

Total Knee Arthroplasty

MEDICAL POLICY NUMBER: 418

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| Effective Date: 1/1/2025 | COVERAGE CRITERIA | 2 |
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INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

Commercial

Medicaid/OHP*

Medicare**

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered “**not medically necessary**” for Medicare members.

COVERAGE CRITERIA

Notes:

- Total knee arthroplasties are reviewed for both medical necessity (criteria below) and inpatient site of service (see criteria in “[Surgical Site of Service](#)” medical policy).
 - Revision knee arthroplasty procedures do not require site of service review.
- This policy is primarily based on the 2024 InterQual® evidence-based procedure guideline criteria, *Total Joint Replacement (TJR), Knee*,¹ and *Removal and Replacement, Total Joint Replacement (TJR), Knee*.²

Initial Knee Arthroplasty

- I. Initial total knee arthroplasty may be considered **medically necessary** when **any** of the following criteria (A.-E.) are met:
 - A. Osteoarthritis or posttraumatic arthritis of the knee is present and all of the following criteria (1.-4.) are met:
 1. Both of following criteria are met (a.-b.):
 - a. Pain interferes with activities of daily living (ADLs); **and**
 - b. Pain with range of motion (ROM); **and**
 2. Two or more of the following criteria are met (a.-c.):
 - a. Limited ROM
 - b. Crepitus
 - c. Joint effusion or swelling; **and**
 3. Either of the following criteria are met (a.-b.):
 - a. Imaging documents bone-on-bone contact and there is no active infection; **or**

b. Imaging documents arthritis and all of the following criteria are met (i.-ii.):

i. Two or more of the following criteria are met:

- Subchondral cysts; **and**
- Subchondral sclerosis; **and**
- Periarticular osteophytes; **and**
- Joint subluxation; **and**
- Joint space narrowing; **and**

ii. No active infection and symptoms or findings continue after all of the following treatment has been attempted within the last year:

- NSAIDs or acetaminophen ≥ 3 weeks or intra-articular corticosteroid injection ≥ 1 injection; **and**
- PT or home exercise ≥ 12 weeks; **and**
- Activity modification ≥ 12 weeks; **or**

B. Avascular necrosis (osteonecrosis) of the tibial plateau and/or femoral condyle is present and all of the following criteria are met (1.-4):

1. Imaging confirms avascular necrosis; **and**
2. Both of the following criteria are met (a.-b.):
 - a. Pain interferes with activities of daily living (ADLs); **and**
 - b. Pain with range of motion (ROM); **and**
3. **Two or more** of the following criteria are met (a.-c.):
 - a. Limited ROM; **or**
 - b. Crepitus; **or**
 - c. Joint effusion or swelling; **and**
4. Patient has no active infection and either of the following criteria are met (a.-b.):
 - a. Collapse of tibial plateau or femoral condyle; **or**
 - b. Symptoms continue after **all** of the following treatment within the last year (i.-iii.):
 - i. NSAIDs or acetaminophen ≥ 3 weeks; **and**
 - ii. PT or home exercise ≥ 12 weeks; **and**
 - iii. Activity modification ≥ 12 weeks; **or**

C. Imaging documents bone tumor involving the knee and there is no active infection; **or**

D. Symptomatic nonunion or malunion of fracture and patient has no active infection; **or**

E. Rheumatoid arthritis of the knee is present and all of the following criteria are met (1.-3.):

1. **Both** of the following criteria are met (a.-b.):
 - a. Pain interferes with ADLs
 - b. Pain with ROM
2. **Two or more** of the following criteria are met (a.-c.):
 - a. Limited ROM
 - b. Crepitus
 - c. Joint effusion or swelling

3. Imaging documents arthritis of the knee and **both** of the following criteria (a. -b.) are met:

a. **Two or more** of the following criteria are met (i.-v.):

- i. Subchondral cysts
- ii. Marginal erosions
- iii. Periarticular osteopenia
- iv. Joint space narrowing
- v. Joint subluxation; **and**

b. No active infection **and** symptoms or findings continue after **all** of the following treatment has been attempted within the past year (i.-iii.):

- i. Disease modifying antirheumatic drugs (DMARDs) ≥ 12 weeks; **and**
- ii. PT or home exercise ≥ 12 weeks; **and**
- iii. Activity modification ≥ 12 weeks.

II. Initial total knee arthroplasty is considered **not medically necessary** when criteria I. above is not met including but not limited to the presence of the following contraindications:

- A. Insufficiency of extensor mechanism/quadriceps
- B. Any process that is rapidly destroying bone
- C. Neurotrophic arthritis.

