

BSC7.11	Total Hip Arthroplasty for Adults		
Original Policy Date:	April 1, 2016	Effective Date:	May 1, 2021
Section:	7.0 Surgery	Page:	Page 1 of 23

Policy Statement

Total hip arthroplasty may be considered **medically necessary** when **ALL** of the following criteria are met:

- I. The reason for the arthroplasty is osteoarthritis (OA), rheumatoid arthritis, avascular necrosis (osteonecrosis), or post-traumatic arthritis of the hip joint
- II. The member and physician have reviewed, completed, and signed the [Total Hip Arthroplasty Decision Aid](#) ensuring shared decision making has occurred
- III. The member has reviewed, completed, and signed the [Hip Dysfunction & Osteoarthritis Outcome Score \(HOOS\), JR. survey](#), with submission of the score with the clinical documentation
- IV. The member has reviewed, completed, and signed the [CollaboRATE](#) survey, with submission of the score with the clinical documentation
- V. It is NOT for a [customized](#) hip replacement, including **all** of the following:
 - A. It does NOT use [customized](#) templates, and/or instrumentation
 - B. It does NOT use [customized](#) hip implant
 - C. It does NOT use a "Gender specific" implant
 - D. It does NOT use Pre-operative imaging studies (e.g., CT scans, MRI) associated with the [customization](#) and/or utilized as part of intraoperative navigation (e.g., MAKOplasty)
- VI. There is NO active infection of the joint or active systemic bacteremia (that has not been treated)
- VII. There is NO skin infection (exception recurrent cutaneous staph infections) or open wound within the planned surgical site of the hip
- VIII. There is NO allergy to components of the implant (e.g., cobalt, chromium or alumina)
- IX. There is NO skeletal immaturity
- X. There is NO paraplegia or quadriplegia, permanent or irreversible muscle weakness (in the absence of pain) that prevents ambulation, or rapidly progressive neurological disease (except in the clinical situation of a concomitant displaced femoral neck fracture)
- XI. A patient has **any** of the following conditions:
 - A. Degenerative joint disease when **all** of the following exist:
 1. Documentation of failure of conservative therapy (non-surgical medical management) or documentation of rationale if conservative therapy is considered inappropriate
 2. Documentation of limited range of motion, antalgic gait, and pain in hip joint with passive range of motion on physical examination
 3. Radiographic evidence of **any** of the following:
 - a. Severe osteoarthritis of hip joint as evidenced by **two or more** of the following:
 - i. Subchondral cysts
 - ii. Subchondral sclerosis
 - iii. Periarticular osteophytes
 - iv. Joint subluxation
 - v. Bone on bone articulation
 - vi. Joint space narrowing
 - b. Avascular necrosis (osteonecrosis) with greater than stage II with collapse and in stage II avascular necrosis with severe recalcitrant hip pain in spite of treatment with medications
 - c. Rheumatoid arthritis (joint space narrowing)
 - d. Post traumatic conditions not amenable to hip preservation (even in the absence of severe osteoarthritis), including but not limited to femoral head fractures or some acetabular fractures

- e. Synovitic and tumorous conditions that do not respond to conservative therapy or hip preservation surgery, including but not limited to synovial osteochondromatosis and pigmented villonodular synovitis
- B. Tumor involving proximal femur or acetabulum
- C. Unstable fracture of the femoral neck or acetabulum
- D. Symptomatic findings of FemoroAcetabular Impingement (FAI) in the presence of significant (advanced) osteoarthritis
- E. Previous arthroplasty or resurfacing revision, indicated by **one or more** of the following conditions:
 1. Joint instability
 2. Implant failure
 3. Infection
 4. Irreducible or recurrent dislocation
 5. Displaced fracture at prosthesis site
 6. Allergy to implant material

Total hip arthroplasty is considered **investigational** for **all** other indications due to insufficient evidence of effectiveness.

NOTE: Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Conservative Treatment

As medically indicated, members with osteoarthritis, traumatic arthritis, rheumatoid arthritis, or avascular necrosis (osteonecrosis) should have non-surgical treatment documented in the medical record, including **all** of the following unless contraindicated:

- Anti-inflammatory medications or analgesics
- Activity modification
- Supervised physical therapy which could include an instructed home exercise program, including flexibility and muscle-strengthening exercises. Post-op physical therapy visits will be allowed in addition to the pre-op physical therapy visits.
- Weight reduction counseling as appropriate
- Assistive device use (as required)
- Intra-articular steroid injections may be appropriate, but are not a requirement for conservative therapy

Relative contraindications to joint replacement include the following: Morbid obesity (BMI greater than 40), or age less than 50 years unless there are no other treatment options for the patient. Patients with relative contraindications should exhaust all appropriate nonsurgical treatment options prior to surgical consideration.

