Medical Policy

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***Current Policy Effective Date: 11/1/12**
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Title: Hip Resurfacing

Description / Background

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.

Background
Hip resurfacing can be categorized as partial hip resurfacing, in which a femoral shell is implanted over the femoral head, and total hip resurfacing (THR), consisting of an acetabular and femoral shell. Total hip resurfacing, investigated in a broader range of patients including those with osteoarthritis, rheumatoid arthritis, and advanced avascular necrosis, may be considered an alternative to total hip arthroplasty (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 to 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 to THA.

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 THR 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 of increasing concern.

Regulatory Status:

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 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.

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.

Total Hip Resurfacing Devices

Device Name	Composition	FDA Status
Buechel-Pappas Integrated Total Hip Replacement	Ceramic femoral component, polyethylene acetabular component	FDA approved
Conserve®Plus	Metal femoral and acetabular component	FDA approved
Cormet Hip Resurfacing System	Metal femoral and acetabular component	FDA approved
Birmingham Hip Resurfacing device	Metal femoral and acetabular component	FDA approved

A variety of devices have been cleared by the FDA for partial hip (femoral) resurfacing under the FDA's 510(k) mechanism. Some surgeons may be using a femoral resurfacing component together with an acetabular cup (total arthroplasty component) as an "off-label" application.

Medical Policy Statement

Metal-on-metal *total* hip resurfacing with a device system approved by the U.S. Food and Drug Administration (FDA) and *partial* hip resurfacing with an FDA-approved device are established therapies. They are useful therapeutic options for patients meeting the appropriate selection criteria. All other types and applications of total hip resurfacing are considered experimental/ investigational.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

Inclusions:

Total hip resurfacing (as an alternative to total hip replacement)-must meet all):

- The patient is a candidate for total hip replacement; AND
- The patient is likely to outlive a traditional prosthesis; AND
- The patient does not have a contraindication for total hip resurfacing

Partial hip resurfacing-must meet all:

- For 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.

Exclusions:

The U.S. Food and Drug Administration (FDA) lists several contraindications for total hip resurfacing. These contraindications include (not a complete listing) the following:

- Bone stock inadequate to support the device due to:
  - Severe osteopenia or a family history of severe osteoporosis or severe osteopenia
  - Osteonecrosis or avascular necrosis with more than 50% involvement of the femoral head.
  - Multiple cysts of the femoral head (more than 1 cm)
- Skeletal immaturity
- Vascular insufficiency, muscular atrophy, or neuromuscular disease severe enough to compromise implant stability or postoperative recovery
- Known moderate to severe renal insufficiency
- Severely overweight
- Known or suspected metal sensitivity
- Immunosuppressed or receiving high doses of corticosteroids

- Females of child bearing age due to unknown effects on the fetus of metal ion release

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

CPT / HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

S2118 27299

Other codes (investigational, not medically necessary, etc.):

N/A

Rationale

At the time this policy was created, there was minimal published medical literature regarding total hip resurfacing (THR), using either polyethylene components or metal-on-metal (MoM) designs. Some of the early reports used two different types of prostheses, the Wagner and McKinn. The acetabular components of the McKinn prosthesis showed progressive loosening. Based on these results, the investigators developed new design and implantation techniques leading to the Conserve®Plus device. In 2004, Amstutz and colleagues reported on 355 patients who received 400 metal-on-metal surface arthroplasties using the Conserve Plus device with a follow-up of 2–6 years. (1) Beaule and colleagues reported on metal-on-metal surface arthroplasty in 56 patients with Ficat stage III and IV osteonecrosis. (2) While these study results were promising, further evaluation was needed to determine appropriate patient selection criteria and the most beneficial techniques for femoral bone preparation and fixation.

