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## Hip Resurfacing (HR)

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Related Policies (if applicable)
None

### Disclaimer

**Carefully check state regulations and/or the member contract.**

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

### Coverage

Metal-on-metal total hip resurfacing with an U. S. Food and Drug Administration (FDA) approved device system **may be considered medically necessary** as an alternative to total hip arthroplasty (THA) when the individual meets **ALL** the following criteria:

- Diagnosis of degenerative joint disease (e.g., osteoarthritis, rheumatoid arthritis, traumatic arthritis, dysplasia, or avascular necrosis; involving less than 50% of the femoral head), AND
- Individual is unsuitable for traditional THA because of increased activity level, OR is of younger age (< 55 years of age) because of increased possibility of requiring future ipsilateral hip joint revision, AND
- Procedure performed by a surgeon who has received appropriate training in the total hip resurfacing technique, AND
- Does **not** have 1 or more of the following FDA listed contraindications for total hip resurfacing:
  - Osteonecrosis or avascular necrosis with more than 50% involvement of the femoral head,
  - Multiple cysts of the femoral head (> 1 cm),
  - Infection of the body or blood,

- Skeletal immaturity,
- Conditions that will prevent the artificial hip joint system from remaining stable (vascular insufficiency, muscular atrophy, or neuromuscular disease),
- Conditions that may prevent following instructions during the recovery period,
- Osteoporosis or family history of severe bone loss,
- Women of childbearing age. It is unknown whether metal ions released by the device could harm an unborn child,
- Moderate to severe renal insufficiency,
- Metal sensitivity (reaction to wearing metal jewelry),
- Immunosuppressed due to diseases such as acquired immune deficiency syndrome (AIDS) or are receiving high doses of corticosteroids, or
- Severely overweight (body mass index [BMI] equal to or greater than 40 kg/m<sup>2</sup>).

Partial hip resurfacing (PHR) with an FDA approved device **may be considered medically necessary** in individuals with osteonecrosis of the femoral head who have 1 or more contraindications for metal-on-metal implants (as listed above) and meet **ALL** the following criteria:

- The individual is a candidate for total hip replacement, AND
- Is likely to outlive a traditional prosthesis, AND
- The individual has known or suspected metal sensitivity or concern about 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.

All other types and applications of hip resurfacing **are considered experimental, investigational and/or unproven.**

## Policy Guidelines

There is no specific CPT code for total hip resurfacing. The American Academy of Orthopaedic Surgeons' coding committee has written several articles stating that this procedure should be reported with the regular total hip CPT code. It might also be reported with 27299.

There is a specific HCPCS code for this procedure: S2118.

## Description

Hip resurfacing is an alternative to total hip arthroplasty (THA; also known as hip replacement) for individuals with advanced arthritis of the hip. Total hip resurfacing describes the placement of a shell that covers the femoral head together with implantation of an acetabular cup in individuals 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**

Total hip resurfacing (THR) has been investigated in individuals 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 total hip resurfacing, 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.

### **Regulatory Status**

In 2006, the Birmingham Hip Resurfacing (BHR) System (Smith & Nephew Orthopaedics), a metal-on-metal resurfacing system, was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (PMA) process for use in patients requiring primary hip resurfacing arthroplasty for noninflammatory or inflammatory arthritis. This decision was primarily based on a series of 2203 patients (2,385 hips) who received this device by a single surgeon in England. A number of post-approval conditions were required, including the following items:

- Study longer-term safety and effectiveness through 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 System 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 metal-on-metal hip resurfacing systems have been approved: in 2007, the Cormet™ Hip Resurfacing System (Corin) and, in 2009, the Conserve® Plus Total Hip Resurfacing System (MicroPort Orthopedics). Both implants were approved for skeletally mature patients with either: noninflammatory 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.)

