



BlueCross BlueShield
of Alabama

Name of Policy:

Hip Resurfacing

Policy #: 153

Category: Surgery

Latest Review Date: April 2018

Policy Grade: A

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- 1. In accordance with generally accepted standards of medical practice; and*
- 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
- 3. Not primarily for the convenience of the patient, physician or other health care provider; and*
- 4. 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.*

Description of Procedure or Service:

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

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

Total hip resurfacing has undergone various evolutions, with modifications in prosthetic design and composition and implantation techniques. For example, similar to total hip prostheses, the acetabular components of THR have been composed of polyethylene. However, over time it became apparent that device failure was frequently related to the inflammatory osteolytic reaction to polyethylene debris wear particles. Metal acetabular components have since been designed to improve implant longevity. Sensitivity to wear particles from metal-on-metal (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). FDA has provided updated safety information and recommendations to patients and health care providers. This new information is based on 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, 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.

Policy:

Metal-on-metal total hip resurfacing with an FDA-approved device system meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage as an alternative to total hip replacement when the patient:

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

Contraindications for total hip resurfacing:

- Bone stock 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 1cm)
- 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 of the fetus of metal ion release

Partial hip resurfacing with an FDA-approved device meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage in patients with osteonecrosis of the femoral head who have one or more contraindications for metal-on-metal implants and meet the following criteria:

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

All other types and applications of hip resurfacing do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered **investigational**.

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

Key Points:

Updated searches of the MEDLINE database have been performed, most recently conducted through February 5, 2018. Key Literature is described in the following sections of this evidence review.

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.

The current policy is based in part on a 2007 TEC Assessment that evaluated studies of individuals 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 one randomized controlled trial (RCT) and 12 uncontrolled series, along with the FDA PMA submission data, and information from the Australian Orthopedic Association (AOA) 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 pre-surgical status.

The TEC Assessment also evaluated the patient safety and effectiveness data considered for FDA submission of the Birmingham device from the McMinn Cohort, four 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 (AAOS) provided a technology overview of modern MoM hip implants. The U.K./Wales registry reported that hip resurfacing patients in all age groups, except males younger than 55 years of age, were at an increased revision risk compared to cemented total hip arthroplasty with an unspecified bearing surface. The Australian registry reported hip resurfacing patients 65 years of age or older to have the highest revision risk. 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 gender/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 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 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 versus THA

THR vs Standard THA

Systematic Reviews

One systematic review compared outcomes from THR and THA in studies with short- to mid-term follow-up. The 7 comparative studies that assessed return to sports and activity showed either similar outcomes for the 2 procedures or advantages for the THR group. Three additional studies assessed gait, and one study was identified that assessed postural balance; all four showed similar or better outcomes for THR than THA.

In 2011, Jiang et al published a meta-analysis comparing MoM THR with THA in patients younger than 65 years. Included were 4 randomized controlled trials with a total of 968 patients. Hip function scores were similar between the 2 groups, although the resurfacing group showed higher activity levels.

In 2008, Quesada and colleagues published a qualitative systematic review that focused on advantages and disadvantages of THR in comparison 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 post-menopausal 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 compared gait analysis in 15 patients following successful THR with 15 patients who had a successful THA using a small femoral head, and with ten 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 (1.0 m/s) or osteoarthritis (1.0 m/s) 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 versus Large-Head THA

Two RCTs were published in 2009 that randomized patients to THR or THA with a large diameter metal-on-metal (MoM) implant. Lavigne et al tested the hypothesis that the observed improvement in activity with THR is due either to patient selection bias or to the larger femoral head with THR. To test this hypothesis, 48 patients were randomized to either THR or large-head THA. The patients and the evaluators at the Gait laboratory were kept blinded to the type of arthroplasty until one year after surgery. There were no differences between the 2 groups for the majority of measures at 3, 6, and 12 months after surgery. Specifically, similar results were observed for normal and fast walking, postural evaluations, timed up and 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), short form-36 (SF-36), Merle d'Aubigne, and University of California at Los Angeles (UCLA) activity scores were similar in both groups.

