Medical Policy

Knee Arthroplasty (Total or Partial)	
MEDICAL POLICY NUMBER	Med_Clin_Ops-009
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

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PURPOSE

The purpose of this policy is to establish the clinical review criteria that support thedetermination of medical necessity for Total Knee Arthroplasty (TKA) and partial or unicompartmental knee arthroplasty.

POLICY

Clinical Review Criteria

KNEE ARTHROPLASTY RELATED TO FRACTURE

Prior Authorization is **NOT** required when Total or Partial Knee Arthroplasty is part of the care of an acute fracture (excluding fracture of implant and periprosthetic fracture).

ELECTIVE KNEE ARTHROPLASTY

A. Initial/Primary Total Knee Arthroplasty or Partial Knee Arthroplasty

Prior Authorization is required for elective Total or Partial Knee Arthroplasty and maybe authorized documentation in the medical records indicates that **ALL** the following criteria are met:

1) The member has advanced joint disease due to conditions such as osteoarthritis, rheumatoid arthritis, osteonecrosis, or traumatic arthritis and **ALL** of the following criteria

are met:

a. Reports of imaging studies obtained within the past twelve (12) months describing the degree of cartilage damage.

b. The results of all imaging studies correlate with the clinical findings in support of the requested procedure.

c. Presence of significant radiographic findings, including knee joint destruction, angular deformity or severe narrowing.

2) Physical exam demonstrates limited range of motion, crepitus, effusion or swelling of knee joint on physical examination.

3) Functional limitation resulting in two (2) impaired activities of daily living.

4) Pain that is persistent, severe and has been present for at least six (6) months. For purposes of this guideline, severe pain is ≥ 4 on the VAS scale.

5) Failure of a minimum of (3) months of intensive conservative non-operative care when **ONE or more** of the following has occurred

a. Improvement of the symptoms has plateaued or failed to occur and the residual symptoms of pain and functional disability are unacceptable

b. An explicit statement in the clinical documents that explains why such conservative therapy is contraindicated. The requirement for physical therapy will not be met if there is a failure to initiate or complete prescribed physical therapy for non-clinical reasons.

6) BMI documentation of **ONE** of the following

a. BMI<35 at the time of the prior authorization request

b. BMI 35 - 40. If the BMI is greater than 35, but less than 40, documentation of failure of concerted effort to lose weight AND documentation that the surgeon has considered the risks of overweight.

7) Documentation in the medical record of tobacco and nicotine status indicating **ONE** of the following:

i. The individual is a non-tobacco and non-nicotine user.

ii. The individual has been tobacco-free for a minimum of six (6) weeks prior tothe date of the prior authorization request.

B. Revision Total Knee Arthroplasty or Partial Knee Arthroplasty

Prior authorization is required for Revision Total or Partial Knee Arthroplasty and maybe authorized when **ONE or more** of the following are met:

1) Adverse local tissue or systemic reaction to previous metal implant, or

2) Component instability, loosening, fracture of implant or other mechanical failure such as implant malposition or impingement as documented by imaging or other demonstration of effect, or

3) Previous removal of prosthesis due to infection or catastrophic failure, or

4) Progressive and substantial bone loss **causing failure of the previous implant, or**
5) Failure of a minimum of (3) months of intensive conservative non-operative care when **ONE** of the following is documented:
    a. Improvement of the symptoms has plateaued or failed to occur and the residual symptoms of pain and functional disability are unacceptable including documentation of antalgic gait and abnormal plain radiography or imaging studies.
    b. An explicit statement in the clinical documents that explains why such conservative therapy is contraindicated. The requirement for physical therapy will not be met if there is a failure to initiate or complete prescribed physical therapy for non-clinical reasons.
6) BMI documentation of **ONE** of the following
    a. BMI < 35 at the time of the prior authorization request
    b. BMI 35 - 40. If the BMI is greater than 35, but less than 40, documentation of failure of concerted effort to lose weight AND documentation that the surgeon has considered the risks of overweight.
7) Documentation in the medical record of tobacco and nicotine statusindicating the following:
    a. The individual is a non-tobacco and non-nicotine user.
    b. The individual has been tobacco-free for a minimum of six (6) weeks prior tothe date of the prior authorization request.