A 2012 FDA advisory panel of experts identified young males with larger femoral heads as the best candidates for hip resurfacing systems. The FDA has advised that a metal-on-metal hip implant should be selected only after determining that the benefit-risk profile of using a metal-on-metal hip implant outweighs that of using an alternative hip system. Factors to consider include the individual's age, sex, weight, diagnosis, and activity level. Individuals should be informed about the benefits and risks of metal-on-metal hip implants, including the risk that the hip implant may need to be replaced. Individual expectations and the potential complications of surgery with a metal-on-metal hip implant should be discussed.

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.

## Rationale

Medical policies assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

### **Total Hip Resurfacing**

#### Clinical Context and Therapy Purpose

The purpose of total hip resurfacing is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conventional surgical methods, in individuals with an indication for hip replacement who are undergoing total hip arthroplasty (THA) and would potentially outlive the prosthesis.

The following PICO was used to select literature to inform this policy.

### *Populations*

The relevant population of interest is individuals with an indication for hip replacement who would outlive a traditional prosthesis and who have no contraindication for hip resurfacing. Younger, physically active individuals are the most suitable candidates for total hip resurfacing.

### *Interventions*

The therapy being considered is total hip resurfacing. Total hip resurfacing describes the placement of a shell that covers the femoral head together with implantation of an acetabular cup. The procedure has evolved since its inception, with modifications in prosthetic design and composition, and implantation techniques.

### *Comparators*

Comparators of interest include conventional THA.

### *Outcomes*

The general outcomes of interest are symptoms, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related morbidity.

The existing literature evaluating total hip resurfacing has varying lengths of follow-up, up to 10 years.

### Study Selection Criteria

Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

### Patient Selection Criteria

Nunley et al. (2009) reviewed 207 publications, most of which had little or no description of the patient population, small sample sizes, poor study designs, limited control of bias, and inadequate statistical analysis. (1) The literature showed no clear consensus on the upper age limit for male patients, but the most commonly used criterion was age (<65 years). Nine articles suggested that female patients should be cautiously evaluated before performing hip

resurfacing, especially if they are postmenopausal or have decreased bone mineral density. Some data reviewed was from the Australian Joint Replacement Registry, in which women 65 or older were observed to have a revision rate of 11% at 4 years. (2) This was compared with men younger than 55 years of age who had a revision rate of less than 2%. Both of these cohorts (older women and younger men) have revision rates of 2% after THA. The Nunley et al. (2009) review also indicated that obesity, defined as body mass index (BMI) greater than 35 kg/m<sup>2</sup>, can be viewed as a relative contraindication to THR, but not THA. Femoral head cysts, head-neck junction abnormalities, and poor bone density may also be considered risk factors for implant failure. At the time of this review, the literature on metal sensitivity and the presence of aseptic lymphocytic vasculitis-associated lesions was evolving, and the potential for transplacental transfer of metal ions was a concern for young female patients with the potential to become pregnant in the future. Reviewers concluded that the best candidates for hip resurfacing were men younger than age 65 with osteoarthritis and relatively normal bony morphology.

### Total Hip Resurfacing Versus Standard Total Hip Arthroplasty

#### *Systematic Reviews*

Multiple qualitative systematic reviews have been published comparing total hip resurfacing to standard THA with short- to mid-term follow-up. Quesada et al. (2008) reported that advantages of total hip resurfacing may include possible bone conservation on the femoral side, lower dislocation rates, more range of motion, more normal gait pattern, increased activity levels, increased ease of insertion with proximal femoral deformities or retained hardware, and straightforward revision. (3) Possible disadvantages of resurfacing were reported to be increased difficulty performing the procedure, increased acetabular bone stock loss, femoral neck fractures, and the effects of metal ions. In their systematic review, Marker et al. (2009) described 7 comparative studies that assessed "return to sports and activity" which revealed either similar outcomes for total hip resurfacing and THA procedures or advantages for the total hip resurfacing group. (4) An additional 4 studies, 3 assessing gait and 1 assessing postural balance, revealed similar or better outcomes for total hip resurfacing than THA. In a review focused on metal-on-metal total hip resurfacing versus THA in individuals younger than 65 years (Jiang et al. [2011]; 4 RCTs; N=968), hip function scores were similar between groups, although the resurfacing group showed higher activity levels. (5) Another systematic review (18 RCTs; N=776 patients) aimed at comparing resurfacing hip arthroplasty and THA in younger patients (less than 65 years old) found that there were no statistically significant differences between hip resurfacing and THA in terms of functional outcomes, complication rates, and revision rates. (6)