Customized refers to something that is made specifically for that patient and could not be used for anyone else.

Total Hip Arthroplasty Decision Aid

Use of decision aids can promote shared decision making and may improve patients' understanding and enable them to make decisions that are fully informed and consistent with their preferences, values, and goals. A decision aid is a tool used to inform patients about available treatments, along with potential benefits, risks and costs, during clinical encounters. The decision aid is intended for use following the patient pre-operative education course. The resulting decision aid is intended to be nondirective, encouraging clinicians to create a conversation with patients using their own communication styles, while simultaneously ensuring that key information is conveyed and that patient preferences are elicited. Blue Shield of California considers the use of decision aids as a higher level of informed consent and requires

patients to acknowledge receipt, review, and sign the Enhanced Clinical Programs (ECP) Total Hip Arthroplasty decision aid as a pre-authorization requirement.

Shared Decision Making

Shared Decision Making (SDM) is a process in which patients openly explore with the aid of their physician both the available evidence supporting each therapeutic intervention, and also determine what matters most to the patient. This allows both the physician and the patient to reach agreed-upon treatment decisions reflecting mutual goals and expected outcomes. The completion of the Total Hip Arthroplasty Decision Aid by the member and physician, and the HOOS, JR. and the CollaboRATE surveys by the member helps to assure the member's personal preferences have been considered.

Tools for Patient-Reported Measure of the Shared Decision Making Process (SDM) for Osteoarthritis and Hip Function

Hip Disability and Osteoarthritis Outcome Score (HOOS) (English version LK 2.0) and HOOS, JR. (English version 1.0)

The Hip disability and Osteoarthritis Outcome Score (HOOS)¹ and the short-form version HOOS, JR.² are tools to assess the patient's opinion about their hip and associated problems. These measures are intended to be used for hip disability with or without osteoarthritis (OA) over both short and long time intervals to assess changes from week to week induced by treatment (medication, operation, physical therapy) or over years due to the primary injury or post traumatic OA.¹

To access more detailed information, please visit the following websites at:

http://www.orthopaedicscore.com/scorepages/hip_disability_osteoarthritis_outcome_score_hoos.html and <https://www.hss.edu/hoos-jr-koos-jr-outcomes-surveys.asp>

CollaboRATE

Patient-centered health care is a central component of current health policy agendas. CollaboRATE is a 3-Item questionnaire that measures the level of shared decision making in the clinical encounter from the patient's perspective. In the questionnaire, the patient rates, on a scale of 1 to 9, the provider's efforts to understand the surgical plan of care from the patient's perspective. The CollaboRATE SDM tool has demonstrated discriminative validity, concurrent validity, intrarater reliability, and sensitivity to change³

To access further information, please visit the following websites: <http://www.jmir.org/2014/1/e2/> and <http://www.glynelwyn.com/collaborate-measure.html>

Description

Total hip arthroplasty (THA), also known as total hip replacement, is a surgical procedure to replace the diseased bone and cartilage of the hip joint with prosthetic components in order to increase mobility, improve the function of the hip joint, and relieve pain. Normally, the hip would function as a "ball-and-socket" joint. The head of the femur (top of the thigh bone) as a ball fits into a part of the pelvis as a socket (the acetabulum). This allows for smooth joint movement in multiple directions. The most common conditions requiring the hip joint to be replaced is osteoarthritis, rheumatoid arthritis, avascular necrosis, or post-traumatic arthritis.

Related Policies

- Knee Arthroplasty for Adults

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

Hip replacement surgery is a procedure and therefore is not regulated by the U.S. Food and Drug Administration (FDA). However, devices and instruments used during the surgery require FDA approval and are regulated by the FDA through the 510(k) marketing process. Hip joint prostheses are regulated by the FDA as Class II devices.