CONTRAINDICATIONS AND UNAUTHORIZED INVESTIGATIVE PROCEDURES

Total or Partial Knee Arthroplasty will not be authorized if medical contraindications are present. Services may be authorized after confirmation of **ALL of the following**

1) No documentation of active (untreated or failed treatment) infection of the knee joint.
2) No documentation of active skin infection or open wounds within the planned surgical site of the knee.
3) No documentation of permanent or irreversible muscle weakness in the absence of pain that prevents ambulation;
4) No documentation of Allergy to components of the implant (for example, cobalt, chromium, or alumina).
5) No documentation of BMI > 40.
6) No documentation of severe cardiopulmonary disease.
7) No documentation of anemia.
8) No documentation of malnutrition.
9) No documentation of active urinary tract infection.
10) No documentation of active dental infection.
11) No documentation of systemic infection.
12) No documentation of skeletal immaturity.

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EXCLUSIONS

Brand New Day/Central Health Medicare Plan considers some procedures **investigative** and those procedures will not be authorized. Services may be authorized after confirmation of **ALL** of the following::

1) The Authorization is NOT for procedures utilizing computer-navigated, patient-specific or gender-specific instrumentation.
2) The Authorization is NOT for Bicompartmental Arthroplasty.
3) The Authorization is NOT for MAKOplasty/MAKO Tactile Guidance System.

BACKGROUND

The incidence of knee osteoarthritis (OA) in the United States is estimated at 240 persons per 100,000 persons per year. It was estimated that 9.9 million adults had symptomatic OA of theknee in 2010. Risk factors for the condition increase with age, especially in women. Genetics,large body mass, certain occupations, and repetitive knee bending or heavy lifting are other factors that increase the risk of developing the disease.

Total Knee Arthroplasty is one of the most commonly performed orthopedic procedures,making it a key driver of health care costs. Many studies have demonstrated that total knee replacement is a cost-effective procedure that improves activity and quality of life. As of 2017, over 840,000 inpatient total knee replacements were performed annually in the United States and were becoming increasingly common. The number of total knee replacements performed annually in the United States is expected to grow by 673 percent to nearly 3.5 million procedures per year by 2030. This expected increase will be driven by an aging population, increased usage in younger individuals, the increasedprevalence of obesity, and the increased demand for an active lifestyle.

Despite the potential benefits of total knee arthroplasty, it is an elective procedure and should only be considered after extensive discussion of the risks, benefits, and alternatives. As with any major surgical procedure, complications, though uncommon and often preventable with careful surgical technique and postoperative management, may result during or after knee replacement. In addition to anesthesia related risks, exacerbation of preexisting medical issuesand medication and allergic reactions, other possible complications include, but are not limited to: thromboembolism, infection, patellofemoral disorders, peroneal nerve palsy, periprosthetic fractures, wound healing, accelerated wear or failure of the prosthetic device, instability, persistent pain, and stiffness. Therefore, health optimization and informed consent are critical.

DEFINITIONS

1. **Arthroplasty**, also called joint replacement, is a surgical procedure in which the worn and/ordamaged surfaces of the knee joint are replaced with a prosthesis made of metal, ceramic material or high-density plastic. Knee arthroplasty may be total or unicompartmental. TKA is performed when all three compartments of the knee are affected by joint disease. TKA involves removal of a thin layer of subchondral bone and overlying articular cartilage, with anatomic resurfacing of all three compartments and insertion of a metal implant and polyethylene bearing surface. The implants are either fixed with bone cement or are cementless and press fit into place.

2. **Authorization:** A decision by Brand New Day/Central Health Medicare Plan that a health care service, treatment plan, prescription drug or durable medical equipment is medically necessary or meets other member contract terms. Sometimes called prior authorization, prior approval or precertification. Brand New Day/Central Health Medicare Plan requires preauthorization for certain services before a member receives them, except in an emergency. Authorization is not a promise that Brand New Day/Central Health Medicare Plan will cover the cost.

3. **Grading systems** may be used to classify the severity of osteoarthritis and identify those injuries that are suitable for repair techniques. The most common grading systems include the Kellgren-Lawrence and the Modified Outerbridge Classification systems.

   i.) **The Kellgren-Lawrence** grading system is based on radiographic evidence ofcartilage damage.
   - Grade 1: Doubtful narrowing of joint space and possible osteophytic lipping.
   - Grade 2: Definite osteophytes, definite narrowing of joint space.
   - Grade 3: Moderate multiple osteophytes, definite narrowing of joint space,some sclerosis and possible deformity of bone contour.
   - Grade 4: Large osteophytes marked narrowing of joint space, severesclerosis and definite deformity.

   ii.) The **Modified Outerbridge Classification** addresses arthroscopic evidence of articular cartilage damage and provides delineation of varying areas of chondralpathology, based on the qualitative appearance of the cartilage surface.
   - Grade 0: Normal
   - Grade I: Cartilage with softening and swelling.
   - Grade II: Partial-thickness defect with fissures on the surface that do notreach subchondral bone or exceed 1.5 centimeters (cm) in diameter.
   - Grade III: Fissuring to the level of the subchondral bone in an areawith a diameter more than 1.5 centimeters.
   - Grade IV: Exposed subchondral bone head. Subchondral bone is thebone underneath the joint cartilage.

