

HIP RESURFACING ARTHROPLASTY

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INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Essential Health Benefits for Individual and Small Group:

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee specific benefit document to determine benefit coverage.

COVERAGE RATIONALE

Hip resurfacing arthroplasty (HRA) with U.S. Food and Drug Administration (FDA) approved devices is proven and medically necessary for the treatment of hip disease in patients who are younger than age 65 and who meet ALL of the following criteria:

- have chronic, persistent pain and/or disability,
- are otherwise fit and active,
- have normal proximal femoral bone geometry and bone quality, and
- would otherwise receive a conventional primary total hip replacement (THR), but are likely to live longer than a conventional THR is expected to last.

Hip resurfacing arthroplasty (HRA) is unproven and not medically necessary for devices not approved by the FDA or for treatment of patients who do not meet the above criteria.

There is a lack of evidence that outcomes after HRA are equivalent or superior to those of THR in other patient populations.

APPLICABLE CODES

The codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit document. This list of codes may not be all inclusive.

CPT [®] Code	Description
27125 (when billed for hip resurfacing)	Hemiarthroplasty, hip, partial (e.g., femoral stem prosthesis, bipolar arthroplasty)
27130 (when billed for hip resurfacing)	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft
27299	Unlisted procedure, pelvis or hip joint

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HCPCS Code	Description
S2118	Metal-on-metal total hip resurfacing, including acetabular and femoral components

DESCRIPTION OF SERVICES

Hip resurfacing arthroplasty (HRA) is a surgical procedure designed as an alternative to total hip replacement (THR) for patients with various etiologies of hip pain, including osteoarthritis (OA), avascular necrosis, rheumatoid arthritis (RA) and traumatic arthritis. In hip resurfacing, the diseased or damaged bone and cartilage are removed, the femoral head is reshaped and capped with a metal ball to cover the damaged surface of the bone, but the femoral head is not removed, as in THR. Compared with THR, femoral resurfacing allows preservation of much more of the patient's own bone, while restoring normal anatomy and joint biomechanics. The theoretical advantages of femoral resurfacing over THR are that it is a less invasive procedure and there is reduced risk of thigh pain since there is no stem in the femoral canal. In addition, patients may be more physically active with the ability to sustain additional stress on their prosthesis for a longer period of time (a theoretical advantage, especially for younger patients, because there may be less risk of dislocation given the greater stability of the large diameter metal ball). The procedure is primarily intended for younger and more active patients who have higher expectations with regard to the use of their joints during the course of their lifetimes, and who may be more suitable candidates for THR later in life (Ontario Health Technology Assessment, 2012).

HRA is sometimes referred to as a metal-on-metal (MoM) procedure. This should not be confused with conventional THR performed with a hard-on-hard hip prosthesis.

CLINICAL EVIDENCE

Aulakh et al. (2015) presented an independent assessment of eleven year follow-up of hip resurfacing outcomes of 4535 patients from an international hip resurfacing register (1997-2002). This assessment looked at “implant survival at maximum follow-up for revision due to any reason, implant survival at maximum follow-up for revision due to major causes of failure, hip function following hip resurfacing and factors affecting hip function, effect of gender and age on hip function and implant survival, effect of femoral component size on hip function and implant survival”. The authors concluded that hip resurfacing has a good implant survival of 96.2% and excellent post-operative function.

Fink et al. (2014) prospectively collected data for total hip resurfacing in the USA. The purpose of the study was to demonstrate the efficacy of MOMHR in comparison with total hip arthroplasty (THA) using validated outcome measures, survivorship and complication rates. The study followed 136 implants in 123 male patients <65 years, all with a primary diagnosis of osteoarthritis and similar comorbidities as determined by the American Society of Anesthesiologists (ASA) score. A single-surgeon cohort of 89 MOMHRs was compared with a similar cohort of 47 THAs. Outcomes were prospectively assessed with the Short-Form Health Survey of 12 questions (SF-12) and Western Ontario and McMaster Universities (WOMAC) questionnaires pre- and postoperatively at yearly intervals. Minimum follow-up was two years, and average follow-up was 3.9 years. Diagnosis, body mass index (BMI), American Association of Anesthesiologists (ASA) and pre-operative pain and function scores were not significantly different between groups. There was no difference in SF-12 scores postoperatively. At one and two years postoperatively, the MOMHR group had better WOMAC scores than the THA group, but no difference was seen at three to five years postoperatively. There were no revisions in either group over the study period. The author noted that this study demonstrated good results for hip resurfacing in men <65 years five years postoperatively and similar function to THA patients.

