Hip Resurfacing

Policy # 00119
Original Effective Date: 09/18/2002
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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

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

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

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

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

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

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

- The patient is a candidate for total hip replacement; and
- Is likely to outlive a traditional prosthesis; and
- The patient has no known or suspected metal sensitivity or concern about potential effects of metal ions; and
- There is no more than 50% involvement of the femoral head; and
- There is minimal change in acetabular cartilage or articular cartilage space identified on radiography.
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Contraindications for Total Hip Resurfacing:
The Food and Drug Administration (FDA) lists several contraindications for total hip resurfacing (THR). These contraindications include (not a complete listing) the following:

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

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

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

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

Background/Overview
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 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 THA, particularly in young active patients who would potentially outlive a total hip prosthesis. 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 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 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
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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 MoM chromium and cobalt implant components are of increasing concern.

In January 2013, U.S. FDA issued a safety communication on MoM hip implants (both THA and THR). The 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.

**FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration

In May 2006, FDA granted premarket application (PMA) approval to the Birmingham Hip Resurfacing (BHR) system 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.

The Coromet™² Hip Resurfacing System (Corin) and the Conserve® Plus (Wright Medical Technology) are MoM THR systems that were FDA approved in 2007 and 2009, respectively. The approval order for the Coromet THR 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) noninflammatory degenerative arthritis such as osteoarthritis and avascular necrosis; (2) inflammatory arthritis such as rheumatoid arthritis. The Coromet Hip Resurfacing System is intended for patients who, due to their relatively younger age or increased activity level, may not be suitable for traditional THA due to an increased possibility of requiring ipsilateral hip joint revision.

A variety of devices have been cleared by FDA for partial hip (femoral) resurfacing under 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.
Updated searches of the MEDLINE database have been performed, most recently from July 31, 2014, through July 21, 2015. Key literature is described in the following sections of this evidence review.

**Rationale/Source**

The current policy is based in part on a 2007 Technology Evaluation Center (TEC) Assessment that evaluated studies of patients 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 THR (or THA). The Assessment included 1 randomized controlled trial (RCT) and 12 uncontrolled series, along with 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 presurgical status. The TEC Assessment also evaluated the patient safety and effectiveness data considered for FDA submission of the Birmingham device from the McMinn Cohort, which are supported by unpublished data on 3374 hips implanted by 140 surgeons and published reports on more than 3800 hips treated by multiple surgeons (Worldwide Cohort). With regard to long-term safety, literature summaries provided to FDA demonstrated increased serum and urinary concentrations of metal ions postoperatively in patients with THA, particularly after 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.

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. PMA product code: NXT

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination (NCD).

**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 with cemented THA 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 (eg, 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 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 criterion 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 bone mineral density (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 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 (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.

**Efficacy of Total Hip Resurfacing Versus Total Hip Arthroplasty**

**THR Versus Standard THA**

**Systematic Reviews**

One systematic review compared outcomes from THR and THA in studies with short- to mid-term -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 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 in patients younger than 65 years. Included were 4 RCTs 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 et al 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 postmenopausal women and small-boned men.

Clinical Studies
An RCT reported in 2015 was intended to evaluate clinical and functional outcomes of THR using the Birmingham system and to compare it with that of cementless hip arthroplasty in patients under the age of 55 years. Between 1999 and 2002, 80 patients were enrolled into the study; however, only 24 consented to random allocation to treatment, 11 to THR and 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, Harris hip, University of California Los Angeles 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%, respectively; p=0.1), were able to participate in sport activities (86% vs 52%, respectively; p=0.09) and were able to perform heavy manual labor (20% vs 13%, respectively; p=0.19). 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 years follow-up all remained below a 7 parts per billion (ppb) 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 10 patients who had osteoarthritis and 30 age- and sex-matched controls from a normative database. Walking speed (1.3 m/s) was found to be faster in the THR group than in the THA (1.0 m/s) or osteoarthritis (1.0 m/s) group. Measurement of abductor and hip flexor and abductor strength ratio. The THR group performed better during the functional reach test, and the THR 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 two groups.

