Clinical Policy Bulletin: Total Hip Replacement

Number: 0287

Policy

Aetna considers an Food and Drug Administration-approved metal-on-metal, metal-on-plastic, ceramic-on-plastic, or ceramic-on-ceramic total hip arthroplasty (THA) prosthesis medically necessary for adult members when the following criteria are met:

I. Member has advanced joint disease demonstrated by:

A. Pain and functional disability that interferes with activities of daily living (ADLs) from injury due to osteoarthritis, rheumatoid arthritis, avascular necrosis, or post-traumatic arthritis of the hip joint; and

B. Limited range of motion (ROM), antalgic gait, and pain in hip joint with passive ROM on physical examination; and

C. Radiographic evidence of severe osteoarthritis (as evidence by 2 or more of the following: subchondral cysts, subchondral sclerosis, periarticular osteophytes, joint subluxation, bone on bone articulation or joint space narrowing) of hip joint, or avascular necrosis (osteonecrosis) with stage III collapse of the femoral head, or rheumatoid arthritis (joint space narrowing); and

D. History of unsuccessful conservative therapy (non-surgical medical management) that is clearly addressed in the medical record (see Note). If conservative therapy is not appropriate, the medical record must clearly document why such approach is not reasonable; or

II. Fracture of the femoral neck by imaging with pain interfering with ADLs; or

III. Malunion of acetabular, femoral head or proximal femur fracture with pain interfering with ADLs; or

IV. Nonunion by imaging or failure of previous hip fracture surgery with pain interfering with ADLs; or
V. Malignancy of the joint involving the bones or soft tissues of the pelvis or proximal femur by imaging.

Note: Members with osteoarthritis, traumatic arthritis, rheumatoid arthritis, or avascular necrosis should have at least 12 weeks of non-surgical treatment documented in the medical record (at least 24 weeks for persons with a relative contraindication* -- see below), including all of the following, unless contraindicated:

A. Anti-inflammatory medications or analgesics; and
B. Flexibility and muscle strengthening exercises, and
C. Activity modification; and
D. Supervised physical therapy (ADLs diminished despite completing a plan of care); and
E. Weight reduction as appropriate; and
F. Assistive device use (required for persons with relative contraindications* to joint replacement, optional for others); and
G. Therapeutic injections into the hip (required for persons with relative contraindications* to joint replacement, optional for others).

* Relative contraindications to joint replacement include the following: morbid obesity (BMI greater than 40), age less than 50 years. Persons with relative contraindications should exhaust all non-surgical treatment options.

VI. Total joint replacement is considered not medically necessary in persons with any of the following absolute contraindications:

A. Active infection of the joint or active systemic bacteremia that has not been totally eradicated; or
B. Active skin infection (exception recurrent cutaneous staph infections) or open wound within the planned surgical site of the hip; or
C. Allergy to components of the implant (e.g., cobalt, chromium or alumina); or
D. Paraplegia or quadriplegia; or
E. Permanent or irreversible muscle weakness in the absence of pain that prevents ambulation; or
F. Rapidly progressive neurological disease except in the clinical situation of a concomitant displaced femoral neck fracture; or
G. Skeletal immaturity

VII. For persons with significant conditions or co-morbidities, the risk/benefit of THA should be appropriately addressed in the medical record.

VIII. Aetna considers THA experimental and investigational for all other indications because of insufficient evidence of effectiveness.

Aetna considers a revision or replacement of a THA or hip resurfacing arthroplasty medically necessary for the following indications when accompanied by pain and functional disability (interference with ADLs):
I. Aseptic loosening of one or more prosthetic components confirmed by imaging, or

II. Fracture or mechanical failure of 1 or more components of the prosthesis confirmed by imaging, or

III. Confirmed periprosthetic infection confirmed by gram stain and culture, or

IV. Displaced periprosthetic fracture confirmed by imaging, or

V. Progressive or substantial periprosthetic bone loss confirmed by imaging, or

VI. Bearing surface wear leading to symptomatic synovitis or local bone or soft tissue reaction*, or

VII. Recurrent (2 or more) dislocations confirmed by imaging not responsive to a reasonable course of conservative management or irreducible dislocation confirmed by imaging; or

VIII. Clinically significant leg length discrepancy; or

IX. Upon individual case review, persistent hip pain of unknown etiology not responsive to a period of non-surgical care for six (6) months.

