Clinical Review Criteria
Ceramic on Ceramic Hip Replacement Systems

• Ceramic TRANSCEND® Articulation Hip System

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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 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 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 make conclusions about the effect of the TRANSCEND® system on health outcomes. As a case series, it is subject to...
and/or SF-36. One of the case series reviewed focused on fracture (Koo et al., 2008) and found 5 ceramic head
significantly better pain or patient functioning with the ceramic systems, as measured by the Harris Hip Score
reported pain and functioning as secondary outcomes, so these were likely underpowered. None found
investigators associated with Stryker, which may lead to bias.

Evidence base is limited by relatively small sample sizes. The largest studies have been conducted by
additional investigation. Although this is largely a nuisance side effect, it is a reason for revision surgeries. The
differences in pain and function. The prevalence of squeaking differed across studies (3-28%) and needs
insufficient evidence on the safety and efficacy of ceramic hip implant systems compared to other types of
studies. The study finding the higher rate required objective verification of the squeaking noise. In conclusion, there is

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:
Res 2005; 436: 164-171. See Evidence Table. Grubl A, Weissinger M, Brodnor 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; 88-B:
1003-1005. See Evidence Table. Zhou Z, Li MG, Borlin N et al. No increased migration in cups with ceramic-on-
The use of ceramic on ceramic hips in total hip replacement surgery does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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<sup>MDCRPC</sup> Medical Director Clinical Review and Policy Committee  
<sup>MPC</sup> Medical Policy Committee

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**Codes**

There is no specific code for ceramic on ceramic hip replacement systems.