



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Total Hip Replacement with Metal-On-Metal and Ceramic-On-Ceramic Prostheses

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Hip Surgery for Femoroacetabular Impingement (FAI) Syndrome
 Hip Resurfacing Arthroplasty
 Minimally Invasive Total Hip Arthroplasty
 Physical Therapy

INSTRUCTIONS FOR USE

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Coverage Policy

CIGNA covers metal-on-metal and ceramic-on-ceramic prostheses for primary total hip replacements.

General Background

Total hip replacement (THR), or hip arthroplasty, is a surgical procedure in which the hip joint is removed and replaced with a prosthetic implant. The major indications for THR are traumatic injury or disease of the hip resulting in chronic, persistent pain and/or disability related to osteoarthritis; rheumatoid arthritis; inflammatory arthritis; avascular necrosis; traumatic arthritis; hip fractures; benign and malignant bone tumors; arthritis associated with Paget's disease; and juvenile rheumatoid arthritis (National Institutes of Health [NIH], 2010; American Academy of Orthopaedic Surgeons [AAOS], 2009; Moran and Tourret, 2001).

The total hip prosthesis is comprised of a ball that replaces the original femoral head; a stem that is inserted into the femur; and a cup or socket that is inserted into the acetabulum of the pelvis. Hip prostheses are broadly grouped according to the various materials out of which they are constructed, including polyethylene, metals (e.g., titanium, cobalt-chrome, stainless steel), ceramic (e.g., aluminum oxide, zirconium oxide), or a combination of these materials (AAOS, 2007; Agency for Healthcare Research and Quality, 2006).

The development of osteolysis is a primary limitation of joint replacement longevity. Osteolysis is a biological response to particulate debris that results in periprosthetic bone loss, resulting in wear, loosening and implant

failure of the prosthetic joint. Osteolysis was more prevalent in polyethylene components which led to a renewed interest in metal and ceramic prostheses (i.e., hard-on-hard bearing surfaces) (Colwell, et al., 2007; Archibeck, et al., 2000; Wagner and Wagner, 2000).

Although advantages of metal-on-metal prostheses include reduced wear rates and the ability to increase the size of the ball component to provide for greater joint stability, there continues to be concerns associated with metal sensitivity, the release of alloy constituents into the surrounding tissue (i.e., metallosis or ion toxicity) and metal carcinogenicity (Mirza, et al., 2010; Antoniou, et al., 2008; McGovern and Moskal, 2002; Hallab, et al., 2001; Moran and Tourret, 2001; Wagner and Wagner, 2000).

The reported advantages of ceramic-on-ceramic prostheses include wear resistance, self-lubricating sliding characteristics, scratch resistance, and a high level of oxidation resistance and tensile strength. The wear of ceramic against polyethylene weight-bearing surfaces has been reported to be lower than that for metal-on-polyethylene components, improving the longevity of the prostheses. Concerns regarding ceramic prostheses include osteolysis, fracture risk, and squeaking noise (Mirza, et al., 2010; Mehmood, et al., 2008; Colwell, et al., 2007; Affatato, et al., 2001; Bizot, et al., 2000; Scholes, et al., 2000; Wagner and Wagner, 2000).

Following hip replacement, physical therapy typically begins on the first postoperative day. Therapy includes teaching the patient a safe way to get out of bed to prevent injuring or dislocating the hip, as well as rising to a standing position and walking. Full recovery can take from three to six months.

U. S. Food and Drug Administration (FDA)

Hip prostheses and articulation systems require Class III approval by the FDA premarket approval (PMA) process. Examples of ceramic hip systems include the Ceramic TRANSCEND[®] (Wright Medical Technology, Inc., Arlington, TN) and the Keramos[™] Ceramic/Ceramic Total Hip System (Encore Medical, L.P., Austin TX). The Epsilon[™] Metasul[®] Acetabular Insert and Metasul Modular Femoral Head (Centerpulse Orthopedics, Inc., a division of Zimmer, Austin, TX) are examples of metal-on-metal systems.

Literature Review

Evidence in the published peer-reviewed scientific literature evaluating metal-on-metal and ceramic-on-ceramic total hip prostheses supports the safety and efficacy of these devices. Outcomes included an assessment of functional status; implant survival; pain relief; mobility; implant failure due to loosening, cup migration, or fracture; and the occurrence of osteolysis, metallosis, and volumetric wear based on clinical, histopathological, and radiological evaluation.