A recent and comprehensive health technology assessment (HTA) evaluating hip resurfacing arthroplasty (HRA) was updated by the Washington State Health Care Authority (WSHCA, 2013). Study authors assessed the safety, efficacy, and effectiveness using functional outcomes, including patient-reported functional and quality of life (QOL) outcome measures, as well as activity scores. Clinician-based outcome measures included the Harris Hip Score. Safety outcomes included revision rates and complications, and specific safety issues regarding blood ion concentrations. Nine randomized controlled trials (RCTs), 12 observational studies, and 3 total hip registry reports were included for detailed review. Authors searched the published medical literature from January, 2009 to June, 2013. Results of this HTA are described below.

Moderate quality evidence derived from three small RCTs demonstrated similar efficacy between THR and HRA with regard to short-term functional, QOL, and activity outcomes. Evidence evaluating efficacy beyond two years was not available for review. There was low quality evidence evaluating effectiveness in head-to-head studies comparing THR with HRA. Results demonstrated that short-term (≤ 5 years) patient-reported outcomes, clinician-based outcomes, and pain were similar between THR and HRA. Patients who underwent THR demonstrated slightly improved activity scores. For mid-term (5-10 years) rates of effectiveness, there was insufficient evidence from a single cohort study to suggest that patients treated with THR may have a better QOL and activity outcomes than patients treated with HRA. High quality evidence from three large registry studies shows that risks of revision over the short- and mid- terms (up to 10 years) are higher in THR than HRA patients. Over the short term (≤ 5 years), the absolute risk ranges from 5 to 6% in THR patients compared with 1 to 4% in the HRA group. Similarly, the absolute risk of revision at 7 years ranges between 6 to 9% in the THR group compared with 3 to

4% in the HRA group. One registry study showed that 11-year revision risks were higher in patients undergoing THR (10%) compared with HRA (7%).

With regard to complications, the HTA described high quality evidence (3 RCTs and 6 observational studies) showing that the loosening of the femoral component occurs 8 times more frequently in THR patients (2.7%) than HRA patients (0.3%). In addition, heterotopic ossification occurs almost twice as often in THR patients (19.8%) than HRA patients (11.4%). However, dislocation occurs less often in THR patients (0.5%) than HRA patients (2.8%). There is moderate level evidence that deep infection occurs less frequently in THR patients (0.4%) than HRA patients (1.8%). Regarding metal ion safety, there are consistently higher median blood levels of primary metal ions (cobalt and chromium) in THR patients compared with non-MoM HRA patients. However, the long term effects of higher blood levels of metal ions are not clear. Results are based on five studies with 3-year follow-up.

In a systematic review, van der Weegen et al. (2011) assessed the revision rate of metal-on-metal (MoM) HRA compared to the National Institute for Health and Care Excellence (NICE) (United Kingdom) benchmark of 10% or less revisions at ten years. A total of 29 articles (10, 621 resurfaced hips) met the inclusion criteria. The mean follow-up period ranged from 0.6 to 10.5 years, and the survival of the implant ranged from 84% to 100%. Of the 10, 621 hips, 370 were revised (3.5%), with aseptic loosening as the most frequent mode of failure. None of the HRA implants used to date met the full ten-year NICE benchmark of survival. A total of 13 studies showed satisfactory survival compared with the three-year NICE benchmark.

Smith et al. (2010) conducted a systematic review and meta-analysis to compare the clinical outcomes of total HRA (3799 hips) to THR (3282 hips). The review included 46 randomized controlled trials (n=10), prospective observational studies (n=28) and retrospective reviews (n=8) that met inclusion criteria. The mean age for the HRA group was 51 years compared to 54 years in the THR group. Follow-up periods ranged from immediate postoperative to 82 months. There were no clinically significant differences between the two groups. There was a reduced risk of dislocation following HRA. The authors noted that studies comprising the evidence base were characterized by numerous methodological flaws, including high levels of statistical heterogeneity, limited use of power calculations, and inadequate or absent blinding of patients and assessors. The implantation of various hip replacement systems and femoral head sizes was another limitation of the studies. Outcomes were not determined by prosthesis type, age or sex. From their analysis, the authors concluded that functional outcomes following total HRA were as good as or better than THR; however, there was an increased risk of heterotopic ossification, aseptic loosening and revision following HRA.

