Title

Total Hip Resurfacing

When services are covered

We cover metal-on-metal total hip resurfacing with FDA-approved device systems as an alternative to total hip replacement in patients who are candidates for total hip replacement and who are likely to outlive a traditional prosthesis and who do not have contraindications for total hip resurfacing.[1]

When services are not covered

We do not cover all other types and applications of total hip resurfacing because they are considered investigational as they do not meet our Medical Technology Assessment Guidelines, #350.[1]

Policy Guidelines[1]

The FDA listed several contraindications for total hip resurfacing. **These contraindications include** (not a complete listing) the following items:

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

Individual consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. For consideration of an individual patient, physicians may send relevant clinical information to:

For services already billed	Prior to performance of service
Blue Cross Blue Shield of Massachusetts Provider Appeals P. O. Box 986065 Boston, MA 02298	Blue Cross Blue Shield of Massachusetts Case Creation/Medical Policy One Enterprise Drive Quincy, MA 02171 Tel: 1-800-327-6716 Fax: 1-888-641-5330

Managed care guidelines

- All specialist visits require a referral for Medicare HMO Blue.
- For all other Managed Care plans, any specialist requires a referral, except for visits performed by OB/GYN specialists.
- Except as above, referrals to a specialist are required.
- Authorization is required.

Indemnity guidelines

- Authorization is required.

Coding information

Procedure codes are from current CPT, HCPCS Level II, Revenue Code, and/or ICD-9-CM manuals, as recommended by the American Medical Association, Centers for Medicare and Medicaid Services and American Hospital Associations. Blue Cross Blue Shield Association national codes may be developed when appropriate.

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

- HCPCS Level II code S2118, metal-on-metal total hip resurfacing, including acetabular and femoral components, effective 10/1/08
- Use ICD 9- Procedure code 00.85 Resurfacing hip, total, acetabulum and femoral head
- **Use ICD 9-Diagnosis code 715.15,** Primary localized osteoarthrosis, pelvic region and thigh
- **Use ICD 9-Diagnosis code 715.25,** Secondary localized osteoarthrosis, pelvic region and thigh
- **Use ICD 9-Diagnosis code 715.35,** Localized osteoarthrosis not specified whether primary or secondary, pelvic region and thigh
- **Use ICD 9-Diagnosis code** 733.42, Aseptic necrosis of head and neck of femur

Policy update history

Policy #046 issued 2/1/08. 8/07 updated to include coverage for total hip resurfacing based upon the 2007 BCBSA National Policy which considers this surgical procedure medically necessary. Coverage is effective 2/1/08. Reviewed 7/08 MPG- orthopedics, no changes in coverage were made. Updated 8/08 based on BCBSA policy #7.01.80 with no change in policy statement and references added. Reviewed 7/08 MPG- orthopedics, no changes in coverage were made. 9/30/08, coding section updated to reflect new HCPCS Level II code for hip resurfacing, effective 10/1/08. 3/09, Updated based on BCBSA policy # 7.01.80 with no change in policy statement. Reviewed 7/09 MPG - Orthopedics, Rehabilitation Medicine, and Rheumatology, no changes in coverage were made.

Scientific background, Rationale and References

[1] Based upon the 2007 BCBSA National Policy # 7.01.80.

Initially, there was very minimal published medical literature regarding total hip resurfacing, using either polyethylene components or metal-on-metal designs. Some of the early reports used 2 different types of prostheses, the Wagner and McKinn. The acetabular components of the McKinn prosthesis showed progressive loosening. Based on these results, the investigators developed new design and implantation techniques leading to the Conserve®Plus device.

During subsequent policy updates, review of the peer-reviewed literature identified additional articles. Amstutz and colleagues reported on 355 patients who received 400 metal-on-metal surface arthroplasties using the Conserve Plus device with a follow-up of 2—6 years. (1) Of the 355 patients, 54% had University of

California Los Angeles activity scores greater than 7; and at 4 years, 94.4% of components survived per Kaplan-Meier survivorship curves. Revision of the surface arthroplasty to total hip replacement occurred in only 12 (3%) hips. Beaule and colleagues reported on metal-on-metal surface arthroplasty in 56 patients with Ficat stage III and IV osteonecrosis. (2) Only 2 hips required total hip replacement during follow-up of an average of 4.9 years. While these study results are promising, the authors noted need for further evaluation to determine appropriate patient selection criteria and the most beneficial techniques for femoral bone preparation and fixation.

Some outcomes have been reported with the Birmingham hip resurfacing device suggesting medium to long-term durability. Treacy and colleagues reported the 5-year survival of Birmingham hip resurfacing arthroplasty in 144 patients was 98% overall. (3) Failure of the femoral component occurred in 3 cases within the first 2 years of the study (2 infections and 1 fracture) in the Treacy study. Shimmin and Back reviewed 3,497 Birmingham hip resurfacings performed by 89surgeons between April 1999 and April 2004.(4) The authors reportedthe incidence of femoral neck fracture was 1.46% (50 of 3,497) and the mean time to fracture was 15.4 weeks. Glyn-Jonesand colleagues evaluated the stability of Birmingham hip resurfacingarthroplastiesby radiographicanalysisin 22 hips in 20 patients. (5) At 24 months, migration of thehead of thefemoral componentwas not statistically significant (0.2 mmtotal three-dimensional).

