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 meets all the following criteria:

- Is a candidate for total hip replacement
- Is likely to outlive a traditional prosthesis
- 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:

- The patient is a candidate for total hip replacement
- Is likely to outlive a traditional prosthesis
- The patient has known or suspected metal sensitivity or concern about potential effects of metal ions
- There is no more than 50% involvement of the femoral head
- 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.

Policy Guidelines

The 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 (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

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

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 the FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

In May 2006, the FDA approved the Birmingham Hip Resurfacing (BHR; Smith & Nephew Orthopaedics, Cordova, TN) system, a MoM resurfacing system, through the premarket approval (PMA) process for use in patients requiring primary hip resurfacing arthroplasty for 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 requirements were agreed to, 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 BHR in the United States by studying 350 patients at up to 8 sites where clinical and radiographic data will be assessed annually through 5 years and at 10 years. Also, determine cobalt and chromium serum concentration and renal function in these patients at 1, 4, and 10 years
• Implement a training program to provide clinical updates to investigators

Two additional MoM hip resurfacing systems have been approved: in 2007, the Comet™ Hip Resurfacing System (Corin, Tampa, FL) and, in 2009, the Conserve® Plus Total Hip Resurfacing System (MicroPort Orthopedics, Arlington, TN). Both implants were approved for skeletally mature patients with either: 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.

As noted above, in January 2013, the FDA issued a safety communication on MoM hip implants (including both hip resurfacing and hip replacement). The FDA stated that MoM hip implants have unique risks in addition to the general risks of all hip implants. Described below, are some of those risks:

• With MoM implants, some tiny metal particles wear off of the device around the implant, which may cause damage to bone and/or soft tissue surrounding the implant and joint
• Some of the metal ions released will enter the bloodstream and travel to other parts of the body, where they may cause symptoms or illnesses elsewhere in the body (systemic reactions)

Currently, the FDA does not have enough scientific data to specify the concentration of metal ions needed in a patient’s body or blood to produce adverse systemic effects. In addition, the reaction seems to be patient-specific.

PMA 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 (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 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 (MoM) chromium and cobalt implant components are of increasing concern.
In January 2013, U.S. Food and Drug Administration (FDA) issued a safety communication on MoM hip implants (both THA and THR). This information was based on the FDA’s current assessment of MoM hip implants, including the benefits and risks, the evaluation of the published literature, and the results of the June 2012 Orthopaedic and Rehabilitation Devices Advisory Panel meeting. As of January 2013, the FDA stated that it had insufficient scientific data to specify a concentration of metal ions in a patient’s body or blood that would produce adverse systemic effects. In addition, the reaction seems to be specific to individual patients, with different patients having different reactions to the metal wear particles.

**Literature Review**

**Total Hip Resurfacing**

This review was informed by a 2007 Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment 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 a randomized controlled trial (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 improvement of pain and 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, 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 the 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 the 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 males younger than 55 years of age, were at an increased revision risk compared with cemented THA with 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 (e.g., 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 2012 FDA advisory panel of experts also identified young males 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 of the 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/m², 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 a septic 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**

One systematic review (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 1 study was identified that assessed postural balance; all 4 studies revealed similar or better outcomes for THR than THA.

In 2011, Jiang et al 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.

In 2008, Quesada et al 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 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 suggests an increased risk of femoral neck fractures in postmenopausal women and small-boned men.

**Clinical Studies**

An RCT reported in 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, 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 found to be faster in the THR group than in the THA group (1.0 m/s) or osteoarthritis group...
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 RCTs, published in 2010, randomized patients to THR or THA with a large diameter MoM implant. Lavigne et al tested the hypothesis that the observed improvement in activity with THR is due to patient selection bias or 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 post surgery. 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 (WOMAC), 36-Item Short-Form Health Survey (SF-36), Merle D’Aubigne, and University of California at Los Angeles (UCLA) Activity Scores were similar in both groups.