Carrothers et al. (2010) prospectively collected data on 5000 Birmingham HRA and analyzed the rate and reasons for failure. A total of 4524 devices survived a mean 7.1 years. Revisions were required in 182 cases. Reasons for the revisions included: femur neck fracture, acetabular component loosening, femoral head collapse/avascular necrosis (AVN), femoral component loosening, infection, pain with aseptic lymphocytic vascular and associated lesions (ALVAL)/metallosis hips, loosening of components, dislocation, and acetabular component malpositioning. Women had a significantly higher prevalence of revision for any reason compared to men. The mean time to failure was 2.9 years with a significantly shorter time to failure in men than women. Compared to men, women had significantly more revisions for acetabular component loosening, dislocation, infection, and pain with ALVAL/metallosis. The authors noted that a limitation of the study was the absence of objective radiological follow-up.

Amstutz et al. (2011) reported 12-year follow-up from the first 100 hip resurfacings at their institution in 2010. 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 required 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

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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 body mass index (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.

A meta-analysis by Springer et al. (2009) analyzed failure rates of modern femoral components in young patients having total hip arthroplasty (22 studies; 6408 hips) or hip resurfacing (15 studies; 3269 hips). The total hip arthroplasty group experienced mechanical failure of the femoral stem in 1.3% of patients at a mean follow-up of 8.4 years. The hip resurfacing group had a 2.6% failure rate at a mean follow-up of 3.9 years. Revision surgery occurred in 70.7% of hip resurfacing patients and 14.7% of total hip arthroplasty patients due to component failure. With twice the failure rate and half the follow-up time, further research with direct comparison trials is needed to further evaluate the efficacy of hip resurfacing.

Marker et al. (2009) conducted a comprehensive review comparing hip resurfacing arthroplasty with total hip replacement. The authors found that overall, hip resurfacing arthroplasty had similar or better outcomes than THR. Gait studies suggest that hip resurfacing provides a more natural gait pattern than conventional total hip arthroplasty. In addition, the authors found that conversion of failed hip resurfacing arthroplasty was similar to primary total hip replacement. The study is manufacturer sponsored and limited by lack of long-term efficacy due to short term follow-up. Howie et al. (2005) conducted a randomized, controlled trial in young patients, which compared M-M cemented, total hip resurfacing arthroplasty (n=11) with cemented total hip replacement (n=13). The trial was stopped early because of a high incidence of failure of the cemented resurfacing acetabular component.

A recent RCT by Vendittoli et al. (2010) compared Durom hip resurfacing (HR) (n=109 hips) with an uncemented 28 mm total hip arthroplasty (THA) (n=100 hips). X-rays of the pelvis and hips were taken at each follow-up visit and compared with the immediate post-operative radiographs. Outcomes were measured using the Western Ontario McMaster osteoarthritis index (WOMAC) pre-operatively (54.4 THA versus 52.7 HR) and at 3, 6, 12 (10.2 versus 8.0) and 24 months (9.0 versus 5.7). Secondary outcomes included the Merle d'Aubigné-Postel scale, UCLA activity score, and functional tests, such as the "hop test" and "step test." There were no significant differences between the two groups for the Merle d'Aubigné-Postel scores, hop test or step test. At a mean of 56 months (range, 36-72), 6 HR and 7 THA underwent re-operation. At last follow-up (mean 56 months, range, 36-72), none of the acetabular components were considered to be loose, there was no migrations and only 2 HR cases had radiolucent lines. The authors concluded that hip resurfacing provides better early functional results, with no differences in results at two years. Limitations included unblinded study design and need for long term follow-up.

Vendittoli et al. (2006) performed a prospective RCT comparing total hip replacement and MoM total hip resurfacing arthroplasty in patients aged < 65 years. Revision was required for one hip in the total hip replacement group due to recurrent dislocation and two hips in the hip resurfacing arthroplasty group for femoral head aseptic loosening. No significant difference was found with the Western Ontario McMaster Osteoarthritis Index (WOMAC) or Merle d'Aubigne-Postel scores of clinical results. A significantly higher UCLA activity level was found in the hip resurfacing arthroplasty group (7.1) at the 1-year postoperative evaluation compared with the total hip replacement group (6.3). A greater percentage of the hip resurfacing arthroplasty patients (72%) returned to heavy or moderate activities at the 1-year postoperative evaluation compared with the total hip replacement group (39%). Both techniques resulted in different types of complications but similar overall complication rates. The authors concluded that hip resurfacing arthroplasty seems to offer better functional recovery in the short-term. Although hip resurfacing arthroplasty offers the benefit of proximal femoral bone preservation, long-term survivorship data for hip resurfacing arthroplasty are necessary to determine which procedure offers the greatest benefit.

