of knee arthritis requiring conversion to a total knee arthroplasty. Ennis et al. reported a 5 and 10-year knee survivorship of 91.7% and 83.3%, respectively, with an annual revision rate of 2.18%.[16]
- Enhanced overall patient satisfaction with the healthcare experience and return of function. Positive patient-reported outcomes include reduced pain, improved function, and increased quality of life for individuals.[17]

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- ➔ **Knee arthroplasty** is considered appropriate if **ANY** of the following is **TRUE**:
  - ◆ The procedure is a **primary total knee arthroplasty,** and **ALL** of the following are **TRUE**[1-7]:
    - **ANY** of the following is true:
      - If a bilateral total knee arthroplasty is performed, documentation of advanced joint disease must be present in both knees[1]; **OR**
      - Not applicable (i.e., single-knee arthroplasty); **AND**
    - **ANY** of the following is **TRUE:**
      - Advanced joint disease and **ALL** of the following:
        - ◆ Pain or functional disability[1-3]; **AND**
        - ◆ Failure of conservative management for greater than 3 months, including **ANY** of the following:
          - Rest or activity restriction as is reasonable[2-4]; **OR**
          - Anti-inflammatory medications, non-opioid analgesics, or prescription medications (e.g., oral steroids, neuropathic pain medications) if not contraindicated[2-4]; **OR**
          - Flexibility and muscle-strengthening exercises[3,4]; **OR**
          - Physical therapy or physician-directed exercise program[3,4]; **OR**
          - Assistive device use[3,4]; **OR**
          - **ANY** of the following:
            - ◆ Corticosteroid injection if medically appropriate[3,4]; **OR**
            - ◆ Documentation that injection is contraindicated[3,4]; **OR**
          - Weight reduction as appropriate[3,4]; **OR**
          - Documentation indicating that conservative, non-surgical management

would be ineffective or counterproductive based on **ANY** of the following[3,4]:
    - Intractable pain or significant disabling interference with activities of daily living (ADLs); **OR**
    - Bone-on-bone articulation; **OR**
    - Severe deformity; **OR**
    - Failure of a previous osteotomy; **OR**
    - Distal femur fracture; **OR**
    - Malignancy of **ANY** of the following:
        - Distal femur; **OR**
        - Proximal tibia; **OR**
        - Knee joint or adjacent soft tissues; **OR**
    - Failure of previous unicompartmental knee replacement; **OR**
    - Avascular necrosis of the knee; **OR**
    - Proximal tibia fracture; **AND**
- **ANY** of the following:
    - Radiographic-supported evidence[1-3]; **OR**
    - When conventional radiography is not adequate, magnetic resonance imaging (MRI) or computed tomography (CT) (in situations when MRI is non-diagnostic or not able to be performed)-supported evidence (i.e., subchondral cysts, subchondral sclerosis, periarticular osteophytes, joint subluxation, joint space narrowing, avascular necrosis)[1-3]; **OR**
- Failure of a previous osteotomy[1,2]; **OR**
- Distal femur fracture[1,2]; **OR**
- Malignancy of **ANY** of the following:
    - Distal femur[1,2]; **OR**
    - Proximal tibia[1,2]; **OR**
    - Knee joint or adjacent soft tissues[1,2]; **OR**
- Failure of previous unicompartmental knee replacement[1,2]; **OR**
- Avascular necrosis of the knee[1,2]; **OR**

