Name of Policy: Hip Resurfacing

Policy #: 153      Latest Review Date: September 2014
Category: Surgery      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. Hip resurfacing may be considered an alternative to hip arthroplasty, particularly in young active patients who would potentially outlive a total hip prosthesis.

Hip resurfacing surgery, also known as resurfacing arthroplasty, can be categorized as hemi or partial hip resurfacing or total hip resurfacing. In partial hip resurfacing, a femoral shell is implanted over the femoral head. Total hip resurfacing involves placing the femoral shell over the femoral head and placing a shell in the acetabulum. The technique conserves femoral bone and maintains normal femoral loading and stresses. Partial hip resurfacing is considered a treatment option for avascular necrosis with collapse of the femoral head and preservation of the acetabulum. Total hip resurfacing has been investigated in a broader range of patients, including those with osteoarthritis, rheumatoid arthritis, and advanced avascular necrosis. It may be considered an alternative to total hip arthroplasty, particularly in young active patients with degenerative hip disease who may potentially outlive a total hip prosthesis. Therefore, total hip resurfacing could be viewed as a time-buying procedure to delay the need for a total hip replacement.

The proposed advantages of total hip resurfacing as compared to total hip arthroplasty include preservation of the femoral neck and femoral canal, which would facilitate a future revision or conversion to a total hip replacement, if required. Also, since the resurfaced head is more similar in size to the normal femoral head, the stability is increased and the risk of dislocation is decreased as compared to total hip arthroplasty.

Total hip resurfacing has undergone various evolutions over the past several decades, with modifications in prosthetic design and composition and implantation techniques. For example, similar to total hip prostheses, the acetabular components of total hip resurfacing have been composed of polyethylene. However, over the years it became apparent that device failure was frequently related to the inflammatory osteolytic reaction to polyethylene debris wear particles. Metal acetabular components have since been designed to improve implant longevity. Sensitivity to wear particles from metal-on-metal chromium and cobalt implant components are also of increasing concern.

The Buechel-Pappas Integrated Total Hip Replacement has been approved by the U.S. Food and Drug Administration (FDA) for total hip resurfacing. The weight-bearing surfaces of this device are composed of a ceramic femoral component and a polyethylene acetabular component.

In May 2006, the FDA granted premarket application (PMA) approval to the Birmingham Hip Resurfacing (BHR) system for use in patients requiring primary hip resurfacing arthroplasty for non-inflammatory or inflammatory arthritis. This decision was based primarily on a series of 2,385 patients who received this device by a single surgeon in England. A number of post-approval 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 eight sites where clinical and radiographic data will be assessed annually through five 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.

The Cormet Hip Resurfacing System (Corin) and the Conserve®Plus (Wright Medical Technology) are metal-on-metal total hip resurfacing systems that were FDA approved in 2007 and 2009, respectively. The approval order for the Cormet system states that the device is intended for use in resurfacing hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients having the following conditions: 1) non-inflammatory degenerative arthritis such as osteoarthritis and avascular necrosis; 2) inflammatory arthritis such as rheumatoid arthritis. The Cormet Hip Resurfacing System is intended for patients who, due to their relatively younger age or increased activity level, may not be suitable for traditional total hip arthroplasty due to an increased possibility of requiring ipsilateral hip joint revision.

A variety of devices have been cleared by the FDA for partial hip resurfacing under the FDA’s 510(k) mechanism. Some surgeons may be using both femoral and acetabular components as an "off-label" application. (See Approved by Governing Bodies)

A 2012 FDA advisory panel of experts identified young males with larger femoral heads as the best candidates for hip resurfacing systems. The FDA advises 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.

In January 2013, the U.S. Food and Drug Administration (FDA) issued a safety communication on metal-on-metal hip implants (including both hip resurfacing and hip replacement). The FDA states that metal-on-metal hip implants have unique risks in addition to the general risks of all hip implants.

• With metal-on-metal 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).

Presently, the 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.

**Policy:**
**Effective for dates of service on or after March 23, 2010:**
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 that 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.**
Effective for dates of service January 10, 2007 through March 22, 2010:
Total hip resurfacing with a fully FDA approved total hip resurfacing device (e.g., the Birmingham Hip Resurfacing System), meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the following criteria are met:

- Patient is age 60 years or younger
- Patient would otherwise require a total hip replacement

Effective for dates of service prior to January 10, 2007:
Total hip resurfacing does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is 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:
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 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.

Updated searches of the MEDLINE database, most recently conducted through July 31, 2014, have identified a number of systematic reviews, RCTs comparing THR with large-diameter head THA, and other publications concerning factors in survival such as patient selection criteria and the surgeon’s learning curve. Also identified are an increasing number of reports of local tissue
reactions (e.g., pseudotumors) with MoM hip components, and in 2013, the FDA issued a safety communication on the use of MoM implants.

