TOTAL KNEE REPLACEMENT SURGERY
(ARTHROPLASTY)

Protocol: ORT016
Effective Date: June 1, 2017

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INSTRUCTIONS FOR USE
This protocol provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Evidence of Coverage (EOC)) may differ greatly. In the event of a conflict, the enrollee's specific benefit document supersedes this protocol. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Protocol. Other Protocols, Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Protocols, Policies and Guidelines as necessary. This protocol is provided for informational purposes. It does not constitute medical advice. This policy does not govern Medicare Group Retiree members.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

COMMERCIAL & MEDICAID COVERAGE RATIONALE

For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 21st Edition, 2017.

- Total Knee Arthroplasty, S-700 (ISC)
- Musculoskeletal Surgery or Procedure (GRG:SG-MS (ISC GRG))

MCG™ Care Guideline: Knee Arthroplasty, S-700 (ISC)

Clinical Indications for Procedure

- Procedure is indicated for 1 or more of the following:
  - Degenerative joint disease as indicated by ALL of the following
    - Presence of significant radiographic findings, including knee joint destruction, angular deformity, or severe narrowing
    - Optimal medical management has been tried and failed.
    - Patient has failed or is not a candidate for more conservative measures (e.g., osteotomy).
    - Treatment indicated due to 1 or more of the following:
- Disabling pain
- Functional disability

- Failure of a previous proximal tibial or distal femoral osteotomy
- Posttraumatic knee joint destruction
- Distal femur fracture repair in an elderly patient with osteoporosis
- Limb salvage for malignancy
- Congenital deformity
- Hemophilic arthropathy
- Replacement (revision) of previous arthroplasty is needed as indicated by 1 or more of the following:
  - Disabling pain
  - Functional disability
  - Progressive and substantial bone loss (osteolysis)
  - Dislocation of patella
  - Aseptic component instability
  - Infection
  - Periprosthetic fracture

Musculoskeletal Surgery or Procedure (GRG: SG-MS (ISC GRG))

Clinical Indications for Procedure
- Surgery or other procedure covered by this guideline is indicated for 1 or more of the following:
  - Fracture, dislocation, or other skeletal injury requiring procedure
    - Closed or open reduction
    - Internal fixation
    - External fixation
    - Other operative repair
  - Wound or soft tissue repair needed
    - Complex wound closure
    - Wound debridement
    - Skin grafting or local flap reconstruction
    - Escharotomy
  - Tumor requiring resection or biopsy
  - Removal of implanted device needed; indications may include
    - Infection
    - Complication such as refracture or nonunion
    - Fracture healed
    - Late operative site pain
  - Osteomyelitis or other infection requiring bone resection
  - Limb reconstruction or amputation needed, indications may include
    - Vascular disease
    - Trauma
    - Severe infection
    - Neoplasm
    - Post-amputation revision required (eg, heterotopic ossification, neuroma)
  - Fasciotomy needed for compartment syndrome or other process
Medial or lateral unicompartmental knee arthroplasty needed as indicated by **1 or more** of the following

- Unicompartmental degenerative joint disease as indicated by all of the following
  - Presence of significant radiographic findings, including knee joint destruction, angular deformity, or severe narrowing
  - Optimal medical management has been tried and failed
  - Patient has failed or is not candidate for more conservative measures (e.g., osteotomy)
  - Treatment indicated due to **1 or more** of the following
    - Disabling pain
    - Functional disability

Patellofemoral arthroplasty needed as indicated by **1 or more** of the following

- Patellofemoral degenerative joint disease as indicated by **ALL** of the following
  - Presence of significant radiographic findings
  - Optimal medical management has been tried and failed
  - Patient has failed or is no candidate for more conservative measures
  - Treatment indicated due to **1 or more** of the following
    - Disabling pain
    - Functional disability
    - Patellofemoral posttraumatic destruction
    - Chondromalacia of the patella or trochlea
    - Dysplasia of the patella or trochlea
    - Replacement (revision) of previous arthroplasty needed (e.g., infection, implant failure)

Bone repositioning procedure (e.g., wedge osteotomy, bone augmentation) needed; indications may include

- Congenital deformities
- Articular damage or deformity
- Posttraumatic deformity

Spinal procedure required (e.g., anterior instrumentation); indications may include

- Congenital or idiopathic deformity (e.g., scoliosis)
- Congenital bone disease
- Vertebral fracture (e.g., without spinal cord injury)
- Muscular dystrophy
- Degenerative sacroiliitis

Musculoskeletal congenital or acquired dysfunction that requires **1 or more** of the following

- Tendon repositioning or transfer
- Tendon length change
- Muscle flap transfer
- Lengthening myoplasty
- Distraction osteogenesis
- Joint repair
- Arthrodesis
- Arthroplasty (e.g., ankle arthroplasty)
- Bursectomy
**MEDICARE COVERAGE RATIONALE**

Medicare does not have a National Coverage Determination (NCD) for total knee replacement surgery. Refer to the Nevada Local Coverage Determination for Total Knee Arthroplasty (L36575). Accessed April 2017.