        - Proximal tibia fracture[1,2]; **OR**
        - Bone-on-bone articulation[3]; **OR**
        - Intractable pain or significant disabling interference with activities of daily living (ADLs)[3]; **OR**
        - Severe deformity[3]; **OR**
- The procedure is a **repeat or revision TKA,** and **ANY** of the following is **TRUE**[13,28-36]:
    - Loosening of one or more components[1,2]; **OR**
    - Fracture or mechanical failure of one or more components[1,2]; **OR**
    - Infection; **OR**
    - Treatment of periprosthetic fracture of distal femur, proximal tibia, or patella[1,2]; **OR**
    - Progressive or substantial periprosthetic bone loss[1,2]; **OR**
    - Bearing surface wear leading to symptomatic synovitis[1,2]; **OR**
    - Implant or knee misalignment[1,2]; **OR**
    - Knee stiffness (arthrofibrosis)[1,2]; **OR**
    - Tibiofemoral instability[1,2]; **OR**
    - Extensor mechanism instability or disruption[1,2]; **OR**
    - Dislocation of the knee joint[1,2]; **OR**
- The procedure is a **unicompartmental knee arthroplasty,** and **ANY** of the following is **TRUE**[11,18-22]:
    - Unicompartmental knee degenerative joint disease and **ALL** of the following are **TRUE**:
        - Disabling pain and/or functional disability limits activities of daily living (ADLs)[11,18-22]; **AND**
        - Failure of conservative management for greater than 3 months, including **ANY** of the following:
            - Rest or activity restriction as is reasonable[2-4]; **OR**
            - Anti-inflammatory medications, non-opioid analgesics, or prescription medications (e.g., oral steroids, neuropathic pain medications) if not contraindicated[2-4]; **OR**
            - Flexibility and muscle-strengthening exercises[3,4]; **OR**
            - Physical therapy or physician-directed exercise program[3,4]; **OR**

        - Assistive device use[3,4]; **OR**
        - **ANY** of the following:
            - Corticosteroid injection if medically appropriate[3,4]; **OR**
            - Documentation that injection is contraindicated[3,4]; **OR**
        - Weight reduction as appropriate[3,4]; **OR**
        - Documentation indicating that conservative, non-surgical management would be ineffective or counterproductive based on **ANY** of the following[3,4]:
            - Intractable pain or significant disabling interference with activities of daily living (ADLs); **OR**
            - Bone-on-bone articulation in one compartment; **OR**
            - Severe deformity; **OR**
            - Failure of a previous osteotomy; **OR**
            - Malignancy of knee joint or adjacent soft tissues; **OR**
            - Avascular necrosis of the knee; **AND**
    - **ANY** of the following:
        - Radiographic-supported evidence in a single compartment[1-3]; **OR**
        - When conventional radiography is not adequate, magnetic resonance imaging (MRI) or computed tomography (CT) (in situations when MRI is non-diagnostic or not able to be performed)-supported evidence (i.e., subchondral cysts, subchondral sclerosis, periarticular osteophytes, joint subluxation, joint space narrowing, avascular necrosis)[1-3]; **AND**
    - Documentation of attempted weight loss or weight loss counseling if BMI is greater than 40[25,26]; **OR**
- Unicompartmental osteonecrosis[11]; **OR**
- Unicompartmental post-traumatic joint destruction[11,18-22]; **OR**
- Partial resection of the knee needed for treatment of malignancy[11,18-22]; **OR**

- The procedure is **patellofemoral arthroplasty** and **ANY** of the following is **TRUE**[11,16,18,22-23]:
  - Knee patellofemoral degenerative joint disease and **ALL** of the following are **TRUE**:
    - Isolated pain in the front of the knee[11,18]; **AND**
    - Disabling pain and/or functional disability limit activities of daily living (ADLs)[11,18]; **AND**
    - Failure of conservative management for greater than 3 months, including **ANY** of the following:
      - Rest or activity restriction as is reasonable[2-4]; **OR**
      - Anti-inflammatory medications, non-opioid analgesics, or prescription medications (e.g., oral steroids, neuropathic pain medications) if not contraindicated[2-4]; **OR**
      - Flexibility and muscle-strengthening exercises[3,4]; **OR**
      - Physical therapy or physician-directed exercise program[3,4]; **OR**
      - Assistive device use[3,4]; **OR**
      - **ANY** of the following:
        - Corticosteroid injection if medically appropriate[3,4]; **OR**
        - Documentation that injection is contraindicated[3,4]; **OR**
      - Weight reduction as appropriate[3,4]; **OR**
      - Documentation indicating that conservative, non-surgical management would be ineffective or counterproductive based on **ANY** of the following[3,4]:
        - Intractable pain or significant disabling interference with activities of daily living (ADLs); **OR**
        - Bone-on-bone articulation in the patellofemoral compartment; **OR**
        - Severe deformity; **OR**
        - Failure of a previous osteotomy; **OR**
        - Malignancy of knee joint or adjacent soft tissues; **AND**

