Total Knee Arthroplasty (Replacement)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

The knee is composed of the lower (distal) end of the femur, the patella, and the upper (proximal) end of the tibia. There is a smooth cartilage surface at the distal end of the femur, the proximal end of the tibia, and the undersurface of the patella. For various reasons, these cartilage surfaces can wear down and sometimes erode away. In general terms, this process is called arthritis, which is the inflammation of a joint. A detailed musculoskeletal examination should be performed to assess functional level, knee anatomy, differential diagnosis, pain patterns, symptoms, and safety.

Total knee arthroplasty (TKA), or total knee replacement, is the surgical reconstruction or replacement of the distal femur, the proximal tibia, and often the undersurface of the patella. Some of the knee ligaments are removed and other ligaments retained.

This guideline does not address partial knee arthroplasty, knee arthroscopy, or knee arthrotomy; please refer to MCG criteria for these procedures.

Definitions

"Ambulatory" is a stay in a facility for up to 23 hours.

"Avascular necrosis" is osteonecrosis (bone death) when there is alteration of blood supply to the bone. There are numerous causes for avascular necrosis, but in some cases the cause is unknown.

"Angular deformity" in the knees is a deviation from the mechanical axis of the lower limb. The mechanical axis is a line from the center of the femoral head through the center of the knee joint to the center of the ankle joint. The usual angular deformities are bow-legs (genu varum), knock-knees (genu valgum), or hyperextension (genu recurvatum).

"Kellgren-Lawrence System" is a five-grade classification system describing radiographic findings for osteoarthritis (Table 1).

Table 1. Kellgren-Lawrence System for classifying osteoarthritis	
Grade	Radiographic Findings
0	No radiographic features of osteoarthritis are present
I	Doubtful joint space narrowing and possible osteophytic lipping
II	Definite osteophytes and possible joint space narrowing
III	Moderate multiple osteophytes, definite joint space narrowing, some sclerosis, and possible deformity of bone contour
IV	Large osteophytes, marked joint space narrowing, severe sclerosis, and definite deformity of bone contour

"Osteoarthritis" (degenerative joint disease) is the most common form of arthritis and occurs when the cartilage cushion over the end of the bone wears away to a varying degree. The primary symptoms are joint pain, stiffness and movement restriction.

"Revision" of a total knee replacement is a surgical procedure to replace or reconstruct a prior knee replacement. The need for a revision procedure occurs when the original replacement fails and the patient is symptomatic. The failure may be due to one or more of the following conditions such as infection, instability, or other indications.

"Rheumatoid arthritis" is an autoimmune disease that causes chronic inflammation in joints and tissue. Over time, this inflammation can lead to joint deformity and erosion of bone and cartilage.

A. Clinical Indications
    1. Medical Necessity Criteria for Clinical Review
        a. General Medical Necessity Criteria
        b. Indication-Specific Criteria
    2. Level of Care

Medical Necessity Criteria for Clinical Review

General Medical Necessity Criteria

(For partial knee arthroplasty, knee arthroscopy, or knee arthrotomy, please see MCG criteria)

Total knee arthroplasty for a unilateral knee is considered medically necessary when ONE of the following criteria are met:

1. The member meets medical necessity for advanced joint disease as indicated by ALL of the following:
    a. Radiologic or arthroscopic findings of advanced knee joint destruction documented by the treating surgeon and/or radiologist for ONE of the following:
        i. Kellgren Lawrence Grade IV radiographic findings (Table 1); *or*
        ii. Exposed subchondral bone, which is erosion of articular cartilage that exposes subchondral bone often designated as Modified Outerbridge Classification IV; *or*
        iii. Symptomatic angular deformity with accompanying radiographic changes; *or*
        iv. Symptomatic avascular necrosis of the femoral condyles or proximal tibia with accompanying radiographic changes; *and*
    b. Severe pain persisting in the affected knee that interferes with functional activity or age-appropriate activities for at least 3 months (e.g., ambulation, prolonged standing, ability to sleep); *and*
    c. There has been a failure to decrease pain or improve function after at least a 3-month trial of conservative treatment (non-surgical) which has included ALL of the following:
        i. Active and ongoing participation in physical therapy (documented) or a well-documented home exercise program under the supervision of a physical therapist or physician (e.g., lower extremity flexibility and strengthening program, activity modification, and/or weight loss program), unless poorly tolerated or contraindicated; *and*
        ii. Oral/topical medications (e.g., analgesics, NSAIDs, serotonin/norepinephrine reuptake Inhibitor (duloxetine)), unless poorly tolerated or contraindicated; *and*
        iii. No intra-articular steroid injections to the knee within three months before the surgery date; *and*
    d. If there is a separate request for the device, implant or prosthesis that will be inserted during surgery, it must be FDA approved (unless the member is enrolled in an approved clinical trial as defined by the plan benefit); *and*
    e. No contraindication present or the request is not considered Experimental or Investigational, or Not Medically Necessary, as listed in this guideline; *or*

