



# Louisiana

## Hip Resurfacing

**Policy #** 00119

**Original Effective Date:** 09/18/2002

**Current Effective Date:** 11/21/2018

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

### **When Services May Be Eligible for Coverage**

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider metal-on-metal (MoM) total hip resurfacing (THR) with a Food and Drug Administration (FDA)-approved device system to be **eligible for coverage** as an alternative to total hip replacement.

#### Patient Selection Criteria

Coverage eligibility for the use of metal-on-metal (MoM) total hip resurfacing (THR) with a Food and Drug Administration (FDA)-approved device system as an alternative to total hip replacement will be considered when all of the following criteria are met:

- Is a candidate for total hip replacement; and
- Is likely to outlive a traditional prosthesis; and
- Does not have a contraindication for total hip resurfacing (THR) (see Contraindications for Total Hip Resurfacing below).

Based on review of available data, the Company may consider partial hip resurfacing with a Food and Drug Administration (FDA)-approved device in patients with osteonecrosis of the femoral head who have one or more contraindications for metal-on-metal (MoM) implants and meet all of the following criteria to be **eligible for coverage**:

#### Patient Selection Criteria

Coverage eligibility for the use of partial hip resurfacing with an Food and Drug Administration (FDA)-approved device in patients with osteonecrosis of the femoral head who have one or more contraindications for metal-on-metal (MoM) implants will be considered when all of the following criteria are met:

- The patient is a candidate for total hip replacement; and
- Is likely to outlive a traditional prosthesis; and
- The patient has no 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.

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### Contraindications for Total Hip Resurfacing:

The Food and Drug Administration (FDA) lists several contraindications for total hip resurfacing (THR). These contraindications include (not a complete listing) 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 (more than 1 cm);
- Skeletal immaturity;
- Vascular insufficiency, muscular atrophy, or neuromuscular disease severe enough to compromise implant stability or postoperative recovery;
- Known moderate to severe renal insufficiency;
- Severely overweight;
- Known or suspected metal sensitivity;
- Immunosuppressed or receiving high doses of corticosteroids;
- Females of child bearing age due to unknown effects on the fetus of metal ion release.

### **When Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers all other types and applications of total hip resurfacing (THR) to be **investigational**.\*

The use of hip resurfacing when patient selection criteria are not met is considered to be **investigational**.\*

### **Background/Overview**

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 (THR) 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.

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

THR 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

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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.

### **FDA or Other Governmental Regulatory Approval**

#### **U.S. Food and Drug Administration (FDA)**

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 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 2385 patients who received this device by a single surgeon in England. A number of postapproval 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 PMA.
- 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<sup>™‡</sup> Hip Resurfacing System (Corin) and, in 2009, the Conserve<sup>®</sup> Plus Total Hip Resurfacing System (MicroPort Orthopedics). Both implants were approved for skeletally mature patients with either: noninflammatory degenerative arthritis (eg, osteoarthritis and avascular necrosis); or inflammatory arthritis (eg, 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 Food and Drug Administration 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.

Food and Drug Administration product code: NXT.

#### **Centers for Medicare and Medicaid Services (CMS)**

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.

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### **Rationale/Source**

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are 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 to 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 a technology, 2 domains are examined: the relevance and the 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 controlled trials 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**

This review was informed by a TEC Assessment (2007) that evaluated studies of patients with advanced degenerative joint disease of the hip who received a total hip resurfacing (THR) device and who reported data on short- and long-term clinical outcomes, including benefits and harms, as an alternative to total hip replacement (total hip arthroplasty [THA]). The Assessment included an RCT and 12 uncontrolled series, along with U.S. Food and Drug Administration (FDA) premarket application submission data, and information from the Australian Orthopedic Association National Joint Replacement Registry. The aggregate data suggested that THR-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 FDA submission of the Birmingham device from the McMinn cohort, which are supported by unpublished data on 3374 hips implanted by 140 surgeons and published reports on more than 3800 hips treated by multiple surgeons (worldwide cohort). With regard to long-term safety, literature summaries provided to FDA demonstrated increased serum and urinary concentrations of metal ions postoperatively in patients with THA, particularly after metal-on-metal (MoM) procedures, but data showed no conclusive evidence of significant detrimental effects. TEC concluded that use of FDA-approved MoM THR 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**

