Clinical Review Criteria
Ceramic on Ceramic Hip Replacement Systems

• Ceramic TRANSCEND® Articulation Hip System

NOTICE: Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc., provide these Clinical Review Criteria for internal use by their members and health care providers. The Clinical Review Criteria only apply to Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. Use of the Clinical Review Criteria or any Kaiser Permanente entity name, logo, trade name, trademark, or service mark for marketing or publicity purposes, including on any website, or in any press release or promotional material, is strictly prohibited.

Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Review Criteria, at Kaiser Permanente’s sole discretion, at any time, with or without notice. Member contracts differ in their benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Customer Service to determine coverage for a specific medical service.

Criteria
For Medicare Members
This service is covered and no medical necessity review required.

For Non-Medicare Members
This service is not recommended for coverage, as the evidence indicates that squeaking with movement is a common side effect, resulting in frequent requests for replacement and insufficient evidence of efficacy.

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
Total hip replacement (THR) is a widely performed procedure to relieve pain and restore joint function in patients with osteoarthritis or injury. In THR, the femoral head is replaced with a synthetic ball fixed through a stem to the femur. The ball fits into a synthetic acetabular cup fixed in the pelvis. Several artificial cup-femoral head material combinations are currently in use. Soft-on-hard combinations consist of a cup made of ultra-high molecular weight polyethylene and head made of stainless steel, cobalt-chromium (Co-Cr) alloy or alumina. There are also hard-on-hard combinations where both the cup and the head are made of Co-Cr (metal-on-metal, MOM) or alumina (ceramic-on-ceramic, COC).

The initial metal-on-metal designs of the 1960s had high premature failure rates compared with metal-on-polyethylene devices. However, the metal-on-polyethylene devices have been associated with polyethylene wear debris, leading to osteolysis and aseptic loosening. Second-generation metal-on-metal implants, believed to have lower wear rates, were introduced in the 1990s. Still, the newer MOM implants may generate metallic debris, and there is concern about the long-term effects of these metallic particles (Figueiredo-Pina et al., 2008; Keurentjes et al., 2008). Advantages of ceramic-on-ceramic implants are durability and biocompatibility. First generation COC implants, however, had relatively high fracture rates. The ceramic material has undergone modifications, and a third-generation ceramic, released in the mid-1990s, is believed to have better wear properties. This has reduced, though not eliminated, the risk of fracture. Potential remaining disadvantages of ceramic-on-ceramic systems include cup migration and osteolysis (Lusty et al., 2007; Takata et al. 2007; Zhou et al., 2006). One documented problem with ceramic-on-ceramic implants is a squeaking sound during walking or other movement. The cause of squeaking remains unknown; possible sources include suboptimal anteversion and inclination of the cup, focally increased surface roughness, and lack of lubrication fluid between the articulating surfaces (Keurentjes et al., 2008). Squeaking problems have led to some revision surgeries to replace the hip systems (FDA website).

Medical Technology Assessment Committee (MTAC)
Ceramic TRANSCEND® Articulation Hip System
10/08/2003: MTAC REVIEW
Evidence Conclusion: There was only one published empirical study on the Ceramic TRANSCEND® Articulation Hip System, a case series with 333 patients (Garino). This study provides insufficient evidence to make conclusions about the effect of the TRANSCEND® system on health outcomes. As a case series, it is subject to selection bias and there was no comparison or control group. The authors found an improvement in the mean Harris hip score and short form-12, but details of the data analysis were not provided. There were 4 ceramic-related complications requiring intraoperative revision and 4 patients received revision surgery; there were no ceramic fractures. There is also insufficient evidence to make conclusions about the effectiveness of two similar ceramic hip systems made by Howmedica Osteonics, which D’Antonio compared to a cobalt-chrome-on-polyethylene hip system in an RCT. D’Antonio did not present statistical comparisons among groups, but scores on the outcome variables appear to be similar (e.g. patients in all three treatment groups had Harris hip scores in the “excellent” range at follow-up). The study may have been underpowered to detect clinically meaningful differences and there were other threats to validity. No ceramic fractures were reported during a mean of 35 months’ follow-up; there was a 2-3% rate of intraoperative insert chips.

Articles: The search yielded 170 articles. Many of the articles were reviews, opinion pieces, non-clinical studies or evaluated other, similar technologies. Preliminary findings from the key clinical study (case series) resulting in FDA approval was published in 2000 and this study was critically appraised. No published randomized or non-randomized controlled trials on the TRANSCEND® system were identified. There was one RCT on a similar ceramic-on-ceramic system manufactured by Howmedica Osteonics. The case series and RCT were critically appraised: Garino JP. Modern ceramic-on-ceramic total hip systems in the United States: Early results. Clinical Orthopedics and Related Research 2000; 379: 41-47. See Evidence Table.

The use of ceramic on ceramic hips in total hip replacement surgery does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

The use of ceramic on ceramic hips in total hip replacement surgery does not meet the Kaiser Permanente Medical Technology Assessment Criteria.