UNICONDYLAR SPACER DEVICES FOR TREATMENT OF PAIN OR DISABILITY

Policy Number: DME 017.17 T2
Effective Date: October 1, 2017

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INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting Oxford benefit plans. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, to modify its policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Clinical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Clinical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Clinical Policy. Other Policies may apply.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

APPLICABLE LINES OF BUSINESS/PRODUCTS

This policy applies to Oxford Commercial plan membership.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.
NON-COVERAGE RATIONALE

Unicondylar spacer devices are unproven and not medically necessary for treating knee joint pain or disability from any cause.

The evidence is lacking to demonstrate that unicondylar spacers are clinically effective, and long-term data are not available to establish the safety and efficacy of these devices. Published evidence consists of small studies with mixed results. It is not evident that this treatment postpones or obviates the need for total joint replacement.

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies may apply.

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<th>CPT Code</th>
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<tr>
<td>27599</td>
<td>Unlisted procedure, femur or knee</td>
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\[CPT^®\] is a registered trademark of the American Medical Association

DESCRIPTION OF SERVICES

The interpositional unicondylar spacer device was developed as an alternative treatment 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.

Interpositional unicondylar spacers are metallic implants which are inserted into the joint space between the affected tibial plateau and femoral condyle. Instead of being fixed, the spacers are held in place by the geometry of the curved implant, ligament tension, and surrounding soft tissue structures.

CLINICAL EVIDENCE

There is a lack of evidence in the published medical literature supporting a unicondylar interpositional spacer device. While this device may provide short-term improvement for osteoarthritis of the medial or lateral knee compartment, long-term effectiveness and durability of the device is not known. Overall, further well-designed clinical studies are required to document long-term effectiveness, durability and improvement in functional outcomes with use of these technologies.

Bailie et al. (2008) conducted a prospective study of 18 patients treated with the UniSpacer to determine the early clinical results of this device. Mean follow-up was 19 months (12 to 26). Mean patient age was 49 years (40 to 57). Eight patients (44%) required revision within two years. Two patients required a revision to a larger spacer, and in 6, conversions to either a unicompartmental or total knee replacement was needed. The mean modified visual analogue score for these patients at follow-up was 3.0 (0 to 11.5). The mean pain level was 30% that of the mean pre-operative level of 10. The authors found the early clinical results disappointing and concluded that the use of the UniSpacer in isolated medial compartment osteoarthritis is associated with a high rate of revision surgery and provides unpredictable relief of pain.

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 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. (Springer, 2006)

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.
Professional Societies

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.

California Technology Assessment Forum (CTAF)
The CTAF (Tice, 2003) reported that no published studies are available to assess the safety and efficacy of the UniSpacer device. Surgical placement of knee joint spacer devices requires evaluations in controlled trials to determine safety and efficacy before widespread adoption can be recommended. Surgical placement of a knee joint spacer for the treatment of osteoarthritis did not meet the CTAF technology assessment criteria.

Washington State Department of Labor and Industries
The Washington State Department of Labor and Industries (2005) has stated that it does not cover the UniSpacer device because of an absence of clinical data and published literature regarding its safety and efficacy.

U.S. Food and Drug Administration (FDA)
The FDA currently lists five unicompartmental spacer devices as having received 510(k) clearance for marketing in the United States.


REFERENCES

The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2017T040L]


POLICY HISTORY/REVISION INFORMATION

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<td>10/01/2017</td>
<td>• Updated supporting information to reflect the most current description of services, FDA information, and references; no change to non-coverage rationale or list of applicable codes</td>
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