In 2011, the American Academy of Orthopaedic Surgeons provided a technology overview of modern MoM hip implants. The National Joint Registry for England and Wales reported that hip resurfacing patients in all age groups, except men younger than 55 years of age, were at an increased revision risk compared with

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cemented THA using an unspecified bearing surface. The Australian registry reported that hip resurfacing patients 65 years of age or older had the highest revision risk. Head size and risk of revision for THR were inversely related to each other. Patients who received the smallest femoral head components (eg, women) had the greatest risk of revision. The implant size was associated with poorer outcomes when the sex by implant size interaction was analyzed. This analysis supports the view that THR is most effective in men who are too young to receive THA. A 2013 FDA advisory panel of experts also identified young men with larger femoral heads as the best candidates for hip resurfacing systems.

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. 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. 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 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.

## **Efficacy of THR vs THA**

### ***THR vs Standard THA***

#### *Systematic Reviews*

A systematic review by Marker et al (2009) compared outcomes from THR with those from THA in studies with short- to mid-term follow-up. The 7 comparative studies that assessed "return to sports and activity" revealed either similar outcomes for the 2 procedures or advantages for the THR group. Three additional studies assessed gait, and another study was identified that assessed postural balance; all 4 studies revealed similar or better outcomes for THR than THA.

Jiang et al (2011) published a systematic review comparing MoM THR with THA in patients younger than 65 years. Included were 4 RCTs (total 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 THR with THA. Advantages were reported to include possible bone conservation on the

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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**

An RCT by Haddad et al (2015) was intended to evaluate clinical and functional outcomes of THR using the Birmingham system and to compare it with that of a cementless hip arthroplasty in patients under the age of 55 years. Between 1999 and 2002, 80 patients were enrolled in the trial; however, only 24 consented to random allocation to treatment (11 to THR, 13 to THA). Eighteen patients refused THR and chose to undergo THA with a 32-mm bearing; 38 patients selected THR. 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 (HHS), 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 THR were able to run than those who underwent THA (53% vs 19%;  $p=0.1$ ), were able to participate in sport activities (86% vs 52%;  $p=0.09$ ), and were able to perform heavy manual labor (20% vs 13%;  $p=0.19$ ), all respectively. Patients who had undergone THR 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 THR); 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 THR 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. 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 THR was closer to normal than the gait of patients who had undergone THA.

### **THR vs Large-Head THA**

Two controlled trials randomized patients to THR or THA with a large diameter MoM implant. 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 THR. To test this hypothesis, 48 patients were randomized to THR 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 THR group performed better during the Functional Reach Test, and the THA group completed the step test 3 seconds faster than the THR group. The Western Ontario and McMaster Universities Osteoarthritis Index,

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36-Item Short-Form Health Survey (SF-36), Merle D'Aubigne, and UCLA Activity Scores were similar in both groups.

In the other trial, Garbuz et al (2010) randomized 107 patients to THR or large-head MoM THA. There were no differences in the Western Ontario and McMaster Universities Osteoarthritis Index 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 MoM THA group than in the THR 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*

A systematic review by Jiang et al (2011) compared revision rates for MoM THR with those for THA from 4 randomized or controlled trials with 968 patients younger than 65 years. Analysis found increased rates of revision with THR 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, which have been shown to have a significant effect on revision rates in registry data. As previously discussed, the National Joint Registry for England and Wales reported that hip resurfacing patients in all age groups, except males younger than 55 years of age, were at an increased revision risk compared with cemented THA using an unspecified bearing surface. Analysis of data from the Australian registry found that head size and risk of revision for THR were inversely related to each other. Patients receiving the smallest femoral head components (eg, women) had the greatest risk of revision. The implant size was associated with poorer outcomes when sex by implant size interaction was analyzed.