Garbuz and colleagues randomized 107 patients to THR or large-head (MoM0 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 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

Systematic Reviews

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 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 has 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 THA with an unspecified bearing surface. Analysis of data from the Australian registry found that head size and risk of revision for THR were inversely related to each other. Patients receiving the smallest femoral head components (e.g., women) had the greatest risk of revision. The implant size was associated with poorer outcomes when 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 (5 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 1 patient. The failure rate was higher in patients who received a THR femoral component size of 46 mm or less (10/16 hips revised).

A 2014 prospective cohort study reported 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, who 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 7 each due to infections, soft-tissue reactions, and other causes. With revision for any reason as the end point, Kaplan-Meier survival analysis showed 97% (95% confidence interval [CI] 97 to 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 1 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 65 years of age or older found 10-year implant 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, 10.8-12.9 years) from the first 100 hip resurfacings at their institution. Kaplan-Meier implant survival was 93.9% at 5 years and 88.5% at 10 years. Subgrouping by femoral component size showed 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 of 42 mm or less. Multivariate analysis showed that low BMI, small femoral component size, and large defects in the femoral head were risk factors for failure. High scores for activity level were not associated with an increased risk of revision.

Other studies suggest a high learning curve for THR related to the increased difficulty in accessing the acetabular compartment. For example, in 1 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 (eg, 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.

**Total Hip Resurfacing to Total Hip Arthroplasty Conversion Systematic Reviews**

A 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 that had been matched by gender, 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' 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, 16 with femoral component loosening) with outcomes in 58 patients of similar age (64 hips from patients younger than 65 years) 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 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, 140-255) and primary THA (169 minutes; range, 110-265), or in complication rates between the 2 groups (14% vs 9%, respectively). At 1- to 9-year 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 (eg, 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 (of 12,093 primary THR, ~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 THR, was performed in 247 of the 397 revisions (62%) undertaken for reasons other than infection. At 3 years, the rate of re-revision THR-THA was 7%, compared with 2.8% of primary conventional THA. Reasons for re-revision included loosening/lysis (n=6), infection (n=4), dislocation of prosthesis (n=1), and fracture (n=2). At 5 years, femoral-only re-revision (7%) was similar to re-revision of both the acetabular and femoral components (5%), but the rate of acetabular-only re-revision was 20%. A more relevant outcome for this 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; assess the prevalence of adverse reactions to metal debris; and, to try to associate blood metal ion levels and symptoms of adverse reactions to metal debris among patients who underwent THR at a single institution. Between May 2001 and May 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 endpoint. At 10-year follow-up, device survival for the entire cohort was 91%, with revision required in 10 men (6%) and 13 women (20%). The prevalence of adverse reactions to metal debris was 7% in male and 9% in female patients; it was associated with revision in 3 men (2%) and 8 women (9%). Pseudotumors were observed most commonly in symptomatic patients with elevated metal ion levels (63%) compared with
asymptomatic patients with elevated metal ion levels (42%) and symptomatic patients with nonelevated metal ions (11%).

In 2011, Williams et al assessed the prevalence of pseudotumor formation by ultrasound in asymptomatic patients with MoM THA (n=31) or MoM THR (n=21). Results were compared with 24 asymptomatic patients with a metal-on-polyethylene THA. At a minimum of 2 years after surgery (mean not reported), 10 patients (32%) in the MoM 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 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 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. 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 >5-year follow-up) reported that failure was possibly related 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 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 radiologic 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). 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 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 (1016 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 (eg, 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 2 cohorts were observed in the Harris Hip Score (93 vs 93) or the SF-12 (eg, 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 hemiresurfacing 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 MoM prosthesis, THR (femoral and acetabular implant) would be preferred over a femoral component alone.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in August 2015 did not identify any ongoing or unpublished trials that would likely influence this review.