Garbuz and colleagues randomized 107 patients to THR or large-head MoM THA. There was no difference in WOMAC or SF-36 scores for the 73 patients who had been followed up for at least one 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 the THR group. This was a 46-fold increase from baseline in serum cobalt and a ten-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 of these studies support 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 meta-analysis by Jiang et al. compared revision rates for MoM THR versus 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-up; the relative risk was 2.60. However, this analysis did not evaluate the effect of age, bearing head size, or gender, which have been shown to have a significant effect on revision rates in registry data. As discussed above, the U.K./Wales registry reported that hip resurfacing patients in all age groups, except males younger than 55 years of age, were at an increased revision risk compared to cemented total hip arthroplasty 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 gender/implant size interaction was analyzed.

Cohort Studies

A 2015 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 OA. 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 female (10%) and 7 male (5%) 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 (five hips), all of whom were female; 2 of the latter had bilateral resurfacing. Other complications included femoral neck stress fractures in 2 patients and acetabular component loosening in one 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 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 with no exclusions, which were prospectively followed-up with mailed questionnaires; the first 350 patients (402 hips) also had clinical and radiological 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 following 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 seven 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 98) and 96% (95% CI, 95 to 96) survival at 10 and 15 years, respectively. Radiologic assessment showed 11 (4%) femoral and 13 (4%) acetabular radiolucencies, and one radiological femoral failure (0.3%). Men appeared to have better implant survival (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 found that the 10-year implant survival 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 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 gender ($p=0.047$) and decreasing femoral head size ($p=0.044$) were significantly associated with an increased risk of revision.

Analysis of 162 patients age 65 or older found 10-year survival 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 gender ($p=0.079$).

Amstutz et al reported 12-year follow-up (range, 10.8 to 12.9 years) from the first 100 hip resurfacings at their institution. The 89 patients in this series were followed annually with radiographs, range of motion, and questionnaires. Two patients were lost to follow-up, and five patients died during the follow-up period of causes unrelated to the surgery. Eleven hips had conversion to THA. Kaplan-Meier survivorship of the resurfacing implant was 93.9% at 5 years and 88.5% at 10 years. Subgrouping by femoral component size showed 10 year survival of 95.6% for a component size of greater than 46mm, 83.8% for component sizes of 44 or 46mm, and 78.9% for a component size equal to or less than 42mm. 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 suggest a high learning curve for THR related to the increased difficulty in accessing the acetabular compartment. For example, in one study most of the failures were related to early acetabular loosening.

A report by Nunley et al suggests that for experienced hip surgeons, the learning curve for avoiding early complications (e.g., early femoral fracture) is 25 cases or less, but the learning curve for achieving the desired component positioning is 75 to 100 cases or more.

Gross et al 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 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 outcomes of revised THR from the Australian Joint Replacement Registry. A total of 437 revisions were reported (out of 12,093 primary THR, approximately 4%) between 1999 and 2008. After excluding 39 cases of revision 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 total hip replacement, was performed in 247 of the 397 revisions (62%) 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%) 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 policy, one that the investigators did not assess, would be a comparison of the re-revision rate of THR-THA versus 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 non-elevated 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 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 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; these 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 (1,016 hips) resulted in a decreased rate of femoral neck fracture (from 7% to <1%). There was also a trend toward reduction in other types of complications (e.g., nerve palsy was reduced from 4.1% to 2.2% and loosening of the acetabular cup from 3.4% to 1.9%). No differences between the two cohorts were observed in the Harris hip score (93 vs 93) or the short form-12 ([SF-12] e.g., physical component score of 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 for Osteonecrosis

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

Section Summary: Partial Hip Resurfacing

The literature on partial hip surfacing for osteonecrosis includes a comparative study. There is an increase in poor outcomes with 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 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.

