

<b>7.01.80</b>	<b>Hip Resurfacing</b>		
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<b>Section:</b>	7.0 Surgery	<b>Page:</b>	Page 1 of 18

### Policy Statement

Metal-on-metal total hip resurfacing with a device system approved by the U.S. Food and Drug Administration (FDA) may be considered **medically necessary** as an alternative to total hip replacement when the patient **all** of the following criteria:

- I. Is a candidate for total hip replacement
- II. Is likely to outlive a traditional prosthesis
- III. Does not have a contraindication for total hip resurfacing (see Policy Guidelines section)

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 and meet **all** of the following criteria:

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

All other types and applications of hip resurfacing are considered **investigational**.

**NOTE:** Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

### Policy Guidelines

The U.S. Food and Drug Administration (FDA) lists several contraindications for total hip resurfacing. These contraindications include, but are not limited to, the following:

- Bone stock 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 (greater 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 on the fetus of metal ion release

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 patient's age, sex, weight, diagnosis, and activity level. Patients 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. Patient expectations and the potential complications of surgery with a metal-on-metal hip implant should be discussed.

Total hip resurfacing should be performed by surgeons adequately trained and experienced in the specific techniques and devices used.

### Coding

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:

- **27130:** Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft

It might also be reported with CPT code:

- **27299:** Unlisted procedure, pelvis or hip joint

There is a specific HCPCS "S" code for this procedure:

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

### Description

Hip resurfacing is an alternative to total hip arthroplasty (also known as hip replacement) for patients 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 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.

### Related Policies

- Surgical Treatment of Femoroacetabular Impingement

### Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

### Regulatory Status

In 2006, the Birmingham Hip Resurfacing 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 process for use in patients requiring primary hip resurfacing arthroplasty for noninflammatory or inflammatory arthritis. This decision was primarily based on a series of 2,385 patients 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 initial 350 patients in the patient cohort that was part of the premarket approval.
- Study the "learning curve" and the longer term safety and effectiveness of the Birmingham Hip Resurfacing 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.)

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

### Background

Hip resurfacing is an alternative to total hip arthroplasty (THA; also known as total hip replacement) for patients 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. Partial hip resurfacing is considered a treatment option for avascular necrosis with collapse of the femoral head.

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 total hip resurfacing compared with THA include preservation of the femoral neck and femoral canal, thus facilitating revision or conversion to a 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 total hip resurfacing 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.

### Literature Review

Evidence reviews 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, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 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 patients with an indication for hip replacement who are undergoing total hip arthroplasty (THA) and would potentially outlive the prosthesis.

The question addressed in this evidence review is: Does the use of total hip resurfacing improve the net health outcome for patients with an indication for hip replacement who would potentially outlive a total hip prosthesis?

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

#### **Populations**

The relevant population of interest is individuals with indication for hip replacement who would outlive a traditional prosthesis and who have no contraindication for hip resurfacing. Younger, physically active patients 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. For example, the acetabular components of total hip resurfacing were once 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.

#### **Comparators**

Comparators of interest include conventional THA. Patients who are undergoing THA are actively managed by orthopedists and orthopedic surgeons.

#### **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.

## Review of Evidence

### Technology Assessment

This review was informed by a Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment (2007) that evaluated studies of patients with advanced degenerative joint disease of the hip who received a total hip resurfacing device and who reported data on short- and long-term clinical outcomes, including benefits and harms, as an alternative to THA. <sup>1</sup> The Assessment included a RCT<sup>2</sup> and 12 uncontrolled series, along with U.S. Food and Drug Administration (FDA) premarket application submission data,<sup>3</sup> and information from the Australian Orthopedic Association National Joint Replacement Registry.<sup>4</sup> The aggregate data suggested that total hip resurfacing treated patients who do not require a revision have substantial symptomatic reductions in pain and improvements in hip function over presurgical status.

The TEC Assessment also evaluated the patient safety and efficacy data considered for the FDA submission of the Birmingham device from the McMinn cohort, <sup>3</sup> which are supported by unpublished data on 3,374 hips implanted by 140 surgeons and published reports on more than 3,800 hips treated by multiple surgeons (worldwide cohort). With regard to long-term safety, literature summaries provided to the FDA demonstrated increased serum and urinary concentrations of metal ions postoperatively in patients with THA, particularly after metal-on-metal procedures, but data showed no conclusive evidence of significant detrimental effects. TEC concluded that use of the FDA-approved metal-on-metal total hip resurfacing 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.

