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Policy Effective Date	<b>10/15/2025</b>

## Unicondylar Interpositional Spacer as a Treatment of Unicompartmental Arthritis of the Knee

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<b>Related Policies (if applicable)</b>
None

### Disclaimer

**Carefully check state regulations and/or the member contract.**

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

### Coverage

Unicondylar interpositional spacer is considered experimental, investigational and/or unproven as a treatment of unicompartmental arthritis of the knee.

### Policy Guidelines

There is no specific procedure code for this procedure.

### Description

Interpositional unicondylar spacers are metallic implants that are inserted into the joint space between the affected tibial plateau and femoral condyle. Instead of being fixed, the spacers are held in place by the geometry of the curved implant, ligament tension, and surrounding soft tissue structures. Metallic interpositional unicondylar spacers have been developed as possible

alternatives to osteotomy or unicompartmental arthroplasty for treatment of unicompartmental knee arthritis.

While osteoarthritis (OA) of the knee may involve both medial and lateral components, some patients may have signs or symptoms confined to only one compartment, often as a result of specific injury. Initial treatment of uni- and bi-compartmental disease is similar, i.e., analgesics, viscosupplementation, and arthroscopic debridement. If focal cartilage defects are present, other therapies such as autologous chondrocyte or osteochondral transplants may be considered. When these more conservative therapies fail, surgical interventions may be indicated.

Older patients with arthritis who typically consider total knee replacement are the type of patients who might be considered for unicondylar knee arthroplasty. The metal-to-plastic unicondylar prosthesis has both tibial and femoral components but leaves intact both cruciate ligaments, the patellofemoral joint, and the opposite compartment, thus preserving nearly normal knee kinematics. Unicompartmental arthroplasties are typically performed in patients with isolated medial arthritis who are older than 60 years, have a low level of physical activity, and weigh less than 180 pounds.

Younger patients are usually not considered ideal candidates for total knee arthroplasty since they would be expected to need at least one additional total knee replacement in their lifetimes. The preferred option for young patients with unicompartmental disease is high tibial osteotomy. Those with medial compartment disease may also be candidates for unicompartmental arthroplasty or for fixed metallic hemiarthroplasty. MacIntosh and McKeever hemiarthroplasty devices were used primarily between 1950 and 1970, but their use has decreased with the refinement of total knee arthroplasty procedures. These devices require bone cuts that might complicate future arthroplasty procedures.

Metallic interpositional unicondylar spacers have been developed as possible alternatives to osteotomy or unicompartmental arthroplasty. These devices do not require any bone resection or mechanical fixation for proper function. Following debridement and resection of the meniscus, the device is fit to the joint space above the affected tibial plateau and held in place by its geometry, ligament tension and the surrounding soft tissue structures. The uncemented implant adapts to the kinematics of the knee, with a smooth metallic curved surface against which the femur articulates. Preservation of bone is important for the use of interpositional spacers as a bridge procedure in active young adults or for overweight patients who would not be candidates for unicompartmental arthroplasty.

### **Regulatory Status**

The United States (U.S.) Food and Drug Administration (FDA) approved unicondylar spacer devices under the 510(k) marketing clearance. Table 1 lists the FDA approved unicondylar spacer devices under FDA product code HSH.

**Table 1. Unicondylar Spacer Devices That Have Received FDA 510(k) Clearance**

Device Name	FDA Approval Date	Indication
Unicondylar Interpositional Spacer or "UniSpacer™" (K003269) (3)	2001	For uncemented use in treatment of moderate degeneration of the medial compartment of the knee (grade III-IV chondromalacia) with no more than minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the lateral condyle and patellofemoral compartments.
Oti Unicondylar Interpositional Spacer (K022779) (4)	2002	For uncemented treatment of the tibia articulating surfaces (medial and lateral) of the following: moderate degeneration of the medial and/or lateral compartment of the knee (grade II-IV chondromalacia) and minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the patellofemoral components.
Knee Interpositional Mini-Repair System™ (K033242) (5)	2003	For uncemented treatment of the medial and/or lateral tibial articulating surfaces of the following:  Moderate degeneration of the medial or lateral compartment of the knee (grade II-IV chondromalacia) and minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the patellofemoral compartments.  The Knee Interpositional Mini-Repair System is intended to be implanted in the knee as a non-fixated, intra-articular support with minimal to no movement of the device after implantation.
Orthoglide Medial Knee Implant™ (K053094) (6) which includes models 9056, 9057, 9060, 9062, 9063, 9064, 9065	2006	For uncemented use in the treatment of moderate degeneration of the medial compartment of the knee (grade II-IV chondromalacia) with no more than minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the lateral and patellofemoral compartments in patients with OA.
Orthoglide® lateral Knee Implant® (K073233) (7)	2008	For uncemented use in the treatment of moderate degeneration of the lateral compartment of the knee (grade II-IV chondromalacia) with no more than minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the medial and patellofemoral compartments in patients with OA.

