

Health Technology Clinical Committee

Findings and Coverage Decision

Topic: Hip Resurfacing

Meeting Date: November 20th, 2009

Final Adoption: May 14th, 2010

Number and Coverage Topic

20091120B – Hip Resurfacing

HTCC Coverage Determination

Hip Resurfacing is a **covered benefit with conditions.**

HTCC Reimbursement Determination

❖ **Limitations of Coverage**

- Total hip resurfacing arthroplasty as medically necessary as an alternative to total hip arthroplasty when all of the following conditions are met:
 - Diagnosis of osteoarthritis or inflammatory arthritis;
 - Individual has failed nonsurgical management and is a candidate for total hip arthroplasty; and
 - The device is FDA approved

❖ **Non-Covered Indicators**

- Not Applicable

❖ **Agency Contact Information**

Agency	Contact Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-762-6004
Health and Recovery Services Administration	1-800-562-3022

Health Technology Background

The Hip Resurfacing topic was selected and published in December 2008 to undergo an evidence review process. Total Hip Arthroplasty (THA) was originally designed for older, relatively inactive patients. Historically, 60 to 80 years of age. The need for hip prostheses in younger patients is increasing. By 2011, more than half of all THA's are estimated to be < 65 years. Total Hip Replacement or Total Hip Arthroscopy (THA) is a proven, effective technique that results in excellent pain relief and function in most patients for many years. Hip resurfacing has had its ups and downs—with implants that were introduced in the early 1990s, then withdrawn from the market, and reintroduced a decade later.

History of Hip Resurfacing (HR): Initial design (1970-80s) abandoned due to high failure rates caused by metal-on-polyethylene design. New design (1990s) includes high-carbide cobalt chrome metal-on-metal bearings and hybrid fixation (cemented femoral component, uncemented acetabular component). Design of HR versus THA: THA – femoral head removed and replaced with a metal prosthetic ball; HR – surface of the femoral head is removed and replaced with a metal cap inserted into the femoral shaft; and both HR and THA replace the acetabulum with a metal cup.

Theoretical advantages of HR versus THA -- reduction in stress-shielding as more normal femoral loads are maintained; improved function due to preservation of femoral head; lower morbidity at time of revision surgery than that which occurs in THA patients; lower risk of dislocation; better replication of normal anatomy; and greater range of motion. Indication for HR (FDA) -- Adults who may not be suitable for THA due to increased risk of ipsilateral hip joint revision as a result of their younger age and/or increased activity level, and who have pain due to: Non-inflammatory degenerative arthritis (e.g., osteoarthritis, traumatic arthritis, avascular necrosis with < 50% involvement of the femoral head, or developmental hip dysplasia), or inflammatory arthritis (e.g., rheumatoid arthritis). Contraindications for HR (FDA) – Infection or sepsis; skeletal immaturity; conditions that could compromise implant stability or postoperative recovery (i.e., vascular insufficiency, muscular atrophy, neuromuscular disease); inadequate bone stock to support the device, including: severe osteopenia or osteoporosis, severe avascular necrosis (> 50% of the femoral head), and multiple femoral neck cysts (< 1 cm in diameter); females of child-bearing age; BMI > 35; known or suspected metal sensitivity; moderate or severe renal insufficiency; and immunosuppression (i.e., AIDS, those receiving high doses of corticosteroids).

Unlike total hip replacement (THA), hip resurfacing does not involve the removal of the femoral head and neck or removal of bone from the femur. Rather, the head, neck and femur bone is preserved in an effort to facilitate future surgery should it be necessary. Hip resurfacing is anatomically and biomechanically more similar to the natural hip joint. Purported benefits include: increased stability, flexibility and range of motion; risk of dislocation; lower and higher activity level possible with less risk than THA; and younger patients needing full joint replacement that are expected to out-live the full replacement may benefit from symptom relief and more bone preservation to tolerate a subsequent replacement surgery later. Questions remain about: unknown longevity and durability of the procedure; reported higher failure rates; appropriate patient selection criteria (e.g.,

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age, gender, tried and failed therapies); impact on long term health outcome; and health system impacts of a surgery designed to delay but not eliminate need for later surgery.

In September 2009, the HTA posted a draft and then followed with a final report from a contracted research organization that reviewed publicly submitted information; searched, summarized, and evaluated trials, articles, and other evidence about the topic. The comprehensive, public and peer reviewed, Hip Resurfacing report is 138 pages, and identified a relatively large amount of literature.