### 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.<sup>5</sup> 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. <sup>4</sup> 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 total hip resurfacing 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

Marker et al (2009) published a systematic review comparing outcomes from total hip resurfacing with those from THA in studies with short- to mid-term follow-up.<sup>6</sup> The 7 comparative studies that assessed "return to sports and activity" revealed either similar outcomes for the 2

procedures or advantages for the total hip resurfacing group. Three additional studies assessed gait, and another study was identified that assessed postural balance; all 4 studies revealed similar or better outcomes for total hip resurfacing than THA.

Jiang et al (2011) published a systematic review comparing metal-on-metal total hip resurfacing with THA in patients younger than 65 years.<sup>7</sup> Included were 4 RCTs (N=968 patients). Hip function scores were similar between groups, although the resurfacing group showed higher activity levels.

Quesada et al (2008) published a qualitative systematic review that compared the advantages and disadvantages of total hip resurfacing with THA.<sup>8</sup> Advantages were reported to 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. Possible disadvantages of resurfacing were reported to be increased difficulty to perform the procedure, increased acetabular bone stock loss, femoral neck fractures, and the effects of metal ions. Although prospective controlled studies with long-term follow-up are needed for conclusive evaluation of these issues, the literature reviewed by these investigators suggested an increased risk of femoral neck fractures in postmenopausal women and small-boned men.

### Clinical Studies

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 with that of a cementless hip arthroplasty in patients under the age of 55 years.<sup>9</sup> 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 Hip Score, Harris Hip Score, 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 sports activities (86% vs. 52%;  $p=0.09$ ), and perform heavy manual labor (20% vs. 13%;  $p=0.19$ ), respectively. 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.

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.<sup>10</sup> Walking speed (1.3 m/s) was faster in the total hip resurfacing 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.<sup>11,12</sup> Lavigne et al (2010) tested the hypothesis that the observed improvement in activity with total hip resurfacing is due to patient selection bias or to the larger femoral head with total hip resurfacing.<sup>11</sup> 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, 36-Item Short-Form Health Survey, 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.<sup>12</sup> There were no differences in the Western Ontario and McMaster Universities Osteoarthritis Index or 36-Item Short-Form Health Survey 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 total hip resurfacing 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.<sup>7</sup> 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.

#### 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.<sup>13</sup> In this retrospective cohort study, revision surgery was considered the endpoint of survivorship. Prosthetic survival analysis was performed with the Kaplan-Meier method. 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.<sup>14</sup> The earliest 1,000 consecutive total hip resurfacing implants comprised 335 hips (288 women) and 665 hips (598 men) of all ages and diagnoses without exclusions, who were prospectively followed with mailed questionnaires; the first 402 hips (350 patients) also had a 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 postsurgery 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 endpoint, Kaplan-Meier survival analysis showed 97% (95% confidence interval [CI], 97% to 9%) 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.

Murray et al (2012) found that in a series of 554 patients, the 10-year implant survival rate in women was 74% compared with 95% in male hips, and the 10-year revision rate for pseudotumor was 7% compared with 1.7% for male hips.<sup>15</sup> Patient-reported outcomes on the Oxford Hip Score and UCLA Activity Score were also higher in men.

Matharu et al (2013) published a series that evaluated 447 patients younger than 50 years of age and found implant survival in women was 96.1% at 10 years and 91.2% at 14 years, compared with 100% for men at both 10 and 14 years.<sup>16</sup> Female sex ( $p=0.047$ ) and decreasing femoral head size ( $p=0.044$ ) were significantly associated with an increased risk of revision.

Pailhe et al (2014) assessed 162 patients 65 years of age or older and found 10-year implant survival rates of 98.9% in men and 91.9% in women.<sup>17</sup> Implant survival was negatively associated with increasing age ( $p=0.014$ ) and decreasing femoral head size ( $p=0.024$ ), with a nonsignificant trend for a negative association with female sex ( $p=0.079$ ).

Amstutz et al (2010) reported on a 12-year follow-up (range, 10.8-12.9 years) from the first 100 hip resurfacing procedures at their institution.<sup>18</sup> Kaplan-Meier implant survival was 93.9% at 5 years and 88.5% at 10 years. Subgrouping by femoral component size showed a 10-year survival rate of 95.6% for a component size of greater than 46 mm, 83.8% for component sizes of 44 or 46 mm, and 78.9% for a component size of 42 mm or less. Multivariate analysis showed that low BMI, small femoral component size, and large defects in the femoral head were risk factors for failure. High scores for activity level were not associated with an increased risk of revision.