In support of the application for U.S. Food and Drug Administration (FDA) premarket approval (PMA), clinical data on 2,385 Birmingham hip resurfacings (BHRs) performed by a single surgeon in the United Kingdom was presented to the FDA Orthopaedic and Rehabilitation Devices Panel (Panel) in September 2005. Of the 2,385 cases, 27 revisions were required including 10 revisions due to femoral neck fracture, 6 for femoral head collapse, 1 for dislocation, 2 for avascular necrosis and 8 for infections. Based on this data, the BHR device was granted PMA by the FDA. In 2005, Treacy and colleagues reported that the 5-year survival of BHR arthroplasty in 144 patients was 98% overall. (3) Shimmin and Back reviewed 3,497 BHRs performed by 89 surgeons between April 1999 and April 2004. (4) The incidence of femoral neck fracture was 1.46% (50 of 3,497) and the mean time to fracture was 15.4 weeks. Glyn-Jones and colleagues evaluated the stability of BHR arthroplasties by radiographic analysis in 22 hips in 20 patients. (5) At 24 months, migration of the head of the femoral component was not statistically significant (0.2 mm total three-dimensional). Although promising, there were ongoing questions about the intermediate and long-term durability of this device compared with standard hip arthroplasty. There also were continued questions about short-term revisions (due to femoral neck fracture) and also potential concerns about shedding of metal particles.

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 that reported data on short- and long-term clinical outcomes, including benefits and harms,

as an alternative to total hip replacement (THA). (6) The Assessment included 1 randomized controlled trial (RCT) (7) and 12 uncontrolled series, along with the FDA PMA submission data, (8) and information from the Australian Orthopedic Association (AOA) National Joint Replacement Registry. (9) In the randomized controlled trial (100 patients in each group), the THR device was implanted in patients who were younger (49 to 51 years old) and had a smaller body mass index ([BMI]:17 to 49 kg/m^2) than those who usually undergo THA ($\geq$65 years old), and the majority comprised male patients (63% to 68%) who were being treated for advanced osteoarthritis (75%). (7) Both groups showed substantial improvement over preoperative status on functional outcomes measures and reported satisfaction or very high satisfaction scores (98%). In comparison to THA, THR reduced the surgical time, decreased the hospital stay (5 vs. 6.1 days), and used a longer incision. The groups had a similar incidence of complications. At 12-month follow-up, 2 patients in the THA group required revision for femoral head aseptic loosening; none experienced femoral head fracture. The 12 published series reporting clinical outcomes after THR included a total of 2,076 patients (71% male) who ranged in mean age from 34 to 57 years. Although most patients had advanced osteoarthritis (80%), some studies enrolled patients with femoral head osteonecrosis and/or developmental hip dysplasia; only 3 used the FDA-approved Birmingham device. Mean follow-up was approximately 3 years, but ranged from less than 1 year to 12 years, and the proportion of patients available at follow-up was generally 90% to 100% but as low as 22%. Of the 2,076 patients treated with THR, 57 (2.7%) required revision to THA, most for femoral neck fracture or component loosening; the proportion of cases that required revision ranged from 0.3% to 22%. Although the 12 published series exhibited little consistency in outcomes measures used, the aggregate data suggested that THR-treated patients who do not require a revision have substantial symptomatic improvement of pain and hip function over presurgical status. Moreover, THR patients report substantial activity levels and returning to playing sports after treatment.

The TEC Assessment also evaluated the patient safety and effectiveness data considered for the FDA submission of the Birmingham device from the McMinn Cohort, (8) which are supported by unpublished data on 3,374 hips implanted by 140 surgeons and published reports on more than 3,800 hips treated by multiple surgeons (Worldwide Cohort). The McMinn Cohort included 71% men and 29% women, ranging in age from 13 to 86 years (average, 53 years). The predominant diagnoses for treatment were advanced osteoarthritis (75%), dysplasia (16%), avascular necrosis (4%), inflammatory arthritis (2%) and “other” (3%). The Worldwide Cohort was reportedly comparable. At the 5-year follow-up, a total of 76 revisions to THA were reported (2.26%), resulting from events similar to those reported for the McMinn Cohort. In addition, results of the Oswestry-Modified Hip Scores for both cohorts showed improvement at 5 years from a baseline mean of 60.1 to 94.8 (58%). With regard to long-term safety, literature summaries provided to the FDA demonstrated increased serum and urinary concentrations of metal ions postoperatively in patients with THA, particularly after metal-on-metal procedures, but data show no conclusive evidence of significant detrimental effects. The AOA registry’s annual report for 2006 is based on 92,210 primary THAs, including 84,872 primary THAs, 7,205 metal-on-metal THRs and 133 thrust-plate procedures. (9) Some of these data may include patients reported in the Worldwide Cohort. In general, resurfacing procedures were used more often in men than in women (73% vs. 56%, respectively) and in younger patients (90% <65 years) than primary THA. At the 5-year follow-up, conventional THAs showed fewer revisions (1.7%) than THRs (2.2%); no patient demographic characteristics were available for comparison.

