Unicondylar Spacer Devices for Treatment of Pain or Disability (for Kentucky Only)

Policy Number: CS128KY.04
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Instructions for Use

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Related Policy

- Surgery of the Knee (for Kentucky Only)

Application

This Medical Policy only applies to the state of Kentucky.

Coverage Rationale

Unicondylar Spacer devices are unproven and not medically necessary for treating knee joint pain or disability from any cause due to insufficient evidence of efficacy.

Definitions

Unicompartmental: Related to either the inside (medial) or outside (lateral) half of the knee joint (AAOS, 2013).

Unicondylar Interpositional Spacer: A specialized hemispheric metallic device that can be surgically implanted into the joint space of the knee; this device has been used as a treatment for arthritis that affects only part of the knee (Unicompartmental arthritis) (AAOS, 2013).

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 Guidelines may apply.

CPT Code	Description
27599	Unlisted procedure, femur or knee

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Description of Services

The Interpositional Unicondylar Spacer device was developed as an alternative treatment for individuals with severe knee pain who have exhausted traditional treatment plans such as anti-inflammatory medications and arthroscopy, but are not yet ready for total knee replacement surgery.

Interpositional Unicondylar Spacers are metallic implants which 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.

Clinical Evidence

Currently, there are few studies published in the medical literature that allow for adequate evaluation of the use of unicondylar interpositional spacers in the clinical setting. High revision rates and adverse events have been reported in some studies. Well-designed studies on outcomes are needed to determine the efficacy of unicondylar interpositional spacers.

Courtine et al. (2021) conducted a follow-up study to provide data on the 10-year outcomes in a cohort investigated previously by Catier et al., 2011. This study provides a re-evaluation of implant survival five years after the first analysis, as well as information on patient satisfaction and functional outcomes. The investigators included the same patients operated on from 2003 to 2009, with 17 UniSpacer™ implants in 16 patients. The operative technique was the same in all patients. At last follow-up, the patients attended a visit designed specifically to allow a clinical evaluation (International Knee Society (IKS) score, revision, forgotten implant) and new radiographic imaging of the treated knee. Mean follow-up of this retrospective study of a prospective database was 118 ±25 months. Of the 17 implants, nine (53%), in eight patients, were still in place. Six (37.5%) patients underwent early revision arthroplasty (between six months and four years). One patient was lost to follow-up and another had died. The mean global IKS knee score was 76 ±15 and the mean IKS function score was 80 ±25. The global IKS score at last follow-up was 157 ±39. Mean range of flexion was 119 ±20°. Of the eight patients (nine implants) who still had their implants at last follow-up, five (56%) reported forgetting their implant. No revisions were performed between four and 10 years of follow-up. The investigators concluded that despite the disappointing medium term implant survival (60% after five years in this cohort), the UniSpacer maintained a stable survival rate after 10 years (53%) with the small decrease being due only to the death of one patient and to another patient being lost to follow-up. According to the investigators, this study has several limitations. The small sample size results in little statistical power and it is difficult to extrapolate the results to a larger scale. All the study data were collected by a single person, who may have influenced the way in which the patients selected the subjective satisfaction criteria. These two facts also imply confounding bias, with conclusions that may vary according to the manner in which the data were collected. A long-term study with a larger number of patients would have allowed an assessment of the usefulness of these implants. However, this implant was last used in 2011 when production was stopped. Therefore, additional patients cannot be added to the cohort.

Catier et al. (2011) conducted a prospective study which included 17 UniSpacer knee systems implanted in 16 patients between April 2003 and March 2009 within the frame of a clinical research project (CRP). Patients were clinically (IKS score) and radiographically evaluated during a mean follow-up period of 40 months. Nine patients (10 implants) had a IKS score > 160. The mean overall knee score at reassessment, including failures, increased from 51 points preoperatively to 78 points postoperatively. The mean overall Knee Society Function score increased from 55 preoperatively to 75/100 postoperatively. The reported complication rate was 35% (pain or implant instability). One-third of the failures were not technique- or implant-related but rather induced by the use of an inappropriate width in the frontal plane. On the basis of its uncertain clinical results and high revision rate (six cases out of 17), the investigators do not recommend this system despite the expected improvements on this range of implants. The role of this implant, if any, should be further defined.

Clinical Practice Guidelines

American Academy of Orthopaedic Surgeons (AAOS)

In an updated 2021 guideline, the AAOS recommended is against the use of a free-floating interpositional device for patients with symptomatic unicompartmental osteoarthritis of the knee. The guideline notes that the supporting evidence is lacking and requires the work group to make a recommendation based on expert opinion by considering the known potential harm and benefits associated with the treatment. Future research should be aimed at producing level one randomized control trials to define clinical efficacy and risk of complication. (AAOS, 2021).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Unicondylar spacer devices are regulated by the FDA as Class II devices under product code HSH. The FDA currently lists five unicondylar spacer devices as having received 510(k) clearance for marketing in the United States.

Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed August 28, 2023)

References

American Academy of Orthopaedic Surgeons (AAOS). Management of Osteoarthritis of the Knee (Non-Arthroplasty) Evidence-Based Clinical Practice Guideline. August 31, 2021 Available at: https://www.aaos.org/globalassets/quality-and-practice-resources/osteoarthritis-of-the-knee/oak3cpg.pdf. Accessed August 28, 2023.

Catier C, Turcat M, Jacquel A, et al. The Unispacer™ unicompartmental knee implant: its outcomes in medial compartment knee osteoarthritis. Orthop Traumatol Surg Res. 2011 Jun;97(4):410-7.

Courtine M, Labattut L, Martz P, et al. The unicompartmental knee implant UniSpacer™: Ten-year outcomes after treatment for medial tibio-femoral osteoarthritis. Orthop Traumatol Surg Res. 2021 May;107(3):102873.

Policy History/Revision Information

Date	Summary of Changes
11/01/2024	**Template Update** • Modified font style; no change to policy content
01/01/2024	• Routine review; no change to coverage guidelines • Archived previous policy version CS128KY.03

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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