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Subject: Unicondylar Interpositional Spacer Devices

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

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DESCRIPTION:

The unicondylar interpositional spacer is a specialized hemispheric spacer that can be surgically implanted in the joint space of the knee. This device is proposed for use as a treatment for osteoarthritis that affects only one part of the knee.

POSITION STATEMENT:

Unicondylar interpositional spacer devices are considered **experimental or investigational** for treating any condition, and specifically to treat joint pain related to unicompartamental arthritis of the knee. There is insufficient published clinical evidence to support the safety, efficacy or improved long-term outcomes for these devices.

BILLING/CODING INFORMATION:

There are no specific CPT or HCPCS codes that describe unicondylar interpositional spacer devices.

REIMBURSEMENT INFORMATION:

Refer to section entitled [POSITION STATEMENT](#).

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

None.

OTHER:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another and is not intended to represent a complete listing of all products available.

Other index terms:

Knee Interpositional Mini-Repair System
OrthoGlide™ Medical Knee Implant
Oti Unicondylar Interpositional Spacer Osteoimplant
Repicci II®
UniSpacer® Knee System

REFERENCES:

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19. U.S. Food and Drug Administration (FDA). 510(k) summary: Advance Bio-Surfaces, Inc. OrthoGlide® Lateral Knee Implant.
20. U.S. Food and Drug Administration (FDA). 510(k) summary: Advance Bio-Surfaces, Inc. OrthoGlide® Medial Knee Implant.
21. U.S. Food and Drug Administration (FDA). 510(k) summary: Imaging Therapeutics, Inc. Knee Interpositional Mini- Repair Systems.
22. U.S. Food and Drug Administration (FDA). 510(k) summary: Osteo implant Technology, Inc. OTI Unicondylar Interpositional Spacer.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 05/25/23.

GUIDELINE UPDATE INFORMATION:

09/15/03	New Medical Coverage Guideline; investigational.
07/15/04	Review to guideline with no changes made; maintain investigational status.
07/15/05	Review and revision of guideline; consisting of updated references and maintain investigational status.
06/15/06	Review and revision of guideline consisting of updated references.
05/15/07	Review and revision of guideline consisting of updated references and reformatted guideline.
05/15/08	Scheduled review; no change in position statement. Update references.
05/15/09	Scheduled review; no change in position statement.
05/15/10	Annual review; no change to position statement, and updated references.
05/15/12	Scheduled review; no change in position statement. Updated description section, index terms and references.

05/15/13	Scheduled review; no change in position statement. Revised MCG title, description and definitions. Updated references.
09/15/19	Scheduled review. Maintained position statement. Revised description, definitions, and related guidelines. Updated references.
05/15/21	Scheduled review. Maintained position statement.
06/15/23	Scheduled review. Revised description, maintained position statement, and updated references.