Rationale

Background

Total hip arthroplasty (THA) or hip replacement surgeries are successful and cost effective interventions for patients with significant symptoms and/or functional limitations associated with reduced health related quality of life despite conservative therapy.⁴ Although THA can provide potential benefits and successful outcomes, it is an elective procedure and should only be considered after extensive discussion of the risks, benefits, and alternatives. The use of shared decision making aides and functional outcome measures have shown to improve a patient's knowledge of the options available, and allows a patient to have a more accurate expectation of possible benefits and harm of their options.⁵

In certain circumstances, a trial of conservative treatment is warranted prior to THA. Conservative treatment (non-surgical medical management) may consist of anti-inflammatory medications or analgesics, activity modification, supervised physical therapy including flexibility and strengthening exercises, weight reduction, use of an assistive device and therapeutic injections as indicated. If these measures fail, then THA is considered an appropriate option.

According to the American Academy of Orthopaedic Surgeons (AAOS) a total hip replacement (also called total hip arthroplasty), involves the removal of damaged bone and cartilage which is replaced with prosthetic components.

- The damaged femoral head is removed and replaced with a metal stem that is placed into the hollow center of the femur. The femoral stem may be either cemented or "press fit" into the bone.
- A metal or ceramic ball is placed on the upper part of the stem. This ball replaces the damaged femoral head that was removed.
- The damaged cartilage surface of the socket (acetabulum) is removed and replaced with a metal socket. Screws or cement are sometimes used to hold the socket in place.
- A plastic, ceramic, or metal spacer is inserted between the new ball and the socket to allow for a smooth gliding surface.⁶

Serious complications after hip replacement surgery are not common and can be minimized by choosing a clinician who is experienced and who performs the procedure frequently; and by choosing a hospital that is experienced in caring for patients before, during, and after surgery.

Complications can occur during surgery, in the immediate postoperative period, or many years after surgery. These risks can include, but are not limited to: blood clots, infection, dislocation of the hip joint, loosening or breakage of the implant, change in leg length and stiffening of the joint. It is important to understand these potential risks before deciding to undergo hip replacement. For most patients, the benefits of reduced pain and improved function outweigh the small risk of complications.⁷

Total hip arthroplasty is one of the most successful orthopedic procedures performed today. It is estimated that over 300,000 total hip arthroplasties are performed each year in the United States alone. Since 1960, improvements in joint replacement surgical techniques and technology have greatly increased the effectiveness of total hip replacement. For patients with hip pain due to a variety of conditions, THA can relieve pain, restore function, and improve quality of life.⁶ The primary reason to undergo a THA is osteoarthritis. Other conditions leading to THA include inflammatory arthritis, fracture, dysplasia, and malignancy.⁸

In an increasingly ageing society coupled with the increased demand for hip-replacement surgery, we will experience an increase in the need to appropriately assess the clinical necessity for surgical intervention. It also emphasizes the need for new strategies to treat early-stage osteoarthritis, which will ultimately reduce the demand for joint-replacement surgery.⁹

Literature Review

Degenerative Joint Disease

Arthritis is a large and growing public health problem in the United States, resulting in costs of \$128 billion annually, and continues to be the most common cause of disability. With the aging of the U.S. population, even assuming that the prevalence of obesity and other risk factors remain unchanged, the prevalence of doctor-diagnosed arthritis and arthritis-attributable activity limitation (AAAL) is expected to increase significantly by 2030.¹⁰

The most common cause of chronic hip pain and disability is arthritis. Osteoarthritis, rheumatoid arthritis, and traumatic arthritis are the most common forms of this disease.¹¹

Osteoarthritis

Osteoarthritis (OA) is the most common cause of chronic disability in older adults. Although classically considered a "wear and tear" degenerative condition of articular joints, recent studies have demonstrated an inflammatory component to OA that includes increased activity of several cytokines and chemokines in joint tissues that drive production of matrix-degrading enzymes. Rather than directly causing OA, aging changes in the musculoskeletal system contribute to the development of OA by making the joint more susceptible to the effects of other OA risk factors that include abnormal biomechanics, joint injury, genetics, and obesity. Age-related sarcopenia and increased bone turnover may also contribute to the development of OA. Understanding the basic mechanisms by which aging affects joint tissues should provide new targets for slowing or preventing the development of OA.¹²

Rheumatoid Arthritis

Rheumatoid arthritis (RA) is a chronic, systemic, inflammatory disorder of unknown etiology that primarily involves synovial joints. The arthritis is typically symmetrical, and usually leads, if uncontrolled, to destruction of joints due to erosion of cartilage and bone, causing joint deformities. The disease usually progresses from the periphery to more proximal joints and results in significant locomotor disability within 10 to 20 years in patients who do not fully respond to treatment.¹³

Post-Traumatic Arthritis

Fractures with joint involvement can cause damage to articular cartilage, ultimately resulting in premature osteoarthritis.