And the member does not have any of the following contraindications to total hip revision or replacement:

A. Loss of musculature (in particular hip abductor musculature), neuromuscular compromise or vascular deficiency in the affected limb, rendering the procedure unjustifiable; or

B. Osteoporosis or other osseous abnormalities which would make the likelihood of a poor outcome more probable; or

C. Poor skin coverage; or

D. Severe instability due to anatomic causes that would make the likelihood of a poor surgical outcome more probable.

Aetna considers a revision or replacement of a THA or hip resurfacing experimental and investigational when criteria are not met.

Aetna considers minimal incision or minimally invasive THA a medically necessary acceptable alternative to conventional THA.

Aetna considers measurement of synovial C-reactive protein experimental and investigational as a marker for peri-prosthetic infection in THA because the effectiveness of this approach has not been established.

* Aetna considers removal and revision surgery due to post total hip replacement (THR) metallosis alone, without evidence of loosening or malposition, experimental and investigational because there is insufficient clinical evidence in the published peer-reviewed medical literature.

See also CPB 0661 - Joint Resurfacing.

Background
Previously, most total hip prostheses utilize an acetabular cup either lined with polyethylene or composed entirely of polyethylene articulating against a cobalt-chromium-molybdenum (CoCr) or ceramic femoral head. Serious problems affecting the outcome of total joint replacement with these types of prostheses have been extensive and progressive peri-prosthetic osteolysis and aseptic loosening, which may result in revision, even though the components are still well fixed and functioning. Polyethylene particulate debris generated from metal-on-polyethylene bearing surfaces and the resulting biologic response to this debris are thought to be largely responsible.

In recent years, there has been renewed interest in metal-on-metal bearing surfaces for total joint arthroplasty. This is especially true in younger and more active patients who face the possibility of multiple revision procedures during their lifetime. In the long-term, the second-generation all-metal prostheses have demonstrated lower friction and wear rates than metal-on-polyethylene bearing surfaces. Recent studies reported that the second-generation metal-on-metal hip replacement prostheses exhibit a lower rate of acetabular revision and loosening than did those with previous metal-on-metal designs and that they had no more acetabular loosening or osteolysis than did those with metal-on-polyethylene articulations for follow-up periods of 5 to 10 years.

Another alternative to standard polyethylene is alumina-on-alumina ceramic. When comparing hard-on-hard bearings, the ceramic-on-ceramic coupling has several theoretical advantages over metal-on-metal. Because of the ceramic's extremely low coefficient of friction and its potential for superior wear resistance, these couples promise both wear rates that are appreciably less than polyethylene-on-metal and metal-on-metal couples.

Available literature indicates that alumina-on-alumina ceramic couplings are a viable alternative to metal-on-polyethylene designs. The combination of new high quality ceramic acetabular and femoral bearing heads with hip systems that have achieved long-term stable fixation can result in a substantial increase in the longevity of fixation for implants especially in the younger and more active patients.

Available studies of metal-on-metal and ceramic-on-ceramic total hip implants primarily involve cohorts of younger, more active patients. The chief advantage of these hip implants over standard metal-on-polyethylene hip implants is their greater longevity. There is no adequate evidence that metal-on-metal or ceramic-on-ceramic total hip implants offer clinically significant benefits over standard metal-on-polyethylene hip implants for older patients.

Bhandari et al (2005) reported a meta-analysis of 6 randomized controlled studies suggested that bisphosphonates have a beneficial effect with regard to maintaining more peri-prosthetic bone mineral density than that in controls. However, the limitations of the available studies and the lack of analyses of clinically relevant outcomes (e.g., functional outcomes, revision rates, and quality of life) necessitate the planning and conduct of a sufficiently sized, methodologically sound trial with clinically relevant end points. Until this has been done, the current evidence regarding the beneficial effects of bisphosphonates on
peri-prosthetic bone following total joint (e.g., knee and hip) arthroplasty should be interpreted with caution.

