



Health Net

National Medical Policy

Subject: Hip Resurfacing

Policy Number: 07-02-280

Effective Date*: July 2006

Updated: February 2007

Important Notice

General Purpose.

Health Net's National Medical Policies (the "Policies") are developed to assist Health Net in administering plan benefits and determining whether a particular procedure, drug, service or supply is medically necessary. The Policies are based upon a review of the available clinical information including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the drug or device, evidence-based guidelines of governmental bodies, and evidence-based guidelines and positions of select national health professional organizations. Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract, including medical necessity requirements. Health Net may use the Policies to determine whether under the facts and circumstances of a particular case, the proposed procedure, drug, service or supply is medically necessary. The conclusion that a procedure, drug, service or supply is medically necessary does not constitute coverage. The member's contract defines which procedure, drug, service or supply is covered, excluded, limited, or subject to dollar caps.

Policy Effective Date and Defined Terms.

The date of posting is not the effective date of the Policy. The Policy is effective as of the date determined by Health Net. All policies are subject to applicable legal and regulatory mandates and requirements for prior notification. If there is a discrepancy between the policy effective date and legal mandates and regulatory requirements, the requirements of law and regulation shall govern. * In some states, new or revised policies require prior notice or posting on the website before a policy is deemed effective. For information regarding the effective dates of Policies, contact your provider representative. The Policies do not include definitions. All terms are defined by Health Net. For information regarding the definitions of terms used in the Policies, contact your provider representative.

Policy Amendment without Notice.

Health Net reserves the right to amend the Policies without notice to providers or Members. In some states, new or revised policies require prior notice or website posting before an amendment is deemed effective.

No Medical Advice.

The Policies do not constitute medical advice. Health Net does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

No Authorization or Guarantee of Coverage.

The Policies do not constitute authorization or guarantee of coverage of particular procedure, drug, service or supply. Members and providers should refer to the Member contract to determine if exclusions, limitations, and dollar caps apply to a particular procedure, drug, service or supply.

Policy Limitation: Member's Contract Controls Coverage Determinations.

The determination of coverage for a particular procedure, drug, service or supply is not based upon the Policies, but rather is subject to the facts of the individual clinical case, terms and conditions of the member's contract, and requirements of applicable laws and regulations. The contract language contains specific terms and conditions, including pre-existing conditions, limitations, exclusions, benefit maximums, eligibility, and other relevant terms and conditions of coverage. In the event the Member's contract (also known as the benefit contract, coverage document, or evidence of coverage) conflicts with the Policies, the Member's contract shall govern. Coverage decisions are the result of the terms and conditions of the Member's benefit contract. The Policies do not replace or amend the Member's contract. If there is a discrepancy between the Policies and the Member's contract, the Member's contract shall govern.

Policy Limitation: Legal and Regulatory Mandates and Requirements

The determinations of coverage for a particular procedure, drug, service or supply is subject to applicable legal and regulatory mandates and requirements. If there is a discrepancy between the Policies and legal mandates and regulatory requirements, the requirements of law and regulation shall govern.

Policy Limitations: Medicare and Medicaid

Policies specifically developed to assist Health Net in administering Medicare or Medicaid plan benefits and determining coverage for a particular procedure, drug, service or supply for Medicare or Medicaid members shall not be construed to apply to any other Health Net plans and members. The Policies shall not be interpreted to limit the benefits afforded Medicare and Medicaid members by law and regulation.

Policy Statement

Partial Hip Resurfacing

Health Net, Inc. considers partial hip resurfacing of the femoral head, using an FDA approved device medically appropriate in patients with osteonecrosis of the femoral head. All other indications are considered investigational.

Total Hip Resurfacing

Health Net considers use of the metal-on-metal Birmingham prosthesis for total hip resurfacing arthroplasty (HRA) medically appropriate in patients who meet **all** of the following:

1. Patient is fit and active; and
2. Patient has normal proximal femoral bone geometry and bone quality; and

3. Patient would otherwise receive a conventional primary total hip replacement (THR); and
4. Patient is likely to live longer than current conventional THR prosthesis are expected to last.