TEC concluded that use of the FDA-approved metal-on-metal 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. A substantial body of evidence shows that THR is associated with consistent and strong symptomatic and functional improvements comparable to those obtained with current THA in patients younger than 65 years old. Total hip resurfacing differs procedurally from arthroplasty in conserving a patient's native femoral bone stock; this difference is important should subsequent revision surgery be required. The available evidence showed that THR's short-term symptomatic and functional health benefits are at least as good as those of THA over midterm follow-up, with no substantial differences in revision rates among patients younger than 65 years who are likely to outlive a traditional prosthesis. Also, inference from the available long-term evidence suggests that THR will be at least as beneficial as THA in patients who are likely to outlive a traditional prosthesis, based on 1) appropriate patient selection, 2) the fact that THR is a bone-conserving procedure that preserves the femoral head and stock largely intact, and 3) substantial 5-year follow-up of device survival. There was minimal published medical literature regarding THR using polyethylene components.

2008-2012 Updates

Updated searches of the MEDLINE database 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 metal-on-metal hip components

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. (10) 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 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 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 metal-on-metal hip implants. (11) The U.K./Wales registry reported that hip resurfacing patients in all age groups, except males less 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.

Efficacy of THR vs THA

THR vs Standard THA: One systematic review compared outcomes from THR and THA in studies with short- to mid-term follow-up. (10) The 7 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 1 study was identified that assessed postural balance; all 4 showed similar or better outcomes for THR than THA.

In 2011, Jiang et al. published a meta-analysis comparing MoM THR with THA inpatients younger than 65 years. (13) Included were 4 randomized and controlled trials with a total of 968 patients. Hip function scores were similar between the 2 groups, although the HRA group showed higher activity levels.

In 2008, Queseda and colleagues published a qualitative systematic review that focused on advantages and disadvantages of THR in comparison with THA. (14) 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 10 patients who had osteoarthritis and 30 age- and sex-matched controls from a normative database. (15) 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 vs Large Head THA: Two RCTs were published in 2009 that randomized patients to THR or THA with a large diameter metal-on-metal implant. (16, 17) 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. (16) 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 1 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 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 the 2 groups. Garbuz and colleagues randomized 107 patients to THR or large-head metal-on-metal THA. (17) There was no difference in WOMAC or SF-36 scores for the 73 patients who had been followed up for at least 1 year. However, for the subset of patients who had been tested for serum levels of cobalt and chromium, cobalt was 10-fold higher and chromium was 2.6-fold higher in the large head metal-on-metal THA group than the THR group. This was a 46-fold increase from baseline in serum cobalt and a 10-fold increase from baseline in serum chromium for the large-diameter head THA group, possibly related to particulate wear at the head-neck junction. Both 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 4 randomized or controlled trials with 968 patients younger than 65. (13) Analysis found increased rates of revision with THR at 1 – 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. (11) As discussed above, the U.K./Wales registry reported that hip resurfacing patients in all age groups, except males less 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.

Amstutz et al. reported 12-year follow-up (range, 10.8 to 12.9 years) from the first 100 hip resurfacings at their institution in 2010, (18) The 89 patients in this series were followed annually with radiographs, range of motion, and questionnaires. Two patients were lost to follow-up and 5 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 46 mm, 83.8% for component sizes of 44 or 46 mm, and 78.9% for a component size equal to or less than 42 mm. 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.

Gross et al. reported mean 8-year follow-up (range, 6-11 years) of 373 hips in 329 consecutive patients from the first multicenter FDA-regulated trial on hip resurfacing with the Cormet prosthesis. (19) All patients were requested to come back for follow-up at 6 weeks, 1 year, 2 years, and every other year. A variety of methods were used to complete follow-up for patients who could not return to the study site, including phone interviews, mail-in questionnaires, radiographs, and physical examination by a local physical therapist. Twenty-one (6%) required revision, 5 for femoral neck fractures, 12 for component loosening, 2 for late deep infections, and 2 for an adverse wear reaction (0.5% at 7 years). Four additional hips showed radiographic signs of loosening but did not undergo revision. Kaplan-Meier survivorship at 11 years was 93% for revision for any reason and 91% including radiographic loosening. The learning curve was at least 200 cases, with survival of 93% for the first 100 cases, 93% for the second 100 cases, and 98% for the last 73 cases.

