UNICONDYLAR INTERPOSITIONAL KNEE SPACER

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member’s specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms “experimental” and “investigational” are considered to be interchangeable.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans.

Description:

Unicondylar interpositional knee spacer has been investigated for treatment of knee joint instability in individuals with unicompartmental osteoarthritis. It is a minimally invasive device intended to improve knee joint stability by restoring ligament tension and normal knee alignment. After arthroscopic debridement and resection of the medial meniscus, the device is implanted between the bony structures of the knee through an open surgical incision where it remains in place without cement or screw fixation. Devices include the UniSpacer™ Knee System, Orthoglide® Knee Implant and the OTI Unicondylar InterpositionalSpacer.
UNICONDYLAR INTERPOSITIONAL KNEE SPACER (cont.)

Criteria:

- Knee spacer device is considered *experimental or investigational* based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes,
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

Resources:


UniSpacer is a trademark of Sulzer Orthopedics, Inc., an independent corporation that is not affiliated with BCBSAZ. Orthoglide is a registered trademark of ABS Corp., an independent corporation that is not affiliated with BCBSAZ.