An independent group of eleven clinicians who practice medicine locally meet in public to decide whether state agencies should pay for the health technology based on whether the evidence report and other presented information shows it is safe, effective and has value. The committee met on November 20th, reviewed the report, including peer and public feedback, and heard agency comments. Meeting minutes detailing the discussion are available through the HTA program or online at <http://www.hta.hca.wa.gov> under the committee section.

Archived

Committee Findings

Having considered the evidence based technology assessment report and the written and oral comments, the committee identified the following key factors and health outcomes, and evidence related to those health outcomes and key factors:

1. Evidence availability and technology features

The committee concludes that the best available evidence on Hip Resurfacing has been collected and summarized.

- Severe hip disease is a prevalent and burdensome disease. Current treatment using surgical total joint replacement (THA) is effective and well established in older patients (aged 60 to 80). However, for younger patients the risk of the artificial joint wearing out, and of its' durability for more active lifestyles has lead to need for alternative.
- Hip resurfacing (HR) acts to preserve the bone and is thought to be more durable because the femoral head and neck are preserved, thus it may be an ideal "bridge" therapy to delay the need for later hip replacement. HR a more invasive and technically difficult surgery than THA (size and placement of cup; and soft tissue disruption).
- In general, the committee noted that for a significant and invasive surgery, there is a paucity of high quality evidence (three RCTs are small and methodologically challenged and apply to non-FDA approved device) while remaining studies are mostly retrospective cohort studies. Country wide data registries may provide the best information to date on critical issue of revision and complications. Committee agreed with evidence suggesting that more experienced surgeons have better outcomes and fewer complications, but that training for device implantation is not uniform or reviewed for quality.
- The committee acknowledged that HR has had several iterations, being introduced and then discredited earlier, and now re-introduced with new materials and techniques, and that modern techniques were reviewed here, though lessons from earlier introduction may apply. The committee noted that even modern era HR has had dissemination issues: the Durom was recalled by the FDA due to mislabeling in 2007 and subsequently in 2008, the manufacturer, Zimmer, pulled the device due to surgeons not having adequate training for implantation (this is the device used in the RCTs).

2. Is the technology safe?

The committee concludes that the comprehensive evidence reviewed showed insufficient evidence to conclude that HR is safe: with five committee members voting unproven; three committee members voting equivalent; and two less safe. Key factors to the committee's conclusion included:

- The committee agreed that the main safety question was whether HR provided lower morbidity, lower revision, or lower other complications. In general, evidence demonstrates a higher revision rate; and no difference in morbidity and complications.
- The primary concern is the revision rates, but also identified femoral neck fracture (which leads to revisions) as another important complication.
 - Femoral neck fractures: a primary theoretical advantage of HR is the durability and preservation of the hip bones, so the complication of a femoral

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neck fracture undermines this advantage and generally requires revision with THA. Femoral neck fracture rates ranged from .4 to 2.6% in short term and up to 5.4% in mid-term follow up. There may be an association with appropriate cup size and with smaller femoral component sizes (generally female) more prone to fracture.

- Revision rates: overall evidence demonstrates higher revision rates in HR than THA; ranging from 0% to 7.8% in HR group and 0% to 4.3% in THA group. Rates in the Australian Joint Replacement Registry, with longest follow up (7 yr) and includes 125,004 THA and 10,263 HR, indicates that the cumulative revision rate for HR is 4.6% and THA is 3.4%. Analysis also revealed a significant difference in dysplasia patients' revision rates: 2% to 3% THA and 5% to 14% HR. Committee agreed that when needed, revision in THA patients is a more invasive and difficult surgery (with potential for more complications) than HR revision.
- The committee acknowledged the concern regarding metal ions and agreed with the evidence report that more data and longer term information is needed. However, this issue is present with both THA and HR devices that are metal on metal.
- The committee agreed that most perioperative adverse events stemmed from the technique of implantation itself, and reinforced the adequacy of training and experience.

3. Is the technology effective?

The majority of committee members conclude that the comprehensive evidence reviewed indicates that Hip Resurfacing is equivalent to THA.