In the other trial, Garbuz et al randomized 107 patients to THR or large-head MoM THA. There were no differences in WOMAC or SF-36 scores for the 73 patients who had been followed for at least 1 year. However, for the subset of patients who had been tested for serum levels of cobalt and chromium, cobalt was 10-fold higher and chromium was 2.6-fold higher in the large-head 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 2011 systematic review by Jiang et al 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 with 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 (e.g., 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 2016 study 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).
A 2014 prospective cohort study reported on long-term implant survival results from a single-surgeon series of Birmingham THR. The earliest 1000 consecutive THR implants comprised 288 women (335 hips) and 598 men (665 hips) of all ages and diagnoses without exclusions, who were prospectively followed with mailed questionnaires; the first 350 patients (402 hips) also had clinical and radiologic review. The mean follow-up was nearly 14 years (range, 12-15 years). In total, 59 patients (68 hips) died 0.7 to 12.6 years post-surgery from unrelated causes. Thirty-eight revisions were required at 0.1 to 14 years (median, 9 years) following 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 99%) 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 females 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 2013 series of 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.

A 2014 analysis of 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 a 2008 study, most of the failures were related to early acetabular loosening.

A report by 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.

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 2009 systematic review identified 2 studies that compared the outcomes of conversion of failed THR to THA with primary THA. One was a 2009 report that 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. 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 Harris Hip Scores were similar for both groups (92 for conversion to THA vs 94 for primary THA).

Clinical Studies

Another study (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 with a primary THA by the same surgeon during the same period. The acetabular component was retained in 18 hips (and revised in three because the matching femoral head was not available at the time of surgery). The study found no significant difference 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 Harris hip scores 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 THR-THA and THA-THA revisions are needed.

In 2010, de Steiger et al 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 THA, was performed in 247 (62%) of the 397 revisions undertaken for reasons other than infection. At 3 years, the rate of re-revision 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%) 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

A 2014 study was intended to evaluate 10-year survivorship of Birmingham THR; to investigate whole blood metal ion levels; to assess the prevalence of adverse reactions to metal debris; and to assess the relation between blood metal ion levels plus symptoms of adverse reactions 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 reactions to metal debris was 7% in male and 9% in female patients; it was associated with revision in 3 (2%) men and 8 (9%) women. Pseudotumors were observed most commonly in symptomatic patients who had elevated metal ion levels (63%) than with asymptomatic patients who had elevated metal ion levels (42%) and symptomatic patients who had nonelevated metal ions (11%).
In 2011, Williams et al 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 in this study. 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.

A 2008 retrospective study 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 gender in the metallosis group was 4.94. Also associated with metallosis were a smaller femoral component, greater abduction angle, and a higher BMI.

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

Partial Hip Resurfacing for Osteonecrosis
A search of the literature on resurfacing for osteonecrosis identified a number of articles, including a 2005 review and a 2009 study on the topic. 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. The increase in poor outcomes with resurfacing is believed to be related to continued abrasion and possible misfit of the femoral component against the native acetabular cartilage. Therefore, for osteonecrosis in younger patients who do not have contraindications for the MoM prosthesis, THR (femoral and acetabular implant) would be preferred over a femoral component alone.

**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 or a partial hip resurfacing device, the evidence includes 2 randomized controlled trials, 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 (partial or total) presents a reasonable alternative for active patients who are considered too young for THA—when performed by surgeons experienced in the technique. The literature on adverse effects (e.g., metallosis, pseudotumor formation, implant failure) is evolving as longer follow-up becomes available. Due to the uncertain risk with metal-on-metal implants, the risk-benefit ratio needs to be considered carefully on an individual basis. In addition, emerging evidence has suggested an increased risk of failure in women, possibly due to smaller implant size. Therefore, these factors should also be considered in the overall patient evaluation for 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.

**Supplemental Information**

**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 the 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**

**Hip Society**

The Hip Society published an algorithmic approach to the diagnosis and management of metal-on-metal (MoM) arthroplasty (total hip arthroplasty [THA], total hip resurfacing [THR]) in 2012. 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 MoM resurfacing arthroplasty in select patients groups. The ideal candidate is a male patient younger than age 55 with osteoarthritis and a femoral head size larger than 50 mm. Another relative indication is the need or desire to return to a very high activity level at work or in recreation. Contraindications to MoM resurfacing include known or suspected metal sensitivity;
moderate or worse renal function; females who may become pregnant; osteoporosis; large cysts; and avascular necrosis more than 50%.