#### *Randomized Controlled Trials*

Haddad et al. (2015) published an RCT that was intended to evaluate clinical and functional outcomes of total hip resurfacing using the Birmingham system and to compare it to a cementless hip arthroplasty in patients under the age of 55 years. (7) Between 1999 and 2002, 80 patients were enrolled in the trial; however, only 24 consented to random allocation to treatment (11 to total hip resurfacing, 13 to THA). Eighteen patients refused total hip resurfacing and chose to undergo THA with a 32-mm bearing; 38 patients selected total hip

resurfacing. The mean follow-up for all patients was about 12 years (range, 10-14 years). Patients were assessed clinically and radiologically at 1 year, 5 years, and 10 years. Outcome measures included Oxford Hip Score, Harris Hip Score, University of California Los Angeles (UCLA), and University College Hospital functional scores. No differences were observed between the 2 groups in the Oxford or Harris Hip Scores or in the quality-of-life scores. At 10 years, more patients who underwent total hip resurfacing than those who underwent THA were able to run (53% vs. 19%;  $p=0.1$ ), to participate in sport activities (86% vs 52%;  $p=0.09$ ) and were able to perform heavy manual labor (20% vs. 13%;  $p=0.19$ ), respectively, although these outcomes were not statistically significant. Patients who had undergone total hip resurfacing exhibited significantly higher functional status scores than those who received a cementless THA at 10 years. Blood levels of cobalt and chromium ions were reported for 72 patients (49 THA, 23 total hip resurfacing); at 5- and 10-year follow-ups, all remained below a 7 parts per billion threshold for toxicity.

### *Cohort Studies*

Mont et al. (2007) compared gait analysis in 15 patients after successful total hip resurfacing with 15 patients who had a successful THA using a small femoral head, and with 10 patients who had osteoarthritis and 30 age- and sex-matched controls from a normative database. (8) Walking speed (1.3 m/s) was faster in the THR group than in the THA group (1.0 m/s) or osteoarthritis group (1.0 m/s). Measurement of abductor and extension moments found that the gait of patients following total hip resurfacing was closer to normal than the gait of patients who had undergone THA.

### Total Hip Resurfacing Versus Large-Head Total Hip Arthroplasty

#### *Randomized Controlled Trials*

Two controlled trials randomized patients to total hip resurfacing or THA with a large diameter metal-on-metal implant. (9, 10) Lavigne et al. (2010) tested the hypothesis that the observed improvement in activity with THR is due to patient selection bias or to the larger femoral head with total hip resurfacing. (9) To test this hypothesis, 48 patients were randomized to total hip resurfacing or large-head THA. The patients and evaluators at the gait laboratory were kept blinded to the type of arthroplasty until 1 year after surgery. There were no differences between groups for most of the measures at 3, 6, and 12 months postsurgery. Specifically, similar results were observed for normal and fast walking, postural evaluations, Timed Up & Go test, hop test, and hip flexor and abductor strength ratio. The total hip resurfacing group performed better during the Functional Reach Test, and the THA group completed the step test 3 seconds faster than the total hip resurfacing group. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), 36-Item Short-Form Health Survey (SF-36), Merle D'Aubigne, and UCLA Activity Scores were similar in both groups.

Garbuz et al. (2010) randomized 107 patients to total hip resurfacing or large-head metal-on-metal THA. (10) There were no differences in the WOMAC or SF-36 scores for the 73 patients who had been followed for at least 1 year. However, for the subset of patients who had been tested for serum levels of cobalt and chromium, cobalt was 10-fold higher, and chromium was 2.6-fold higher in the large-head metal-on-metal THA group than in the total hip resurfacing

group. This was a 46-fold increase from baseline in serum cobalt and a 10-fold increase from baseline in serum chromium for the large-diameter head THA group, possibly related to particulate wear at the head-neck junction. Both studies supported the hypothesis that the improved activity observed in THR patients is due to the larger diameter components used in resurfacing.