Knee Arthroplasty Removal and Replacement

III. Knee arthroplasty removal and replacement may be considered **medically necessary** and when any of the following criteria (A.-H) are met:

- A. Imaging documents fractured prosthesis or cement and there is no active infection; **or**
- B. Joint infection and imaging documents sinus tract communicating with prosthetic joint; **or**
- C. Prosthetic joint infection by positive synovial fluid culture or tissue culture and **both** of the following criteria are met (1.-2.):
 - 1. **Any** of the following criteria are met (a.-d.):
 - a. Two cultures positive for same organism; **or**
 - b. Culture positive for *Staphylococcus aureus* (*S. aureus*); **or**
 - c. Culture positive for gram negative organism; **or**
 - d. Culture positive for enterococci; **and**
 - 2. **Any** of the following criteria are met (a.-c.):
 - a. Joint infection onset within 4 weeks of total joint replacement **and** imaging documents loosening of prosthesis or cement; **or**
 - b. Any **one** of the following are met (i.-iii.):
 - i. No new joint symptoms and findings ≤ 3 weeks; **or**
 - ii. Imaging documents loosening of the prosthesis or cement; **or**

- iii. Symptoms or findings continue after all of the following treatments have been attempted:
 - IV anti-infectives \geq 4 weeks; **and**
 - Joint lavage and drainage; **or**
- c. Joint infection within 4 weeks of total joint replacement **and** the symptoms or findings persist after attempting **both** of the following treatments (i.-ii.):
 - i. IV anti-infectives \geq 4 weeks; **and**
 - ii. Joint lavage and drainage; **or**
- D. Joint infection and **all** of the following criteria (1.-3.) are met:
 - 1. **Either** of the following criteria are met (a.-b.):
 - a. Joint pain; **or**
 - b. Erythema or drainage or swelling at joint by physical examination; **and**
 - 2. **Two or more** of the following criteria are met (a.-d.):
 - a. Temperature $>$ 100.4 F (38.0 C); **or**
 - b. Synovial white blood count (WBC) or neutrophil levels above normal; **or**
 - c. ESR $>$ 30 mm/hr; **or**
 - d. C-reactive protein levels above normal; **and**
 - 3. **Any** of the following criteria are met (a.-i.):
 - a. Joint infection within 4 weeks of total joint replacement and imaging documents loosening of prosthesis or cement; **or**
 - b. Joint infection within 4 weeks of total joint replacement and symptoms or findings persist after attempting **both** of the following treatments (i.-ii.):
 - i. IV anti-infectives \geq 4 weeks; **and**
 - ii. Joint lavage and drainage
 - c. There are no new joint symptoms and findings \leq 3 weeks; **or**
 - d. Imaging documents loosening of prosthesis or cement; **or**
 - e. Both of the following criteria are met (i.-ii.):
 - i. IV anti-infectives \geq 4 weeks; **and**
 - ii. Joint lavage and drainage; **or**
 - E. Imaging documents malposition of tibial or femoral component and there is no active infection; **or**
 - F. Imaging documents recurrent dislocation and there is no active infection; **or**
 - G. Imaging documents symptomatic loosening of prosthesis or cement and there is no active infection; **or**
 - H. Imaging documents worn or dislocated plastic insert and there is no active infection.

IV. Knee arthroplasty removal and replacement is considered **not medically necessary** when criterion III. above is not met including but not limited to the presence of the following contraindications:

- A. Insufficiency of extensor mechanism/quadriceps
- B. Any process that is rapidly destroying bone
- C. Neurotrophic arthritis.

Link to [Evidence Summary](#)

POLICY CROSS REFERENCES

- [Surgical Site of Service](#), MP184

The full Company portfolio of current Medical Policies is available online and can be [accessed here](#).

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

The devices/implants utilized for total knee replacement surgeries are regulated by the FDA as medical devices. The devices used should be class II or class III devices that meet the requirements outlined in CFR 21, Chapter 1, subchapter H, Part 888.

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

In order to determine the medical necessity of the request, the following information must be submitted in order to determine if medical necessity criteria are met:

- Indication for the requested surgery
- Clinical notes documenting that the individual has been evaluated at least once by the requesting surgeon before submitting a request for surgery.
- Clinical documentation of extent and response to conservative care, as applicable to the policy criteria, including outcomes of any procedural interventions, medication use and physical therapy notes
- Evaluation and documentation of the extent and specifics of one or more of the functional impairments or disabilities (see Policy Guidelines)
 - Imaging requirements:
 - Documented interpretation of x-rays, which may be performed and read by the operating surgeon.
 - If advanced imaging is required, a radiologist's report (for CT, MRI, US or bone scan).
- Documentation of any criteria-specific lab values or reports.

