

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE:

HIP RESURFACING

Initial HERC approval 08/09/2012

Reaffirmed 11/13/2014

This coverage guidance was created under HERC's 2012 coverage guidance process and does not include strength of recommendation, a GRADE-informed framework or coverage guidance development framework.

As a part of the normal evidence review process, the Health Technology Assessment Subcommittee reviewed new evidence in September, 2014 (see Appendix A) and found two new systematic reviews and one guideline from trusted sources. They determined that this guidance is supported by the updated literature scan. However, the guidance's recommendation language has been altered to be consistent with that of more recent guidances.

HERC Coverage Guidance

Hip resurfacing is recommended for coverage for patients who are likely to outlive a traditional prosthesis and who would otherwise require a total hip replacement, and should only be done by surgeons with specific training in this technique.

The following criteria should be required:

- Diagnosis of osteoarthritis or inflammatory arthritis;
- Individual has failed nonsurgical management; and
- The device is FDA approved

Patients who are candidates for hip resurfacing must not have FDA contraindications including:

- Patients with active or suspected infection in or around the hip joint, or sepsis
- Patients who are skeletally immature
- Patients with any vascular insufficiency, muscular atrophy, or neuromuscular disease severe enough to compromise implant stability or postoperative recovery
- Patients with bone stock inadequate to support the device, including severe osteopenia or a family history of severe osteoporosis or osteopenia
- Patients with osteonecrosis or avascular necrosis with >50% involvement of the femoral head
- Patients with multiple cysts of the femoral head
- Females of childbearing age
- Patients with known moderate-to-severe renal insufficiency
- Patients who are immunosuppressed with diseases such as AIDS or persons receiving high doses of corticosteroids
- Patients who are severely overweight
- Patients with known or suspected metal sensitivity.

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Health Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

EVIDENCE SOURCES

Washington State Health Care Authority Health Technology Assessment Program. (2009). HTA final report: Hip resurfacing. Olympia, WA: Health Technology Assessment Program.
[Retrieved from http://www.hta.hca.wa.gov/documents/hip_final_report_102309.pdf](http://www.hta.hca.wa.gov/documents/hip_final_report_102309.pdf)

The summary of evidence in this document is derived directly from this evidence source, and portions are extracted verbatim.

SUMMARY OF EVIDENCE

Clinical background

Total hip arthroplasty is a well-established and effective treatment for severe degenerative diseases of the hip that has historically been performed in older, relatively inactive patients between 60 and 80 years of age. Over the past decade, however, total hip arthroplasty has become increasingly common in patients under 65 years of age. As the growth of joint replacement continues in younger patients, the demand for total hip arthroplasty among patients under 65 years is expected to exceed 50% of all total hip arthroplasties by 2011, up from 44% in 2005. Younger patients receiving hip replacement often have more active life styles than those who are older, causing concern about the longevity of the implant. Evidence suggests that higher rates of implant failure occur as the age of patients receiving the implant gets younger.

Total hip resurfacing is proposed as a bone-conserving alternative to the conventional total hip arthroplasty for young and active patients after optimal medical therapy fails. In contrast to total hip arthroplasty, total hip resurfacing preserves the femoral head and neck, which may facilitate future revision surgery should it be necessary, and additionally, enable the patient to take advantage of newer technology or treatments in the future. Furthermore, hip resurfacing was

designed to more closely mimic normal joint biomechanics and load transfer, and may be associated with a lower morbidity rate at the time of revision surgery. There are currently two devices for total hip resurfacing that are FDA approved, as well as a variety of devices that have not been approved.

Evidence review

Efficacy/Effectiveness

There is moderate evidence from three small randomized controlled trials that total hip resurfacing is similar to total hip arthroplasty with respect to short-term (1 year) functional, quality of life and activity outcomes. There is low evidence from studies directly comparing total hip resurfacing with total hip arthroplasty to suggest that short-term (<5 years) patient-reported outcomes, clinician-based outcomes, and pain are similar comparing total hip resurfacing and total hip arthroplasty. Activity scores tend to be slightly higher (better) in total hip resurfacing patients. There is very low evidence from one cohort study to suggest that at an average of 5.9 years follow-up, patients treated with total hip resurfacing may have better quality of life and activity outcome scores, but similar functional scores, compared with those treated with total hip arthroplasty.