### *Revision Rates*

#### *Systematic Reviews*

Jiang et al. (2011) published a systematic review comparing revision rates for metal-on-metal total hip resurfacing with those for THA from 4 randomized or controlled trials with 968 patients younger than 65 years. (5) Analysis found increased rates of revision with total hip resurfacing at 1 to 10-year follow-ups; the relative risk was 2.60. However, this analysis did not evaluate the effect of age, bearing head size, or sex on revision rates.

Another systematic review by Kumar et al. (2022) compared mid- to long-term outcomes for hip resurfacing (n=304 hips) versus THA (n=308 hips) from 6 RCTs. (11) Follow-up period of the studies ranged from 5 to 14 years. There was a lower overall complication rate in the total hip resurfacing group compared to THA (odds ratio [OR], 2.17; 95% confidence interval [CI], 1.21 to 3.88; p=.009). There was no significant difference in terms of revision rates found between the 2 groups (OR, 1.06; 95% CI, 0.57 to 1.99; p=.85). The overall risk of bias for included studies was deemed moderate.

A systematic review by Davey et al. (2023) evaluated long-term outcomes for Birmingham hip resurfacing from 12 studies (N=7132 hips). (12) The minimum follow-up period was 10 years, with a mean follow-up of 11.5 years (range, 10 to 15.3 years). The overall surgical revision rate was 4.7% at final follow-up (n=334 hips); the most commonly reported complication following the hip resurfacing procedure was peri-prosthetic fracture (0.9%; n=65).

#### *Cohort Studies*

Azam et al. (2016) published a study that evaluated long-term (minimum, 10-year follow-up) survivorship and functional outcomes of Birmingham total hip resurfacing performed by a single surgeon between 1999 and 2004 in patients with hip osteoarthritis. (13) In this retrospective cohort study, revision surgery was considered the end point of survivorship. A total of 222 patients (244 hips) included 153 men and 69 women. At a mean follow-up of 12 years, 94% of implants were intact. In males, implant survival was 95% while in females, it was 90%. Failure was seen in 14 patients (16 hips), which included 7 (10%) female and 7 (5%) male patients. Femoral components failed due to aseptic loosening and varus collapse in 8 patients after a mean of 9.6 years. Metal allergy was reported in 3 patients (5 hips), all of whom were female; 2 of the latter had bilateral resurfacing. Other complications included femoral neck stress fractures in 2 patients and acetabular component loosening in 1 patient. The failure rate was higher in patients who received a total hip resurfacing femoral component size of 46 mm or less (10/16 hips revised).



Daniel et al. (2014) reported results of a prospective cohort study on long-term implant survival from a single-surgeon series of Birmingham total hip resurfacing. (14) The earliest 1000 consecutive total hip resurfacing implants comprised 288 women (335 hips) and 598 men (665 hips) of all ages and diagnoses without exclusions, who were prospectively followed with mailed questionnaires; the first 350 patients (402 hips) also had clinical and radiologic review. The mean follow-up was nearly 14 years (range, 12-15 years). In total, 59 patients (68 hips) died 0.7 to 12.6 years post-surgery from unrelated causes. Thirty-eight revisions were required at 0.1 to 14 years (median, 9 years) following the operation. These included 17 femoral failures (2%) and 7 each due to infections, soft-tissue reactions, and other causes. With revision for any reason as the end point, Kaplan-Meier survival analysis showed 97% (95% CI, 97% to 98%) and 96% (95% CI, 95% to 96%) survival rates at 10 and 15 years, respectively. Radiologic assessment showed 11 (4%) femoral and 13 (4%) acetabular radiolucencies, and 1 (0.3%) radiologic femoral failure. Men appeared to have better implant survival rates (98%; 95% CI, 97% to 99%) at 15 years than women (92%; 95% CI, 90% to 93%); women younger than 60 years had the poorest implant survival rate (90%; 95% CI, 88% to 93%). Patients younger than 50 years with osteoarthritis had the best results (99% survival at 15 years; 95% CI, 99% to 100%), with no failures in men in this group.