This study did not meet the 2-year minimum (not reported, but presumed < 2 years) follow-up inclusion criteria, but was included because it is a randomized clinical trial.

Girard et al. (2006) performed a randomized study comparing total hip replacement with Durom total hip resurfacing arthroplasty. The contralateral hip was used as a control. Postoperatively, the femoral offset was significantly increased with total hip replacement and decreased with hip resurfacing arthroplasty. Femoral offset was restored to within mm in 14 (25%) patients in the total hip replacement group and in 29 (59%) patients in the hip resurfacing arthroplasty group. In the total hip replacement group, the leg was lengthened by a mean of 2.6 mm. In the hip resurfacing arthroplasty group, the leg was shortened by a mean of 1.9 mm, compared with the contralateral side. Leg-length inequality was restored to within mm in 33 (60%) patients in the total hip replacement group and in 42 (86%) patients in the hip resurfacing arthroplasty group. The radiological parameters of acetabular reconstruction were similar in both groups. The authors concluded that restoration of the normal proximal femoral anatomy was more precise with hip resurfacing arthroplasty because the anatomy of the hip is less distorted during surgery and better stability was afforded by the large-diameter femoral head. Leg length was more easily restored to normal with hip resurfacing arthroplasty, and although femoral offset was slightly reduced, more precise reconstruction on the mechanics was achieved with hip resurfacing arthroplasty. Although this study did not meet the 2-year minimum (not reported, but presumed < 2 years) follow-up, it was included because it is a randomized clinical trial.

Daniel et al. (2004) studied the safety and efficacy of total hip resurfacing arthroplasty for patients (n=446 hips) with osteoarthritis and under the age of 55 years. Revision surgery was required for 1 (0.02%) of 440 hips. The implant survival was 99.8%. The mean Oxford score of the surviving 439 hips was 13.5 points (median, 12). Post hip resurfacing arthroplasty, 31% of the men with unilateral resurfacings and 28% with bilateral resurfacings were involved in jobs that they considered heavy or moderately heavy; 92% of men with unilateral hip resurfacings and 87% of the whole group participate in leisure-time sports activities.

A prospective study by Ollivere et al. (2010) examined 5-year outcomes of 104 (98 patients) Birmingham hip resurfacings (BHR). Mean follow-up was 61.2 months (range: 38–76). Mean age was 56 (range 36–68) and mean body mass index (BMI) of 27 (range 19–43). Outcomes were measured via Harris Hip Score (HHS) and x-ray exam. Mean HHS improved significantly from 46 preoperatively to 90 post-operatively with no significant change over five years. No revision procedures were required with in the 5 year follow-up. Patients with a BMI >30 had lower post-operative functional scores compared to those of normal patients. On x-ray, there were no cases of femoral notching or poor component seating. Radiolucent lines were present in a single zone in 9.4% (9/96) acetabular and 3.1% (3/96) femoral components. Neck narrowing of up to 20 mm was also noted. The authors concluded that BHR has excellent results with little early evidence of radiographic failure; however it is recommended that regular radiographic follow-ups be conducted to monitor for neck narrowing in order to reach definitive conclusions about long term effectiveness.

Back et al. (2005) performed a prospective study of the clinical and radiographic results of total hip resurfacing arthroplasty with the Birmingham Hip Replacement System (n=230 hips). Revision to total hip replacement was required in 1 patient due to a loose acetabular component. At a mean follow-up of three years, survivorship was 99.14%. The Harris Hip Score improved from a mean of 62.54 (range, 8 to 92) to 97.74 (range, 61 to 100). The range of movement improved in all patients; the mean flexion improved from 91.52 degrees to 110.41 degrees.

