HIP RESURFACING ARTHROPLASTY

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COVERAGE RATIONALE

Hip resurfacing arthroplasty (HRA) with U.S. Food and Drug Administration (FDA) approved devices is proven for the treatment of hip disease in patients who are younger than age 65 and who meet 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, but are likely to live longer than a conventional total hip replacement (THR) is expected to last.

Hip resurfacing arthroplasty (HRA) is unproven 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 total hip replacement in other patient populations.
BACKGROUND

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. The procedure is primarily intended for active patients who would be expected to have to undergo more than one THR during their lifetimes. The procedure involves removing diseased bone and cartilage from the surface of the femoral head and the acetabulum; fitting the femoral head with a short-stemmed cap; lining the acetabulum with a cup; and replacing the acetabular component with a prosthesis.

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

CLINICAL EVIDENCE

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-ups 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 the evidence base included numerous methodological flaws including the high levels of statistical heterogeneity, limited use of power calculations and poor 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 follow total HRA were as good as or better than THR, and that there was an increased risk of heterotopic ossification, aseptic loosening and revision following HRA.

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 total hip replacement. 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 randomized controlled trial 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 2 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 2 years. Limitations included unblinded study design and need for long term follow-up.

Vendittoli et al. (2006) performed a prospective randomized clinical trial comparing total hip replacement and M-M total hip resurfacing arthroplasty in patients aged < 65 years. Revision was required for 1 hip in the total hip replacement group due to recurrent dislocation and 2 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 present 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 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 THA, 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

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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) 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%, 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 females and 1.3% of males 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 (2011) concluded that although published evidence is limited, metal on metal total hip resurfacing may offer an appealing option to patients younger than 60 years of age with severe hip pain from arthritis that are no longer responding to medical management and are seeking a surgical alternative less radical than total hip replacement.
BlueCross and BlueShield Association (BCBSA) published a TEC assessment on metal-on-metal total hip resurfacing (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.

National Institute for Health and Clinical Excellence (NICE) published a guidance report in (reviewed in 2005) on the use of metal on metal total hip resurfacing arthroplasty. They state that hip resurfacing arthroplasty is one option for patients with advanced hip disease who would otherwise receive, and most likely outlive, a conventional primary total hip replacement. In considering hip resurfacing arthroplasty, it is recommended that surgeons take into account activity levels of potential recipients and bear in mind that the current evidence for the clinical and cost effectiveness of M-M hip resurfacing arthroplasty is principally in individuals less than 65 years of age.

Professional Societies

American Academy of Orthopaedic Surgeons (AAOS): A 2009 overview of metal-on-metal hip resurfacing found the following:

- 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.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

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

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](http://www.accessdata.fda.gov/cdrh_docs/pdf4/P040033b.pdf). Accessed September 26, 2011

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](http://www.accessdata.fda.gov/cdrh_docs/pdf5/P050016b.pdf). Accessed September 26, 2011
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.


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.

**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) for THRA do not exist at this time. (Accessed September 15, 2011)

**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.

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<td>S2118</td>
<td>Metal-on-metal total hip resurfacing, including acetabular and femoral components</td>
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**REFERENCES**


Vendittoli PA, Lavigne M, Roy AG, Lusignan D. A prospective randomized clinical trial comparing metal-on-metal total hip arthroplasty and metal-on-metal total hip resurfacing in patients less than 65 years old. Hip International. 2006; 16(2):S73-S81.

### POLICY HISTORY/REVISION INFORMATION

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| 12/01/2011 | • Updated description of services to reflect most current clinical evidence and references; no change to coverage rationale or lists of applicable CPT and HCPCS codes  
• Archived previous policy version 2010T0503F |