DEFINITIONS

Activities of Daily Living

The activities of daily living (ADLs) is a term used to describe essential skills that are required to independently care for oneself. Examples may include, but are not limited to, the following:

- Ambulating
- Feeding
- Dressing
- Personal hygiene
- Transportation and shopping
- Meal preparation
- Housecleaning and home maintenance

Total Knee Arthroplasty

Total knee replacement may also be referred to as total knee arthroplasty (TKA). A TKA is a surgical procedure that consists of removing the damaged articular surfaces of the knee, and then resurfacing with metal or polyethylene prosthetic components. Mostly commonly, a TKA is indicated for damaged joint cartilage caused by osteoarthritis (OA), rheumatoid arthritis/inflammatory arthritis, posttraumatic degenerative joint disease, or osteonecrosis/joint collapse with cartilage destruction. In OA, cartilage is degraded and causes remodeling of the underlying bone. The cascading effect is a response of chondrocytes in the articular cartilage and the inflammatory cells in the surrounding tissues. The most common joints affected by osteoarthritis are the small joints of the hands and feet, and the hip and knee joint. A TKA performed for damage caused by OA is indicated for severe pain that inhibits normal functioning that is refractory to nonsurgical management. Rheumatoid arthritis and other inflammatory arthritis may also lead to total degradation of the knee joint, though this has declined since the introduction of antirheumatic pharmacologics. A TKA may also be considered for posttraumatic arthritis following an acute injury, tumor involving the bone, avascular necrosis (osteonecrosis), tibial plateau, or femoral condyle.

Removal and Replacement of Knee Arthroplasty

"Removal and replacement" of total knee arthroplasty refers to a surgical procedure where an existing knee prosthesis is first removed and then replaced with a new artificial knee joint. The objective of this surgery is to alleviate pain, restore proper alignment and function, and improve the overall mobility of the patient. This type of surgery may also be more complex than a primary total knee replacement due to potential issues like bone loss or scar tissue from the previous surgery.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

Medical necessity criteria are based largely on evidence-based standards provided by InterQual. Therefore, no secondary evidence review was conducted.

HEALTH EQUITY CONSIDERATIONS

The Centers for Disease Control and Prevention (CDC) defines health equity as the state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving health equity requires addressing health disparities and social determinants of health. A health disparity is the occurrence of diseases at greater levels among certain population groups more than among others. Health disparities are linked to social determinants of health which are non-medical factors that influence health outcomes such as the conditions in which people are born, grow, work, live, age, and the wider set of forces and systems shaping the conditions of daily life. Social determinants of health include unequal access to health care, lack of education, poverty, stigma, and racism.

The U.S. Department of Health and Human Services Office of Minority Health calls out unique areas where health disparities are noted based on race and ethnicity. Providence Health Plan (PHP) regularly reviews these areas of opportunity to see if any changes can be made to our medical or pharmacy policies to support our members obtaining their highest level of health. Upon review, PHP creates a Coverage Recommendation (CORE) form detailing which groups are impacted by the disparity, the research surrounding the disparity, and recommendations from professional organizations. PHP Health Equity COREs are updated regularly and can be found online [here](#).

BILLING GUIDELINES AND CODING

- **Separate SOS Review Required:** In addition to general medical necessity review using this policy, CPT codes 27445 and 27447 may require inpatient site of service review, which is performed using criteria found in the medical policy, [Surgical Site of Service](#) (MP184).
- **Separate SOS Review Not Required:** Revision knee arthroplasty CPT codes (27486 and 27487) are **not** subject to the site of service policy criteria linked above.

| CODES* | | |
|--------|-------|--|
| CPT | 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) |
| | 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 |

*Coding Notes:

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- See the non-covered and prior authorization lists on the Company [Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website](#) for additional information.

- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. InterQual. Mar. 2024 Release CP:Procedures - Total Joint Replacement (TJR), Knee. In:2024.
2. InterQual. Mar. 2024 Release CP:Procedures - Removal and Replacement, Total Joint Replacement (TJR), Knee. In:2024.

POLICY REVISION HISTORY

| DATE | REVISION SUMMARY |
|--------|------------------|
| 1/2025 | New policy. |