Mont et al. (2009) compared hip resurfacing to hip replacement in 108 patients. Each group consisted of 54 closely matched patients with a mean age of 55 (range 35-79). At a minimum follow-up of 24 months (mean, 40 months; range, 24–60 months), the mean Harris hip scores increased similarly in both groups (from 52 to 90 points and from 50 to 91 points for the resurfacing and conventional groups, respectively). Radiographic outcomes, revision rates, complications, pain scores, and satisfaction ratings of the two groups were similar. The patients

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who underwent resurfacing had higher postoperative weighted activity scores than the patients who underwent conventional total hip arthroplasty, although they had higher preoperative weighted activity scores as well. The authors concluded that resurfacing is comparable to conventional hip arthroplasty.

A retrospective review by Rahman et al. (2010) analyzed midterm survivorship and function following hip resurfacing with the Birmingham hip resurfacing device in 302 patients (329 hips). Mean age at time of surgery was 56.0 years (range 28.2 – 75.5 years). The minimum follow-up was 5 years (mean, 6.6 years; range, 5-9.2 years). Kaplan-Meier analysis showed survival of 96.5% at 9 years. All functional hip scores (HHS, OHS, WOMAC, UCLA) improved. The authors found that medium-term survivorship and functional scores of hip resurfacing were comparable to those from earlier studies. Hip resurfacing is a good alternative to HRA, particularly in the younger male population with relatively large femoral head sizes.

A multi-center study by Ollivere et al. (2009) examined the records of 463 patients receiving Birmingham hip resurfacing (BHR) arthroplasty surgery to evaluate causes for early failure. Mean age was 56 years and mean follow-up was 43 months. Patients were evaluated both clinically and radiologically at 6 weeks and at 1, 2 and 5 years after surgery. Patients lost to follow-up (n=3) were treated as failures for the purposes of survivorship analysis. There were 13 revisions (n=12 patients) due to pain (n=7), fracture (n=3), dislocation (n=2) and infection (n=1). All of the 7 revised for pain and the 2 for fracture were found to have evidence of metallosis. Rate of survival for all causes of revision was 95.8 at five years and 96.7% at a mean follow-up of 3.5 years. For metallosis requiring revision, survival was 96.9% at five years. Patients at risk for metallosis are obese patients, females, and those with a small femoral head and high abduction angles which are associated with higher rates of wear. Due to a significant rate of early failure which may be as high as 3% at five years, the authors caution against the use of this prosthesis in patients with these risk factors.

Della Valle (2009) reported on the initial American experience with hip resurfacing following the U.S. Food and Drug Administration approval. Safety surveys were completed on the first 537 cases performed and included patient age, gender, diagnosis, and occurrence of any unexpected events. Intraoperative data were available for all 537 cases (100%) and one-year data were available for 449 cases (83.6%); the mean follow-up was 10.4 months. Adverse events were documented in 40 (32 major, 8 minor) of the 537 cases including nine nerve injuries and eight dislocations. There were 14 component revisions (3.1%) within the first year, including 10 for femoral neck fracture, two for dislocations, and two for acetabular component loosening. Complications were frequently seen among patients older than 55 years of age and in women, emphasizing the importance of appropriate patient selection for the procedure.

McGrath et al. (2008) compared the clinical and radiographic outcomes after hip resurfacing in two cohorts of patients: those who were 60 years of age or older (n= 40 hips), and those who were younger than 60 years of age (n=153 hips). At a mean follow-up time of thirty-six months, the mean Harris hip scores improved from 52 points to 94 points in the older patient cohort and from 53 points to 92 points in the younger patient cohort. The final Short Form-12 scores of the two groups were also similar. Two patients who were sixty years or older and five of the younger patients required conversion to a conventional total hip arthroplasty. Femoral neck fracture was the reason for one conversion in each group. There were no impending radiographic failures in either group. The investigators concluded that although national registries indicate that the risk of femoral neck fracture is higher in older patients, the present study found that these patients had excellent clinical outcomes that were similar to those of patients who were younger.

Newman et al. (2008) reported functional outcomes after metal-on-metal (MoM)OM hip resurfacing in a cohort of 126 MOM hip resurfacing operations. A total of 120 hips were reviewed in patients (71 men, 49 women; mean age, 56+/-9y; range, 24-76y). One year after surgery, overall examination was satisfactory with few complications. High functional levels were reported. The median OHS was 15 and median UCLA Activity Score 7 (active). For 25% of patients,

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outcome was poor with persistent pain, reduced hip flexion (mean, 94.46 degrees +/-12.7 degrees), decreased strength, restricted walking, and functional limitations.