Other studies also 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. (20) 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. (21)

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 2 studies that compared the outcomes of conversion of failed THR to THA with primary THA. (12) 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. (22) 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 2 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 THRs performed between 1997 and 2005) requiring conversion surgery for failed THR (5 femoral neck fractures and 16 with femoral component loosening) with outcomes in 58 patients of similar age (64 hips from patients <65 years old) who had been treated with a primary THA by the same surgeon during the same period. (23) The acetabular component was retained in 18 hips (and revised in 3 because the matching femoral head was not available at the time of surgery). The study found no significant 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 2 groups (14% vs. 9%, respectively). At 1 to 9 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. (24) 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: The AAOS technology overview found that limited data exists comparing the prevalence of adverse clinical problems with metal-on-metal 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 metal-on-metal 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 metal-on-metal components is an area of increasing concern. In 2011, Williams assessed the prevalence of pseudotumor formation by ultrasound in asymptomatic patients with metal-on-metal THA (n=31) or metal-on-metal THR (n=21). (25) 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 patients (32%) in the metal-on-metal THA group had a solid (n=7) or cystic mass (n=3), 5 patients (25%) in the THR group had a solid (n=3) or cystic mass (n=2), and 1 patient (4%) in the metal-on-polyethylene THA group had a cystic mass. Isolated fluid collection was similar in the 3 groups (10%, 5%, and 8%, respectively). Serum chromium and cobalt ion levels in patients with metal-on-metal prostheses ranged from 2 to 720 times the upper limit of normal.

There was no correlation between the serum metal ion levels and the size of pseudotumor abnormality and no significant difference in serum metal ion levels in patients with pseudotumor formation than in patients without pseudotumors in this small study. The high percentage of patients diagnosed with a pseudotumor in this study is due in part to a definition of pseudotumor that included cystic without solid mass.

Kwon et al. determined the prevalence of asymptomatic pseudotumors after metal-on-metal THR in 201 hips. (26) 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 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 (6 female, 1 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 5-year follow-up) reported that failure was possibly related to metal debris in 0.5% of THRs. (27) 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 5 years. (28) 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 7 cases, the histological findings were consistent with a response to metal wear debris. Survivorship analysis gave an overall survival rate of 95.8% at 5 years, with an endpoint survival of 96.9% at 5 years for metallosis requiring revision. The relative risk for female 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. (29)

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. (30) 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. (31,32) Both articles discussed comparisons of hemi-resurfacing to THR, referencing a single comparative study by Beaule et al. from 2004; thus, it is unlikely that additional comparative resurfacing studies have been published since 2004. (2) 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
Based on potential ease of revision when compared with THA, the evidence available at this time supports the conclusions that hip resurfacing (partial or total) presents a reasonable effective alternative for active patients who are considered too young for THA, when performed by surgeons experienced in the technique. The efficacy of 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 decreased bone strength 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
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. (33) 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 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 2011, the American Academy of Orthopaedic Surgeons (AAOS) provided a technology overview of modern metal-on-metal hip implants (both THA and THR). (11) 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.

Government Regulations

National:
There is no national coverage decision on this topic. Procedure is payable under NOC code 27299.

Local:
There is no national coverage decision on this topic. Procedure is payable under NOC code 27299.

Michigan Department of Community Health:
No Medicaid policy on this topic. Procedure is payable under NOC code 27299.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 5/7/12, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/07	5/14/07	7/1/07	Joint policy established
11/1/08	8/19/08	10/3/08	Revised the inclusionary and exclusionary guidelines, Updated references.
11/1/12	8/21/12	8/21/12	Updated policy to mirror BCBSA policy. No change in policy statement. Updated references. Policy title changed from “Total Hip Resurfacing” to “Hip Resurfacing.”

Next Review Date: 3rd Qtr, 2013

BLUE CARE NETWORK BENEFIT COVERAGE POLICY: HIP RESURFACING

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply.
BCNA (Medicare Advantage)	Covered; criteria apply/
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.
Blue Cross Complete of Michigan	Covered; criteria apply/

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.