Scientific Rationale – Revision February 2007

Total hip resurfacing has undergone various evolutions over the past several decades, with modifications in prosthetic design and composition and implantation techniques. Prior to the advent of metal on metal (MoM) devices, standard hip resurfacing and replacement devices have used a metal femoral component and a polyethylene acetabular component. Research into the reason for failure of hip prostheses has discovered that a frequent reason for device failure is related to polyethylene debris created by friction and wear between the polyethylene articulating surface against the surface of the metal femoral component. This polyethylene debris collects in the joint space where it solicits an immune inflammatory response. The immune response is not effective against the polyethylene particles, so the body's defenses attack the bone adjacent to the prostheses, leading to osteolytic bone loss and loosening of the implant. The problem of debris collection and subsequent immune response is potentially greater in hip resurfacing procedures because resurfacing procedures involve the use of a femoral component with a much greater surface area compared to that used in total hip replacement procedures. It is proposed that this increase in surface area increases the volume of polyethylene debris in resurfacing procedures using polyethylene on metal (PoM) devices, thus increasing the likelihood of immune response and device failure. The results of case series in the 1980's and 1990's studying patients who underwent PoM hip resurfacing procedures reported a device survival rate of 47% over a 10 year period. This survival of PoM hip resurfacing devices was deemed unacceptable.

In total hip resurfacing operations, the surgeon removes only the diseased or damaged surfaces of the head of the femur and the acetabulum. Less bone has to be removed for MoM resurfacing than to fit a conventional cup and ball artificial hip joint. The femoral head is fitted with a spherical shell and the hip socket is lined with a thin spherical cup. Both spherical cups form a pair of metal bearings. Total hip resurfacing has been investigated in a broader range of patients including those with osteoarthritis, rheumatoid arthritis, and advanced avascular necrosis. It has been proposed as an alternative to total hip arthroplasty, particularly in young active patients who would potentially outlive a total hip prosthesis. Therefore, total hip resurfacing could be viewed as a time-buying procedure to delay the need for a total hip arthroplasty. Proposed advantages of total hip resurfacing compared to total hip arthroplasty include preservation of the femoral neck and femoral canal, thus facilitating revision or conversion to a total hip replacement, if required. In addition, the resurfaced head is more similar in size to the normal femoral head, thus increasing the stability and decreasing the risk of dislocation compared to total hip arthroplasty.

It is difficult to find solid scientific evidence regarding the long-term safety and effectiveness of MoM hip resurfacing arthroplasty. No randomized controlled trials of MoM hip resurfacing arthroplasty and no studies comparing MoM hip resurfacing

arthroplasty with conventional total hip replacement (THR) can be found in the medical literature because most studies relating to conventional THRs have considered patients older than 65 years and have not differentiated between patients who were considered to be more active and those who were not. On the other hand, MoM hip resurfacing arthroplasty has been almost exclusively done in young active patients less than 65 years of age (actually less than 55 years of age).

Data are available from case series and observational studies, with some studies conducted by the manufacturers of these devices. Most studies reported the percentage of patients who required device revisions, i.e., MoM hip resurfacing devices to THR. However, only a few studies explicitly provided information on time to device failure, and so it is difficult to make comparisons between studies of MoM devices and THRs. Comparisons were also made difficult as few details were provided on the proportions of patients with specific preoperative diagnoses and nearly all studies examined the outcome with more than one type of prosthesis. There are no long-term (> 10 year) observational data on the outcomes associated with MoM hip resurfacing devices, and some of the existing short- to medium-term data relate to devices that are no longer commercially available. However, there is sufficient short-term evidence of the effectiveness of MoM hip resurfacing devices to conclude that they are at least as effective as conventional THRs for patients younger than 55 years.