Multiple other studies have found similar conclusions in large patient cohorts. For example, 10-year or greater implant survival rate was greater in male hips than in female hips, across multiple age groups. (15-19) Additionally, decreasing femoral head size was significantly associated with an increased risk of revision in multiple studies. (17, 20) Another study (Kim et al. [2008]) found that most failures were related to early acetabular loosening. (21)

Gross et al. (2012) reported that in 373 hips from the first multicenter FDA regulated trial on hip resurfacing with the Cormet prosthesis, the learning curve was at least 200 cases, with survival at 11 years of 93% for the first 100 cases, 93% for the second 100 cases, and 98% for the last 73 cases. (22, 23) Nunley et al. (2010) suggested that, for experienced hip surgeons, the learning curve for avoiding early complications (e.g., early femoral fracture) is 25 or fewer cases, but the learning curve for achieving the desired component positioning is 75 to 100 or more cases. (24)

### Total Hip Resurfacing to Total Hip Arthroplasty Conversion

#### *Systematic Reviews*

Marker et al. (2009) published a systematic review that included 2 studies comparing the outcomes of hip resurfacing versus conventional THA. (4) McGrath et al. (2009) published 1 of the studies, which compared outcomes of 39 patients whose resurfacing was converted to THA with a group of primary THA patients matched by sex, age, BMI, and preoperative Harris Hip Score; all procedures had been performed by the same surgeon. (25) Perioperative measures were similar except for the mean operating time, which was 19 minutes longer for the revision group. At an average of 45 months of follow-up, the mean Harris Hip Scores were similar for both groups (92 for conversion to THA vs. 94 for primary THA).

#### *Cohort Studies*

De Steiger et al. (2010) reported on outcomes for revised total hip resurfacing from the Australian Joint Replacement Registry. (26) A total of 437 revisions were reported (of 12,093 primary total hip resurfacing; ~4%) between 1999 and 2008. After excluding 39 revisions for infection, the major reason for revision of primary total hip resurfacing was fracture of the femoral neck (43%), followed by loosening/lysis (32%), metal sensitivity (7%), and pain (6%). A femoral-only revision, which converts the joint to a conventional total hip resurfacing, was performed in 247 (62%) of the 397 revisions undertaken for reasons other than infection. At 3 years, the rate of re-revised total hip resurfacing THA was 7%, compared with 2.8% of primary conventional THA. Reasons for re-revision included loosening/lysis (n=6), infection (n=4), dislocation of prosthesis (n=1), and fracture (n=2). At 5 years, femoral-only re-revision (7%) was similar to re-revision of both the acetabular and femoral components (5%), but the rate of acetabular-only re-revision was 20%. A more relevant outcome for this evidence review, one that the investigators did not assess, would be a comparison of the revision rates for total hip resurfacing versus conventional THA.

Stoney et al. (2020) reported on outcomes for revised total hip resurfacing from the same Australian Joint Replacement Registry between 1999 and 2018. (27) This study specifically looked at male patients younger than 65 years old and compared Birmingham hip resurfacing (n=4790 procedures) to 3 conventional THA prostheses (n=2696 procedures). Birmingham hip resurfacing prostheses had a higher statistically significant rate of all-cause revision at 17 years than THA prostheses (hazard ratio [HR] 2.77; 95% CI, 1.78 to 4.32; p<.001); revisions occurred in 4.5% of primary Birmingham hip resurfacing procedures and all revisions were major revisions (e.g., removal or exchange of femoral or acetabular components). The study authors concluded that the design and bearing surface of the Birmingham hip resurfacing prostheses could impact the increase in revision rate compared to THA prostheses since the Birmingham hip resurfacing prostheses had a higher rate of septic loosening, fracture, lysis, and metal-related pathology.