- The committee agreed that one key assumption is that patients cannot be active with THA; the other key assumption is that relatively younger patients may outlive a prosthesis and will have an easier second surgery (THA) if the first surgery is an HR.
- The physical procedure does conserve bone; clinical expert experience indicates that a second THA surgery is much more complicated than a THA surgery after an HR.
- Overall, there is agreement with the evidence report showing low level data of short to mid- term time frame that functional and pain outcomes are same and activity scores slightly higher for HR.
- From evidence, data demonstrates two procedures are equivalent with tradeoffs in different benefits. Both surgeries appear equivalent at alleviating pain and improving function from severe hip disease.
- HR is a more complicated surgery with higher (double) revision rates, but if successful, can provide a better opportunity for a second THA surgery and may provide slightly better activity level.
- THA is surgically less complex with lower complication and revision rate, but second surgeries, if needed are more difficult and complicated and activity level may be more limited.
- Committee members expressed concern that endorsement of HR may lead to encouragement of more surgery and in patients not previously being considered for surgery. Comparative trials and evidence are limited to patients that would otherwise be treated with THA.

4. Is the technology cost-effective?

The committee split on whether the evidence sufficiently addressed cost: with five members voting that costs are equivalent and five voting unproven (not sufficient data yet).

- Committee acknowledged that the limited agency utilization experience to date indicated that HR and THA are equivalent in cost.
- Committee agree with the evidence report that most cost studies utilized outdated revision rates (generally lower than showed for HR) and this significantly impacts cost analysis.

5. Evidence about the technology's special populations, patient characteristics and adjunct treatment

- The committee discussed selected population and patient characteristics of gender and component size, as well as dysplasia patients within the revision context.

6. Medicare Decision and Expert Treatment Guidelines

Committee reviewed and discussed the Medicare coverage decision and expert guidelines as identified and reported in the technology assessment report.

- Centers for Medicare and Medicaid Services (clarification at meeting) – does not have a national coverage decision. One local Wisconsin carrier covers HR as medically necessary in select patients requiring primary hip resurfacing due to the following conditions:
 - Non-inflammatory arthritis (degenerative joint disease) such as osteoarthritis, traumatic arthritis, avascular necrosis, or dysplasia / developmental dislocation of the hip.
 - Inflammatory arthritis, such as rheumatoid arthritis.
- Guidelines – a search of the National Guideline Clearinghouse (NGC) returned zero potential guidelines on HR. No clinical guidelines related to HR procedures were found when the NGC database was searched.
 - Additional searching of the AAOS web site did not yield any guidelines specific to HR.
- The following provides a summary of the National Institute for Health and Clinical Excellence (NICE) guidelines:
 - The NICE hip resurfacing arthroplasty is recommended as one option for people with advanced hip disease who would otherwise receive and are likely to outlive a conventional primary total hip replacement.
 - Although there is sufficient short-term evidence to conclude that MOM hip resurfacing can be as effective as total hip replacement (THA) in patients less than 55 years, NICE acknowledges that there are no randomized controlled trials comparing MOM hip resurfacing arthroplasty with conventional THA. There are also no long-term (> 10 years) observational data on the outcomes associated with MOM HR devices.

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Committee Decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, agency and state utilization information. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. The committee concluded that there is sufficient evidence to cover with conditions the use of Hip Resurfacing as an alternative to total hip arthroplasty. Primary considerations were that a majority of committee members concluded evidence demonstrated that HR is equivalent to THA in treating severe hip disease. With equivalence in efficacy at treating the condition demonstrated, this procedure is one where the trade-offs between THA and HR are between potentially better activity levels but higher risk of revision and complications, and these trade-offs should be discussed by patient and physician, within certain limits (the conditions imposed). Cost was not a significant factor.

Based on these findings for Hip Resurfacing, the committee voted 10 to 0 for coverage with conditions.

Hip Resurfacing is a covered benefit with conditions. Total hip resurfacing arthroplasty as medically necessary as an alternative to total hip arthroplasty when all of the following conditions are met:

1. Diagnosis of osteoarthritis or inflammatory arthritis;
2. Individual has failed nonsurgical management and is a candidate for total hip arthroplasty; and
3. The device is FDA approved

Health Technology Clinical Committee Authority

Washington State's legislature believes it is important to use a scientific based, clinician centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority, through its Health Technology Assessment program to gather and assess the quality of the latest medical evidence using a scientific research company and take public input at all stages. Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State Health Technology Clinical Committee (HTCC), determines how selected health technologies are covered by several state agencies. RCW 70.14.080-140. These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases their decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. Selected technologies are considered for re-review on the basis of new evidence.