A literature search through December 2006 returned studies reporting favorable outcomes with the Birmingham hip resurfacing (BHR) device suggesting medium to long-term durability. Although, there continues to be no randomized, controlled clinical trial comparing hip resurfacing to hip arthroplasty, there is good evidence that for patients, due to their relatively younger age, may not be suitable candidates for traditional total hip arthroplasty due to an increased possibility of requiring future ipsilateral hip joint revision. Therefore, active young patients age 55 and younger with advanced hip disease who are candidates for conventional total hip replacement and are likely to outlive conventional hip replacements should have the choice of receiving total MoM hip resurfacing arthroplasty. There is concern that substances from the metal surfaces might be absorbed into the body, although at the moment there have been no reported cases of this happening. For all other patients, firm conclusions cannot be reached concerning the long-term safety and reliability of total hip resurfacing on the health outcomes of the patient compared to conventional total hip arthroplasty.

Scientific Rationale - Initial

Hip replacements can restore joint function and pain relief for patients with degenerative hip disease or hip injury. Some of the current options in hip replacement surgery include total hip replacement (THR) or total hip arthroplasty, hemi-arthroplasty (bipolar or unipolar), and partial or total hip resurfacing of the femoral head.

The standard total hip replacement procedure is performed by removing the femoral head and neck, and reaming out the femoral canal. A prosthesis consisting of a femoral head with a stem is inserted into the femur and wedged into place using bone cement or press fitted for the bone to grow into. An acetabular cup component is implanted into the acetabulum. The femoral component of the prosthesis is usually made from metal (stainless steel or cobalt chrome) and the acetabulum

replacement from high-density polyethelene, metal or ceramics. (See Health Net's National Medical Policy Metal-on-Metal Total Hip replacement for more information.)

Partial Hip Resurfacing

An alternative to total hips replacement is partial or hemi hip resurfacing. The principle of hip resurfacing is to minimize the amount of bone that is removed. In resurfacing, the femoral head is preserved and reshaped, then covered with a small cobalt-chrome disc. The acetabulum is left intact. Several case studies have published in the medical literature that established it as medically appropriate for patients with avascular necrosis of the femoral head. In one case series of 33 hips, 91% of the devices were still implanted for a minimum of five years, with good or excellent results in 61%. Another case series of 37 prostheses followed for seven years reported that 9 failed, requiring revision, but that 24 of the remaining 28 implants continued to function well with excellent or good hip scores.

Partial hip resurfacing is not indicated when the femoral head is too damaged to hold the resurfacing component. It should also be used with caution in the following scenarios:

- previous operation on the hip joint, especially an operation that left the neck of the femur deformed
- very active, heavy patients
- patients with bone cysts (voids) in the femoral heads and necks
- patients with very small and/or severely deformed hip joints

The FDA has approved the following partial hip resurfacing devices under Section 510 premarketing approval:

- Cemented Femoral Head Resurfacing Device
- Nelson Resurfacing Head.
- Moduilar Unipolar made
- Orthomet Resurfacing Femoral Component.
- Modified New Jersey Femoral Hip Resurfacing
- Compo Biopro Proximal Femora Articular Replacement.
- Bipolar Hip System LSF (R) Total Hip System-Bipolar Component New Jersey Femoral Resurfacing Component Tillman Hip Resurfacing Replacement Prosthesis
- Resurface Prostheses for Hip Joint

Total Hip Resurfacing

Total hip resurfacing has been investigated in a broader range of patients including those with osteoarthritis, rheumatoid arthritis, and advanced avascular necrosis. It has been proposed as an alternative to total hip arthroplasty in young active patients who would potentially outlive a total hip prosthesis and to delay the need for a total hip arthroplasty.

The perceived advantages of total hip resurfacing compared to total hip arthroplasty include preservation of the femoral neck and femoral canal, which would facilitate revision or conversion to a total hip replacement in the future if necessary. Another advantage is that the resurfaced femur head is virtually the same size as the normal femur head. This provides more stability and lessens the risk of dislocation compared to total hip arthroplasty.

In total hip resurfacing, the surgeon removes only the diseased or damaged surfaces of the head of the femur and the acetabulum. There have been various modifications in prosthetic design, composition and implantation techniques over the past several years. The femoral head may be fitted with a spherical metal shell and the hip socket is lined with a thin spherical metal cup, forming a pair of metal bearings. Another type of resurfacing material is the use of polyethylene for the acetabular component. Failure of this device was frequently related to the polyethylene debris created by wear of polyethylene articulating surfaces. The body's immune system reacted to the polyethylene debris and caused the macrophages to devour the adjacent bone because the immune system is not effective against the plastic debris. Additionally, the debris accumulates in the area adjacent to the implant; the bone loss leads to loosening of the implant stem. Because of the debris problem, metal-on-metal designs as a technique to reduce the debris wear particles in total hip resurfacing are being evaluated.