A technology assessment of hip implants by the Institute for Clinical Effectiveness and Health Policy (Augustovsky et al, 2006) found that the clinical trials comparing ceramic against conventional prostheses found no significant differences in the revision rate among the different types of prostheses. In case series of patients with the ceramic prosthesis, reported revision rates at 10 years were less than 10\%, which is considered within acceptable limits and comparable to those reported for conventional prostheses. Similar results have been reported for metal-on-metal hip prostheses, where randomized controlled trials with follow-up up to 5 years found no differences between metal-on-metal and conventional prostheses in effectiveness and complication rates (Augustovsky et al, 2006). The assessment noted that, although there are some reports of an increase in cancer in persons with metal-on-metal hip prostheses, there are other reports evaluating metal-on-metal prostheses with follow-up up to 28 years that have found no increase in the incidence of any cancer. The assessment stated that no study comparing ceramic prosthesis with metal-on metal prosthesis was found. The assessment concluded that, although interim results with both the ceramic and metal-on-metal prostheses are promising, available studies have found no significant differences in revision rates during follow-up periods of 10 to 15 years. The assessment stated that, because the advantages of these materials may be observed at longer terms, their potential benefits would be greatest for younger patients (under 50 years of age) (Augustovsky et al, 2006).

In a meta-analysis, Smith and colleagues (2010) compared the clinical and radiological outcomes and complication rates of hip resurfacing (HRS) and total hip arthroplasty (THA). A systematic review was undertaken of all published (Medline, CINAHL, AMED, EMBASE) and unpublished or gray literature research databases up to January 2010. Clinical and radiological outcomes as well as complications of HRS were compared to those of THA using risk ratio, mean difference, and standardized mean difference statistics. Studies were critically appraised using the CASP appraisal tool. A total of 46 studies were identified from 1,124 citations. These included 3,799 HRSs and 3,282 THAs. On meta-analysis, functional outcomes for subjects following HRS were better than or the same as for subjects with a THA, but there were statistically significantly greater incidences of heterotopic ossification, aseptic loosening, and revision surgery with HRS compared to THA. The evidence base showed a number of methodological inadequacies such as the limited use of power calculations and poor or absent blinding of both patients and assessors, possibly giving rise to assessor bias. The authors concluded that on the basis of the current evidence base, HRS may have better functional outcomes than THA, but the increased risks of heterotopic ossification, aseptic loosening, and revision surgery following HRS indicate that THA is superior in terms of implant survival.

Garbuz and associates (2010) conducted a prospective randomized clinical trial to compare clinical outcomes of resurfacing versus large-head metal-on-metal THA. These researchers randomized 107 patients deemed eligible for resurfacing arthroplasty to have either resurfacing or standard THA. Patients were assessed for quality-of-life outcomes using the PAT-5D index, WOMAC, SF-36, and UCLA activity score. The minimum follow-up was 0.8 years (mean of 1.1 years; range of
0.8 to 2.2 years). Of the 73 patients followed at least 1 year, both groups reported improvement in quality of life on all outcome measures. There was no difference in quality of life between the 2 arms in the study. Serum levels of cobalt and chromium were measured in a subset of 30 patients. In both groups cobalt and chromium was elevated compared to baseline. Patients receiving a large-head metal-on-metal total hip had elevated ion levels compared to the resurfacing arm of the study. At 1 year, the median serum cobalt increased 4.6-fold from baseline in patients in the large-head total hip group, while the median serum chromium increased 10-fold. At 1 year, serum cobalt was 10-fold higher and serum chromium 2.6-fold higher than in the resurfacing arm. Due to these excessively high metal ion levels, the authors recommended against further use of this particular large-head THA.

Kim and colleagues (2013) stated that the timing of total hip replacement (THR) in patients with active tuberculosis (TB) of the hip is controversial, because of the potential risk of re-activation of infection. There is little information about the outcome of THR in these patients. These investigators performed a systematic review of published studies that evaluated the outcome of THR in patients with active TB of the hip. A review of multiple databases referenced articles published between 1950 and 2012 was carried out. A total of 6 articles were identified, comprising 65 patients. Tuberculosis was confirmed histologically in all patients. The mean follow-up was 53.2 months (range of 24 to 108). Anti-TB treatment continued post-operatively for between 6 and 15 months, after debridement and THR. One non-compliant patient had re-activation of infection. At the final follow-up the mean Harris hip score was 91.7 (range of 56 to 98). The authors concluded that THR in patients with active TB of the hip is a safe procedure, providing symptomatic relief and functional improvement if undertaken in association with extensive debridement and appropriate anti-TB treatment.

