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## **Medicare Advantage Medical Coverage Policy**

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#### Disclaimer

The Coverage Summaries are reviewed by the iCare Medicare Utilization Management Committee. Policies in this document may be modified by a member's coverage document. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT<sup>®</sup> codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from iCare.

## **Related Medicare Advantage Medical/Pharmacy Coverage Policies**

None

#### **Related Documents**

Please refer to <u>CMS website</u> for the most current applicable National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

Туре	Title	ID	Jurisdiction	Applicable
		Number	Medicare	States/Territories

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			Administrative	
LCD LCA	Lower Extremity Major Joint Replacement (Hip and Knee)	<u>L36007</u> <u>A56796</u>	JH - Novitas Solutions, Inc. (Part A/B MAC) JL - Novitas Solutions, Inc. (Part A/B MAC)	AR, CO, NM, OK, TX, LA, MS DE, D.C., MD, NJ, PA
LCD LCA	Major Joint Replacement (Hip and Knee)	<u>L33618</u> <u>A57765</u>	JN - First Coast Service Options, Inc. (Part A/B MAC)	FL, PR, U.S. VI
LCD LCA	Total Joint Arthroplasty	<u>L36039</u> <u>A57428</u>	J6 - National Government Services, Inc. (Part A/B MAC) JK - National Government Services, Inc. (Part A/B MAC	IL, MN, WI CT, NY, ME, MA, NH, RI, VT
LCD LCA	Total Joint Arthroplasty	<u>L33456</u> <u>A56777</u>	JJ - Palmetto GBA (Part A/B MAC) JM - Palmetto GBA (Part A/B MAC)	AL, GA, TN NC, SC, VA, WV
LCD LCA	Total Knee Arthroplasty	<u>L36575</u> <u>A57685</u>	JE - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands
LCD LCA	Total Knee Arthroplasty	<u>L36577</u> <u>A57686</u>	JF - Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY

## Description

Knee arthroplasty is a surgical procedure with the primary goal to relieve pain caused by severe arthritis with or without the presence of a deformity. Knee arthroplasty procedures may include a partial or total replacement or focal resurfacing of the knee.

Knee arthroplasty, partial or total replacement, is performed for destruction of articular cartilage from osteoarthritis, rheumatoid/inflammatory arthritis, posttraumatic degenerative joint disease or osteonecrosis/joint collapse with cartilage destruction. Arthritic damage may occur in one or more of the

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compartments of the knee.<sup>14</sup> The compartments are the medial or inner, lateral or outer and patellofemoral (kneecap and thigh bone).

The arthroplasty/replacement procedures are described as follows:

- Total (TKA) consists of a resecting the entire knee by removing diseased articular surfaces of all three compartments of the knee, followed by resurfacing with metal and polyethylene prosthetic femoral, patellar and tibial components. Based on the design of the prosthesis, ligaments may be retained, released or resectioned. The patella may or may not be resurfaced.<sup>13</sup>
- Unicompartmental (UKA), also known as a partial knee replacement, resects and replaces one knee compartment, either the lateral, medial or patellofemoral.
- **Bicompartmental** resurfaces the medial and patellofemoral compartments and replaces them with an implant.
- **Bi-unicompartmental** a UKA performed on the contralateral or opposite compartments of a knee (eg, lateral and medial).

**Focal resurfacing of a knee joint** surgically removes a localized or limited amount of damaged bone from the surface of the joint. The damaged area is replaced with an implant. This technology is purportedly viewed as an early or bridging treatment before a total knee arthroplasty for an individual with the following conditions:

- Between 40 and 60 years of age
- Diagnosed with early-stage osteoarthritic damage which is confined to the inside of the knee
- Overweight
- Physically active

Examples of US Food & Drug Administration (FDA) approved focal knee resurfacing systems include, but may not be limited to, the HemiCAP patello-femoral resurfacing prosthesis and the UniCAP compartmental resurfacing implant system.