Su et al. (2021) evaluated the 10-year survivorship of Birmingham total hip resurfacing to assess the safety and efficacy of this device. (28) Between 2006 to 2009, there were 280 hip procedures performed at 5 different sites. Outcome measures assessed were Kaplan-Meier survivorship, Harris hip scores, radiographic component stability and osteolysis, reasons for revision, and metal levels including cobalt and chromium. At 10-year follow-up, using all-cause component revision as an endpoint, the 10-year survivorship for all-cause component revisions for all hips was 92.9% (95% CI, 89.8% to 96.1%). Male patients had significantly better survivorship of (95.6%; 95% CI, 92.7% to 98.6%) compared to females (85.5%; 95% CI, 77.1% to 93.8%). Younger males (less than 65 years old at the time of procedure) had a slightly better survivorship of 96.0% (95% CI, 93.1% to 98.9%). Twenty hips (out of the 280 included) underwent revision; reasons for revision were for femoral loosening (n=5), femoral neck fracture (n=3), pseudotumor (n=3), osteolysis (n=2), acetabular loosening (n=1), and a combination of pain, noise, or metal levels (n=6); mean time to revision was 5.4 years. Among patients with unrevised hips, the Harris hip score improved from the preoperative phase to 1 year postoperatively and continued to remain stable 10 years postoperatively.

### Adverse Events

Reito et al. (2014) intended to evaluate 10-year survivorship of Birmingham total hip resurfacing, to investigate whole blood metal ion levels, to assess the prevalence of adverse events to metal debris, and to assess the relationship between blood metal ion levels plus symptoms of adverse events and metal debris among patients who underwent total hip resurfacing at a single institution. (29) Between 2001 and 2004, 219 patients received 261 total hip resurfacing implants. All patients with intact devices underwent systematic screening comprising clinical examination, whole blood cobalt and chromium measurements, and targeted cross-sectional imaging; any implant revision was the key study endpoint. At 10-year follow-up, device survival for the entire cohort was 91%, with revision required in 10 (6%) men and 13 (20%) women. The prevalence of adverse events to metal debris was 7% in male and 9% in female patients; it was associated with revision in 3 (2%) men and 8 (9%) women. Pseudotumors were observed most commonly in symptomatic patients who had elevated metal ion levels (63%) than with asymptomatic patients who had elevated metal ion levels (42%) and symptomatic patients who had nonelevated metal ions (11%).

Williams et al. (2011) assessed the prevalence of pseudotumor formation by ultrasound in asymptomatic patients with metal-on-metal THA (n=31) or metal-on-metal total hip resurfacing (n=21). (30) Results were compared with 24 asymptomatic patients with a metal-on-metal polyethylene THA. At a minimum of 2 years after surgery (mean, not reported), 10 (32%) patients in the metal-on-metal THA group had a solid (n=7) or cystic mass (n=3), 5 (25%) patients in the total hip resurfacing group had a solid (n=3) or cystic mass (n=2), and 1 (4%) patient in the metal-on-polyethylene THA group had a cystic mass. Isolated fluid collection was similar across the 3 groups (10%, 5%, and 8%, respectively). Serum chromium and cobalt ion levels in patients with metal-on-metal prostheses ranged from 2 to 720 times the upper limit of normal. There was no correlation between the serum metal ion levels and the size of pseudotumor abnormality and no significant difference in serum metal ion levels in patients with pseudotumor formation than in patients without pseudotumors in this small study. The high percentage of patients diagnosed with a pseudotumor in this study is due in part to a definition of pseudotumor that included cystic without solid mass.

Kwon et al. (2011) determined the prevalence of asymptomatic pseudotumors after metal-on-metal total hip resurfacing in 201 hips. (31) All patients who had surgery at least 3 years previously (n=228) were invited to participate. The 158 patients who agreed to participate underwent evaluation by ultrasound, followed by biopsy and magnetic resonance imaging (MRI) if a tumor was identified on ultrasound. Mean follow-up was 61 months (range, 36-88 months). Pseudotumors that contained both cystic and solid components were identified in 4.4% of patients (6 female, 1 male) and 6.5% of resurfaced hips. Histologic examination of the pseudotumors showed extensive necrosis of connective tissue and scattered aggregates of metal particles within necrotic macrophages in extracellular tissue. The pseudotumors were associated with significantly higher cobalt and chromium levels from serum and hip aspirate.