In a multi-center randomized, controlled trial with a non-inferiority design based on a minimal clinically important difference of 2.0 %, Anderson et al (2013) compared extended prophylaxis with aspirin and dalteparin for prevention of symptomatic venous thrombo-embolism (VTE) after THA. Randomization was electronically generated; patients were assigned to a treatment group through a Web-based program. Patients, physicians, study coordinators, health care team members, outcome adjudicators, and data analysts were blinded to interventions. The setting of this study was 12 tertiary care orthopedic referral centers in Canada; and a total of 778 patients who had elective unilateral THA between 2007 and 2010 were enrolled. After an initial 10 days of dalteparin prophylaxis after elective THA, patients were randomly assigned to 28 days of dalteparin (n = 400) or aspirin (n = 386). Main outcome measures were symptomatic VTE confirmed by objective testing (primary efficacy outcome) and bleeding. Five of 398 patients (1.3 %) randomly assigned to dalteparin and 1 of 380 (0.3 %) randomly assigned to aspirin had VTE (absolute difference, 1.0 percentage point [95 % confidence interval [CI]: -0.5 to 2.5 percentage points]). Aspirin was non-inferior (p < 0.001) but not superior (p = 0.22) to dalteparin. Clinically significant bleeding occurred in 5 patients (1.3 %) receiving dalteparin and 2 (0.5 %) receiving aspirin. The absolute between-group difference in a composite of all VTE and clinically significant bleeding events was 1.7 percentage points (CI: -0.3 to 3.8 percentage points; p = 0.091) in favor of aspirin. The authors concluded that extended prophylaxis for 28 days with aspirin was non-inferior to and as safe as dalteparin for the prevention of
VTE after THA in patients who initially received dalteparin for 10 days. Given its low cost and greater convenience, aspirin may be considered a reasonable alternative for extended thrombo-prophylaxis following THA.

An UpToDate review on “Total hip arthroplasty” (Erens et al, 2014) states that: “Contraindications -- Total hip arthroplasty (THA) should not be undertaken in a number of clinical settings, including:

- Active infection (local or systemic)
- Preexisting significant medical problems (e.g., recent myocardial infarction, unstable angina, heart failure, or severe anemia)
- Skeletal immaturity
- Paraplegia or quadriplegia
- Permanent or irreversible muscle weakness in the absence of pain

Relative contraindications include a neuropathic (Charcot) joint, inability to ambulate that is not related to the hip disorder per se, absence of hip abductor muscle mass, progressive neurologic loss, and morbid obesity. However, the effects of obesity on outcome remain uncertain. Most studies do show an increased risk of infection, particularly in the highly obese. This must be weighed against the fact that some morbidly obese patients can have significant improvement postoperatively. A 2011 study from Canada noted that patients with morbid obesity can experience substantial benefit, despite a very small but statistically significant increase in the need for revision due to septic complications. Other studies have emphasized the increased risk of both superficial and deep infections and have described an increased risk of dislocation in such patients".

Omar et al (2015) examined the role of synovial C-reactive protein (CRP) in the diagnosis of chronic peri-prosthetic hip infection. These researchers prospectively collected synovial fluid from 89 patients undergoing revision hip arthroplasty and measured synovial CRP, serum CRP, erythrocyte sedimentation rate (ESR), synovial white blood cell (WBC) count and synovial percentages of polymorphonuclear neutrophils (PMN). Patients were classified as septic or aseptic by means of clinical, microbiological, serum and synovial fluid findings.

The high viscosity of the synovial fluid precluded the analyses in 9 patients permitting the results in 80 patients to be studied. There was a significant difference in synovial CRP levels between the septic (n = 21) and the aseptic (n = 59) cohort. According to the receiver operating characteristic curve, a synovial CRP threshold of 2.5 mg/L had a sensitivity of 95.5 % and specificity of 93.3 %. The area under the curve was 0.96. Compared with serum CRP and ESR, synovial CRP showed a high diagnostic value. The authors concluded that according to these preliminary results, synovial CRP may be a useful parameter in diagnosing chronic peri-prosthetic hip infection.