Jameson et al. (2008) assessed the influence of age and sex on early survivorship and functional outcome by comparing 100 female hips resurfaced with male hips resurfaced for the same period. In patients older than 55 years, Harris hip score improved to 97.4 in males compared with 91.2 in females with a revision rate of 2.2% and 7.4%, respectively. There was no correlation between age and functional score. Three percent of female patients and 1.3% of male patients sustained a femoral neck fracture. Hip resurfacing provides excellent early functional recovery in males and females. However, the revision rate in older females is high. Changes to surgical technique may minimize the risk of early failure in this group.

Steffen et al. (2008) reported the five-year clinical outcome and seven-year survival of an independent series. A total of 610 Birmingham Hip Resurfacing arthroplasties were performed in 532 patients with a mean age of 51.8 years (16.5 to 81.6). They were followed for between two and eight years; 107 patients (120 hips) had been followed up for more than five years. Two patients were lost to follow-up. At a minimum of five years' follow-up, 79 of 85 hips (93%) had an excellent or good outcome according to the Harris hip score. The mean Oxford hip score was 16.1 points and the mean University of California Los Angeles activity score was 6.6 points. There were no patients with definite radiological evidence of loosening or of narrowing of the femoral neck exceeding 10% of its width. There were 23 revisions (3.8%), giving an overall survival of 95% at seven years. Fractured neck of femur in 12 hips was the most common indication for revision, followed by aseptic loosening in four. The investigators concluded that considering that these patients are young and active these results are good, and support the use of resurfacing.

An ECRI Institute Emerging Technology Report concluded that although published evidence is limited, metal on metal (MoM) total hip resurfacing may offer an appealing option to patients younger than 60 years of age with severe hip pain from arthritis, who are no longer responding to medical management, and are seeking a surgical alternative less radical than total hip replacement (ECRI, 2011).

BlueCross and BlueShield Association (BCBSA) published a TEC assessment on metal-on-metal total hip resurfacing (BCBSA, 2007). This report evaluated safety and efficacy data from 14,000 cases to assess hip resurfacing as an alternative to total hip replacement (THR) in younger or more active patients who are likely to outlive the 10-year functional lifespan of a traditional total hip replacement. Although data beyond 5-year follow-up on durability of resurfacing compared to total hip replacement are not available, the authors concluded that resurfacing improves health outcome and is as beneficial as total hip replacement in patients less than 65 years of age.

In a recent update, the National Institute for Health and Care Excellence (NICE) recommended that metal on metal (MoM) hip resurfacing arthroplasty for individuals with advanced hip disease who would otherwise receive and are likely to outlive a conventional primary total hip replacement. They further state that surgeons considering hip resurfacing arthroplasty should assess activity levels of potential patients since the current evidence for the clinical and cost effectiveness of MoM hip resurfacing arthroplasty is primarily in individuals younger than 65 years of age (NICE, 2012).

In an updated National Institute for Health and Care Excellence (NICE) Technology Appraisal Guidance report (review of technology appraisal guidance 2 and 44), data for revision rates of prostheses was reviewed. Prostheses for resurfacing arthroplasty were recommended for end-stage arthritis of the hip only if the prostheses have rates (or projected rates) of revision of 5% or less at 10 years.

It concluded that, because the predicted revision rate of total hip replacement (THR) was less than 5% at 10 years in those patients for whom both THR and resurfacing arthroplasty were suitable, the revision rate standard for resurfacing arthroplasty should be the same as that for THRs. (NICE 2014).

The Ontario Health Technology Assessment Series reported safety concerns regarding the potential adverse effects of metal ion levels in the blood. An updated report published in 2012 reported an evidence base consisting of 3 randomized controlled trials, 2 large registry studies, 18 prospective cohort studies, and 24 case series (OHTA, 2012).

Professional Societies

American Academy of Orthopaedic Surgeons (AAOS)

In 2011, the AAOS published an updated clinical guideline providing an overview of metal-on-metal hip resurfacing (AAOS, 2011). They reported the following:

- Although hip resurfacing arthroplasty demonstrated better 1- and 2-year WOMAC scores, there were no clinically significant differences between hip resurfacing arthroplasty and total hip arthroplasty.
- Overall, total hip resurfacing arthroplasty patients have a higher risk of surgical revision surgery than total hip replacement patients
- Patients with a diagnosis of osteoarthritis are at the lowest risk for revision with either procedure
- The evidence is conflicting regarding whether age influences revision rates
- Risk of revision is greater with smaller prosthetic components

AAOS concluded that due to limited data, conclusions regarding efficacy or health outcomes of hip resurfacing arthroplasty could not be determined.