Kim et al (2008) found in their study that most failures were related to early acetabular loosening.<sup>19</sup>

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.<sup>20</sup>

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.<sup>21</sup>

## **Total Hip Resurfacing to Total Hip Arthroplasty Conversion Review of Evidence**

### **Systematic Reviews**

Marker et al (2009) published a systematic review that included 2 studies comparing the outcomes of hip resurfacing versus conventional THA.<sup>6</sup> 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.<sup>22</sup> 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).

### **Clinical Studies**

Ball et al (2007), compared outcomes in 20 patients (from a group of 844 primary total hip resurfacings performed between 1997 and 2005) requiring conversion surgery for failed total hip resurfacing (5 femoral neck fractures, 16 with femoral component loosening) with outcomes in



58 patients of similar age (64 hips from patients <65 years) treated using a primary THA by the same surgeon during the same period.<sup>23</sup> The acetabular component was retained in 18 hips (and revised in 3 because the matching femoral head was not available at the time of surgery). The study found no significant differences in operative time between conversion (178 minutes; range, 140-255 minutes) and primary THA (169 minutes; range, 110-265 minutes), or in complication rates between groups (14% vs. 9%, respectively). At 1- to 9-year follow-up (average, 46 months for the total hip resurfacing THA revision group vs. 57 months for the primary THA group), outcomes as measured by the UCLA, 12-Item Short-Form Health Survey, and Harris Hip Score were similar (e.g., Harris Hip Score, 92 for the revision group vs. 90 for the primary THA control group). Although this small study suggested that a resurfaced femoral component might be converted to THA without additional complication, larger comparative studies assessing total hip resurfacing versus THA would be needed.

De Steiger et al (2010) reported on outcomes for revised total hip resurfacing from the Australian Joint Replacement Registry.<sup>24</sup> 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, 1 that the investigators did not assess, would be a comparison of the revision rates for total hip resurfacing versus conventional THA.

### 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.<sup>25</sup> 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 in 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).<sup>26</sup> Results were compared with 24 asymptomatic patients with a metal-on-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.<sup>27</sup> 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 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 resurfacings.<sup>28</sup> Ollivier 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.<sup>29</sup> 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 magnetic resonance imaging (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 endpoint 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 prospective, multicenter trial of the Conserve Plus hip resurfacing system in 2007.<sup>30</sup> 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 a 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 12-Item Short-Form Health 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 patients with

avascular necrosis with collapse of the femoral head who are undergoing THA and would potentially outlive the prosthesis.

The question addressed in this evidence review is: Does the use of partial hip resurfacing improve the net health outcome for patients with collapse of the femoral head who would potentially outlive a total hip prosthesis?

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

### **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.

Patients who are undergoing partial hip resurfacing are actively managed by orthopedists and orthopedic surgeons. Partial hip resurfacing should be performed by surgeons adequately trained and experienced in the specific techniques and devices used.

### **Comparators**

Comparators of interest include conventional THA. Patients who are undergoing THA are actively managed by orthopedists and orthopedic surgeons.

### **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.

### **Review of Evidence**

#### **Comparative Study**

A search of the literature on resurfacing for osteonecrosis identified a number of articles. Grecula (2005)<sup>31</sup> and Stulberg et al (2009)<sup>32</sup> both discussed comparisons of partial hip resurfacing to total hip resurfacing, referencing a single comparative study by Beaulé et al (2004).<sup>33</sup> 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 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 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 events (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.

### Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

### Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests from Blue Cross Blue Shield Association, input was received from 1 physician specialty society and 1 academic medical center in 2013. Input was mixed, although both reviewers agreed that evidence is not sufficient to conclude that the potential for harm with metal-on-metal hip resurfacing outweighs the benefit for all patients. One reviewer noted that current cross-linked polyethylene total hip components may last 20 to 30 years, limiting the number of patients who would outlive a total hip prosthesis and be considered an appropriate candidate for total hip resurfacing.

### Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### Hip Society

In 2012, the Hip Society published an algorithmic approach to the diagnosis and management of metal-on-metal arthroplasty (total hip arthroplasty [THA], total hip resurfacing).<sup>34</sup> 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 patients 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 more than 50%.

### American Academy of Orthopaedic Surgeons

In 2010, the American Academy of Orthopaedic Surgeons published a technology overview on metal-on-metal hip resurfacing.<sup>35</sup> 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 men 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.

### National Institute for Health and Care Excellence

In 2014, the NICE updated its guidance on THA and total hip resurfacing for end-stage arthritis of the hip.<sup>36</sup> NICE concluded that both THA and total hip resurfacing 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 total hip resurfacing 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.