**Patient Selection Criteria**

For a 2009 report on patient selection criteria for THR, Nunley and colleagues reviewed 207 publications, the majority of which had little or no description of the patient population, small sample sizes, poor study design, 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 criteria was age younger than 65 years. Nine articles suggested that female patients should be cautiously evaluated before performing hip resurfacing, especially if they are postmenopausal or have decreased BMD. 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 four 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 evidence reviewed by Nunley et al also indicates that obesity, defined as 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 (ALVAL) was evolving, and the potential for transplacental transfer of metal ions was a concern for young female patients who have the potential to become pregnant in the future. The authors concluded that the best candidates for hip resurfacing are men younger than age 65 with osteoarthritis and relatively normal bony morphology.

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.

**Efficacy of THR versus THA**

**THR versus Standard THA**

One systematic review compared outcomes from THR and THA in studies with short- to midterm follow-up. The seven comparative studies that assessed return to sports and activity showed either similar outcomes for the two 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 four randomized controlled trials with a total of 968
patients. Hip function scores were similar between the two 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.

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 two 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 three 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 the two 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

A 2011 meta-analysis by Jiang et al. compared revision rates for MoM THR versus THA from four randomized or controlled trials with 968 patients younger than 65 years. Analysis found increased rates of revision with THR at one to ten 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.

Large case series have also found decreased implant survival with smaller implant size and female gender. In a series of 554 patients, Murray et al found that the ten-year implant survival in females was 74% compared with 95% in male hips and the ten-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 ten years and 91.2% at 14 years, compared with 100% for men at both ten 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 65 years of age or older found ten-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 five years and 88.5% at ten years. Subgrouping by femoral component size showed ten 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 75–100 cases or more.
THR to THA Conversion
It is thought that revision of THR to THA might have better outcomes than THA-THA revision, but little data are available to support this assumption.

A systematic review identified two 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 that had been matched by gender, age, BMI, and pre-operative 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’ follow-up, the mean Harris hip scores were similar for the two groups (score of 92 for conversion to THA and 94 for primary THA).

Another study compared outcomes in 20 patients (from a group of 844 primary THRIs performed between 1997 and 2005) requiring conversion surgery for failed THR (five femoral neck fractures and 16 with femoral component loosening) with outcomes in 58 patients of similar age (64 hips from patients younger than 65 years-old) who had been 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 of 140 to 255) and primary THA (169 minutes, range of 110 to 265), or in complication rates between the two groups (14% vs. 9%, respectively). At one to nine years’ follow-up (average of 46 months for the THR-THA revision group and 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 of 92 for the revision group and 90 for the primary THA control group). Although this small study suggests that a resurfaced femoral component might be converted to THA without additional complication, larger comparative studies between 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 three 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 five 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
In January 2013, the FDA issued a safety communication on metal-on-metal hip implants (both THA and THR). The FDA is providing updated safety information and recommendations to
patients and healthcare providers. This new information is 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 states that it 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.

The 2011 AAOS technology overview found that limited data exist comparing the prevalence of adverse clinical problems with MoM hip implants (both THR and THA) or for implants with other bearing surfaces. Several studies noted a correlation between suboptimal hip implant positioning and higher wear rates, local metal debris release, and consequent local tissue reactions to metal debris (e.g., soft tissue masses or “pseudotumors”). Several studies reported elevated serum metal ion (cobalt and chromium) concentrations in patients with MoM hip articulations, especially in patients with malpositioned implants. However, the technology overview concluded that the clinical significance of elevated serum metal ion concentrations remains unknown. The U.K./Wales registry began gathering data on soft tissue reactions in July of 2009, but had too little data when the most recent report was published.

Local tissue reaction to wear particles (cobalt and chromium ions) with MoM components is an area of increasing concern. 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 two years after surgery (mean not reported), ten patients (32%) in the metal-on-metal THA group had a solid (n=7) or cystic mass (n=3), five patients (25%) in the THR group had a solid (n=3) or cystic mass (n=2), and one patient (4%) in the metal-on-polyethylene THA group had a cystic mass. Isolated fluid collection was similar in the three 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. determined the prevalence of asymptomatic pseudotumors after MoM THR in 201 hips. All patients who had surgery at least three 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 (MRI) if a tumor was identified on ultrasound. The mean follow-up was 61 months (range, 36-88). Pseudotumors that contained both cystic and solid components were identified in 4.4% of patients (six female, one male) and 6.5% of resurfaced hips. Histological 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 retrospective study of 610 consecutive hip resurfacings (120 with more than five year follow-up) reported that failure was possibly related to metal debris in 0.5% of THRs. However, after examining histological samples taken at the time of revision, Ollivere and colleagues concluded that the rate of metallosis-related revision in their series of 463 consecutive patients was 3% at five years. All of the 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 radiological follow-up with a mean follow-up of 43 months (range, 6-90 months). Case notes, radiographs, and magnetic resonance scans were available for the 13 revisions (2.8%, 12 patients). Histological findings were available for 12 cases and were re-reviewed by a histopathologist with experience in metal wear and debris. In seven cases, the histological findings were consistent with a response to metal wear debris. Survivorship analysis gave an overall survival rate of 95.8% at five years, with an endpoint survival of 96.9% at five 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.