2. Failure of previous surgical interventions such as ONE of the following:
    a. Previous proximal tibial or distal femoral osteotomy; *or*
    b. Previous unicompartmental knee replacement with continued pain interfering with ADLs; *or*
3. Post-traumatic injury (e.g., fracture, infection) causing debilitating knee joint destruction affecting movement, causing pain and stiffness; *or*
4. Bone tumor involving the knee that requires resection and total reconstruction.

Please Note: If the member is a smoker or nicotine product user, it is recommended the member has stopped using within 4 weeks of surgery or has been provided a well-documented education plan on options to quit such as referral to a cessation program, pharmacologic, and over-the-counter treatments.

Indication-Specific Criteria

Simultaneous Bilateral Total Knee Arthroplasty

Total knee arthroplasty for simultaneous bilateral surgery is considered medically necessary if ALL of the following criteria are met:

1. Each knee meets the General Medical Necessity Criteria; *and*
2. Meets the inpatient hospital Level of Care criteria.

Removal or Revision of Total Knee Arthroplasty

Removal (resection with subsequent reimplantation at a later time or permanent resection arthroplasty with no reimplantation planned) or Revision (members may require one or multi-staged surgeries to complete revision over time)

The removal or revision of a total knee prosthesis is considered medically necessary when ALL of the following criteria are met:

1. The affected knee requested is without a history of prior infection, current or ongoing knee infection (e.g., supporting labs and cultures, no longer on antibiotics, assessment by treating surgeon); *and*
2. One of the following conditions exist:
    a. Prosthesis/hardware failure, damage or fracture*; or*
    b. Loosening of prosthesis, implant or components that is confirmed by imaging*; or*
    c. Periprosthetic knee fracture*; or*
    d. Instability or dislocation of the knee*; or*
    e. The member has functional disability AND persistent pain for more than 6 months*; or*
    f. Bearing surface wear leading to symptomatic synovitis*; or*
    g. Significant limb malalignment post TKA*; or*
    h. Symptomatic abnormal joint line on imaging as it pertains to physical exam and clinical findings; *or*
3. If the member has an actively infected knee prosthesis or periprosthetic infection, one of the following criteria must be met:

a. The member must first have completed medical management (e.g., antibiotics), or interventions such as washouts (including irrigation and debridement) or spacer placement/replacement prior to surgery day of inserted prosthesis, i.e., the member must clear out all infection (e.g., negative cultures) prior to the day of planned procedure whether one-stage or two-stage exchange)*; or*
b. There is documentation for either planned medical or interventional management to address the source of infection prior to revision/replacement of the prosthesis (e.g., debridement of infected tissue, removal of implants and/or insertion of antibiotic impregnated prosthesis); *or*

4. Additional staged surgery is needed as part of a multispecialty approach to any one of the conditions listed above. This could include, but is not limited to, the replacement of impregnated antibiotic spacers, additional joint washouts, and the removal or replacement of hardware.

Level of Care

Level of Care Initial Clinical Review

Ambulatory Surgical Center or Outpatient Hospital

Ambulatory surgical center or outpatient hospital level of care is considered medically necessary for total knee arthroplasty (TKA) if ONE of the following indications is met:

1. Unilateral TKA; *or*
2. Staged TKA on both knees (each knee must still meet medical necessity, and the procedures are typically staggered between 30-90 days following the first TKA); *or*
3. An additional day as an ambulatory or observation level of care might be needed for a safe transition to oral pain medication.

Inpatient Hospital Simultaneous Bilateral Total Knee Arthroplasty

Inpatient hospital level of care for simultaneous bilateral total knee arthroplasty may be considered medically necessary if an ambulatory or outpatient hospital is unable to monitor the member's needs. Furthermore, each knee must meet medical necessity.

