

MEDICAL POLICY

| MEDICAL POLICY DETAILS | |
|-------------------------|--|
| Medical Policy Title | Metal-on-Metal Total Hip Resurfacing |
| Policy Number | 7.01.74 |
| Category | Technology Assessment |
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| Product Disclaimer | <ul style="list-style-type: none"> Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit. If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit. If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit. If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line. |

POLICY STATEMENT

- I. Based upon our criteria and assessment of the peer-reviewed literature, use of a metal-on-metal hip resurfacing device that has been approved by the United States Food and Drug Administration (FDA) has been medically proven to be effective and, therefore, is considered **medically appropriate**, when **ALL** of the following criteria are met:
- The individual is age 64 years or younger;
 - Imaging shows **EITHER** of the following findings:
 - Osteoarthritis or an inflammatory arthroplasty affecting **BOTH** the femoral head and the acetabulum, with joint space narrowing on weight-bearing radiographs; or
 - Avascular necrosis of the femoral head with possible acetabular surface involvement and there is less than 50% involvement of the femoral head;
 - The individual has function-limiting pain at short distances (e.g., walking less than ¼ mile, limiting activity to two city blocks, the equivalent to walking the length of a shopping mall) for at least three (3) months duration.*
*Criteria exception: Three (3) months of function-limiting pain is not required when the medical record clearly documents why provider-directed non-surgical management is inappropriate (e.g., collapse of the femoral head, inflammatory arthritis, advanced dysplasia);
 - Loss of hip function which interferes with the ability to carry out age appropriate activities of daily living and/or demands of employment;
 - Failure of at least three (3) months of provider-directed non-surgical management.*
*Criteria exception: Three (3) months of provider-directed non-surgical management is not required when the medical record clearly documents why provider-directed non-surgical management is inappropriate (e.g., collapse of the femoral head, inflammatory arthritis, advanced dysplasia).
- II. Based upon our criteria and assessment of the peer-reviewed literature, total hip resurfacing has not been medically proven to be effective and, therefore, is considered **not medically necessary** for **ANY** other indication including but not limited to:

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- A. There is evidence of avascular necrosis of the femoral head involving more than 50% of the femoral head;
- B. The individual is skeletally immature;
- C. The individual has an active local or systemic infection;
- D. There is evidence of vascular insufficiency, significant muscular atrophy of the hip or leg musculature, or neuromuscular disease severe enough to compromise implant stability or post-operative recovery;
- E. The individual has Charcot joint;
- F. The individual is undergoing dialysis and on a renal transplant list.

POLICY GUIDELINE

This policy does not address partial hip resurfacing involving resurfacing of only the femoral component.

DESCRIPTION

Total hip resurfacing is an alternative to watchful waiting or total hip arthroplasty for younger, active individuals with hip disease such as osteoarthritis, rheumatoid arthritis, or advanced avascular necrosis.

In total hip resurfacing, the surface of the femoral head is trimmed and covered with a hollow metal hemisphere that fits into a metal acetabular cup. It is believed to optimize stress transfer to the proximal femur, and, because of the large diameter of the articulation, to offer stability and optimal range of movement. Because resurfacing preserves proximal femoral bone stock, it may not compromise future total hip replacements.

Non-surgical management with regard to the treatment of hip osteoarthritis is defined as any provider-directed, non-surgical treatment that has been demonstrated in the scientific literature to be efficacious and/or that is considered reasonable care in the treatment of hip pain from osteoarthritis. Types of treatment may include but are not limited to: relative rest/activity modification, weight loss, supervised physiotherapy modalities and therapeutic exercises, oral prescription and non-prescription medications, assistive devices (e.g., cane, crutches, walker, wheelchair), and/or intra-articular injections (e.g., steroid).

RATIONALE

The Birmingham Hip Resurfacing Device (BHR), a metal-on-metal system, received FDA premarket approval in May 2006. The Cormet Hip Resurfacing system, another metal-on-metal system, received FDA premarket approval in July 2007. In March 2019, the FDA confirmed that there are two FDA-approved metal-on-metal hip resurfacing devices available (as identified).

Reports of long-term outcomes of metal-on-metal hip resurfacing are not available. However, evidence from numerous case series demonstrates symptomatic and functional improvements that appear to be comparable to those obtained with the current generation of total hip replacement in individuals younger than age 65 years at similar follow-up duration. In addition, because hip resurfacing leaves femoral bone stock intact, revision is technically similar to primary total hip replacement. Increased concentrations of metal ions have been documented after metal-on-metal hip resurfacing; however, the effects of this, if any, are not known. The effect of metal ion release on a fetus is also unknown.

There is minimal published medical literature regarding total HR using polyethylene components. More studies are emerging, investigating total HR as a treatment for developmental dysplasia of the hip (DDH). Outcomes of studies thus far are insufficient to determine the overall health outcome of HR in this patient-population (Li et al., 2009; Naal et al., 2009; McBryde et al., 2008).

In a 2019 retrospective cohort study, Inoue et al. compared post-operative complications and survivorship of total hip and knee arthroplasty in dialysis and renal transplantation patients. They included a total of 107 patients undergoing primary total joint arthroplasty, including 50 who were receiving dialysis and 57 who had a prior renal transplantation. The end point was defined as revision surgery secondary to post-operative complications. Researchers found a significantly higher rate of post-operative complications in the dialysis cohort (28%, n=14 of 50 joints), compared to the renal transplant cohort (7.1%, n= 4 of 57 joints). There was a higher rate of SSI and PJI in dialysis patients, compared with renal transplantation patients (18% versus 3.5%, P=0.02). In addition, there was an increased rate of revision surgery in the dialysis cohort, compared to transplant cohort (24% versus 3.5%, P=0.002). A multi-variate analysis considering

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demographics and comorbidities revealed that patients with renal transplantation were less likely to have revision surgery, compared to patients on dialysis as the time of arthroplasty (95 % CI, P=0.031) and demonstrated a strong trend for lower complications (95% CI, P=0.76), although the latter was not statistically significant. Researchers concluded that transplantation was independently associated with reduced rates of revision surgery in the setting of chronic renal failure, suggesting that those who are candidates may benefit from renal transplantation before undergoing elective total joint arthroplasty.

CODES

- Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.
- **CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.**
- Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.
- Code Key: Experimental/Investigational = (E/I), Not medically necessary/appropriate = (NMN).

CPT Codes

| Code | Description |
|-------------------|-------------|
| No specific codes | |

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HCPCS Codes

| Code | Description |
|-------|---|
| S2118 | Metal-on-metal total hip resurfacing, including acetabular and femoral components |

ICD10 Codes

| Code | Description |
|-----------------|--|
| M16.0-M16.9 | Osteoarthritis of hip (code range) |
| M87.050 | Idiopathic aseptic necrosis of pelvis |
| M87.051-M87.059 | Idiopathic aseptic necrosis of femur (code range) |
| M87.150 | Osteonecrosis due to drugs, pelvis |
| M87.151-M87.159 | Osteonecrosis due to drugs, femur (code range) |
| M87.250 | Osteonecrosis due to previous trauma, pelvis |
| M87.251-M87.256 | Osteonecrosis due to previous trauma, femur (code range) |
| M87.350 | Other secondary osteonecrosis, pelvis |
| M87.351-M87.353 | Other secondary osteonecrosis, femur (code range) |
| M87.850 | Other osteonecrosis, pelvis |
| M87.851-M87.859 | Other osteonecrosis, femur (code range) |

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*Key Article

KEY WORDS

Hip Resurfacing

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, Total Hip Resurfacing is not specifically addressed in National or Regional Medicare coverage determinations or policies.