Steeply inclined component positioning along with a small size of component have been shown to be associated with metal ion levels, possibly due to an increase in edge loading.

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).

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 articles discussed comparisons of hemi-resurfacing to THR, referencing a single comparative study by Beaule et al from 2004. This literature shows total resurfacing/replacement to provide 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 metal-on-metal prosthesis, total hip resurfacing (femoral and acetabular implant) would be preferred over a femoral component alone.

Summary
Hip resurfacing may be considered an alternative to total hip arthroplasty (THA), particularly in young active patients who would potentially outlive a total hip prosthesis. Based on potential ease of revision when compared with total hip arthroplasty (THA), the evidence available at this
time supports the 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 efficacy of total hip resurfacing (THR) performed with current techniques is similar to THA over the short- to medium term, and THR may allow for easier conversion to a THA for younger patients who are expected to outlive their prosthesis. The literature on risk factors for metallosis, pseudotumor formation, and 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 carefully considered on an individual basis. In addition, emerging evidence indicates an increased risk of failure in women, possibly due to smaller implant size. Therefore, these risk factors should also be considered in the overall patient evaluation for total hip resurfacing, and patients should make an informed choice in conjunction with their treating physicians.

**Practice Guidelines and Position Statements**

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%.

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 BHR, 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.

In 2009, the American Academy of Orthopaedic Surgeons (AAOS) provided a technology overview on metal-on-metal hip resurfacing. For a comparison of revision rates between MoM hip resurfacing and total hip arthroplasty, analysis by three joint registries indicates that patients who received THR are at greater risk for revision than patients who receive 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/ unsuccessful outcomes.
In 2011, the AAOS provided a technology overview of modern MoM hip implants (both THA and THR). This document does not make recommendations for or against the use of metal-on-metal hip implants. Readers are encouraged to consider the information presented in the technology overview and reach their own conclusions.

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 ten 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 ten years.

**U.S. Preventive Services Task Force Recommendations**
Total or partial hip resurfacing are not preventive services.

**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:

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Composition</th>
<th>FDA Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buechel-Pappas Integrated</td>
<td>Metal femoral component, polyethylene acetabular component</td>
<td>FDA approved</td>
</tr>
<tr>
<td>Total Hip Replacement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conserve Plus</td>
<td>Metal femoral and acetabular component</td>
<td>FDA approved</td>
</tr>
<tr>
<td>Cormet 2000</td>
<td>Metal femoral and acetabular component</td>
<td>Awarded 510K from FDA, February 25, 2000</td>
</tr>
<tr>
<td>BHR Implants</td>
<td>Metal femoral and acetabular component</td>
<td>FDA approved May 9, 2006</td>
</tr>
<tr>
<td>Birmingham Hip Resurfacing (BHR) System</td>
<td>Metal femoral and acetabular component (high carbon, cobalt-chromium alloy)</td>
<td>FDA approved</td>
</tr>
<tr>
<td>Cormet Hip Resurfacing System</td>
<td>Metal femoral head resurfacing component</td>
<td>FDA approved July 3, 2007</td>
</tr>
</tbody>
</table>
**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

**References:**


45. National Institute for Health and Care Excellence (NICE). Technology Assessment 304. Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip 2014; publications.nice.org.uk/total-hip-replacement-and-resurfacing-arthroplasty-for-end-stage-

Policy History:
Medical Policy Group, March 2004
Medical Policy Administration Committee, April 2004
Available for comment May 17-June 30, 2004
Medical Policy Group, March 2006 (1)
Medical Policy Group, January 2007 (2)
Medical Policy Administration Committee, January 2007
Available for comment January 19-March 5, 2007
Medical Policy Group, January 2009 (1)
Medical Policy Group, December 2009 (3)
Medical Policy Group, January 2010 (2)
Medical Policy Administration Committee, February 2010
Available for comment February 6-March 22, 2010
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.

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.