Metal-on-Metal Prostheses: Evidence in randomized controlled trials and case series (Zijlstra, et al., 2010; Grubl, et al., 2007; Amstutz, et al., 2004; Jacobs, et al., 2004; Lombardi, et al., 2004; Long, et al., 2004; Pabinger, et al., 2003; MacDonald, et al., 2003; Clarke, et al., 2003; Dorr, et al., 2000; Wagner and Wagner, 2000) support the safety and efficacy of metal-on-metal hip prostheses.

Although the clinical outcomes (e.g., Harris hip scores, Short-Form 36 scores) in studies comparing metal-on-metal prosthesis with metal-on-polyethylene or ceramic-on-polyethylene were as good as or better than the comparator, some studies reported significantly elevated serum erythrocytes, chromium, cobalt, and aluminum levels, as well as urine metal ion levels in metal-on-metal recipients. Osteolytic lesions have also been reported following metal-on-metal implantation. Technical failures, aseptic loosening, and septic failure have been attributed to metallosis and extensive lymphocytic and plasma-cell infiltration around metal debris. Revision rates have been reported as high as 10.8%. The long-term outcomes of metal-on-metal prostheses regarding these side effect are unknown and continue to be evaluated on an ongoing basis (Engh, et al., 2009; Sauve, et al., 2007; Gruble, et al., 2007; Gruble, et al., 2006; Korovessis, et al., 2006; Savarino, et al., 2006; Park, et al., 2005; Brown, et al., 2002).

Ceramic-on-Ceramic Prostheses: Randomized controlled trials and case series with up to 10 years follow-up (Boyer, et al., 2010; Bascarevic, et al., 2009; Zhou, et al., 2006; D'Antonio, et al., 2005; Yoo, et al., 2005; Bierbaum, et al., 2002; D'Antonio, et al., 2002; Böhler, et al., 2000) support the safety and efficacy of ceramic-on-ceramic prostheses. Five-year postoperative radiographic outcomes have included an absence of hip dislocations, component loosening, wear, and osteolysis.

Professional Societies/Organizations

In their discussion of implant construction, the American Academy of Orthopaedic Surgeons (AAOS) (2007) explained that the stem portions of most hip implants are made of titanium- or cobalt/chromium-based alloys, the ball portions are cobalt/chromium-based alloys or ceramic materials (i.e., aluminum oxide or zirconium oxide), and the acetabular may be made of metal, ultra-high molecular-weight polyethylene, or a combination of polyethylene backed by metal. All the materials are biocompatible; corrosion, degradation and wear resistant; and can mechanically support weight-bearing loads and stress while moving smoothing against each other. AAOS stated that the type of implant used depends on many factors including the patient's needs based on "age, weight, bone quality, activity level, and health, the doctor's experience and familiarity with the device, and the cost and performance record of the implant".

Summary

Evidence in the published peer-reviewed scientific literature supports total hip replacement with metal-on-metal and ceramic-on-ceramic hip prostheses. Study results indicate that these prostheses may reduce the risk of wear and implant failure compared to prostheses composed of metal- or ceramic-on-polyethylene.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT [®] * Codes	Description
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

ICD-9-CM Diagnosis Codes	Description
170.7	Malignant neoplasm of bone and articular cartilage; long bones of lower limb
213.7	Benign neoplasm of bone and articular cartilage; long bone of lower limb
714.0	Rheumatoid arthritis
714.30-714.33	Juvenile chronic polyarthritis
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
715.90	Osteoarthritis, unspecified whether generalized or localized
715.95	Osteoarthritis, unspecified whether generalized or localized, pelvic region and thigh
716.15	Traumatic arthropathy; pelvic region and thigh
716.55	Unspecified polyarthropathy or polyarthritis; pelvic region and thigh
716.65	Unspecified monoarthritis; pelvic region and thigh
716.85	Other specified arthropathy; pelvic region and thigh
716.95	Arthropathy, unspecified; pelvic region and thigh
718.65	Unspecified intrapelvic protrusion acetabulum, pelvic region and thigh
719.35	Palindromic rheumatism, pelvic region and thigh
719.45	Hip/pelvic region pain
731.0	Osteitis deformans without mention of bone tumor

733.14	Pathologic fracture of neck of femur
733.40-733.43	Aseptic necrosis of bone
733.82	Nonunion of fracture
754.30	Congenital dislocation of hip, unilateral
755.63	Other congenital deformity of hip (joint)
820.00-820.09	Closed transcervical fracture of neck of femur
	Multiple/varied

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	10/15/2008	0214	Total Hip Replacement with Metal-On-Metal and Ceramic-On-Ceramic Prostheses

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