Safety

Revision: There is moderate evidence that short term revision rates are slightly higher in patients treated with total hip resurfacing compared with those treated with total hip arthroplasty. The difference in 3-year revision rates between total hip resurfacing and total hip arthroplasty in 3 registry studies range from 0.6% to 2.5% in favor of total hip arthroplasty. The difference in 1-year revision rates in one RCT is 0.9% in favor of total hip arthroplasty. The difference in short-term revision rates between total hip resurfacing and total hip arthroplasty in eight cohort studies varied: 4 favored total hip arthroplasty, 2 favored total hip resurfacing and 2 reported equal rates. There is low evidence from one large registry study that 7-year revision rates are higher in patients receiving total hip resurfacing versus total hip arthroplasty (hazard ratio = 1.42, rate difference = 1.3%). Data from one small cohort study with a mean follow-up of 5.9 years reports revision rates that are similar between total hip resurfacing and total hip arthroplasty. There is no evidence comparing long-term (> 10 years) revision rates between total hip resurfacing and total hip arthroplasty.

Other complications: Reported risks of other complications in the short-term for total hip resurfacing are generally low except for heterotopic ossification; the risk of femoral neck fractures range from 0.4–2.6%, avascular necrosis from 0.4-2%, femoral component loosening from 0-3.6%, acetabular component loosening from 0-1.8%, acetabular component migration from 0–1.9%, and femoral component migration was not detected in any hips. Heterotopic ossification rates ranged from 0-42.7%.

Learning curve threshold: A number of studies identified that the rate of major complications (including femoral neck fracture and revisions) decreases as surgeons gain experience performing total hip resurfacing. The studies suggested that experience is associated with

improved surgical technique and patient selection. However, with respect to identifying the number of procedures necessary for improved outcome, no consistent threshold was identified.

Metal ion safety: Patients with metal-on-metal total hip resurfacing are likely to experience elevated metal serum levels (Co and Cr). Concerns have been raised regarding the safety of and risks associated with prolonged exposure to metal ions, and whether such exposure may increase the risk of cancers or metabolic disorders. However, an association between total hip resurfacing and cancer or metabolic disorders has not been reported with the current length of follow-up. The results from long-term monitoring will be needed to assess the risk of metal ion exposure.

Differential efficacy or safety

There is low evidence to suggest that short-term revision rates are twice as high in patients who receive total hip resurfacing for a primary diagnosis of dysplasia compared with patients of primary osteoarthritis. The 5-year cumulative revision percent for dysplasia is four times greater in those receiving total hip resurfacing compared with total hip arthroplasty (12% vs. 3%) in one registry study. One small prognostic study supported this data, with 5.2% revision rates in dysplasia patients compared with 0% revision rates in osteoarthritic patients.

There is low evidence to suggest that short-term revision rates are slightly higher in patients who receive total hip resurfacing for a primary diagnosis of osteonecrosis compared with patients of primary osteoarthritis. The 5-year cumulative revision percent for dysplasia is two times greater in those receiving total hip resurfacing compared with total hip arthroplasty (6% vs. 3%) in one registry study and rates are the same in one small prognostic study.

There is moderate evidence from three registries that 3- and 5-year revision rates are higher in females than in males (hazard ratios range from 1.57 to 2.5). Much of the difference in rates between sexes disappeared in one study when controlling for femoral component head size; the smaller the head, the higher the failure rate.

Two low quality studies evaluated the effect of obesity on total hip resurfacing with conflicting results. One reported lower revision risk with increasing obesity, and one reported higher.

Two low quality studies evaluated the effect of the Surface Arthroplasty Risk Index (SARI) on total hip resurfacing. Both suggest a SARI score > 3 preoperatively results in an increased risk of early complications and revision.

Overall summary

There is moderate evidence that total hip resurfacing is similar to total hip arthroplasty with respect to short-term (< 5 years) functional, quality of life and activity outcomes, although the short-term revision rates are slightly higher for total hip resurfacing, particularly for women and for patients with diagnoses of dysplasia and osteonecrosis (compared to osteoarthritis).

