HIP RESURFACING ARTHROPLASTY

Policy Number: SURGERY 087.9 T2

Effective Date: December 1, 2016

INSTRUCTIONS FOR USE

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CONDITIONS OF COVERAGE

<table>
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<tr>
<th>Applicable Lines of Business/ Products</th>
<th>This policy applies to Oxford Commercial plan membership.</th>
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<tr>
<td>Benefit Type</td>
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<td>Special Considerations</td>
<td>¹Precertification with review by a Medical Director or their designee is required.</td>
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BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

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, 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 policy, it is important to refer to the member specific benefit plan 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 treating 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 treating 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 following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies may apply.

<table>
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<tr>
<th>CPT Code</th>
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<tr>
<td>27125</td>
<td>(when billed for hip resurfacing) Hemiarthroplasty, hip, partial (e.g., femoral stem prosthesis, bipolar arthroplasty)</td>
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<td>27130</td>
<td>(when billed for hip resurfacing) Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft</td>
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<td>27299</td>
<td>Unlisted procedure, pelvis or hip joint</td>
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HCPCS Code Description

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

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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. Metal-on-metal resurfacing hip systems consist of a trimmed femoral head capped with a metal covering. Any damaged bone and cartilage within the socket are removed and replaced with a metal acetabular component.

**CLINICAL EVIDENCE**

Brooks (2016) studied the safety and effectiveness of one hip resurfacing device (Birmingham Hip Resurfacing) in a single-surgeon series. One thousand three hundred and thirty three cases were followed for a mean of 4.3 years using a prospective, observational registry. The mean patient age was 53.1 years; 70% were male and 91% had osteoarthritis. There were no dislocations or femoral component loosening. Complications included two femoral neck fractures (0.15%), one socket loosening (0.08%), three deep infections (0.23%), and three cases of metallosis (0.23%). There were no destructive pseudotumours. Overall survivorship at up to 5.7 years was 99.2%. Aseptic survivorship in males under the age of 50 was 100%.

Azam et al. (2016) conducted a retrospective clinical study to evaluate the long term survivorship and functional outcome of Birmingham hip resurfacing surgery in osteoarthritic hip patients performed by a single surgeon. The study included 222 patients (244 hips); 153 males and 69 females and the mean follow-up was 12.05 years. Revision surgery was considered the end point of survivorship. The overall survival was 93.7 %. Survival in males was 95.43 % while in females it was 89.86 %. Failure was seen in 14 patients (16 hips), which included seven female (10.14 %) and seven male (4.57 %) patients. Failure of femoral components due to aseptic loosening and varus collapse was seen in eight patients after a mean 9.6 years. Metal allergy was seen in three patients (five hips); all of them were female of which two had bilateral resurfacing. Other complications included femoral neck stress fractures in two patients and acetabular component loosening in one patient. The authors stated that if patient selection is judiciously done and surgical technique is meticulously followed, hip resurfacing offers acceptable survivorship, satisfactory range of motion and enables patients to resume high demand activities including sports. They further suggest that improvements in the bearing surfaces and design might alleviate concerns posed by high serum metal level and provide options that continue to benefit younger patients.

Koutras et al. (2015) performed a systematic review to investigate the effect of total hip resurfacing arthroplasty (HRA) on general health-related quality of life (HRQOL) and disease/hip-specific measures. Original studies published after 2000, enrolling at least ten skeletally mature patients with a minimum follow-up of 6 months were considered. The study included 1898 patients (2123 HRA) and the mean follow-up duration was 4 years. The physical component score and mental component score of the 2-Item Short Form Health Survey (SF-12), and the EuroQol-5D improved significantly. The disease-specific quality of life outcomes as measured with the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) global score and the subscales of pain, stiffness and function were also significantly improved. The functional status of the University of California, Los Angeles activity scale was improved postoperatively and the patient satisfaction was favorable. The mean conversion rate to total hip arthroplasty (THA) was 3.7% and the mean rate of an additional operation (excluding conversions to THA) was 1.1%. The authors concluded that total hip resurfacing arthroplasty exhibited substantial improvements in generic and hip or disease-specific HRQOL measurement scales and that the following factors have an increasing negative influence: comorbidities, medication, psychological and social factors, and implant complications. They further state that the quality of the studies included in this review reflects the deficiencies of the available evidence. Future studies need to further assess factors affecting quality of life following HRA.

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.

A 2015 Hayes Technology Report concluded that for patients with osteoarthritis who are younger than 65 years old, hip resurfacing arthroplasty (HRA) and total hip replacement (THR) offer comparable effectiveness. Safety is also generally comparable between the 2 procedures with different risk profiles for certain complications for the respective treatments. Femoral head diameter size may be an important factor in determining revision risk, and women may be at greater risk for revision with HRA than THR. The report further recommends that patients with MoM implants, whether HRA or THR, must be monitored regularly to ensure safety with regard to metal ion levels and debris (Hayes, 2015).

A 2015 ECRI Health Technology Hotline Response concluded that metal-on-metal (MOM) total hip resurfacing, designed as an alternative to total hip replacement (THR) for patients with severe chronic hip pain from arthritis, is
primarily intended for active patients younger than 60 years of age who would be expected to need more than one THR during their lifetime. Hip resurfacing is more conservative than THR because it preserves femoral bone stock, which may be advantageous when a future THR is needed (ECRI, 2015).

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 authors concluded 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 (WHSACA, 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-term (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.

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 both 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 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.

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.

Girard et al. (2006) performed a randomized study comparing the THR with Durom total HRA. 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.

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

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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.

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

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.

Newman et al. (2008) reported functional outcomes after metal-on-metal (MoM) 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, outcome was poor with persistent pain, reduced hip flexion (mean, 94.46 degrees ±12.7 degrees), decreased strength, restricted walking, and functional limitations.

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 (HHS). 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.

A National Institute for Health and Care Excellence (NICE) 2014 Technology Appraisal Guidance report 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 recommended prostheses for resurfacing arthroplasty as a treatment option for individuals with 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).

**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 HRA patients have a higher risk of surgical revision surgery than THR 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 HRA 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 HRA 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 August 31, 2016)

The Cormet Hip Resurfacing System received FDA approval in July 2007 and is intended for use in HRA 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 August 31, 2016)

The CONSERVE Plus Hip system received FDA approval on November 3, 2009 and is intended for use in HRA 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.


In January 2013, the FDA issued a safety communication regarding the ongoing concern related to adverse events associated with increased blood levels of cobalt and chromium following implant of MoM systems. The communication acknowledged reports in the medical literature of the potential for systemic effects of elevated metal ion levels resulting from device wear in MoM hip. At this time, however, the current body of evidence is insufficient to identify any specific metal ion levels that would cause adverse effects (FDA, 2013).
The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2016T0503L]


California Technology Assessment Forum. Metal on Metal Hip Resurfacing as an alternative to Total Hip Arthroplasty. October 2011.


Fink Barnes LA, Johnson SH, Patrick DA Jr. Metal-on-metal hip resurfacing compared with total hip arthroplasty: two to five year outcomes in men younger than sixty five years. Int Orthop. 2014 Sep 25.


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| 12/01/2016 | • Reformatted and reorganized policy; transferred content to new template  
• Updated benefit considerations; added instruction to check the member specific benefit plan document and any federal or state mandates, if applicable, before using this policy  
• Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references; no change to coverage rationale or lists of applicable codes  
• Archived previous policy version SURGERY 087.8 T2 |