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. The evidence base consisted of 8 randomized controlled trials, 16 cohort studies, 15 case series, and 2 meta-analyses. Revision rates appear to be higher in patients receiving THR procedures than in those receiving HRA, which is of particular importance since the THR procedure targets young people who may be subject to harm over their lifetimes. This risk may be particularly high in women. In addition, the elevated levels of metal ions are concerning. 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.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

The following devices have received FDA approval under product code NXT.

Total hip resurfacing systems are approved by the FDA Premarket Approval (PMA) process. The three FDA approved total hip resurfacing systems include the Birmingham Hip Resurfacing (BHR) System (Smith & Nephew Inc., Memphis, TN), the Cormet Hip Resurfacing System™ (Corin USA, Tampa, FLA) and the CONSERVE® Plus Total Resurfacing Hip System (Wright Medical Technology, Inc., Arlington, TN).

The Birmingham Hip Resurfacing (BHR) System received FDA approval on May 9, 2006 and is intended for use in patients requiring primary hip resurfacing arthroplasty due to:

- Non-inflammatory arthritis (degenerative joint disease) such as osteoarthritis, traumatic arthritis, avascular necrosis, or dysplasia/developmental dislocation of the hip (DDH) or
- Inflammatory arthritis such as rheumatoid arthritis.

The BHR 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 future ipsilateral hip joint revision. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf4/P040033b.pdf. Accessed September 24, 2015

The Cormet Hip Resurfacing System received FDA approval in July 2007 and 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:

- non-inflammatory degenerative arthritis such as osteoarthritis and avascular necrosis;
- 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. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf5/P050016b.pdf. Accessed September 24, 2015

The CONSERVE Plus Hip system received FDA approval on November 3, 2009 and 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:

- Non-inflammatory arthritis (degenerative joint disease) such as osteoarthritis, traumatic arthritis, avascular necrosis, or dysplasia/developmental dislocation of the hip (DDH), or
- Inflammatory arthritis such as rheumatoid arthritis.

Additional information is available at:

http://www.accessdata.fda.gov/cdrh_docs/pdf3/P030042a.pdf. Accessed September 24, 2015.

The Biomet ReCap Total Hip Resurfacing System has received FDA investigational device exemption (IDE) status allowing use for research purposes or through "continued access" in the United States.

In August 2010, the DePuy ASR System was recalled. The device is being phased out and is no longer available.

No metal-on-polyethylene hip resurfacing devices have received FDA approval.

FDA issued a public health communication regarding the ongoing concern related to adverse events associated with increased blood levels of cobalt and chromium following metal-on-metal systems. FDA stated that a limited number of case reports in the medical literature have suggested the potential for systemic effects (e.g., cardiomyopathy, thyroid dysfunction, and neurological changes including sensory, auditory, and visual impairments) of elevated metal ion levels resulting from device wear in metal-on-metal (MoM) hip systems. "Because of the limited number of case reports in published literature, the true incidence or prevalence of adverse systemic effects from MoM hip implants is not known at this time, but is believed to be rare. There are currently insufficient data to identify any specific metal ion levels that would cause adverse systemic effects. As a result, it is not possible to cite a metal ion threshold value in the blood that would serve to confirm the etiology of the symptoms." On May 6, 2011 the FDA issued orders for "postmarket surveillance studies to manufacturers of metal-on-metal hip systems. The FDA sent 145 orders to 21 manufacturers. Manufacturers will be required to submit a research protocol to the FDA that addresses specific safety issues related to these devices. Data from the studies conducted will enable the agency to better understand these devices and their safety profiles." However, FDA stated that there is no evidence to support the need for checking metal ion levels in asymptomatic patients (FDA, 2011).

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for total hip resurfacing arthroplasty (THRA). Local Coverage Determinations (LCDs) do exist. Refer to the LCDs for [Major Joint Replacement \(Hip and Knee\)](#), [Surgery: Major Joint Replacement \(Hip and Knee\)](#) and [Total Joint Arthroplasty](#). (Accessed October 2, 2015)

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
12/01/2015	<ul style="list-style-type: none"> • Added reference link to policy titled <i>Hip Replacement Surgery (Arthroplasty)</i> • Updated supporting information to reflect the most current clinical evidence and references; no change to coverage rationale or lists of applicable codes • Archived previous policy version 2015T0503J