



BlueCross BlueShield
of Alabama

Name of Policy:

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

Policy #: 125
Category: Surgery

Latest Review Date: November 2010
Policy Grade: **Active policy but no longer
scheduled for regular
literature reviews and update.**

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- 1. In accordance with generally accepted standards of medical practice; and*
- 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
- 3. Not primarily for the convenience of the patient, physician or other health care provider; and*
- 4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

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 UniSpacer™ is a small, kidney-shaped insert made of cobalt alloy chrome. 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 Unicondylar Interpositional Spacer Osteoimplant (2002) and the Knee Interpositional Mini-repair System (2003).

Other interpositional unicondylar devices have received 510(k) approval: the Oti Unicondylar Interpositional Spacer Osteoimplant (2002), the Knee Interpositional Mini-Repair 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.

Policy:

Unicondylar interpositional spacer device does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered as **investigational** for treatment of osteoarthritis of the knee.

Blue Cross and Blue Shield of Alabama 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 Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate 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.

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 (**UniSpacer™**) 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.

Some of the potential risks associated with the use of the interpositional unicondylar spacer (**UniSpacer™**) 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.

The interpositional unicondylar spacer (**UniSpacer™**) device is only used by specially trained surgeons. There are no peer-reviewed articles in the literature on this device. In the past, the McKeever, MacIntosh, and Sbarbaro prosthesis devices were used for arthroplasty, but it appears they are rarely used now.

June 2007 Update

No new information has been located that would alter the coverage statement of this policy.

February 2009 Update

A literature search identified 1 prospective study of 18 consecutive patients with isolated medial compartment osteoarthritis who provided informed consent for insertion of a Unispace[®] 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.

November 2009 Update

In their review article Borus and Thornhill 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.”

November 2010 Update

A recent literature search identified no new articles regarding this device. The policy statement remains unchanged.

Key Words:

Osteoarthritis (OA), UniSpace[™], unicondylar interpositional spacer, Oti Unicondylar Interpositional Spacer Osteoimplant, Knee Interpositional Mini-Repair System, Repicci II[®] (2002).

Approved by Governing Bodies:

FDA approved, January 2001, 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”. (UniSpace[™])

Oti Unicondylar Interpositional Spacer Osteoimplant (2002)

Knee Interpositional Mini-Repair System (2003)
Repicci II (2002)

Benefit Application:

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

ITS: Home Policy provisions apply

FEP contracts: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.

Pre-certification/Pre-determination requirements: Not applicable

CURRENT Coding:

CPT codes:	29999	Unlisted procedure, arthroscopy
	27599	Unlisted procedure, femur or knee

References:

1. Bailie AG, Lewis PL, Brumby SA, et al. *The Unispacer knee implant: Early clinical results*. Br J Bone Joint Surg, April 2008; 90(4): 446-450.
2. Blue Cross Blue Shield Association. *Unicondylar interpositional spacer as a treatment of unicompartmental arthritis of the knee*. Medical Policy Reference Manual, May 2008.
3. Borus T, Thornhill T. *Unicompartmental knee arthroplasty*. J Am Acad Orthop Surg. 2008 Jan;16(1):9-18.
4. Hallock RH. *The unispacer knee system: Have we been there before*. Orthopedics 2003; 26(9): 953-954.
5. Hochberg Marc C, et al. *Guidelines for the medical management of osteoarthritis*. Arthritis and Rheumatism; 38(11): 1541-1546.
6. Sisto DJ and Mitchell IL. *UniSpacer arthroplasty of the knee*. J Bone Joint Surg Am 2005; 87(8): 1706-1711.
7. Scott RD *UniSpacer: Insufficient data to support its widespread use*. Clin Orthop 2003; 416: 164-166.
8. Zimmer formerly Centerpulse Orthopedics, Inc.,
http://www.centerpulseorthopedics.com/unispacer/unispacer_solution.

Policy History:

Medical Policy Group, June 2003 **(3)**

Medical Policy Administration Committee, July 2003

Available for comment July 28-September 10, 2003

Medical Policy Group, June 2004

Medical Policy Group, June 2005 **(1)**

Medical Policy Group, June 2006 **(1)**

Medical Policy Group, June 2007 **(1)**

Medical Policy Group, February 2009 (1)

Medical Policy Group, November 2009 (2)

Medical Policy Administration Committee, 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: Effective March 12, 2012 Policy no longer scheduled for regular literature reviews and updates

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date 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.