In support of the application for FDA premarket approval, clinical data on 2,385 Birmingham hip resurfacings performed by a single surgeon in the United Kingdom was presented to the FDA Orthopaedic and Rehabilitation Devices Panel (Panel) in September 2005. Of the 2,385 cases, 27 revisions were required including 10 revisions due to femoral neck fracture, 6 for femoral head collapse, 1 for dislocation, 2 for avascular necrosis, and 8 for infections.

2006 update
Since the last update, the Birmingham hip resurfacing device has been granted PMA by the FDA. However, there still are ongoing questions about the intermediate and long-term durability of this device compared with standard hip arthroplasty. There also are continued questions about short-term revisions (due to femoral neck fracture) and also potential concerns about shedding of metal particles. Thus the policy statement is unchanged.

2007 update
In February 2007, a TEC Assessment reviewed evidence published through January 2007 on metal-on-metal total hip resurfacing. (6) The Assessment evaluated studies of individuals with advanced degenerative joint disease of the hip who received a hip resurfacing (HR) device and that reported data on short- and long-termclinical outcomes, including benefits and harms, as an alternative to total hip replacement (THA). TEC identified 1 randomized controlled trial, (7) and 12 uncontrolled series. (8-16) For the assessment, these published trials, the FDA PMA submission data (17), and information from the Australian Orthopedic Association (AOA) National Joint Replacement Registry (18) were evaluated.

In the randomized controlled trial (100 patients in each group), the HR device was implanted in patients who were younger (49 to 51 years old) and had a smaller body mass index (17 to 49 kg/m 2) than those who usually undergo THA (>= 65 years old), and the majority comprised male patients (63% to 68%) who were being treated for advanced osteoarthritis (75%). (7) In comparison to THA, the perioperative differences demonstrate that HR reduced the surgical time ($p<0.001$), decreased the hospital stay (5 vs. 6.1 days), and used a longer incision ($p<0.001$). Both groups had a similar incidence of complications; with 2 deep vein thromboses per group, and 2 THA patients had deep infections without recurrence. At 12 months' follow-up, 2 patients in the THA group required revision for femoral head aseptic loosening at 6 and 9 months, respectively, and none experienced femoral head fracture. Both groups showed substantial improvement over preoperative status on functional outcomes measures and reported satisfaction or very high satisfaction scores (98%).

The 12 published series reporting clinical outcomes after HR included a total of 2,076 patients (71% male) who ranged in mean age from 34 to 57 years. Although most patients had advanced osteoarthritis (80%), some studies enrolled patients with femoral head osteonecrosis (10, 13) and/or developmental hip dysplasia (3), and only 3 used the FDA-approved Birmingham device. (2, 8, 9) Mean follow-up was approximately 3 years, but ranged from less than 1 year (14) to 12 years, (13) and the proportion of enrolled patients available at follow-up was generally 90% to 100%, (8, 12, 13) but as low as 22%. (16) Of the 2,076 patients treated with HR, 57 (2.7%) required revision to THA, most for femoral neck fracture or component loosening; the proportion of cases that required revision ranged from 0.3% (12) to 22% (14).

Although the 12 published series exhibit little consistency in outcomes measures used, the aggregate data suggest that HR-treated patients who do not require a revision have substantial symptomatic improvement of pain and hip function over presurgical status. Moreover, HR patients report substantial activity levels and returning to playing sports after treatment. (3, 12)

The TEC Assessment also evaluated the patient safety and effectiveness data considered for the FDA submission of the Birmingham device from the McMinn Cohort (17), which are supported by unpublished data on 3,374 hips implanted by 140 surgeons and published reports on more than 3,800 hips treated by multiple surgeons (Worldwide Cohort).

The McMinn Cohort included 71% men and 29% women, ranging in age from 13 to 86 years (average, 53 years). The predominant diagnoses for treatment were advanced osteoarthritis (75%), dysplasia (16%), avascular necrosis (4%), inflammatory arthritis (2%), and "other" (3%). The Worldwide Cohort was reportably comparable. At the 5-year follow-up, a total of 76 revisions to THA were reported (2.26%), resulting from events similar to those reported for the McMinn Cohort. (17) In addition, results of the Oswestry-Modified Hip Scores for both cohorts showed improvement at 5 years from a baseline mean of 60.1 to 94.8 (58%). With regard to long-term safety, literature summaries provided to the FDA demonstrated increased serum and urinary concentrations of metal ions postoperatively in patients with THA, particularly after metal-on-metal procedures, but data show no conclusive evidence of significant detrimental effects. (17)

The AOA registry's annual report for 2006 is based on 92,210 primary THAs, including 84,872 primary THAs, 7,205 metal-on-metal HRs, and 133 thrust-plate procedures. (18) Some of these data may include patients reported in the Worldwide Cohort. In general, resurfacing procedures were used more often in men than women (73% vs. 56%) and in younger patients (90% <65 years) than primary THA. At 5 years' follow-up, conventional THAs showed fewer revisions (1.7%) than HRs (2.2%), but THA prostheses may not be reflected, and no patient demographic characteristics were available for comparison.