    - **ANY** of the following:
        - Radiographic-supported evidence in the patellofemoral compartment[1-3]; **OR**
        - When conventional radiography is not adequate, magnetic resonance imaging (MRI) or computed tomography (CT) (in situations when MRI is non-diagnostic or not able to be performed)-supported evidence (i.e., subchondral cysts, subchondral sclerosis, periarticular osteophytes, joint subluxation, joint space narrowing, avascular necrosis)[1-3]; **AND**
    - Documentation of attempted weight loss or weight loss counseling if BMI is greater than 40[25,26]; **OR**
- Patellofemoral post-traumatic destruction (i.e., history of patella fracture)[11,18]; **OR**
- Dysplasia of the trochlea.[11,18]

Non-Indications

➔ **Knee arthroplasty** is not considered appropriate if **ANY** of the following is **TRUE**[11,18,24]:

- Active infection of the knee joint[1,2]; **OR**
- Active systemic bacteremia[1,2]; **OR**
- Active urinary tract or dental infection[1,2]; **OR**
- Active skin infection (except recurrent cutaneous staph infections)[1,2]; **OR**
- Open wound within the planned surgical site of the knee[1,2]; **OR**
- Rapidly progressive neurological disease[5].

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Codes	Code Description
27437	Arthroplasty, patella; without prosthesis
27438	Arthroplasty, patella; with prosthesis
27440	Arthroplasty, knee, tibial plateau

27441	Arthroplasty, knee, tibial plateau; with debridement and partial synovectomy
27442	Arthroplasty, femoral condyles or tibial plateau(s), knee
27443	Arthroplasty, femoral condyles or tibial plateau(s), knee; with debridement and partial synovectomy
27445	Arthroplasty, knee, hinge prosthesis (e.g., Walldius type)
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
27488	Removal of prosthesis, including total knee prosthesis, methylmethacrylate with or without insertion of spacer, knee
27599	Unlisted procedure, femur or knee

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Bin et al. (2023) performed a meta-analysis of 17 randomized controlled trials (RCTs) to compare surgical interventions for knee osteoarthritis, including total knee arthroplasty (TKA), unicompartmental knee arthroplasty (UKA), high tibial osteotomy (HTO), bicompartmental knee arthroplasty (BCA), bi-unicompartmental knee arthroplasty (BIU), and knee joint distraction (KJD). The authors analyzed 21 studies (including 17 RCTs) on surgical complications, revisions, reoperations, and functional outcomes. Overall, TKA and UKA offered the best outcomes in the treatment of osteoarthritis.[13]

Papakostidis et al. (2021) analyzed serious adverse events (SAEs) following TKA. The authors noted a reduction in SAEs over the last decade, specifically emphasizing the decrease in surgical complications, venous thromboembolism (VTE) events, and infections. These improvements have resulted from stricter protocols for VTE prevention, patient decolonization procedures, surgical air quality optimization, preoperative cardiac clearance, diabetic control, and participation in weight reduction programs.[14]

Shichman et al. (2023) analyzed data from the Centers for Medicare & Medicaid Services (CMS) Medicare/Medicaid Part B National Summary and the number of procedures based on Current Procedural Terminology (CPT) codes. The codes were separated into primary total hip arthroplasty (THA) or total knee arthroplasty (TKA). A total of 480,958 primary TKA were performed in 2019. The values were a baseline for producing point forecasts for procedures expected to be performed between 2020-2060 and 95% forecast intervals (FIs). From 2000 to 2019, TKA increased annually by 156%. Regression analysis predicts annual growth rates of 4.44% for TKA - an expected increase of 24.28% for TKA every five years post-2020. By 2040, TKAs are expected to be 1,222,988. That number will increase to 2,917,959 for TKAs by 2060. The authors note that by 2040, the number of TKAs is projected to rise by 139% by 2040 and 469% by 2060. Accurately projecting future arthroplasty needs is crucial for understanding future healthcare utilization and surgeon demand. The findings are specific to the Medicare population; additional analysis is required to determine if other groups apply.[24]

