

Name of Blue Advantage Policy: Hip Resurfacing

Policy #: 153 Latest Review Date: April 2024 Category: Surgery

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

- 1. Safe and effective;
- 2. Not experimental or investigational*;
- *3. Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
 - Furnished in a setting appropriate to the patient's medical needs and condition;
 - Ordered and furnished by qualified personnel;
 - One that meets, but does not exceed, the patient's medical need; and
 - At least as beneficial as an existing and available medically appropriate alternative.

*Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare** for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).

POLICY:

Blue Advantage will treat metal-on-metal total hip resurfacing with an FDA-approved device system as a covered benefit as an alternative to total hip replacement when the patient:

- Is a candidate for total hip replacement; AND
- Is likely to outlive a traditional prosthesis; AND
- Does not have a contraindication for total hip resurfacing (See below).

Contraindications for total hip resurfacing:

- Bone stock is inadequate to support the device due to:
 - Severe osteopenia or a family history of severe osteoporosis or severe osteopenia
 - Osteonecrosis or avascular necrosis with more than 50% involvement of the femoral head
 - Multiple cysts of the femoral head (more than 1 cm)
- Skeletal immaturity
- Vascular insufficiency, muscular atrophy, or neuromuscular disease severe enough to compromise implant stability or postoperative recovery
- Known moderate to severe renal insufficiency
- Severely overweight
- Known or suspected metal sensitivity
- Immunosuppressed or receiving high doses of corticosteroids
- Females of childbearing age due to unknown effects of the fetus of metal ion release

Blue Advantage will treat partial hip resurfacing with an FDA-approved device as a

covered benefit in patients with osteonecrosis of the femoral head who have one or more contraindications for metal-on-metal implants and meet the following criteria:

- The patient is a candidate for total hip replacement; and
- Is likely to outlive a traditional prosthesis; and
- The patient has known or suspected metal sensitivity or concern about the potential effects of metal ions; and
- There is no more than 50% involvement of the femoral head; and
- There is minimal change in acetabular cartilage or articular cartilage space identified on radiography.

Blue Advantage will treat all other types and applications of hip resurfacing as a non-covered benefit and as investigational.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contracts and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Hip resurfacing is an alternative to total hip arthroplasty (THA, also known as hip replacement) for patients with advanced arthritis of the hip. Total hip resurfacing (THR) describes the placement of a shell that covers the femoral head together with implantation of an acetabular cup in patients with painful hip joints. Partial hip resurfacing is considered a treatment option for avascular necrosis with collapse of the femoral head. Available prostheses are metal-on-metal devices.

Total hip resurfacing has been investigated in patients with osteoarthritis, rheumatoid arthritis, and advanced avascular necrosis as an alternative to THA, particularly in young active patients who would potentially outlive a total hip prosthesis. Therefore, hip resurfacing could be viewed as a time-buying procedure to delay the need for a THA. Proposed advantages of THR compared with THA include preservation of the femoral neck and femoral canal, thus facilitating revision or conversion to a THR, if required. In addition, the resurfaced head is more similar in size to the normal femoral head, thus increasing the stability and decreasing the risk of dislocation compared with THA.

Total hip resurfacing has undergone various evolutions, with modifications in prosthetic design and composition and implantation techniques. For example, similar to total hip prostheses, the acetabular components of THR have been composed of polyethylene. However, over time it became apparent that device failure was frequently related to the inflammatory osteolytic reaction to polyethylene debris wear particles. Metal acetabular components have since been designed to improve implant longevity. Sensitivity to wear particles from metal-on-metal chromium and cobalt implant components are of increasing concern.

KEY POINTS:

The most recent literature update was performed through March 5, 2024.

Summary of Evidence

For individuals who have an indication for hip replacement who would outlive a traditional prosthesis and have no contraindication for hip resurfacing who receive a metal-on-metal total hip resurfacing device, the evidence includes RCTs, numerous large observational studies, large registry studies, and systematic reviews. Relevant outcomes are symptoms, changes in disease status, functional outcomes, health status measures, quality of life, and treatment-related morbidity. The efficacy of total hip resurfacing performed with current techniques is similar to that for THA over the short-to-medium term, and total hip resurfacing may permit easier conversion to a THA for younger patients expected to outlive their prosthesis. Based on the potential ease of revision of total hip resurfacing compared with THA, current evidence supports conclusions that hip resurfacing presents a reasonable alternative for active patients who are considered too young for THA when performed by surgeons experienced in the technique. The literature on adverse events (e.g., metallosis, pseudotumor formation, implant failure) is evolving as longer follow-up data become available. Due to the uncertain risk with metal-on-metal implants, the risk-benefit ratio needs to be considered carefully on an individual basis. In addition, emerging evidence has suggested an increased risk of failure in women, possibly due to smaller implant size. Therefore, these factors should also be considered in the overall patient

evaluation for total hip resurfacing, and patients should make an informed choice with their treating physicians. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have an indication for hip replacement who would outlive a traditional prosthesis and have no contraindication for hip resurfacing who receive a partial hip resurfacing device, the evidence includes a comparative study. Relevant outcomes are symptoms, changes in disease status, functional outcomes, health status measures, QOL, and treatment-related morbidity. Although evidence has shown better outcomes with THR than with partial hip resurfacing, partial hip resurfacing would be appropriate in younger patients with osteonecrosis who have contraindications for a metal-on-metal prosthesis. These factors should be considered in the overall patient evaluation for THR, and patients should make an informed choice with their treating physicians. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

