UNICONDYLAR SPACER DEVICES FOR TREATMENT OF PAIN OR DISABILITY

Policy Number: 2014T04081
Effective Date: October 1, 2014

INSTRUCTIONS FOR USE
This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee’s document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD)) may differ greatly. In the event of a conflict, the enrollee’s specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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.

BENEFIT CONSIDERATIONS

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 (such as maternity benefits), 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 guideline, it is important to refer to the enrollee’s specific plan document to determine benefit coverage.
COVERAGE RATIONALE

Unicondylar spacer devices are unproven and not medically necessary for the treatment of 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 Current Procedural Terminology (CPT®) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit 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 claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

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

DESCRIPTIONS OF SERVICES

Implantation of unicondylar spacer devices is a treatment for isolated medial compartment degenerative osteoarthritis of the knee. The device consists of a metal wedge that is surgically placed in the medial compartment of the knee joint, between the tibial plateau and the femoral condyle. The surgery is minimally invasive, and condylar bone does not need to be excised in order to insert the device. The device is held in place by knee soft tissues without cement or screws. It is intended for younger, more active patients who are not candidates for total knee replacement or osteotomy. Proponents claim that unicondylar spacer devices relieve pain, improve joint function, and delay the need for total knee replacement. (ECRI, 2009)

CLINICAL EVIDENCE

No studies that provide substantial new evidence regarding unicondylar spacer devices for treatment of pain or disability were identified in a July 2014 literature search.

There is also a lack of evidence in the published medical literature supporting a unicondylar interpositional spacer device, such as the UniSpacer. 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
In an updated 2013 guideline, the American Academy of Orthopaedic Surgeons (AAOS) recommended against using a free-floating interpositional device for patients with symptomatic unicompartmental osteoarthritis of the knee.

The California Technology Assessment Forum (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.

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 four unicompndylar spacer devices as having received 510(k) clearance for marketing in the United States: the Orthoglide® Medical Knee Implant, the Knee Interpositional Mini-repair System, the OTI Unicondular Interpositional Spacer, and the Unicondylar Interpositional Spacer, also called the UniSpacer™ clearance between 2001 and 2006 and are indicated for moderate degeneration of the medial compartment of the knee (grade III-IV chondromalacia). The patient must also have no more than minimal degeneration in the lateral condyle and the patellofemoral compartments of the knee. Additional information, product code HSH, is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmncfm.

Accessed July 9, 2014

The McKeever and MacIntosh prosthesis is similar to the unicompndylar spacer devices listed above. The major difference between this device and the others is the T-shaped keel on the inferior surface that allows for fixation to the tibia with or without cement. A small amount of bone must be removed from the tibial plateau to form a slot for the keel. This device is considered a pre-amendment device by the FDA (i.e., a device that was commercially distributed before May 28, 1976, the date of the Medical Device Amendments of 1976 were signed into law). Therefore no formal FDA approvals are listed for this device.

Additional Products
Preservation™ Unicondylar Knee Prosthesis
Medicare does not have a National Coverage Determination (NCD) for unicondylar spacer devices used in the treatment of knee joint pain or disability from any cause. Local Coverage Determinations (LCDs) specific to the use of unicondylar spacers does not exist. However, there are LCDs that address CPT code 27599. Refer to the LCDs for Noncovered Services.

(Accessed July 10, 2014)

REFERENCES


POLICY HISTORY/REVISION INFORMATION

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| 10/01/2014 | • Reorganized policy content  
|           | • Added benefit considerations language for Essential Health Benefits for Individual and Small Group plans to indicate:  
|           |   o 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”):  
|           |   o 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 (such
as maternity benefits), 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 guideline, it is important to refer to the enrollee’s specific plan document to determine benefit coverage

- Updated coverage rationale; added language to indicate the unproven services are “not medically necessary”

- Updated supporting information to reflect the most current clinical evidence, CMS information and references

- Archived previous policy version 2013T0408H