FDA Contraindications

- Patients with active or suspected infection in or around the hip joint, or sepsis;

- Patients who are skeletally immature;
- Patients with bone stock inadequate to support the device including:
 - Patients with severe osteopenia should not receive a Hip Resurfacing procedure. Patients with a family history of severe osteoporosis or severe osteopenia;
 - Patients with osteonecrosis or avascular necrosis with >50% involvement of the femoral head (regardless of FICAT Grade) should not receive a Hip Resurfacing device;
 - Patients with multiple cysts of the femoral head (>1cm) should not receive a Hip Resurfacing device;
 - Note – In cases of questionable bone stock, a DEXA scan may be necessary to assess inadequate bone stock.
- Patients with any vascular insufficiency, muscular atrophy, or neuromuscular disease severe enough to compromise implant stability or postoperative recovery;
- Females of child bearing age due to unknown effects on the fetus of metal ion release.
- Patients with known moderate or severe renal insufficiency;
- Patients who are immunosuppressed with diseases such as AIDS or persons receiving high doses of corticosteroids;
- Patients who are severely overweight;
- Patients with known or suspected metal sensitivity (e.g., jewelry).

Procedure

Hip resurfacing

Diagnoses

Osteoarthritis of the hip

Dysplasia of the hip

Avascular necrosis of the hip

APPLICABLE CODES

| CODES | DESCRIPTION |
|------------------------------|---|
| ICD-9 Diagnosis Codes | |
| 715.15 | Osteoarthritis, localized, primary, pelvic region and thigh |

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| | |
|---|---|
| 715.25 | Osteoarthritis localized secondary involving pelvic region and thigh |
| 715.35 | Osteoarthritis, localized, not specified whether primary or secondary, pelvic region and thigh |
| 715.95 | Osteoarthritis, unspecified whether generalized or localized, pelvic region and thigh |
| 733.42 | Aseptic necrosis of head and neck of femur |
| 755.63 | Other congenital deformity of hip (joint) |
| 755.8 | Other specified anomalies of unspecified limb |
| ICD-9 Volume 3 (Procedure Codes) | |
| 00.85 | Resurfacing Hip, Total, Acetabulum And Femoral Head |
| 00.86 | Resurfacing Hip, Partial, Femoral Head |
| 00.87 | Resurfacing Hip, Partial, Acetabulum |
| 81.51 | Total Hip Replacement |
| 81.52 | Partial Hip Replacement |
| 81.53 | Revision Of Hip Replacement, Not Otherwise Specified |
| CPT Codes | |
| 27125 | Hemiarthroplasty, hip, partial (eg, femoral stem prosthesis, bipolar arthroplasty) |
| 27130 | Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft |
| 27132 | Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft |
| 27134 | Revision of total hip arthroplasty; both components, with or without autograft or allograft |
| 27137 | Acetabular component only, with or without autograft or allograft |
| 27138 | Femoral component only, with or without allograft |
| HCPCS Codes | |
| S2118 | Metal-on-metal total hip resurfacing, including acetabular and femoral components |

APPENDIX A

Scanning results

Two reviews were identified in the core sources that were published after the date of the WA HTA, one of which is an update to the WA HTA report, as well as a Cochrane protocol and one guideline. The main results and author's conclusions are reported below.

CADTH. (2012). Metal on Metal Total Hip Replacements or Hip Resurfacing for Adults: A Review of Clinical Effectiveness and Cost Effectiveness.

<http://www.cadth.ca/media/pdf/htis/nov-2012/RC0405%20MOM%20Final.pdf>

Main results

- Metal on metal (MOM) hip resurfacing arthroplasty (HRA) patients experienced higher rates of revision, femoral neck fractures and component loosening than total hip replacement (THR) patients.
- There was a reduced incidence of dislocation following HRA compared to THR.
- Stemmed MOM THR had survival rates of 71% and 100% at mean follow-ups ranging from 36 months to 336 months.
- MOM HRA had survival rates of 84% to 100% at mean follow-ups ranging from 39 to 89 months.

No significant differences in the rates of mortality, dislocation or deep hip joint infection were found between groups.

Washington State Health Care Authority Health Technology Assessment Program. (2013). HTA final report: Hip resurfacing (Re-review). Olympia, WA: Health Technology Assessment Program. Retrieved from

http://www.hca.wa.gov/hta/Documents/hip_final_report_100913.pdf

Main results

Efficacy (<=2 year)

There is MODERATE evidence from three small randomized controlled trials that hip resurfacing (HR) is similar to total hip arthroplasty (THA - replacement) with respect to short-term (<2 year) functional, quality of life, and activity outcome.