#### *Cohort Studies*

A study by Azam et al (2016) evaluated long-term (minimum, 10-year follow-up) survivorship and functional outcomes of Birmingham THR performed by a single surgeon between 1999 and 2004 in patients with hip osteoarthritis. In this retrospective cohort study, revision surgery was considered the end point 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; two 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 THR femoral component size of 46 mm or less (10/16 hips revised).

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A prospective cohort study by Daniel et al (2014) reported on long-term implant survival results from a single surgeon series of Birmingham THR. The earliest 1000 consecutive THR 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 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 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% 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.

In a series of 554 patients, Murray et al (2012) found that 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. Patient-reported outcomes on the Oxford Hip Score and UCLA Activity Score were also higher in men.

In a series by Matharu et al (2013), which evaluated 447 patients younger than 50 years of age, 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. Female sex ( $p=0.047$ ) and decreasing femoral head size ( $p=0.044$ ) were significantly associated with an increased risk of revision.

An analysis by Pailhe et al (2014) assessed 162 patients 65 years of age or older found 10-year implant survival rates of 98.9% in men and 91.9% in women. 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 12-year follow-up (range, 10.8-12.9 years) from the first 100 hip resurfacings at their institution. 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.

Other studies have suggested a high learning curve for THR related to the increased difficulty in accessing the acetabular compartment. For example, in the study by Kim et al (2008), most failures were related to early acetabular loosening.

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A report by Nunley et al (2010) suggested that, for experienced hip surgeons, the learning curve for avoiding early complications (eg, 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.

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.

### ***THR to THA Conversion***

#### *Systematic Reviews*

A systematic review by Marker et al (2009) identified 2 studies that compared the outcomes of conversion of failed THR with THA for primary THA. One was the report by McGrath et al (2009), 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 HHS; all procedures had been performed by the same surgeon. Perioperative measures were similar except for the mean operating time, which was 19 minutes longer for the revision group. At an average 45 months of follow-up, the mean HHS were similar for both groups (92 for conversion to THA vs 94 for primary THA).

#### *Clinical Studies*

Another study, by Ball et al (2007), compared outcomes in 20 patients (from a group of 844 primary THRs performed between 1997 and 2005) requiring conversion surgery for failed THR (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. 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 THR-THA revision group vs 57 months for the primary THA group), outcomes as measured by the UCLA, SF-12, and HHS were similar (eg, HHS, 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 THR-THA and THA-THA revisions would be needed.

De Steiger et al (2010) reported on outcomes for revised THR from the Australian Joint Replacement Registry. A total of 437 revisions were reported (of 12,093 primary THR, ≈4%) between 1999 and 2008. After excluding 39 revisions for infection, the major reason for revision of primary THR 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 THR, was performed in 247 (62%) of the 397 revisions undertaken for reasons other than infection. At 3 years, the rate of re-revised THR-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%)

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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 re-revision rates for THR-THA with THA-THA revisions.

### Adverse Events

The study by Reito et al (2014) was intended to evaluate 10-year survivorship of Birmingham THR; to investigate whole blood metal ion levels; to assess the prevalence of adverse events to metal debris; and to assess the relation between blood metal ion levels plus symptoms of adverse events and metal debris among patients who underwent THR at a single institution. Between 2001 and 2004, 219 patients received 261 THR 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 end point. 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 MoM THA (n=31) or MoM THR (n=21). 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 MoM THA group had a solid (n=7) or cystic mass (n=3), 5 (25%) patients in the THR 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 MoM 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 MoM THR in 201 hips. 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.

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## Hip Resurfacing

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A retrospective study by Steffen et al (2008) of 610 consecutive hip resurfacings (120 with >5-year follow-up) attributed failure to metal debris in 0.5% of THRs. However, after examining histologic samples taken at the time of revision, Ollivere et al (2009) concluded that the rate of metallosis-related revision in their series of 463 consecutive patients was 3% at 5 years. 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 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 FDA-regulated investigational device exemption prospective, multicenter trial of the Conserve Plus hip resurfacing system in 2007. 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 (eg, 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 HHS (93 vs 93) or the SF-12 (eg, Physical Component Summary score, 50 vs 50).

