MEDICAL POLICY

MEDICAL POLICY DETAILS

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<tr>
<th>Medical Policy Title</th>
<th>METAL-ON-METAL TOTAL HIP RESURFACING</th>
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Product Disclaimer

- 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 product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.
- If a Medicare 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.

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, use of an FDA approved metal-on-metal hip resurfacing device has been medically proven to be effective and therefore medically appropriate for patients meeting all of the following criteria:

A. Function-limiting pain at short distances (e.g. walking less than ¼ mile, limiting activity to two city blocks, the equivalent of walking the length of a shopping mall) for at least three(3) months duration;
B. Individual is age 64 years or younger;
C. Loss of hip function which interferes with the ability to carry out age-appropriate activities of daily living and/or demands of employment;
D. Presence of either of the following:
   1. Degenerative arthritis or an inflammatory arthropathy affecting both the femoral head and acetabulum with joint space narrowing on weight bearing radiographs; or
   2. Osteonecrosis (vascular necrosis) of the femoral head with possible acetabular surface involvement when the disease is detected early and there is less than 50% involvement of the femoral head; and
E. Failure of at least three(3) months of provider-directed non-surgical management, unless contraindicated and the reasons for the contraindication are clearly documented:
   1. For patients with BMI greater than 40, there must be failure of at least six(6) months of provider-directed non-surgical management.

II. Based upon our criteria and assessment of peer-reviewed literature, total hip resurfacing has not been medically proven to be effective and therefore is considered not medically necessary when any of the following criteria are met:

a. Osteonecrosis (avascular necrosis) of the femoral head involving more than 50% of the femoral head;
b. Skeletal immaturity;
c. Active local or systemic infection;
d. One or more uncontrolled or unstable medical conditions that would significantly increase the risk of morbidity or mortality (e.g., cardiac, pulmonary, liver, genitourinary, or metabolic disease; hypertension; abnormal serum electrolyte levels);
e. Vascular insufficiency, significant muscular atrophy of the hip or leg musculature or neuromuscular disease severe enough to compromise implant stability or post-operative recovery;
f. Osseous abnormalities that cannot be optimally managed prior to surgery which would increase the likelihood of a poor surgical outcome (i.e., inadequate bone stock to support the implant);
g. Severe immunocompromised state; or

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h. Charcot joint.

III. Based upon our criteria and assessment of peer-reviewed literature, any other applications (e.g., developmental hip dysplasia, ankylosing spondylitis) of total hip resurfacing have not been medically proven to be effective and therefore are considered investigational.

POLICY GUIDELINES

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 patients with hip diseases including osteoarthritis, rheumatoid arthritis, and 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.

Partial hip resurfacing (of the femoral component only) has been proposed as a treatment option for avascular necrosis with collapse of the femoral head and preservation of the acetabulum.

Non-surgical management with regard to the treatment of hip osteoarthritis is defined as any provider-directed non-surgical treatment which has been demonstrated in the scientific literature as efficacious and/or is considered reasonable care in the treatment of hip pain from osteoarthritis. The types of treatment can 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 (i.e., 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, a metal-on-metal system, received FDA premarket approval in July 2007. The Buechel-Pappas Integrated Total Hip Replacement, has been approved by the FDA for total hip resurfacing. The weight bearing surfaces of this device are composed of a metal femoral component and a polyethylene acetabular component. The Conserve® Plus device, a metal-on-metal system, received FDA approval in November 2009.

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 patients less than 65 years old 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 the fetus is not known.

In February 2007, a BCBSA TEC Assessment reviewed evidence published through January 2007 on metal-on-metal total hip resurfacing. The Assessment evaluated studies of individuals with advanced degenerative joint disease of the hip who received a hip resurfacing (HR) device and that reported data on short- and long-term clinical outcomes, including benefits and harms, as an alternative to total hip replacement (THA). TEC identified 1 randomized controlled trial, and 12 uncontrolled series. For the assessment, these published trials, the FDA PMA submission data, and information from the Australian Orthopedic Association (AOA) National Joint Replacement Registry were evaluated. TEC concluded that use of the FDA-approved metal-on-metal HR devices meets the TEC criteria as an alternative to THA in patients who are candidates for THA and who are likely to outlive a traditional prosthesis. A substantial body of evidence shows that total hip resurfacing is associated with consistent and strong symptomatic and functional
improvements comparable to those obtained with current total hip arthroplasty in patients less than 65 years old. Total hip resurfacing differs procedurally from arthroplasty in conserving a patient’s native femoral bone stock; this difference is important should subsequent revision surgery be required. The available evidence shows that HR’s short-term symptomatic and functional health benefits are at least as good as those of THA over midterm follow-up, with no substantial differences in revision rates, among patients younger than 65 years who are likely to outlive a traditional prosthesis. Also, inference from the available long-term evidence suggests that HR will be at least as beneficial as THA in patients who are likely to outlive a traditional prosthesis, based on 1) appropriate patient selection, 2) the fact that HR is a bone-conserving procedure that preserves the femoral head and stock largely intact, and 3) substantial 5-year follow-up of device survival.


**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.

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REFERENCES


Proprietary Information of Excellus Health Plan, Inc.


*Proprietary Information of Excellus Health Plan, Inc.*


*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.