APPENDIX to Unicondylar Interpositional Spacer Policy

Prior Authorization Requirements

This service (or procedure) is considered **investigational** in all instances. If you would like to submit additional information please forward to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

Evidence Basis for the Policy

Rationale

While osteoarthritis of the knee typically involves 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. When patients fail to respond to these more conservative therapies, surgical interventions may be indicated.

Older patients with arthritis typically consider total knee replacement, but may 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 lifetime. 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.

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.

In 2001, a cobalt alloy device, referred to as a "unicondylar interpositional spacer" or "UniSpacer™," received clearance for marketing through a United States Food and Drug Administration (FDA) 510(k) process as an interpositional arthroplasty device, listing the MacIntosh and McKeever prostheses as predicate devices. The FDA clearance for the UniSpacer device is for "moderate degeneration of the medial compartment of the knee (grade III to IV chondromalacia) with not more than minimal degeneration (grade I to II chondromalacia, no loss of joint space) in the lateral condyle and patellofemoral compartments." The Orthoglide Medical Knee Implant, which received 510(k) approval in 2006, is also indicated for “uncemented use in the treatment of moderate degeneration of the medial compartment of the knee,” but for grade II to IV chondromalacia.

Two other interpositional devices have received 510(k) approval, the Oti Unicondular Interpositional Spacer Osteoimplant (2002)(Osteoimplant Technology, Inc., Hunt Valley, MD) and the Knee Interpositional Mini-Repair System (2003)(Imaging Therapeutics, Inc., San Mateo, CA), listing the UniSpacer™ as a predicate device. The Knee Interpositional Mini-Repair System is a patient-specific design, with specifications 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 to IV chondromalacia.

In 2003 the California Technology Assessment Forum™ concluded the UniSpacer device did not meet their assessment criteria. In addition, the assessment stated:

Surgical placement of knee joint spacer devices requires evaluation in controlled trials in order to assess the efficacy and safety of the procedure before its widespread adoption can be advocated.

Two retrospective reports were identified on the use of the UniSpacer. The largest group of patients reported was 71 UniSpacer implants in 67 patients (ages ranged from 38 to 83 years and weights ranged from 53 to 168 kg) (Hallock & Fell, 2003). At one-year follow-up, 63 patients (66 knees) still had the implant; the five failed implants (7%) were converted to total knee arthroplasty for inadequate pain relief. Ten patients (14%) had their implants revised to another size because of persistent pain (n = 6) or dislocation (n = 4), and 17 patients (24%) required manipulation under anesthesia to correct postoperative arthrofibrosis. The rate of revision at one year was 21%, with an additional 24% requiring manipulation due to arthrofibrosis.

Another group reported their experience with 37 UniSpacer implants in 34 patients (ages ranging from 42 to 75 years) with baseline Knee Society functional and objective rating scales of 69 and 62 points, respectively (Sisto & Mitchell, 2005). At two-year follow-up, functional and objective ratings had improved by about 10 points; there were no excellent, 10 good, 15 fair, and 12 poor results. Six of the 12 poor results were due to dislocation, and the 12 were revised to total knee arthroplasty. There was no significant change in average pain scores (preoperative: 22, postoperative: 26), with complaints of pain during normal walking for 32 knees and activities

limited by pain in 15 patients (41% of implants). Persistent postoperative swelling was present in nine patients.

A prospective study of 18 consecutive patients with isolated medial compartment osteoarthritis provided informed consent for insertion of a Unispacer knee implant. Seventeen patients (94%) reported persistent symptoms between three and six months after surgery (Bailie et al., 2008). At an average 17-month follow-up (range, three to 26 months), 12 (67%) patients had required further interventions, and eight (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.

A study from Germany evaluated clinical and radiological results of the Unispacer in the first five postoperative years (Clarius et al., 2009). Anteroposterior long leg stance radiographs of 20 legs were digitally analyzed to assess alignment change: two relevant angles and the deviation of the mechanical axis of the leg were analyzed before and after surgery. Four of 19 knees had to be revised to a total knee arthroplasty or UKA due to persistent pain. The authors concluded that this was an unacceptable high revision rate when looking at the alternative treatment options of medial osteoarthritis of the knee.

Based on the lack of controlled trials, combined with the high proportion of failures and adverse events in the identified retrospective reports, the use of interpositional unicondylar spacers is considered investigational.

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

Type	Number	Description
CPT	27599	Unlisted procedure, femur or knee

Type	Number	Description
HCPC	None	
ICD9 Procedure	None	
ICD9 Diagnosis	All Diagnoses	
Place of Service	All Places of Service	

Tables

N/A

Definitions

N/A

Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

N/A

Key / Related Searchable Words

N/A

References

- Bailie AG, Lewis PL, Brumby SA et al. The Unispacer knee implant: early clinical results. J Bone Joint Surg Br 2008; 90-B(4):446-450.
- Blue Cross Blue Shield Association. Medical Policy Reference Manual, No. 7.01.88 (September 2009).
- Clarius M, Becker JF, Schmitt H. et al. The UniSpacer: correcting varus malalignment in medial gonarthrosis. Int Orthop. 2009 Nov 28. [Epub ahead of print].
- Hallock RH, Fell BM. Unicompartmental tibial hemiarthroplasty: early results of the UniSpacer knee. Clin Orthop Relat Res 2003; (416):154-63.

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

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
6/1/2003	MPC Policy adopted; CTAF Review February 2003	Medical Policy Committee
1/7/2011	Policy title change from Unicondylar Interpositional Spacer System Policy revision with position unchanged	Medical Policy Committee

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

Click here to view the policy statement for this policy

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