FDA: Food and Drug Administration; OA: Osteoarthritis.

## Rationale

This policy is based on the following professional guidelines and/or position statements.

### **Professional Guidelines and Position Statements**

#### American Academy of Orthopaedic Surgeons (AAOS)

In an updated 2022 guideline, the AAOS (1) consensus statement recommends against the use of a free-floating interpositional device in patients with symptomatic unicompartmental knee osteoarthritis (OA) as there is no reliable evidence to support its use.

#### National Institute for Health and Care Excellence (NICE)

The 2015 NICE guideline for mild to moderate knee OA states “Current evidence on the safety and efficacy of implantation of a shock or load absorber for mild to moderate symptomatic medial knee osteoarthritis is inadequate in quality and quantity therefore should only be used in the context of research.” (2)

### **Coding**

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

<b>CPT Codes</b>	27599, 29999
<b>HCPCS Codes</b>	C1776

\*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

### **References**

#### **Professional Guidelines and Position Statements:**

1. Brophy R and Fillingham Y. American Academy of Orthopaedic Surgeons (AAOS) Clinical Practice Guideline Summary: Management of osteoarthritis of the knee (non-arthroplasty), Third edition. 2022 May 1. Available at: <<https://www.journals.lww.com>> (accessed March 4, 2025).
2. National Institute for Health and Clinical Excellence (NICE). Implantation of a shock or load absorber for mild to moderate symptomatic medical knee osteoarthritis. Interventional procedure guidance 512 (2015 Jan). Available at: <<https://www.nice.org.uk>> (accessed March 5, 2025).

#### **Other:**

3. FDA 510(k) summary: Unicondylar Interpositional Spacer (K003269). Sulzer Orthopedics Inc. Available at: <<https://www.accessdata.fda.gov>> (accessed March 4, 2025).

4. FDA 510(k) summary: Oti Unicondular Interpositional Spacer Osteoimplant (K022779). Osteoimplant Technology Inc. Available at: <<https://www.accessdata.fda.gov>> (accessed March 4, 2025).
5. FDA 510(k) summary: Knee Interpositional Mini-Repair System. Imaging Therapeutics, Inc. (K033242). Available at: <<https://www.accessdata.fda.gov>> (accessed March 4, 2025).
6. FDA 510(k) summary: Orthoglide® Medial Knee Implant (K053094). Advanced Bio-Surfaces Inc. Available at: <<https://www.accessdata.fda.gov>> (accessed March 4, 2025).
7. FDA 510(k) summary: Orthoglide® Lateral Knee Implant (K073233). Advanced Bio-Surfaces Inc. Available at: <<https://www.accessdata.fda.gov>> (accessed March 4, 2025).

## Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <<https://www.cms.hhs.gov>>.

## Policy History/Revision

Date	Description of Change
10/15/2025	Document updated with literature review. Coverage unchanged. No new references added; others updated and/or removed.
03/15/2024	Reviewed. No changes.
07/01/2023	Document updated with literature review. Coverage unchanged. Added reference 12, others updated.
01/01/2023	Reviewed. No changes.
09/01/2021	Document updated with literature review. Coverage unchanged. Reference 5 added, others updated.
09/01/2020	Reviewed. No changes.
04/15/2019	Document updated with literature review. Coverage unchanged. References 3-4 added; others updated and some removed.
03/15/2018	Reviewed. No changes.
04/15/2017	Document updated with literature review. Coverage unchanged.
06/15/2016	Reviewed. No changes.
10/15/2015	Document updated with literature review. Coverage unchanged.
11/15/2014	Reviewed. No changes.
11/01/2013	Document updated with literature review. Coverage unchanged. Codes updated.

12/01/2010	Document updated with literature review. Coverage unchanged.
10/15/2009	Revised/updated entire document
08/15/2009	Revised/updated entire document
04/01/2005	New Medical Document