**Interpositional unicompartmental or unicondylar spacer device** is a non-fixed or free floating concaved shaped metallic implant developed to treat isolated medial compartment osteoarthritis purportedly for an individual that has failed conservative treatments but is not a candidate for a TKA.<sup>1</sup> Examples of FDA-approved interpositional unicompartmental or unicondylar devices include, but may not be limited to, the Orthoglide and the Unicondylar Interpositional Spacer (previously named Unispacer).

**Customized knee replacement implants** are prostheses that are uniquely designed to copy an individual's knee anatomy based on a computed tomography (CT) scan. A computer assisted design using digital formulas converts the CT scan into a 3 -dimensional (3D) model of the knee that is used to make the

customized prosthesis. Purportedly, the customized devices allow for greater knee flexion or motion, improved implant durability and surgical outcomes than conventional knee prostheses.

**Revision arthroplasty** is performed on an individual who has had a prior knee arthroplasty. Revision arthroplasty may be needed when pain or other symptoms occur as a result of failure of the prior surgery. Failure may occur as a result of infection of the joint, bone loss in the structures supporting the prosthesis, fracture, aseptic loosening of the components, wear of the prosthetic components, and for other reasons.

## **Coverage Determination**

iCare follows the CMS requirement that only allows coverage and payment for services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

*In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the criteria contained in the following:* 

## **Total Knee Arthroplasty**

**Total Knee Arthroplasty** will be considered medically reasonable and necessary when (all) the following requirements are met:

- Absence of <u>contraindications</u>; AND
- The device is FDA approved;

## AND ONE of the following:

- Angular deformity of greater than 20 degrees; **OR**
- Avascular necrosis of the knee; OR
- Congenital deformity; OR
- Distal femur or proximal tibia fracture; **OR**
- Failure of a previous osteotomy; OR
- Failure of previous unicompartmental knee replacement; OR

- Hemophilic arthropathy with knee contracture; OR
- Malignancy of the distal femur, proximal tibia, knee joint or adjacent soft tissues; **OR**
- Malunion or nonunion of a distal femur or tibia fracture; **OR**
- Pigmented vilonodular synovitis with joint destruction; OR
- Post traumatic knee joint destruction; **OR**
- Progressive flexure contracture <sup>5,6, 11, 19</sup>; **OR**
- 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) <sup>5,6</sup>; AND
  - Pain or functional disability from injury due to trauma or arthritis of the joint <sup>5,6</sup>; **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
    - Assistive device use; **OR**
    - Flexibility and muscle strengthening exercises; OR
    - Supervised physical therapy [Activities of daily living (ADLs) diminished despite completing a plan of care); OR
    - Therapeutic injections into the knee as appropriate; **OR**
    - Weight reduction as appropriate <sup>5,6</sup>; OR

\*In some circumstances, for example, if the patient has bone on bone articulation, severe deformity, pain or significant disabling interference with activities of daily living, the surgeon may determine that

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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 <sup>5,6</sup>.

#### **Replacement/Revision of TKA**

Replacement/Revision knee arthroplasty is considered reasonable and necessary for individuals with <u>one or</u> <u>more</u> of the following:

- Bearing surface wear with symptomatic synovitis; OR
- Dislocation of the patella; OR
- Extensor mechanism instability; OR
- Fracture or mechanical failure of one or more components; OR
- Implant or knee misalignment; OR
- Infection; OR
- Knee stiffness/arthrofibrosis; OR
- Loosening of one or more component; OR
- Other destructive conditions that render the knee impaired to the extent to preclude employment or functional activities; **OR**
- Periprosthetic fracture of distal femur, proximal tibia or patella; OR
- Progressive or substantial periprosthetic bone loss; OR
- Tibiofemoral instability; **OR**
- Tissue or systemic reaction to metal implant <sup>5,6,19</sup>

#### **Unicompartmental Knee Arthroplasty**

**Unicompartmental Knee Arthroplasty** will be considered medically reasonable and necessary when the following requirements are met:

• Absence of <u>contraindications</u>; AND

• The device is FDA approved;

AND ONE of the following:

- Angular deformity that corrects to neutral; OR
- Partial resection of the knee required for treatment of malignancy; OR
- Unicompartmental post traumatic joint destruction; OR
- Replacement (revision) of previous arthroplasty needed (eg, infection, implant failure)<sup>20,22</sup>; OR
- Documentation of painful, disabling joint disease of the knee that interferes with activities of daily living (ADLs) resulting from non-inflammatory joint disease (avascular necrosis, osteoarthritis or traumatic arthritis) including:
  - Failure of at least 3 months of conservative treatment under the direction of a healthcare professional, which includes:
    - Activity/lifestyle modifications; AND
    - Ambulatory assistive device if medically appropriate; AND
    - Individual with a BMI greater than 40 have documentation of attempted weight loss; AND
    - Intra-articular injections when medically appropriate and not contraindicated. Intra-articular steroid injections should be avoided 3 months prior to unicompartmental knee arthroplasty; AND
    - Medications (eg, nonsteroidal anti-inflammatory drugs [NSAIDs] or non-narcotic analgesics) when medically appropriate and not contraindicated; AND
    - Physical therapy including home exercise program (HEP); AND
  - Radiographic confirmation of bone and joint pathology of the knee joint as evidenced one of the following:
    - Exposed subchondral bone (<u>Outerbridge</u> Grade 4); OR
    - Large osteophytes, marked narrowing of joint space, definite deformity of bone ends, severe sclerosis (<u>Kellgren</u> Lawrence Grade 4); OR
  - Radiological confirmation (MRI preferred if not contraindicated) of avascular necrosis of the femoral condyles or proximal tibia

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The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

## **Coverage Limitations**

<u>US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 -</u> <u>Particular services excluded from coverage</u>

## **Total Knee Arthroplasty**

TKA/TKR will not be considered medically reasonable and necessary for the following contraindications:

- Active infection of the hip or knee joint or active systemic bacteremia; OR
- Active skin infection (exception recurrent cutaneous staph infections) or open wound within the planned surgical site of the hip or knee; **OR**
- Active urinary tract or dental infection; OR
- Neuropathic arthritis; OR
- Progressive neurological disease, etiologic for pain, instability or disability; OR
- Rapidly progressive neurological disease except in the clinical situation of a concomitant displaced femoral neck fracture; **OR**

The following conditions are relative contraindications to TKA/TKR 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; OR
- Any process that is rapidly destroying bone; OR
- Insufficiency of extensor mechanism/quadriceps; OR
- Neurotrophic arthritis <sup>3-7</sup>

#### **Unicompartmental Knee Arthroplasty**

UKA will not be considered medically reasonable and necessary for the following contraindications:

• Angular deformity of more than 5 degrees from the mechanical axis for valgus knees; OR

- Angular deformity of more than 10 degrees from the mechanical axis for varus knees; **OR**
- Anterior cruciate ligament deficiency not able to be corrected by a non-mobile bearing implant and the knee joint cannot be balanced at the time of surgery; **OR**
- Exposed subchondral bone beneath the patella; OR
- Flexion contracture of 10 degrees or more; OR
- Inflammatory arthritis (eg, rheumatoid arthritis); OR
- Lateral subluxation of patella or joint space loss along lateral patella facet; OR
- Preoperative arc of motion of less than 90 degrees; OR
- Significant cartilaginous erosion in the weight-bearing areas of the opposite compartment <sup>11, 20</sup>

#### **Other Miscellaneous Knee Procedures/Devices**

The following services/items will not be considered medically reasonable and necessary:

- Bicompartmental/bi-unicompartmental knee arthroplasty; OR
- Customized knee replacement implants; OR
- Focal resurfacing; OR
- Interpositional unicompartmental device (eg, Orthoglide, Unicondylar Unispacer)