Steffen et al. (2008) published a retrospective study of 610 consecutive hip resurfacings (120 with >5-year follow-up) that attributed failure to metal debris in 0.5% of total hip resurfacing. (32) Ollivere et al. (2009), however, examined histologic samples taken at the time of revision

and concluded that the rate of metallosis-related revision in their series of 463 consecutive patients was 3% at 5 years. (33) All patients in this series had been recruited into the local arthroplasty follow-up program at the time of the primary surgery; 437 (94%) returned for clinical and radiologic follow-up at a mean follow-up of 43 months (range, 6-90 months). Case notes, radiographs, and MRI scans were available for the 13 revisions (2.8%, 12 patients). Histologic findings were available for 12 cases and were re-reviewed by a histopathologist with experience in metal wear and debris. In 7 cases, the histologic findings were consistent with a response to metal wear debris. Survivorship analysis gave an overall survival rate of 95.8% at 5 years, with an end point survival of 96.9% at 5 years for metallosis requiring revision. The relative risk for female sex in the metallosis group was 4.94. Also associated with metallosis were a smaller femoral component, greater abduction angle, and a higher BMI.

Mont et al. (2007) described the results of the FDA-regulated investigational device exemption (IDE) prospective, multicenter trial of the Conserve Plus hip resurfacing system in 2007. (34) The investigators identified a number of risk factors for complications after the first 292 procedures; they included the presence of cysts, poor bone quality, leaving reamed bone uncovered, minimizing the size of the femoral component to conserve acetabular bone, and malpositioning of the acetabular shell. Modification of inclusion criteria and surgical technique in the next 906 patients (1016 hips) resulted in a decreased rate of femoral neck fracture (from 7% to <1%). A trend was reported suggesting reduction in other types of complications (e.g., nerve palsy was reduced from 4.1% to 2.2%, loosening of the acetabular cup from 3.4% to 1.9%). No differences between the 2 cohorts were observed in the Harris Hip Score (93 vs 93) or the SF-12 survey (e.g., Physical Component Summary score, 50 vs 50).

#### Section Summary: Total Hip Resurfacing

The evidence on total hip resurfacing includes RCTs, numerous large observational studies, large registry studies, and systematic reviews. 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 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. The literature on adverse events (e.g., metallosis, pseudotumor formation, implant failure) is evolving as longer follow-up becomes available.

#### **Partial Hip Resurfacing**

##### Clinical Context and Therapy Purpose

The purpose of partial hip resurfacing is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conventional surgical methods, in individuals with avascular necrosis with collapse of the femoral head who are undergoing THA and would potentially outlive the prosthesis.

The following PICO was used to select literature to inform this policy.

### *Populations*

The relevant population of interest is individuals with avascular necrosis of the femoral head with no greater than 50% involvement of the femoral head. Younger, physically active patients are the most suitable candidates for partial hip resurfacing.

### *Interventions*

The therapy being considered is partial hip resurfacing.

### *Comparators*

Comparators of interest include conventional THA.

### *Outcomes*

The general outcomes of interest are symptoms, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related morbidity.

Based upon what little literature exists about partial hip resurfacing, follow-up of a minimum of 10 years would be appropriate.

### Study Selection Criteria

Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

### Comparative Study

A search of the literature on resurfacing for osteonecrosis identified a number of articles. Grecula (2005) (35) and Stulberg et al. (2009) (36) both discussed comparisons of partial hip resurfacing to total hip resurfacing, referencing a single comparative study by Beaulé et al. (2004). (37) This literature showed that total resurfacing/replacement provided more consistent and better initial pain relief than partial resurfacing.