Efficacy (>2 year)

There are NO DATA available to assess efficacy beyond two-year follow-up.

Effectiveness (Short-term, <5 years)

There is LOW evidence from studies directly comparing HR with THA to suggest that short term (≤ 5 years) patient-reported outcomes, clinician-based outcomes, and pain are similar comparing HR and THA. Activity scores tend to be slightly higher (better) in HR patients.

Effectiveness (Mid-term, 5-10 years)

There is INSUFFICIENT evidence from one cohort study to suggest that at an average of 5.9 years follow-up, patients treated with HR may have better quality of life and activity outcome scores, but similar functional scores, compared with those treated with THA.

Revision (Short-term, ≤ 5 years)

There is HIGH evidence from three large registry studies that short-term revision risks are higher in patients treated with HR compared with those treated with THA. At three years, there is between 20-50% higher risk of revision among those receiving HR vs. THA. The absolute risk is 3% in the HR group and between 2- 3% in the THA group. At five years, the higher risk is between 30-80%. The absolute risk ranges from 5 to 6% in the HR group and 1 to 4% in the THA group.

Revision (Mid-term, 6-10 years)

There is HIGH evidence from three large registry studies that 7 and 10-year revision risks are higher ranging from 40-100% in patients receiving HR versus THA. The absolute risk at 7 years is between 6-9% in the HR group and between 3- 4% in the THA group.

Revision (Long-term, 10+ years)

There is LOW evidence from one registry study that 11-year revision risks are higher in patients receiving HR (10%) versus THA (7%).

Complications: There is HIGH evidence from up to 3 RCTs and up to 6 observational studies that:

- Femoral component loosening occurs 8 times more frequently in HR patients than in THA patients, 2.7% vs. 0.3%
- Heterotopic ossification occurs nearly twice as often in HR patients compared with THA patients, 19.8% vs. 11.4%
- Dislocation occurs less frequently in HR vs. THA patients, 0.5% vs. 2.8%
- There is MODERATE evidence that deep infection occurs less frequently in patients undergoing HR compared with THA, 0.4% vs. 1.8%.
- The risk of femoral neck fracture and avascular necrosis in HR patients is 2% and 1%, respectively.

Metal Ion Safety

There are consistently higher median concentrations of the primary metal ions cobalt and chromium in the blood or hair of HR patients compared with non-MoM THA (MoP and ceramic) patients in 5 studies with up to 3-year follow-up. High blood levels of cobalt and chromium are associated with poor outcomes (revision or poorly functioning hip) compared with low blood levels in patients receiving HR in 3 studies. Higher serum ion levels of cobalt and chromium are associated with pseudotumor formation following MoM HR and MoM THA in 3 studies. MoM hip prostheses (both HR and THA) are not associated with an increased risk of cancer compared with THA with other bearing surfaces in 3 registry studies. There is no negative impact on renal function across 6 studies evaluating patients following MoM HR or MoM THA.

Revisions

There is INSUFFICIENT evidence from one small study reporting similar functional and quality of life outcomes comparing HR revision with THA revision at final follow-up (range, 2-7 years).

Subpopulations

There is HIGH evidence from a large registry study that the diagnosis of developmental dysplasia (DD) modifies the rate of revision in HR and THA; those with DD receiving HR have significantly higher revision rates than those receiving THA or those with other diagnoses receiving HR or THA. There is HIGH evidence from a large registry study that gender modifies the rate of revision in HR and THA; females receiving HR have significantly higher revision rates than females receiving THA or males receiving HR or THA. Smaller femoral component head size results in significantly higher revision rates for those receiving HR while larger femoral component heads result in higher revision rates in those receiving THA.

NICE. (2014). Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip (review of technology appraisal guidance 2 and 44).

<http://www.nice.org.uk/guidance/ta304/resources/guidance-total-hip-replacement-and-resurfacing-arthroplasty-for-endstage-arthritis-of-the-hip-review-of-technology-appraisal-guidance-2-and-44-pdf>

Prostheses for total hip replacement and resurfacing arthroplasty are recommended as treatment options for people 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.

Summary

The recently published evidence does not contradict the current coverage guidance recommendations.