**California Technology Assessment Forum**
In 2011, the California Technology Assessment Forum concluded there was no evidence that the potential benefits of hip resurfacing outweighed the potential risks. Revisions rates appeared to be higher in patients receiving THR procedures than in those receiving THA, which is of particular importance because the THR procedure targets young people. This risk may be particularly high in women. In addition, the elevated levels of metal ions were concerning. Although the clinical significance of these elevated ion levels is still uncertain, they are implicated in the development of aseptic lymphocytic vasculitis-associated lesions, often seen in aseptic failure of THR. Pseudotumors appear to be a more severe manifestation of aseptic lymphocytic vasculitis-associated lesions. It was recommended that MoM hip resurfacing using the Birmingham Hip Resurfacing, Comet 2000, or Conserve Plus devices did not meet California Technology Assessment Forum criteria for safety, efficacy, and improvement in health outcomes for patients as an alternative to THA.

**American Academy of Orthopaedic Surgeons**
In 2010, the American Academy of Orthopaedic Surgeons published a technology overview on MoM hip resurfacing. To compare revision rates between MoM hip resurfacing and THA, the Academy analyzed 3 joint registries, which indicated that patients who received THR were at greater risk for revision than patients who received THA. One registry suggested that younger males may have a lower revision rate after THR than THA, although the available data were not found to clearly establish an advantage for this subgroup. There was no conclusive evidence on predictors of successful or unsuccessful outcomes.

In 2011, the Academy provided a technology overview of modern MoM hip implants (both THA and THR). This document did not recommend for or against use of MoM hip implants.

**National Institute for Health and Care Excellence**
In 2014, the U.K.’s National Institute for Health and Care Excellence (NICE) updated its guidance on THA and THR for end-stage arthritis of the hip. NICE concluded that both THA and THR were options for treating end-stage arthritis of the hip, although clinicians may be more likely to offer resurfacing arthroplasty to men than to women because of higher revision rates observed in women. NICE concluded that THA was more effective and less costly than THR in all analyses, that the revision rate was the most important key driver of costs and quality-adjusted life years, and that, because the predicted revision rate of THA was less than 5% at 10 years in the population for whom both THA and THR were suitable, the revision rate standard for THR should be the same as that for THA. NICE recommended specific prostheses for THA and THR 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 April 2017 did not identify any ongoing or unpublished trials that would likely influence this review.

**References**

Radiological findings including involvement of femoral head and acetabular cartilage changes (if applicable)
• Specific procedure requested (total or partial hip) and reason requested
• Whether patient is likely to outlive a traditional prosthesis

Post Service
• 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. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

MN/IE
The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT®</td>
<td>27130</td>
<td>Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft</td>
</tr>
<tr>
<td></td>
<td>27299</td>
<td>Unlisted procedure, pelvis or hip joint</td>
</tr>
<tr>
<td>HCPCS</td>
<td>S2118</td>
<td>Metal-on-metal total hip resurfacing, including acetabular and femoral components</td>
</tr>
<tr>
<td>ICD-10 Procedure</td>
<td>OSUA0BZ</td>
<td>Supplement Right Hip Joint, Acetabular Surface with Resurfacing Device, Open Approach</td>
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<tr>
<td></td>
<td>OSUE0BZ</td>
<td>Supplement Left Hip Joint, Acetabular Surface with Resurfacing Device, Open Approach</td>
</tr>
<tr>
<td></td>
<td>OSUR0BZ</td>
<td>Supplement Right Hip Joint, Femoral Surface with Resurfacing Device, Open Approach</td>
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<td>Supplement Left Hip Joint, Femoral Surface with Resurfacing Device, Open Approach</td>
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<tr>
<td>ICD-10 Diagnosis</td>
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<td>All Diagnoses</td>
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Policy History

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

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>04/05/2007</td>
<td>Policy revision with position change</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>01/11/2008</td>
<td>Policy title change from Total Hip Resurfacing. Policy revision without position change</td>
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<tr>
<td>04/25/2008</td>
<td>Policy revision with coding update</td>
<td>Medical Policy Committee</td>
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</tbody>
</table>
### Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**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. Please call (800) 541-6652 or visit the provider portal at 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.