Furthermore, an UpToDate review on “Total hip arthroplasty” (Erens et al, 2014) does not mention the use of synovial CRP as a post-operative management tool.

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CPT Codes / HCPCS Codes / ICD-9 Codes

Total hip replacement (THA):
CPT codes covered if selection criteria are met:

27130   Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft [minimally invasive or conventional approach]

27132   Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft [minimally invasive or conventional approach]

HCPCS codes covered if selection criteria are met:

C1776   Joint device (implantable)

ICD-9 codes covered if selection criteria are met:

170.7   Malignant neoplasm of long bones of lower limb

198.5   Secondary malignant neoplasm of bone and bone marrow

714.0   Rheumatoid arthritis

715.15  Osteoarthritis, localized, primary, pelvic region and thigh

715.25  Osteoarthritis, localized, secondary, 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, involving pelvic region and thigh

716.15  Traumatic arthropathy pelvic region and thigh

733.14  Pathologic fracture of neck of femur (hip)

733.81 - 733.82  Malunion and nonunion of fracture

733.40  Aseptic necrosis of bone, site unspecified

733.42  Aseptic necrosis of bone, head and neck of femur

808.0   Fracture of acetabulum, closed

808.1   Fracture of acetabulum, open

820.00 - 820.9  Fracture of neck of femur

905.3   Late effects of fracture of neck of femur

996.40 - 996.48  Mechanical complication of internal orthopedic device, implant, and graft

V43.64  Joint replaced by other means, hip
ICD-9 codes not covered if selection criteria are met:

001.0 - 139.8 Infectious and Parasitic Diseases [active infection of the joint, active systemic bacteremia or active skin infection]

711.05 Pyogenic arthritis involving pelvic region and thigh

711.45 Arthropathy involving pelvic region and thigh associated with other bacterial diseases

711.55 Arthropathy involving pelvic region and thigh associated with other viral diseases

711.85 Arthropathy involving pelvic region and thigh associated with other infectious and parasitic diseases

711.95 Unspecified infective arthritis involving pelvic region and thigh

890.0 - 890.2 Open wound of hip and thigh

985.6 Toxic effect of Chromium [not covered for metallosis alone without evidence of loosening or malposition]

985.8 Toxic effect of other specified metals [not covered for metallosis alone without evidence of loosening or malposition]

995.3 Allergy, unspecified, NEC

Other ICD-9 codes related to the CPB:

V13.51 - V13.52 Personal history of pathologic and stress fracture

V15.51 Personal history of traumatic fracture, presenting hazards to health

Revision, replacement of total hip arthroplasty, or revision hip resurfacing arthroplasty:

No specific code

CPT codes covered if selection criteria are met:

27125 Hemiarthroplasty, hip, partial (eg, femoral stem prosthesis, bipolar arthroplasty) [Revision of resurfacing arthroplasty]

27130 Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft [revision of resurfacing arthroplasty]

27130 Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft [revision of resurfacing arthroplasty]
Revision of total hip arthroplasty; with or without autograft or allograft

**HPCPCS codes covered if selection criteria are met:**

C1776 Joint device (implantable)

S2118 Metal-on-metal total hip resurfacing, including acetabular and femoral components

**ICD-9 codes covered if selection criteria are met:**

996.42 - Mechanical complication of internal orthopedic device

996.47

996.66 Infection and inflammatory reaction due to internal joint prosthesis

**Other ICD-9 codes related to the CPB:**

V43.64 Hip joint replacement status

The above policy is based on the following references:

46. Walsh J. Metal-on-metal hip resurfacing as an alternative to total hip arthroplasty. Technology Assessment. San Francisco, CA: California Technology Assessment Forum (CTAF); October 19, 2011.


72. Erens GA, Thornhill TS, Katz JN. Total hip arthroplasty. UpToDate [online serial], Waltham, MA: UpToDate; reviewed December 2014.