Practice Guidelines and Position Statements

Hip Society

The Hip Society published an algorithmic approach to the diagnosis and management of MoM arthroplasty (THA and THR) in 2012. The review indicates 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 closely 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 states 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 50mm. 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 (CTAF) concluded that there is no evidence that the potential benefits of hip resurfacing outweigh the potential risks. Revision rates appear to be higher in patients receiving THR procedures than in those receiving THA, which is of particular importance since the THR procedure targets young people. This risk may be

particularly high in women. In addition, the elevated levels of metal ions are 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 (ALVAL), often seen in aseptic failure of THR. Pseudotumors appear to be a more severe manifestation of ALVAL. It is recommended that metal-on-metal hip resurfacing using the Birmingham Hip Resurfacing, Cormet 2000, or Conserve®Plus devices does not meet CTAF criteria 3-5 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 United Kingdom's National Institute for Health and Care Excellence (NICE) issued updated technology guidance on THA and THR for end-stage arthritis of the hip. NICE concluded that both THA and THR are 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 higher revision rates have been observed in women. The appraisal committee concluded that THA was more effective and less costly than THR in all analyses, that 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 THAs. NICE recommends 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.

Key Words:

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

Approved by Governing Bodies:

In May 2006, 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 Cormet™ Hip Resurfacing System (Corin, Tampa, FL) and, in 2009, the Conserve® Plus Total Hip Resurfacing System (MicroPort Orthopedics, Arlington, TN). Both implants were approved for skeletally mature patients with either: non-inflammatory degenerative arthritis (e.g., osteoarthritis and avascular necrosis); or inflammatory arthritis (e.g., rheumatoid arthritis). (Note: patients with the latter arthritis might be individuals who, due to younger age or increased activity level, may not be suitable for traditional THA because it would increase the possibility of requiring ipsilateral hip joint revision.)

Various devices have been cleared for marketing by 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.

In January 2013, FDA issued a safety communication on MoM hip implants (including both hip resurfacing and hip replacement). FDA stated that MoM hip implants have unique risks in addition to the general risks of all hip implants.

- 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, FDA does not have enough scientific data to specify the concentration of metal ions in a patient’s body or blood necessary to 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.

Benefit Application:

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

ITS: Home Policy provisions apply

FEP contracts: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA and will be reviewed for medical necessity.

Current Coding:

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

CPT:	27299	Unlisted procedure, pelvis or hip joint
	27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement [total hip replacement], with or without autograft or allograft
HCPCS:	S2118	Metal-on-metal total hip resurfacing, including acetabular and femoral components

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Policy History:

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Medical Policy Administration Committee, April 2004

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Medical Policy Group, March 2006 (1)

Medical Policy Group, January 2007 (2)

Medical Policy Administration Committee, January 2007

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Medical Policy Group, January 2009 (1)

Medical Policy Group, December 2009 (3)

Medical Policy Group, January 2010 (2)

Medical Policy Administration Committee, February 2010

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Medical Policy Group, October 2012 (2): 2012 Updates to Key Points and References

Medical Policy Panel, September 2013

Medical Policy Group, November 2013 (2): Description, References, Current Coding, and References updated with results of literature review through August 2013. No change in policy statement.

Medical Policy Panel, September 2014

Medical Policy Group, September 2014 (3): 2014 Updates to Key Points & References; no change in policy statement.

Medical Policy Panel, September 2015

Medical Policy Group, October 2015 (2): 2015 Updates to Description, Key Points, and References; no change in policy statement.

Medical Policy Panel, August 2017

Medical Policy Group, September 2017 (7): 2017 Updates to Description, Key Points and References. No change in Policy Statement.

Medical Policy Panel, April 2018

Medical Policy Group, May 2018 (7): Updates to Key Points and References. No change in Policy Statement.

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

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