4. **Visual Analog Scale (VAS) for Pain** The pain VAS is a unidimensional measure of pain intensity, which has been widely used in diverse adult populations, including those with rheumatic diseases). The pain VAS is available in the public domain at no cost. http://www.amda.com/tools/library/whitepapers/hospiceinltc/appendix-a.pdf.
   The VAS takes <1 minute to complete. The VAS is administered as a paper and pencil measure. As a result, it cannot be administered verbally or by phone. No training is requiredother than the ability to use a ruler to measure distance to determine a score Caution is required when photocopying the scale as this may change the length of the 10-cm line As slightly lower scores have been reported on the HVAS compared to the VVAS the same alignment of scale should be used consistently within the same patient. The VAS is widely used due to its simplicity and adaptability to a broad range of populations and settings. Its acceptability as a generic pain measure was demonstrated in the early 1970s.

5. **Nonsurgical management** is typically used to treat early arthritis. The purpose of

treatmentis to reduce pain, increase function and generally reduce symptoms. Nonsurgical treatmentsfall into the following major categories:

- Lifestyle modification, including weight loss and minimizing activities that aggravate the condition.
- Exercise including flexibility and muscle strengthening exercises and supervised physical therapy.
- Assistive devices, such as canes, crutches, walkers, and knee braces. iv.)Drug treatment, including over -the-counter analgesics, anti-inflammatory
- medications, intra-articular steroids and hyaluronic acid derivative injection.
- Other conservative measures such as applications of heat or ice, water exercises, liniments or elastic support bandages.

6. **Osteoarthritis** (OA) is the most common form of knee arthritis. OA is usually a slowly progressive degenerative disease in which the joint cartilage gradually wears away. It mostoften affects middle-aged and older people. It is also known as degenerative joint disease (DJD).

7. **Osteonecrosis** is the destruction of bone tissue due to ischemia (disruption of the blood supply), infection, malignant disease, or trauma.

8. **Post-traumatic arthritis** can develop after an injury to the knee. This type of arthritis is likeosteoarthritis and may develop years after a fracture, ligament injury, or meniscus tear.

9. **Rheumatoid arthritis** (RA) is an inflammatory type of arthritis that can destroy the joint cartilage. RA can occur at any age. RA generally affects both knees.

10. **Tobacco/Nicotine** products can result in nicotine addiction and health problems, includinga negative effect on bone healing. This includes delayed unions, non-unions and other complications (e.g., decreased blood flow; wound complications). Products containing nicotine include, but are not limited to;
    - Smoked tobacco (cigarettes, cigars, cigarillos, pipe tobacco).
    - Smokeless tobacco (chewing tobacco, snuff).
    - Nicotine replacements (patches, gum, nasal spray, inhalers).

CODING

The codes listed below are for reference purposes. This list does not imply whether the code is covered or not covered. The benefit document should be referenced for coverage determination. This list of applicable codes may not be all-inclusive.

CPT 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 (eg, Walldius type)

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CPT CODE	DESCRIPTION
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

HCPCS CODE	DESCRIPTION
n/a	

EVIDENCE BASED REFERENCES

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POLICY HISTORY

This policy has been approved by the approval body listed below or has received other necessary approval pursuant to Brand New Day/Central Health Medicare Plan's policies on clinical criteria and policy development.

Approval Body	Utilization Management Committee		
Version History	**Approval Date**	**Effective Date**	**Action**
V1	07-31-2018	08-01-2018	New Policy
V2	12-18-2018	12-18-2018	Noted that policies appy to 2019 markets
V3	05-03-2019	05-03-2019	Edits made to radiography language
V4	02-01-2020	02-01-2020	Include appropriate 2020 markets
V5	12-20-2020	12-20-2020	Small Group added as applicable product
V6	05-20-2021	05-20-2021	Annual review
V7	06-17-2021	06-17-2021	Clarified documentation requirements, included partial knee arthroplasty
V8	05-09-2022	05-09-2022	Annual review
V9	10-12-2022	10-12-2022	Codes confirmed, criteria confirmed and reorganized for clarity
V10	10-12-2022	03-01-2023	Adopted by MA UM Committee (no policy revisions made)