Clinical Review Criteria

UniSpacer Knee System

- McKeever Hemiarthroplasty Prosthesis
- MacIntosh Hemiarthroplasty Prosthesis
- Shabaro Tibial Plateau Prosthesis

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Criteria

For Medicare Members
This device is not called out by Medicare as separate from knee arthroplasty.

For Non-Medicare Members
There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KPWA will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background
The UniSpacer is a small, kidney shaped insert made of cobalt chrome that is intended to correct the knee alignment, decrease pain and improve joint stability for patients with early stages of osteoarthritis. It is a device that fits between the natural bone structures of the knee and stays in place without the aid of bone cement or screws. Not everyone is a candidate for the UniSpacer. It is suitable for patients with isolated, moderate degeneration of the medial compartment, patellofemoral compartment, or lateral condyle, and not suitable for patients with subchondral bone loss, significant patellofemoral disease, or significant lateral compartment disease. The anterior and posterior cruciate ligaments must be intact.

According to the manufacturer, the operation is conducted under general or regional anesthesia and takes about one hour to complete. After surgery patients need physical therapy for 6-8 weeks and may need to wear braces 1-2 weeks or more. Recovery may take as long as one year.

The UniSpacer has been approved by FDA on 1/4/2001 as a Class II device.

Medical Technology Assessment Committee (MTAC)

UniSpacer Knee System
12/11/2002: MTAC REVIEW

Evidence Conclusion: Due to lack of scientific data, there is no evidence to determine the role of the UniSpacer Knee System in the treatment of osteoarthritis.

Articles: The search did not yield any articles on the UniSpacer knee system or its equivalents.

The use of UniSpacer Knee System in the treatment of osteoarthritis of the knee does not meet the Kaiser Permanente Medical Technology Assessment Criteria.
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**MDCRPC** Medical Director Clinical Review and Policy Committee

**MPC** Medical Policy Committee

### Revision History

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### Codes

No specific codes