**Total Joint Arthroplasty (L36575)**

**Total Knee Arthroplasty (TKA)**

**Indications:**

Noridian will consider total knee replacement surgery *medically necessary* in the following circumstances:

- Advanced joint disease demonstrated by:
  - Radiographic supported evidence or when conventional radiography is not adequate, magnetic resonance imaging (MRI) and/or computed tomography (CT) (in situations when MRI is non-diagnostic or not able to be performed) supported evidence (subchondral cysts, subchondral sclerosis, periarticular osteophytes, joint subluxation, joint space narrowing, avascular necrosis); and
  - Pain or functional disability from injury due to trauma or arthritis of the joint; and
  - If appropriate, history of unsuccessful conservative therapy (non-surgical medical management) that is clearly addressed in the pre procedure medical record. (If conservative therapy is not appropriate, the medical record must clearly document why such approach is not reasonable). Non-surgical medical management is usually but not always implemented prior to scheduling total joint surgery. Non-surgical treatment as clinically appropriate for the patient’s current episode of care typically includes one or more of the following:
    - anti-inflammatory medications or analgesics, or
    - flexibility and muscle strengthening exercises, or
    - supervised physical therapy [Activities of daily living (ADLs) diminished despite completing a plan of care], or
    - assistive device use, or
    - weight reduction as appropriate, or
    - therapeutic injections into the knee as appropriate.

In some circumstances, for example, if the patient has bone on bone articulation, severe deformity, or pain or significant disabling interference with activities of daily living, the surgeon may determine that nonsurgical medical management would be ineffective or counterproductive, and that the best treatment option, after explaining the risks, is surgical. If medical management is deemed inappropriate, the medical record should indicate the rationale for and circumstances under which this is the case.

- Failure of a previous osteotomy; or
- Distal femur fracture; or
- Malignancy of the distal femur, proximal tibia, knee joint or adjacent soft tissues; or
- Failure of previous unicompartmental knee replacement; or
- Avascular necrosis of the knee; or
• Proximal tibia fracture

**Indications for Replacement/Revision of Total Knee Arthroplasty**

• Loosening of one or more components, or
• Fracture or mechanical failure of one or more component, or
• Infection, or
• Treatment of periprosthetic fracture of distal femur, proximal tibia or patella, or
• Progressive or substantial periprosthetic bone loss, or
• Bearing surface wear leading to symptomatic synovitis, or
• Implant or knee misalignment, or
• Knee stiffness/arthrofibrosis, or
• Tibiofemoral instability, or
• Extensor mechanism instability

**Limitations**

Noridian will not consider a total knee replacement or total hip replacement medically necessary when the following contraindications are present:

• Active infection of the hip or knee joint or active systemic bacteremia
• Active skin infection (exception recurrent cutaneous staph infections) or open wound within the planned surgical site of the hip or knee
• Rapidly progressive neurological disease except in the clinical situation of a concomitant displaced femoral neck fracture

The following conditions are relative contraindications to total knee or total hip replacement and if such surgery is performed in the presence of these conditions, it is expected that the rationale for proceeding with the surgery under such circumstances is clearly documented in the medical record:

• Absence or relative insufficiency of abductor musculature
• Any process that is rapidly destroying bone
• Neurotrophic arthritis

**For Medicare and Medicaid Determinations Related to States Outside of Nevada:**

Please review Local Coverage Determinations that apply to other states outside of Nevada.


**Important Note:** Please also review local carrier Web sites in addition to the Medicare Coverage database on the Centers for Medicare and Medicaid Services’ Website.

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**U.S.FOOD AND DRUG ADMINISTRATION (FDA)**

Knee replacement surgery is a procedure and therefore is not regulated by the FDA. However, devices and instruments used during the surgery require FDA approval. See the following website for additional information (product codes MBH, JWH, KRO):

FDA-approved knee replacement surgery devices are generally approved for any or all of the following:

- Non-inflammatory degenerative joint disease such as osteoarthritis
- Rheumatoid arthritis
- Post-traumatic arthritis
- Complex fracture(s) of the distal (lower) femur
- Revision of failed knee replacement surgery
- Correction of functional deformity

### APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination (NCD) for Total Joint Guidelines may apply.

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<th>CPT® Codes</th>
<th>Description</th>
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<tr>
<td>27445</td>
<td>Arthroplasty, knee, hinge prosthesis (e.g., Walldius type)</td>
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<tr>
<td>27446</td>
<td>Arthroplasty, knee, condyle and plateau; medial OR lateral compartment</td>
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<tr>
<td>27447</td>
<td>Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)</td>
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<td>27486</td>
<td>Revision of total knee arthroplasty, with or without allograft; 1 component</td>
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<tr>
<td>27487</td>
<td>Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component</td>
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### PROTOCOL HISTORY/REVISION INFORMATION

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The foregoing Health Plan of Nevada/Sierra Health & Life Health Operations protocol has been adopted from an existing UnitedHealthcare coverage determination guideline that was researched, developed and approved by the UnitedHealthcare Coverage Determination Committee.