### Section Summary: Partial Hip Resurfacing

The literature on partial hip surfacing for osteonecrosis includes a comparative study. There is an increase in poor outcomes with partial hip resurfacing compared with total hip resurfacing, which is believed to be related to continued abrasion and possible misfit of the femoral component against the native acetabular cartilage. Therefore, for younger patients who do not have contraindications for the metal-on-metal prosthesis, total hip resurfacing (femoral and acetabular implant) would be preferred over a femoral component alone. Partial hip resurfacing would be appropriate in patients with osteonecrosis who have contraindications for a metal-on-metal prosthesis.

## **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 randomized controlled trials (RCTs), numerous large observational studies, large registry studies, and systematic reviews. Relevant outcomes are symptoms, change 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 total hip arthroplasty (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 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 effects (e.g., metallosis, pseudotumor formation, implant failure) is evolving as longer follow-up becomes 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, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related morbidity. Although evidence has shown better outcomes with total hip resurfacing 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 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.

## **Practice Guidelines and Position Statements**

### American Academy of Orthopaedic Surgeons

In 2010, the American Academy of Orthopaedic Surgeons published a technology overview on metal-on-metal hip resurfacing. (38) To compare revision rates between metal-on-metal hip resurfacing and THA, the Academy analyzed 3 joint registries, which indicated that patients who received total hip resurfacing were at greater risk for revision than patients who received THA. One registry suggested that younger males may have a lower revision rate after total hip resurfacing 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.

### Hip Society

In 2012, the Hip Society published an algorithmic approach to the diagnosis and management of metal-on-metal arthroplasty. (39) 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 male patient 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 more than 50%.

### National Institute for Health and Care Excellence (NICE)

In 2014, the NICE updated its guidance on THA and total hip resurfacing for end-stage arthritis of the hip. (40) 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. 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 10 years in the population for whom both THA and total hip resurfacing were suitable, the revision rate standard for total hip resurfacing should be the same as that for THA. NICE recommended specific prostheses for THA and total hip resurfacing only if the prostheses have revision rates of 5% or less at 10 years.

### **Ongoing and Unpublished Clinical Trials**

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 1.

**Table 1. Summary of Key Trials**

<b>NCT Number</b>	<b>Trial Name</b>	<b>Planned Enrollment</b>	<b>Completion Date</b>
<b><i>Ongoing</i></b>			
NCT00611585 <sup>a</sup>	Birmingham Hip Resurfacing System (BHR) Post Approval Study: A Prospective, Multi-Centered Study of the Birmingham Hip Resurfacing System	360	Dec 2026

NCT: National clinical trial.

<sup>a</sup> Denotes an industry-sponsored or cosponsored study.

## Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

<b>CPT Codes</b>	27130, 27299
<b>HCPCS Codes</b>	S2118

\*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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## Centers for Medicare and Medicaid Services (CMS)

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A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <<https://www.cms.hhs.gov>>.

<b>Policy History/Revision</b>	
<b>Date</b>	<b>Description of Change</b>
12/15/2024	Document updated with literature review. Coverage unchanged. Added references 12 and 6.
12/01/2023	Document updated with literature review. Minor editorial refinement in Coverage although no change in intent. Added references 10, 16, 17, 21, 26, 27; others updated, some removed.
08/15/2022	Reviewed. No changes.
01/01/2022	Document updated with literature review. Coverage unchanged. No new references added; some references removed.
01/01/2021	Reviewed. No changes.
11/15/2019	Document updated with literature review. Coverage unchanged. No new references added.
07/15/2018	Reviewed. No changes.
12/15/2017	Document updated with literature review. Coverage unchanged.
09/15/2016	Reviewed. No changes.
02/15/2015	Document updated with literature review. Coverage unchanged. The following example was added to the FDA listed contraindications for conditions that will prevent the artificial hip joint system from remaining stable: vascular insufficiency.
08/01/2011	Document updated with literature review. Coverage unchanged.
09/15/2010	Document updated with literature review. Title changed from Total Hip Resurfacing to Hip Resurfacing. The following was added: Partial hip resurfacing with an FDA-approved device may be considered medically necessary in patients with osteonecrosis of the femoral head who have one or more contraindications for metal-on-metal implants when noted criteria are met. All other types and applications of partial hip resurfacing are considered experimental, investigational and unproven.