Hip Society

In 2012, the Hip Society published an algorithmic approach to the diagnosis and management of metal-on-metal arthroplasty. The review indicated that adverse local tissue reactions to metal debris are escalating and that all arthroplasty patients returning for follow-up should be queried for pain, discomfort, or compromise of function. Symptomatic patients should be evaluated for all intra-articular and extra-articular causes of pain, including aseptic loosening, sepsis, component malposition, or fluid collections, and/or masses about the hip. The Hip Society stated that there is still a role for metal-on-metal resurfacing arthroplasty in select patient groups. The ideal candidate is a man younger than age 55 with osteoarthritis and a femoral head size larger than 50 mm. Another relative indication is the need or desire to return to a very high activity level at work or in recreation. Contraindications to metal-on-metal resurfacing include known or suspected metal sensitivity; moderate or worse renal function; women who may become pregnant; osteoporosis; large cysts; and avascular necrosis of more than 50%.

American Academy of Orthopaedic Surgeons

In 2010, the American Academy of Orthopaedic Surgeons published a technology overview on MoM hip resurfacing. To compare revision rates between MoM hip resurfacing and THA, the Academy analyzed three joint registries, which indicated that patients who received THR were at greater risk for revision than patients who received THA. One registry suggested that younger men may have a lower revision rate after THR than THA, although the available data were not found to clearly establish an advantage for this subgroup. There was no conclusive evidence on predictors of successful or unsuccessful outcomes.

National Institute for Health and Care Excellence

The NICE (2014) updated its guidance on THA and THR for end-stage arthritis of the hip. The NICE concluded that both THA and THR were options for treating end-stage arthritis of the hip, although clinicians may be more likely to offer resurfacing arthroplasty to men than to women because of higher revision rates observed in women. The NICE concluded that THA was more effective and less costly than THR in all analyses, that the revision rate was the most important key driver of costs and quality-adjusted life years, and that because the predicted revision rate of

THA was less than 5% at ten years in the population for whom both THA and THR were suitable, the revision rate standard for THR should be the same as that for THA. The NICE recommended specific prostheses for THA and THR only if the prostheses have revision rates of 5% or less at ten years.

U.S. Preventive Services Task Force Recommendations

Not applicable.

KEY WORDS:

Total hip resurfacing, partial hip resurfacing, total hip arthroplasty, Buechel-Pappas Integrated Total Hip Replacement, Conserve Plus, Cormet 2000, Birmingham hip resurfacing device, BHR

APPROVED BY GOVERNING BODIES:

In 2006, the FDA approved the Birmingham Hip Resurfacing (BHR; Smith & Nephew Orthopaedics, Cordova, TN) system, a MoM resurfacing system, through the premarket approval (PMA) process for use in patients requiring primary hip resurfacing arthroplasty for non-inflammatory or inflammatory arthritis. This decision was primarily based on a series of 2203 patients (2385 hips) who received this device by a single surgeon in England. A number of post-approval requirements were agreed to, including the following items:

- Study longer-term safety and effectiveness through a 10-year follow-up of the first consecutive 350 cases in the 2385 hip case-cohort that was part of the PMA.
- Study the "learning curve" and the longer-term safety and effectiveness of the BHR in the United States by studying 350 patients at up to 8 sites where clinical and radiographic data will be assessed annually through 5 years and at 10 years. Also, determine cobalt and chromium serum concentration and renal function in these patients at 1, 4, and 10 years.
- Implement a training program to provide clinical updates to investigators.

Two additional MoM hip resurfacing systems have been approved: in 2007, the Cormet[™] Hip Resurfacing System (Corin, Tampa, FL) and, in 2009, the Conserve® Plus Total Hip Resurfacing System (MicroPort Orthopedics, Arlington, TN). Both implants were approved for skeletally mature patients with either non-inflammatory degenerative arthritis (e.g., osteoarthritis and avascular necrosis) or inflammatory arthritis (e.g., rheumatoid arthritis). (Note: patients with the latter arthritis might be individuals who, due to younger age or increased activity level, may not be suitable for traditional THA because it would increase the possibility of requiring ipsilateral hip joint revision.)

Various devices have been cleared for marketing by the FDA through the 510(k) process for partial hip (femoral) resurfacing. Some surgeons may be using a femoral resurfacing component together with an acetabular cup (total arthroplasty component) as an "off-label" application. FDA product code: NXT.

BENEFIT APPLICATION:

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:

There is no specific CPT code for total hip resurfacing. The American Academy of Orthopaedic Surgeon's coding committee has written several articles stating that this procedure should be reported with the regular total hip CPT code 27130.

CPT:

27299	Unlisted procedure, pelvis or hip joint
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement [total hip replacement], with or without autograft or allograft

HCPCS:

S2118	Metal-on-metal total hip resurfacing, including acetabular and femoral components
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POLICY HISTORY:

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This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, predeterminations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.