There is a paucity of studies in the medical literature on the effectiveness of total hip resurfacing compared to the conventional total hip replacement. The Health Technology Program of the National Institute of Clinical Excellence in the United Kingdom commissioned a systematic review of the scientific evidence for metal-on-metal total hip resurfacing. The results were made public in 2005 and noted that only short-term (less than 5 years) outcomes data are available on metal on metal resurfacing hip arthroplasty. Long-term data are important because for total hip replacement, failure rates have been noted to increase substantially beyond 10 years. There are no randomized controlled clinical trials of metal on metal hip resurfacing arthroplasty. In addition, there are no studies directly comparing the outcomes of metal on metal resurfacing hip arthroplasty to total hip replacement or other alternatives, which limit the conclusions one can draw about the comparative effectiveness of these procedures. The review concluded that while short-term results are promising, it is unclear if such results would be replicated in more rigorous studies, and what the long-term performance might be. The report suggested that more rigorous research is needed with long-term outcomes from randomized, controlled clinical trials comparing metal-on-metal total hip replacement to alternative approaches to the clinical management of hip disease.

Several additional reviews and studies published since January 2005 have addressed several unresolved issues such as the failure rate, new osteonecrosis and fracture of resurfaced femoral heads, metal ion production secondary to wear debris or corrosion and subsequent hypersensitivity, and appropriate patient selection.

In May 2006, Smith & Nephew received FDA approval of its Birmingham metal-on-metal hip resurfacing implant. The company has agreed to conduct a large 10 year study to evaluate longer-term safety and effectiveness of the BHR. Outcome measures that will be assessed include patient pain, function, movement, revision status and adverse events. Another device that has been approved for total hip resurfacing is the Buechel-Pappas Integrated Total Hip Replacement. The weight-bearing surfaces of this device Buechel-Pappas Integrated Total Hip Replacement are composed of a ceramic femoral component and a polyethylene acetabular component. Other devices currently in the FDA approval process include the ConservePlus, Cormet 2000 Hemi Hip Metallic Resurfacing Prosthesis, Depuy ASR Resurfacing Femoral Head, Press-Fit Head Resurfacing Device and the Contoured Articular Prosthesis (CAP) Femoral Head.

As with metal on metal total hip replacement, there is a concern the release of metal debris (metallosis) can occur with metal implants. These implants produce corrosion products that are biologically active and may cause chronic inflammatory reactions

that can lead to loosening of the implant. It is reported that the concentration of metal debris is higher if the prosthesis is worn or loose, or if the joint is infected. It is not clear what the normal levels of ions in human tissue should be; however, animal studies show that cobalt doses up to 1000 times normal may be tolerated. Larger doses than that can induce anemia, loss of appetite and weight, and an increase in the number of red blood cells, lesions in mucous membranes, local malignant skin tumors, and death. Additionally, though inconclusive, there is concern that extensive metal ion release may cause changes to the immune function which may lead to lymphomas and leukemia's.

Codes Related to this Policy

ICD-9 Codes

- 733.43 Aseptic necrosis of head and neck of femur
- 715.15 Osteoarthritis, localized, primary, generalized, pelvic region and thigh
- 715.25 Osteoarthritis, localized, secondary, generalized, pelvic region and thigh
- 715.35 Osteoarthritis, localized, not specified whether primary or secondary, generalized, pelvic region and thigh
- 715.95 Osteoarthritis, unspecified whether generalized or localized, pelvic region and thigh

CPT Codes

- 27299 Unlisted procedure, pelvis or hip joint

HCPCS Codes

N/A

Review History

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| July 2006 | Medical Advisory Council initial approval |
| February 2007 | Revised to make total hip resurfacing medically appropriate with criteria |
| March 2007 | Coding Updates |

Patient Education Websites

<http://www.webmd.com/content/article/122/114538>

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