### **Section Summary: Total Hip Resurfacing**

The evidence on THR includes 2 RCTs, numerous large observational studies, large registry studies, and systematic reviews. The efficacy of THR performed with current techniques is similar to that for THA over the short-to-medium term, and THR may permit easier conversion to a THA for younger patients expected to outlive their prosthesis. Based on potential ease of revision of THR 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 (eg, metallosis, pseudotumor formation, implant failure) is evolving as longer follow-up becomes available.

### **PARTIAL HIP RESURFACING**

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

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### 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 hemi-resurfacing compared with THR, 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 MoM prosthesis, THR (femoral and acetabular implant) would be preferred over a femoral component alone. Hemi-resurfacing would be appropriate in patients with osteonecrosis who have contraindications for a MoM 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 MoM THR device or a partial hip resurfacing device, the evidence includes 2 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 THR performed with current techniques is similar to that for THA over the short-to-medium term, and THR may permit easier conversion to a THA for younger patients expected to outlive their prosthesis. Based on potential ease of revision of THR 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 (eg, metallosis, pseudotumor formation, implant failure) is evolving as longer follow-up becomes available. Due to the uncertain risk with MoM 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 THR, and patients should make an informed choice with their treating physicians. The evidence is sufficient to determine that the technology results in a meaningful 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, the evidence includes 2 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. Therefore, these factors should also be considered in the overall patient evaluation for THR, and patients should make an informed choice with their treating physicians. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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### **Policy History**

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|------------|--|
| 09/04/2002 | Medical Policy Committee review  |
| 09/18/2002 | Managed Care Advisory Council approval   |
| 11/02/2004 | Medical Director review  |
| 11/16/2004 | Medical Policy Committee review. Format revision. Clinical criteria revised.   |
| 11/29/2004 | Managed Care Advisory Council approval   |
| 07/07/2006 | Format revision including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.  |
| 12/06/2006 | Medical Director review  |
| 12/20/2006 | Medical Policy Committee approval. Coverage eligibility unchanged.   |
| 06/13/2007 | Medical Director review  |
| 06/20/2007 | Medical Policy Committee approval. Policy updated with TEC Assessment; metal-on-metal total hip resurfacing with an FDA-approved device system now may be considered medically necessary as an alternative to total hip replacement in patients who are candidates for total hip replacement and who are likely to outlive a traditional prosthesis. All other types and applications of total hip resurfacing remain investigational. |
| 08/06/2008 | Medical Director review  |
| 08/20/2008 | Medical Policy Committee approval. Eligible for coverage with added contraindications. Updated rationale.  |
| 08/06/2009 | Medical Policy Committee approval  |
| 08/26/2009 | Medical Policy Implementation Committee approval. No change to coverage eligibility.   |
| 08/05/2010 | Medical Policy Committee review  |
| 08/18/2010 | Medical Policy Implementation Committee approval. Statement added for partial resurfacing; considered medically necessary in specific conditions. Title changed to Hip Resurfacing.  |

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08/04/2011	Medical Policy Committee review
08/17/2011	Medical Policy Implementation Committee approval. No change to coverage.
08/02/2012	Medical Policy Committee review
08/15/2012	Medical Policy Implementation Committee approval. No change to coverage.
09/05/2013	Medical Policy Committee review
09/18/2013	Medical Policy Implementation Committee approval. No change to coverage.
11/06/2014	Medical Policy Committee review
11/21/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed
10/29/2015	Medical Policy Committee review
11/16/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/03/2016	Medical Policy Committee review
11/16/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
11/02/2017	Medical Policy Committee review
11/15/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/08/2018	Medical Policy Committee review
11/21/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date:	11/2019

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HCPCS	S2118
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\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
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- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and 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 that patient's illness, injury or disease.

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