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

Policy Number: CS128LA.~~H~~I
Effective Date: ~~October 1, 2020~~TBD

➲ Instructions for Use

Table of Contents **Page**

Application

This Medical Policy only applies to the state of Louisiana.

Coverage Rationale

Unicondylar Spacer ~~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** ~~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 federal, state, or contractual requirements 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

Description of Services

The Interpositional Unicondylar Spacer ~~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** ~~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 5 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, 9 (53%), in 8 patients, were still in place. Six (37.5%) patients underwent early revision arthroplasty (between 6 months and 4 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 8 patients (9 implants) who still had their implants at last follow-up, 5 (56%) reported forgetting their implant. No revisions were performed between 4 and 10 years of follow-up. The investigators concluded that despite the disappointing medium term implant survival (60% after 5 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 1 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

~~Bailie et al. (2008) conducted a prospective study of 18 patients treated with the Unispacer to determine the early clinical results of this device. Mean follow-up was 19 months (12 to 26). Mean patient age was 49 years (40 to 57). Eight patients (44%) required revision within two years. Two patients required a revision to a larger spacer, and in 6, conversions to either a unicompartmental or total knee replacement was needed. The mean modified visual analogue score for these patients at follow-up was 3.0 (0 to 11.5). The mean pain level was 30% that of the mean pre-operative level of 10. The authors found the early clinical results disappointing and concluded that the use of the Unispacer in isolated medial compartment osteoarthritis is associated with a high rate of revision surgery and provides unpredictable relief of pain.~~

~~A study evaluated 24 patients (26 knees) with unicompartmental knee osteoarthritis who were managed with McKeever tibial hemiarthroplasty. A total of 13 knees were successfully revised at an average of 8 years after the original procedure. Ten knees retained devices with an average follow-up of 16.8 years. The investigators concluded that the McKeever device is a reasonable surgical option for patients who are not candidates for osteotomy or total knee replacement. (Springer, 2006)~~

~~Sisto and Mitchell (2005) reported on the experience of a single surgeon who performed 37 Unispacer arthroplastics for treatment of medial compartment arthritis in 34 patients. After a mean duration follow-up of 26 months, there were no excellent, 10 good, 15 fair, and 12 poor results. Six of the poor results occurred because of Unispacer dislocation. The investigators do not recommend Unispacer arthroplasty for treatment of arthritis of the knee.~~

~~Hallock and Fell (2003) reported 1- and 2-year data on 71 Unispacer knee devices. The mean Knee Society knee score improved 169% in the 1-year group and 193% in the 2-year group. A total of 5 implants were revised to total knee arthroplasty and 10 implants were revised to another Unispacer knee device.~~

~~**Professional Societies**~~

American Academy of Orthopaedic Surgeons (AAOS)

In an updated ~~2013~~ **2021** guideline, the AAOS recommended against **the** ~~using~~ **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,** ~~2013~~ **2021).**

~~*California Technology Assessment Forum (CTAF)*~~

~~The CTAF (Tice, 2003) reported that no published studies are available to assess the safety and efficacy of the UniSpacer device. Surgical placement of knee joint spacer devices requires evaluations in controlled trials to determine safety and efficacy before widespread adoption can be recommended. Surgical placement of a knee joint spacer for the treatment of osteoarthritis did not meet the CTAF technology assessment criteria.~~

~~*Washington State Department of Labor and Industries*~~

~~The Washington State Department of Labor and Industries (2005) has stated that it does not cover the UniSpacer device because of an absence of clinical data and published literature regarding its safety and efficacy.~~

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.

~~Unicondylar spacer devices are regulated by the FDA as Class II devices under product code HSH.~~ Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed **July 21, 2022** ~~June 17, 2020~~)

References

American Academy of Orthopaedic Surgeons (AAOS). Management of Osteoarthritis of the Knee (Non-Arthroplasty) Evidence-Based Clinical Practice Guideline. August 31, 2021 ~~Treatment of Osteoarthritis of the Knee – 2nd Edition. Evidence-Based Clinical Practice Guideline. May 18, 2013~~**. Available at: https://www.aaos.org/globalassets/quality-and-practice-resources/osteoarthritis-of-the-knee/oak3cpg.pdf**
~~https://www.aaos.org/globalassets/quality-and-practice-resources/osteoarthritis-of-the-knee/osteoarthritis-of-the-knee-2nd-edition-clinical-practice-guideline.pdf~~**. Accessed** ~~August 10, 2021~~**July 21, 2022.**

Catier C, Turcat M, Jacquel A ~~American Academy of Orthopaedic Surgeons (AAOS). Treatment of Osteoarthritis of the Knee (Non-Arthroplasty). May 18, 2013.~~

~~Bailie AG, Lewis PL, Brumby SA~~, et al. The Unispacer™ **unicompartmental** knee implant: **its outcomes in medial compartment knee osteoarthritis. Orthop Traumatol**~~early clinical results. J Bone Joint~~ Surg **Res. 2011 Jun;97** ~~Br. 2008 Apr;90~~(4):**410-7**~~446-50~~.

Courtine M, Labattut L, Martz P, et al. The unicompartmental knee implant ~~Hallock RH, Fell BM. Unicompartmental tibial hemiarthroplasty: early results of the~~ UniSpacer™**: Ten-year outcomes after treatment** ~~knee. Clin Orthop Relat Res. 2003 Nov;(416):154-63.~~

~~Sisto DJ, Mitchell IL. UniSpacer arthroplasty of the knee. J Bone Joint Surg Am. 2005 Aug;87(8):1706-11.~~

~~Springer BD, Scott RD, Sah AP, et al. McKeever hemiarthroplasty of the knee in patients less than sixty years old. J Bone Joint Surg Am. 2006 Feb;88(2):366-71.~~

~~Tice JA. Knee joint spacer (UniSpacer) system~~ for **medial tibio-femoral** osteoarthritis**. Orthop Traumatol Surg Res. 2021 May;107(3):102873** ~~of the knee. Technology Assessment. San Francisco, CA: California Technology Assessment Forum. Published February 12, 2003.~~

~~Washington State Department of Labor and Industries. UniSpacer Coverage Decision. Coverage Decisions for Medical Technologies and Procedures. Olympia, WA: Washington State Department of Labor and Industries; 2005~~.

Policy History/Revision Information

Date	Summary of Changes
TBD	**Supporting Information** • **Updated *Clinical Evidence* and *References* sections to reflect the most current information** • **Archived previous policy version CS128LA.H**

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.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies 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.