Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

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

Policy #: 125
Latest Review Date: June 2023
Category: Surgery
ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **unicondylar interpositional spacer device** as a **non-covered** benefit and considered as **investigational** for treatment of osteoarthritis of the knee.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

The interpositional unicondylar spacer (e.g., UniSpacer™) device was developed as an alternative treatment for patients suffering from the early stages of osteoarthritis of the knee. The interpositional unicondylar spacer UniSpacer™ is indicated for the treatment of isolated, moderate degeneration of the medial compartment (grade III-IV chondromalacia) with no more than minimal degeneration (grade I-II chondromalacia, no loss of joint space) in the lateral condyle or patellofemoral compartment.

This device was developed for patients 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.

The interpositional unicondylar spacer is a small, kidney-shaped insert made of cobalt alloy. It is geometrically designed to self-center within the knee and move with the knee, not against it. The femoral articulating surface is cup shaped (concave) to capture the femoral condyle. The tibial surface is designed to replicate the anatomy of the tibial plateau with the meniscus removed. It is not fixed in place, but remains centered under the weight-bearing portion of the femur through all angles of flexion. The ligaments surrounding the knee are re-tensioned and act as cables that hold the femur against the device. It comes in a wide range of sizes, depending on the weight and size of each patient.

The procedure is done under general or regional anesthesia. Using arthroscopy, debridement and resection of the medial meniscus is done. The device is inserted into the joint space, above the affected medial tibial plateau, and rests within the boundaries of the resected meniscus. The procedure takes about one hour to complete, and the patient usually goes home within 24 hours.

The procedure is not suitable for patients with significant patellofemoral disease or significant lateral compartment disease, or those with subchondral bone loss. The anterior and posterior cruciate ligament structures must be intact.

The UniSpacer™ is manufactured by Sulzer Orthopedics in Austin, Texas. The device received U.S. FDA clearance for marketing in January 2001. The FDA approved indication is for 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". Additional unicondylar interpositional spacers have received FDA clearance. They include the Oti Unicondular Interpositional Spacer Osteoimplant (2002) and the Knee Interpositional Mini-repair System (2003).

Other interpositional unicondylar devices have received 510(k) approval: the Oti Unicondular Interpositional Spacer Osteoimplant (2002), the Knee Interpositional Mini-Repare System (2003), and the Repicci II® (2002). The Knee Interpositional Mini-Repair System is a patient-specific design with specification taken from magnetic resonance scans. These devices are indicated for the uncemented treatment of medial and/or lateral tibial articulating surfaces of the osteoarthritic knee with grade ii-IV chondromalacia. The Recippi II is a partial knee replacement designed to remove as little bone from the knee as possible.

KEY POINTS:

Osteoarthritis (OA), previously called degenerative joint disease, is the most prevalent form of arthritis in the U.S. The causes of OA of the knee are not always known, but biomechanical stresses affecting the articular cartilage and subchondral bone and biochemical changes in the articular cartilage and synovial membrane are important in its pathogenesis. The guidelines for medical management of OA of the knee, published by the American College of Rheumatology, include: patient education, weight loss, PT and OT, acetaminophen, nonsteroidal antiinflammatory drugs, topical analgesics, and intraarticular steroid injections.

If patient response is inadequate, referral to an orthopedic surgeon may be indicated. Surgical treatment options include arthroscopy with debridement, proximal tibial osteotomy, and total knee replacement. The decision to proceed with total knee replacement is usually only considered in people over the age of 60.

The interpositional unicondylar spacer device was designed for patients who are in general good health, still fairly young, and have arthritis only in the medial compartment of their knee. The majority of patients treated are under age 65 and, therefore, not yet ideal candidates for total knee replacement. The device helps to relieve the arthritic pain and improve joint stability by restoring ligament tension and normal knee alignment, while preserving the patient's natural bone. The interpositional unicondylar spacer (UniSpacer™) device is only used by specially trained surgeons.

Some of the potential risks associated with the use of the interpositional unicondylar spacer include the general risks associated with any surgical procedure, such as infection, cardiovascular, pulmonary, and urinary complications, and the risks associated with knee surgery, such as scarring from incision, pain, dislocation, need for revision, numbness, and weakness.

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. Bailie et al. (2008) identified 1 prospective study of 18 consecutive patients with isolated medial compartment osteoarthritis who provided informed consent for insertion of a Unispacer knee

implant. Seventeen patients (94%) reported persistent symptoms between 3 and 6 months after surgery. At an average 17-month follow-up (range, 3 to 26 months), 12 (67%) patients had required further interventions, and 8 (44%) were classified as implant failures. The authors described these results as "disappointing." While current data indicate that the unicondylar interpositional spacer does not improve the net health outcome, this technology is in an early stage of research and development. The unicondylar interpositional spacer is considered investigational; the policy statement remains unchanged.

In their review article Borus and Thornhill (2008) state, "Recent increased interest in less invasive surgical techniques has led to a concurrent resurgence in unicompartmental knee arthroplasty. The procedure has evolved significantly over the past three decades. Proponents of unicompartmental knee arthroplasty cite as advantages lower perioperative morbidity and earlier recovery. Both clinical outcome and kinematic studies have indicated that successful unicompartmental knee arthroplasty functions closer to a normal knee. Recent reports have demonstrated success in expanding the classic indications of unicompartmental knee arthroplasty to younger and heavier patients. Both fixed- and mobile-bearing implants can yield excellent clinical outcomes at >10 years, but with different modes of long-term failure. Proper execution of surgical technique remains critical to optimizing outcome. Long-term studies are needed to appropriately define the role of less invasive unicompartmental surgical approaches as well as the role of computer navigation."

Sisto and Mitchell (2005) reported on the experience of a single surgeon who performed 37 Unispacer arthroplasties 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.

A 2006 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.

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.

Practice Guidelines and Position Statements

American Academy of Orthopaedic Surgeons (AAOS)

In an updated 2013 guideline, the AAOS recommended against using 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.

KEY WORDS:
Osteoarthritis (OA), UniSpacer™, unicondylar interpositional spacer, Oti Unicondular Interpositional Spacer Osteoimplant, Knee Interpositional Mini-Repare System, Repicci II® (2002), OrthoGlide

APPROVED BY GOVERNING BODIES:
The FDA currently lists five unicondylar spacer devices as having received 510(k) clearance for marketing in the United States.

- Knee Interpositional Mini-Repair System (KIMRS)- K033242
- OrthoGlide Lateral Knee Implant- K073233
- OrthoGlide Medical Knee Implant- K053094
- Oti Unicondular Interpositional Spacer- K022779
- Unicondylar Interpositional Spacer- K003269

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:
CPT codes:

29999	Unlisted procedure, arthroscopy
27599	Unlisted procedure, femur or knee

REFERENCES:

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POLICY HISTORY:

Available for comment May 1-June 14, 2005
Medical Policy Group, June 2006
Medical Policy Group, June 2007
Medical Policy Group, February 2009
Medical Policy Group, November 2009
Medical Policy Group, November 2010 (1) Verbiage updated to reflect generic device in policy, no policy statement change
Medical Policy Group, March 2012: Policy no longer updated effective March 12, 2012
Medical Policy Group, August 2019
Medical Policy Group, June 2021
Medical Policy Group, June 2022: Reviewed by consensus. There is no new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, June 2023: Reviewed by consensus. There is no new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, November 2023: Archived effective 11/1/2023.

services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review)in Blue Cross and Blue Shield's administration of plan contracts.