KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Ceramic on Ceramic Hip Replacement Systems

- Ceramic TRANSCEND® Articulation Hip System

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, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage

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 bearings 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

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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.*

10/06/2008 MTAC REVIEW
Ceramic TRANSCEND® Articulation Hip System
Evidence Conclusion*:* There are RCTs published since 2003 comparing ceramic-on-ceramic hip implants to metal-on-metal or metal-on-polyethylene systems. Two had a safety/durability measure as their primary outcomes. Zhou et al., 2006 did not find a significant difference in cup migration with a ceramic-on-ceramic vs. a metal-on-polyethylene implant system. In the Grubl et al. (2006) study, serum levels of aluminum and cobalt, the primary outcomes, did not appear to differ with a ceramic-on-ceramic versus a metal-on-metal implant, although p-values were not reported. The third study (D'Antonio et al., 2005) did not list its primary outcome measure. The D'Antonio study, conducted by the team with substantial financial links to Stryker, found a significantly lower rate of revision in the group receiving ceramic-on-ceramic implants compared to metal-on-polyethylene systems after a mean follow-up of 5 years. However, the absolute difference in revision rate was small (8% vs. 6%). All of the studies reported pain and functioning as secondary outcomes, so these were likely underpowered. None found significantly better pain or patient functioning with the ceramic systems, as measured by the Harris Hip Score and/or SF-36. One of the case series reviewed focused on fracture (Koo et al., 2008) and found 5 ceramic head fractures out of 367 hip implants (1.4%) after a mean of 23 months. In the Murphy et al. (2006) series, there were 3 implant-related complications in 174 hips (1.7%) after a mean of 4 years. Both of these series found statistically significant improvement in patient functioning after the THA compared to baseline, but there was no comparison group that received a different type of implant. Two studies (case series and case-control) were identified that specifically investigated the issue of noise or squeaking associated with ceramic hip implants. The study funded by Stryker found a lower rate of squeaking than the study without industry funding (28/999, 2.8% versus 9/42, 21%). The study finding the higher rate required objective verification of the squeaking noise. In conclusion, there is insufficient evidence on the safety and efficacy of ceramic hip implant systems compared to other types of systems. Studies tended to be small, assess different safety variables, and be underpowered to measure differences in pain and function. The prevalence of squeaking differed across studies (3-28%) and needs additional investigation. Although this is largely a nuisance side effect, it is a reason for revision surgeries. The evidence base is limited by relatively small sample sizes. The largest studies have been conducted by investigators associated with Stryker, which may lead to bias.
Articles: Three randomized controlled trials evaluating ceramic-on-ceramic hip implants were identified and critically appraised. All had at least some industry funding, but the research group led by James D'Antonio, which published the largest RCT, has substantial financial links with the implant manufacturer. Several authors are paid consultants to Stryker. The two other RCTs were smaller and focused on potential adverse effects associated with ceramic implants. Several case series were also identified. Two series with larger sample sizes, no reporting of industry funding and using FDA-approved ceramic implants were critically appraised (Koo et al., 2008; Murphy et al. 2006). In addition, the findings of the two series that specifically addressed squeaking are included (Keurentjes et al., 2008; Restrepo et al., 2006). *References for the studies critically appraised are as follows*: RCTs D'Antonio J, Capello W, Manley M et al. Alumina ceramic bearings for total hip arthroplasty. Clin Orthop Rel Res 2005; 436: 164-171. See Evidence Table. Grubl A, Weissinger M, Brodner W et al. Serum aluminum and cobalt levels after ceramic-on-ceramic and metal-on-metal total hip replacement. J Bone Joint Surg (Br); 2006;

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88-B: 1003-1005. See Evidence Table. Zhou Z, Li MG, Borlin N et al. No increased migration in cups with ceramic-on-ceramic bearing. Clin Orthop Rel Res 2006; 448: 39-45. See Evidence Table.

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Applicable Codes

Medicare - Medical necessity review not required
Commercial - Considered not medically necessary

CPT® or HCPC Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
10/08/2003	10/08/2003[MDCRPC], 10/06/2008[MDCRPC], 07/07/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 11/06/2018[MPC], 11/05/2019[MPC], 11/03/2020[MPC], 11/02/2021[MPC], 11/01/2022[MPC]	07/07/2015

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description

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