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

There is minimal published medical literature regarding total hip resurfacing using polyethylene components.

2008 Update
A search of the MEDLINE database for the period of February 2007 through April 2008 did not identify any literature that would prompt a change in the policy statements.

Mont et al described the results of the FDA-approved Investigational Device Exemption (IDE) prospective, multicenter trial of the Conserve Plus hip resurfacing system. (19) The investigators identified a number of risk factors for complications after the first 292 procedures; these included the presence of cysts, poor bone quality, leaving reamed bone unconvered, minimizing the size of the femoral component to conserve acetabular bone, and malpositioning of the acetabular shell. Modification of inclusion criteria and surgical technique in the next 906 patients (1,016 hips) resulted in a decreased rate of femoral neck fracture (from 7% to <1%). There was also a trend toward reduction in other types of complications (e.g., nerve palsy was reduced from 4.1% to 2.2% and loosening of the acetabular cup from 3.4% to 1.9%). No differences between the two cohorts were observed in the Harris hip score (93 vs. 93) or the SF-12 (e.g., physical component score of 50 vs. 50). Another study compared gait analysis in 15 patients following successful HR with 15 patients who had a successful THA using a small femoral head, and with 10 patients who had osteoarthritis and 30 age- and sex-matched controls from a normative database. (20) Walking speed (1.3 m/s) was found to be faster in the HR group than in the THA (1.0 m/s) or osteoarthritis groups (1.0 m/s). Measurement of abductor and extension moments found that the gait of patients following HR was closer to normal than the gait of patients who had undergone THA.

It is thought that revision of HR to THA might have better outcomes than THA-THA revision, but little data support this assumption. One recent study compared outcomes in 20 patients (from a group of 844 primary HRs performed between 1997 and 2005) requiring conversion surgery for failed HR (5 femoral neck fractures and 16 with femoral component loosening) with outcomes in 58 patients of similar age (64 hips from patients <65 years old) who had been treated with a primary THA by the same surgeon during the same period. (21l) The acetabular component was retained in 18 hips (and revised in 3 because the matching femoral head was not available at the time of surgery). The study found no significant difference in operative time between conversion (178 minutes, range of 140 to 255) and primary THA (169 minutes, range of 110 to 265), or in complication rates between the 2 groups (14% vs. 9%, respectively). At 1 to 9 years' follow-up (average of 46 months for the HR-THA revison group and 57 months for the primary THA group) outcomes as measured by the UCLA, SF-12, and Harris hip scores were similar (e.g., Harris hip score of 92 for the revision group and 90 for the primary THA control group). Although this small study suggests that a resurfaced femoral component might be converted to THA without additional complication, larger comparative studies between HR-THA and THA-THA revisions are needed. As noted previously, long-term health outcomes (pain, function, and implant survival) following HR are not yet known; the policy statements remain unchanged.

References:

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FDA-approval status

The Buechel-Pappas Integrated Total Hip Replacement has been approved by the U.S. Food and Drug Administration (FDA) for total hip resurfacing. The weight-bearing surfaces of this device are composed of a ceramic femoral component and a polyethylene acetabular component. There has also been interest in metal-on-metal designs as a technique to reduce the debris wear particles. The Conserve®Plus (Wright Medical Technology) is a metal-on-metal design that is currently undergoing investigation as part of the FDA approval process. This trial will include 300 patients who will be followed up for a minimum of 2 years. The Cormet 2000 hemi-arthroplasty device has 510(k) marketing clearance from the FDA.

In May 2006, the FDA granted premarket application (PMA) approval to the Birmingham Hip Resurfacing (BHR) system for use in patients requiring primary hip resurfacing arthroplasty for non-inflammatory or inflammatory arthritis. This decision was based primarily on a series of 2,385 patients who received this device by a single surgeon in England. A number of post-approval requirements were agreed to including the following items:

- Study longer term safety and effectiveness through 10-year follow-up of the initial 350 patients in the patient cohort that was part of the PMA.
- Study the "learning curve" and the longer term safety and effectiveness of the BHR in the United States by studying 350 patients at up to 8 sites where clinical and radiographic data will be assessed annually through 5 years and at 10 years. Also, determine cobalt and chromium serum concentration and renal function in these patients at 1, 4, and 10 years.
- Implement a training program to provide clinical updates to investigators.

Device Name	Composition	FDA Status
Buechel-Pappas Integrated Total Hip Replacement	Ceramic femoral component, polyethylene acetabular component	FDA approved
Conserve®Plus	Metal femoral and acetabular component	Not FDA approved; investigated under an investigational device exemption (IDE)
Cormet 2000	Metal femoral and acetabular component	FDA approved
Birmingham hip resurfacing device	Metal femoral and acetabular component	FDA approved

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