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

#### **Summary of Evidence**

## Bicompartmental/Bi-Unicompartmental Knee Arthroplasty

Shrednitzki (2020) and colleagues completed a prospective randomized study to compare the outcome of bicompartmental knee arthroplasty (BCA) to a TKA. The study randomly enrolled eighty patients to either a BCA or TKA group. The length of time for the surgical procedure was longer in the bicompartmental surgery group compared to TKA (73.5  $\pm$  9.9 minutes compared to 58.8  $\pm$  12.8 minutes) and resulted in less blood loss. Participants received evaluations evaluated preoperatively, 3, 6, and 12 months, and 2 and 5 years after the procedure. Knee Society Scores, Oxford Knee scores and the University of California Los Angeles were used for each evaluation while the Forgotten Knee Score was used in the final follow up. The BCA

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group did show in improvement in range of motion at 1 year, however, both groups showed s no significant difference in score. This result caused the authors to question support for the BCA over the TKA despite increased range of motion and less surgical blood loss.<sup>13</sup>

The American Academy of Orthopedic Surgeons (AAOS) does not mention a bicompartmental or biunicompartmental arthroplasty as a surgical option for the treatment of knee osteoarthritis in the clinical guideline surgical management of osteoarthritis of the knee (2022).<sup>2</sup>

## **Customized Knee Replacement Implants**

The available comparative evidence from 5 studies suggests that 3D-printed orthopedic implants for the hip, knee, and spine are generally safe and may achieve at least similar results to standard implants for most efficacy and safety outcomes. The noncomparative evidence suggests that 3D-printed orthopedic implants appear to be safe and consistently reduce pain and improve function compared with baseline. The clinical significance of any differences detected from baseline or between groups was not discussed in the evaluated studies and remains unclear. The majority of the studies had methodological flaws and lacked controls so that comparisons with standard therapies is very limited. There is a need for additional, larger, well-designed controlled trials to better determine risks and benefits over the long term and to define patient selection criteria.<sup>16</sup>

## Focal Resurfacing

A review of current medical literature failed to result in any clinical studies on the use of focal resurfacing for mild osteoarthritis of the knee. The American Academy of Orthopedic Surgeons (AAOS) does not mention focal resurfacing as a surgical option for the treatment of knee osteoarthritis in the clinical guideline surgical management of osteoarthritis of the knee (2022).<sup>2</sup>

## Interpositional Unicompartmental Device

The American Academy of Orthopedic Surgeons (AAOS) in the clinical guideline management of osteoarthritis of the knee (non-arthroplasty) (2021) reached a consensus opinion to not use free floating (unfixed) or interpositional devices in patients with medial osteoarthritis of the knee due to the lack of evidence to support its use.<sup>1</sup>

## **Coding Information**

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
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	

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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)	
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	
CPT®		
Category III Code(s)	Description	Comments
No code(s) identified		
HCPCS Code(s)	Description	Comments
No code(s) identified		

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## Appendix

## Appendix A

## **Outerbridge Classification for Cartilage Lesions**

Grade of Lesion	Articular Cartilage Damage
Grade 0	Normal Cartilage
Grade 1	Cartilage with softening and swelling
Grade 2	Partial thickness defect with fissures on the surface that do not reach
	subchondral bone or exceed 1.5 centimeters in diameter
Grade 3	Fissuring to the level of subchondral bone in an area with a diameter
	more than 1.5 centimeters
Grade 4	Exposed subchondral bone

## Appendix B Kellgren Lawrence Radiographic Classification of Osteoarthritis of the Knee

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Grade of Lesion	Joint Pathology
Grade 1	Doubtful joint space narrowing, possible osteophytic lipping
Grade 2	Definite osteophytes, possible joint space narrowing
Grade 3	Moderate osteophytes, definite joint space narrowing, some sclerosis,
	possible bone-end deformity
Grade 4	Large osteophytes, marked joint space narrowing, severe sclerosis,
	definite bone ends deformity

## Change Summary

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- Click or tap to enter a date. Choose Action.