Summary
The evidence for hip resurfacing in young active patients who would potentially outlive a traditional total hip prosthesis includes 2 RCTs, numerous large observational studies, large registry studies, and systematic reviews. Relevant outcomes are symptoms, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related morbidity. The efficacy of THR performed with current techniques is similar to 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. 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 alternative for active patients who are considered too young for THA, when performed by surgeons experienced in the technique. The literature on adverse effects such as metallosis, pseudotumor formation, and implant failure is evolving as longer follow-up becomes available. Due to the uncertain risk with MoM implants, the risk-benefit ratio needs to be 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 factors should also be considered in the overall patient evaluation for THR, and patients should make an informed choice in conjunction with their treating physicians. The evidence is sufficient to determine quantitatively that the technology results in a meaningful improvement in the net health outcome.

Clinical Input Received From Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received
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does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 1 physician specialty society and 1 academic medical center while this policy was under review in 2013. The input on the policy was mixed, although both reviewers agreed that evidence is not sufficient to conclude that the potential for harm with MoM hip resurfacing outweighs the benefit for all patients. One reviewer noted that current cross-linked polyethylene total hip components may last 20 to 30 years, limiting the number of patients who would outlive a total hip prosthesis and be considered an appropriate candidate for THR.

References
2. Blue Cross and Blue Shield Association Technology Evaluation Center. Metal-on-metal total hip resurfacing. TEC Assessments. 2007;Vol 22, Tab 3. PMID

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11/29/2004 Managed Care Advisory Council approval

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Hip Resurfacing

Policy # 00119
Original Effective Date: 09/18/2002
Current Effective Date: 11/16/2016

07/07/2006 Format revision including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
12/06/2006 Medical Director review
06/13/2007 Medical Director review
06/20/2007 Medical Policy Committee approval. Policy updated with TEC Assessment; metal-on-metal total hip resurfacing with an FDA-approved device system now may be considered medically necessary as an alternative to total hip replacement in patients who are candidates for total hip replacement and who are likely to outlive a traditional prosthesis. All other types and applications of total hip resurfacing remain investigational.
08/06/2008 Medical Director review
08/20/2008 Medical Policy Committee approval. Eligible for coverage with added contraindications. Updated rationale.
08/06/2009 Medical Policy Committee approval
08/26/2009 Medical Policy Implementation Committee approval. No change to coverage eligibility.
08/05/2010 Medical Policy Committee review
08/18/2010 Medical Policy Implementation Committee approval. Statement added for partial resurfacing; considered medically necessary in specific conditions. Title changed to Hip Resurfacing.
08/04/2011 Medical Policy Committee review
08/17/2011 Medical Policy Implementation Committee approval. No change to coverage.
08/02/2012 Medical Policy Committee review
08/15/2012 Medical Policy Implementation Committee approval. No change to coverage.
09/05/2013 Medical Policy Committee review
09/18/2013 Medical Policy Implementation Committee approval. No change to coverage.
11/06/2014 Medical Policy Committee review
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed
10/29/2015 Medical Policy Committee review
11/16/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/03/2016 Medical Policy Committee review
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes

Next Scheduled Review Date: 11/2017

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®), copyright 2015 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>27299</td>
</tr>
<tr>
<td>HCPCS</td>
<td>S2118</td>
</tr>
<tr>
<td>ICD-10 Diagnosis</td>
<td>M15.0, M15.4-M15.9, M16.0-M16.9, M87.051-M87.059, M87.150-M87.159, M87.251-M87.256, M87.350-M87.353, M87.850-M87.859, M90.551-M90.559</td>
</tr>
</tbody>
</table>

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

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
   1. Consultation with the Blue Cross and Blue Shield Association TEC or other nonaffiliated technology evaluation center(s);
   2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
   3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;

B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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