### U.S. Preventive Services Task Force Recommendations

Not applicable.

### Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

### Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in March 2021 did not identify any ongoing or unpublished trials that would likely influence this review.

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## Documentation for Clinical Review

### Please provide the following documentation:

- History and physical and/or consultation report including:
  - Radiological findings including involvement of femoral head and acetabulum including cartilage changes (if applicable)
  - Specific procedure requested (total or partial hip) and reason requested
  - Whether patient is likely to outlive a traditional prosthesis
  - Any known or suspected metal sensitivity
- Radiology report(s)

**Post Service (in addition to the above, please include the following):**

- Operative report(s)

**Coding**

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

Type	Code	Description
CPT®	27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft
	27299	Unlisted procedure, pelvis or hip joint
HCPCS	S2118	Metal-on-metal total hip resurfacing, including acetabular and femoral components

**Policy History**

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
12/07/2006	New Policy Adoption Policy Adopted - BCBSA MPP
04/05/2007	Policy revision with position change
01/11/2008	Policy title change from Total Hip Resurfacing. Policy revision without position change
04/25/2008	Policy revision with coding update
12/18/2009	Policy title change from Total and Partial Hip Resurfacing/Metal on Metal. Policy revision without position change
01/11/2013	Policy revision with position change
06/30/2015	Coding Update
01/01/2016	Policy revision without position change
07/01/2017	Policy revision without position change
10/01/2017	Policy revision without position change
06/01/2018	Policy revision without position change
06/01/2019	Policy revision without position change
06/01/2020	Annual review. No change to policy statement. Literature review updated.
06/01/2021	Annual review. No change to policy statement. Literature review updated.

**Definitions of Decision Determinations**

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis;



(c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

### Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*

**Appendix A**

POLICY STATEMENT (No changes)	
BEFORE	AFTER
<p><b>Hip Resurfacing 7.01.80</b></p> <p><b>Policy Statement:</b> Metal-on-metal total hip resurfacing with a device system approved by the U.S. Food and Drug Administration (FDA) may be considered <b>medically necessary</b> as an alternative to total hip replacement when the patient meets <b>all</b> of the following criteria:</p> <ul style="list-style-type: none"> <li>• Is a candidate for total hip replacement</li> <li>• Is likely to outlive a traditional prosthesis</li> <li>• Does not have a contraindication for total hip resurfacing (see Policy Guidelines section)</li> </ul> <p>Partial hip resurfacing with an FDA-approved device may be considered <b>medically necessary</b> in patients with osteonecrosis of the femoral head who have one or more contraindications for metal-on-metal implants and meet <b>all</b> of the following criteria:</p> <ul style="list-style-type: none"> <li>• The patient is a candidate for total hip replacement</li> <li>• Is likely to outlive a traditional prosthesis</li> <li>• The patient has known or suspected metal sensitivity or concern about potential effects of metal ions</li> <li>• There is no more than 50% involvement of the femoral head</li> <li>• There is minimal change in acetabular cartilage or articular cartilage space identified on radiography</li> </ul> <p>All other types and applications of hip resurfacing are considered <b>investigational</b>.</p>	<p><b>Hip Resurfacing 7.01.80</b></p> <p><b>Policy Statement:</b> Metal-on-metal total hip resurfacing with a device system approved by the U.S. Food and Drug Administration (FDA) may be considered <b>medically necessary</b> as an alternative to total hip replacement when the patient <b>all</b> of the following criteria:</p> <ol style="list-style-type: none"> <li>I. Is a candidate for total hip replacement</li> <li>II. Is likely to outlive a traditional prosthesis</li> <li>III. Does not have a contraindication for total hip resurfacing (see Policy Guidelines section)</li> </ol> <p>Partial hip resurfacing with an FDA-approved device may be considered <b>medically necessary</b> in patients with osteonecrosis of the femoral head who have one or more contraindications for metal-on-metal implants and meet <b>all</b> of the following criteria:</p> <ol style="list-style-type: none"> <li>I. The patient is a candidate for total hip replacement</li> <li>II. Is likely to outlive a traditional prosthesis</li> <li>III. The patient has known or suspected metal sensitivity or concern about potential effects of metal ions</li> <li>IV. There is no more than 50% involvement of the femoral head</li> <li>V. There is minimal change in acetabular cartilage or articular cartilage space identified on radiography</li> </ol> <p>All other types and applications of hip resurfacing are considered <b>investigational</b>.</p>