Inpatient Hospital Unilateral or Bilateral Total Knee Arthroplasty

Inpatient hospital level of care for unilateral or bilateral total knee arthroplasty (TKA) may be considered medically necessary if ONE of the following is met:

1. Non-elective surgery for unilateral or bilateral; *or*
2. For members requesting unilateral or bilateral revision procedures that require an extended stay outside of the ambulatory or outpatient hospital timeframe, or are unable to be discharged and expected to be admitted/transferred to acute or subacute rehab facility (the member must also meet Oscar's utilization review criteria for the rehabilitation facility); *or*
3. The member requires more prolonged postoperative treatment or management for unilateral or bilateral due to comorbidities which may include ANY of the following:

a. Need for parenteral bridging anticoagulation
b. NYHA class III or IV heart failure
c. Pulmonary fibrosis
d. Pulmonary hypertension
e. History of thromboembolism
f. Extensive edema
g. Chronic systemic corticosteroid use
h. Severely reduced renal function
i. Poorly controlled type 1 diabetes
j. Recent history of falls
k. Significant dementia
l. BMI > 40
m. Age > 70 and an additional comorbidity as listed in this section
n. Significant movement abnormalities (eg, stroke, Parkinson disease, dependent functional status); *or*

4. For a member to meet inpatient level of care for pain management after TKA surgery, the member must meet the criteria in MCG Pain Management GRG (PG-PM) criteria for unilateral or bilateral; *or*
5. An inpatient admission for a unilateral or bilateral request may be considered medically necessary when the member meets MCG Ambulatory Surgery Exception Criteria (CG-AEC).

Level of Care Subsequent Clinical Review

Inpatient Hospital Subsequent Clinical Review

The Plan considers extension requests for inpatient (IP) level of care medically necessary when the member continues to meet extension criteria in MCG Knee Arthroplasty, Total for milestones of recovery, clinical status is improving during IP stay, and is not ready to be transitioned to an alternative or lower level of care. Extension requests should be based on medical records of progress.

Experimental or Investigational / Not Medically Necessary

The Plan considers the following conditions as contraindications to total knee arthroplasty (TKA):

1. Generalized infection or active illness currently under medical management that would affect surgical risk or outcomes
2. Active infection in the knee, unless surgery is for revision for TKA
3. Active wound or skin infection at the planned knee joint for surgery
4. The member has not reached skeletal maturity
5. Known allergy to components of the implant

The following indications are considered not medically necessary:

1. Customized joint implants, whether total or in part
2. Progressive neurologic disease affecting lower extremity and extensor mechanism
3. Chronic lower extremity ischemia or vascular insufficiency severe enough to compromise recovery
4. Anemia has not been investigated and managed
5. Joint instability that has not been managed prior to TKA

The following indications are considered experimental, investigational, or unproven:

1. UniSpacer interpositional spacer
2. Persona IQ Smart Knee Implant (Zimmer Biomet) for total knee arthroplasty

Applicable Billing Codes

Table 1	
Initial Total Knee Arthroplasty (TKA)	
CPT/HCPCS codes considered medically necessary if criteria are met:	
Code	*Description*
20999	Unlisted procedure, musculoskeletal system, general
27445	Arthroplasty, knee, hinge prosthesis (eg, Walldius type)
27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)
C1776	Joint device (implantable)

Table 2	
Removal or Revision of Total Knee Arthroplasty (TKA)	
CPT/HCPCS codes considered medically necessary if criteria are met:	
Code	*Description*
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

Table 3	
CPT/HCPCS codes not considered medically necessary for indications in this guideline:	
Code	*Description*
C1776	Joint device (implantable) ● Due to the broad nature of this code and lack of specificity in certain scenarios, clarification is provided below: ● When this code is billed for customized knee implants or devices that are not FDA-approved, then it is considered NOT medically necessary

Table 4	
CPT/HCPCS codes considered experimental or investigational for indications in this guideline:	
Code	*Description*
27599	Unlisted procedure, femur or knee ● Due to the broad nature of this code and lack of specificity in certain scenarios, clarification is provided below: ● When this code is billed for the UniSpacer interpositional spacer or Persona IQ Smart Knee Implant (Zimmer Biomet), it is considered experimental/investigational

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Clinical Guideline Revision / History Information

Original Date: 1/31/2023
Reviewed/Revised: 5/02/2023, 10/19/2023, 01/23/2024, 4/16/2024, 11/1/2024, 02/01/2026