Unicompartmental knee arthroplasty has been traditionally considered for elderly patients because of its relatively shorter rehabilitation period, smaller incision, and preservation of range of motion and function. However, a large study of 11-year knee survivorship among patients less than 60 years old found a 92% rate of survivorship; a similar study of elderly patients undergoing cemented UKA found a 10-year survivorship of 98%.[11] Patellofemoral arthroplasty necessitates careful patient selection, as evidenced by risk of subsequent revision to TKA - most commonly resultant from progressive tibiofemoral arthritis. The current body of research also suggests a higher rate of revision to TKA among patients with obesity, with knee survivorship and satisfactory results generally lower than primary TKA.[11] Revision rates of knee arthroplasty are low, as most primary implants are both well-tolerated and durable. As the field has evolved, the most common etiologies prompting revision are now infection and instability, rather than bone destruction or mechanical loosening. Clinical outcomes of revision TKA are less favorable than primary TKA, and 5-year follow-up satisfaction rates have been reported up to 74%, versus primary TKA satisfaction approaching 100%.[11]

The American Academy of Orthopaedic Surgeons (AAOS) has issued position statements pertaining to knee arthroplasty. Information statement 1047, published in 2016, acknowledges the increased patient safety risks conferred by tobacco use - including pneumonia, impeded healing, surgical site infection, postoperative cardiopulmonary events, and death.[27] The AAOS states that patients who are active smokers may reduce these risks through cessation of smoking prior to surgery; they also note the special role orthopaedic surgeons play in counseling patients on the benefits of reduced or eliminated tobacco use prior to surgery.[27] Importantly, unconfirmed cessation is not endorsed as a hard stop to surgery; rather, the surgeon's unique role as an advocate for preoperative smoking cessation is emphasized.[27] Statements 1040 and 1184 discuss the impact of obesity on musculoskeletal conditions.[25,26] Statement 1184 endorses the importance of continued patient-surgeon conversation around the increased surgical risks associated with obesity, including increased complications and rates of hardware failure following knee replacement. Patients with morbid obesity (BMI of 40 or above) are encouraged to participate in a weight loss program, obtain weight reduction resources through their physician, rectify nutritional deficiencies, and consider a delay in surgical treatment if it would facilitate

participation in weight loss interventions that may improve surgical outcomes. Statement 1040 reinforces the risks associated with obesity and total joint arthroplasty and encourages adequate patient counseling prior to surgery.[25,26] Social determinants of health remain an important area of ongoing orthopaedic surgery research, with recent literature raising questions regarding the healthcare disparities that may be potentiated by care limitations based on obesity and smoking status/nicotine dependence.[37-39,43-46] Other ongoing research interrogates the impacts that biological sex, race, and socioeconomic status have on TKA utilization and outcomes.[41-42]

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Clinical Guideline Revision History/Information

Original Date: May 29, 2024		
Review History		
Version 2	6/10/2024	422.101 Disclaimer added
Version 3	2/21/2025	Annual policy review & restructure: • Improved references • Separated out non-indications for readability. • Reordered UKA, patellofemoral arthroplasty indications for readability. • Removed note regarding exception to conservative management and instead absorbed that information into the appropriate indications. • Expanded medical evidence to reflect current literature. • Conservative management criteria reorganized to better align with CMS guidance. • UKA, PKA indications taken from current commercial version of policy as CMS is silent on these subservices. • Clarified language of indication for surgical management of infection to avoid confusion with non-indication of active infection. • Conservative care language standardized across TKA, UKA, PFA - not more stringent than CMS. Revision indications expanded - not more stringent than CMS. • Defined clinical scenarios where nonsurgical management may be harmful or ineffective - not more stringent than CMS. • Conservative care language modified to reflect non-opioid pain control. • Provided avenue to approve without conservative care for specific UKA, PKA scenarios.

		• Modified steroid injection language for clarity.
Version 3.1	3/21/2025	• Updated policy per CMS revisions for 2/28/2025 • Updated Effective date • Updated Links and Bookmarks
Version 4	5/22/2025	Added CPT code: 27488. No associated criteria change. Removal of “disabling pain, functional disability” as revision indications due to concern for inappropriate approval.