Avascular Necrosis

Osteonecrosis, also known as aseptic necrosis, avascular necrosis (AVN), atraumatic necrosis, and ischemic necrosis, is a pathologic process that has been associated with numerous conditions and therapeutic interventions. In patients in whom there is direct damage to bone vasculature (e.g., femoral neck fracture) or direct injury of bone or marrow elements (e.g., radiation injury, dysbarism, or caisson disease), the cause is clearly identifiable. However, in many patients, the mechanisms by which this disorder develops are not fully understood. Compromise of the bone vasculature, leading to the death of bone and marrow cells (bone marrow infarction), and ultimate mechanical failure appear to be common to most proposed etiologies. The process is most often progressive, resulting in joint destruction within a few months to two years in the majority of patients.^{14,15}

Conservative Treatment

Before proceeding to total hip arthroplasty for an indication of osteoarthritis, a multifaceted regimen of nonoperative treatment should be attempted. Societies such as The Osteoarthritis Research Society international and The American College of Rheumatology have extensive guidelines on the pharmacologic and non-pharmacologic treatment of Osteoarthritis. These guidelines include (See Practice Guidelines section and Position Statements):

- Exercise for strength, endurance, and flexibility
- Use of walking aids
- Use of thermal agents
- Use of oral medication such as acetaminophen, oral NSAIDs and Tramadol
- Interarticular corticosteroid injections

Shared Decision Making (SDM)

Shared decision making (SDM) is promoted as an ideal model to incorporate in the treatment plan between patient and physician. This is based on the premise that the best medical decision for an individual patient incorporates the patient's preferences and values through the process of information sharing and planning. This idea involves at least two participants; the clinician and the patient.¹⁶⁻²¹ It represents the optimal physician-patient communication. Patients most likely to perceive their physicians as providing excellent care are those experiencing their preferred decision-making style with their primary physicians.²²⁻²³ Studies show that patient satisfaction, medication compliance, and health outcomes are improved by shared decision making.²⁴⁻²⁶

On July 19, 2015, the first joint International Shared Decision-Making/International Society for Evidence-Based Health Care (ISDM/ISEHC) Conference met in Sydney, Australia with over 300 people from around the globe to share knowledge and inspire action to improve the entire health care experience. Highlights of this meeting included:

- Informed consents are gaining importance connected with the use of the SDM, which includes a collaborative conversation around the patient's informed preferences and the best available scientific evidence.
- Aligned incentives are necessary to maximize SDM, but not necessarily monetary.
- Increasing in interest and gaining support is the inclusion of family engagement in the decision-making process with the patient/family/care team (called a triad) rather than the patient/care team (called a dyad). The discussion was how to make this a reality, as it has long been felt the family needed to be part of the SDM, but not easily implemented.
- Development of learning programs/greater communication skills for medical students was repeatedly discussed, looking for ways to include training for these as learned skills to build conversations around patient preferences and evidence-based scientific medicine/practice.²⁷

According to author David Arterburn, a general Internist, associate investigator at Group Health Research Institute, and affiliate associate professor at the University of Washington:

"Decision aids are evidence-based sources of health information that can help patients make informed treatment decisions. However, little is known about how

decision aids affect health care use when they are conducted an observational study to examine the associations between introducing decision aids for hip and knee osteoarthritis and rates of joint replacement surgery and costs in a large health system in Washington State. Consistent with prior randomized trials, our introduction of decision aids was associated with 26 percent fewer hip replacement surgeries, 38 percent fewer knee replacements, and 12–21 percent lower costs over six months. These findings support the concept that patient decision aids for some health conditions, for which treatment decisions are highly sensitive to both patients' and physicians' preferences, may reduce rates of elective surgery and lower costs."²⁸

He includes a recent review of 86 RCTs of decision aides which found that:

"These aids consistently increase patients' knowledge; improve treatment expectations; increase active participation in decision making; reduce decisional conflict or uncertainty about the appropriate course of action; decrease the proportion of people remaining undecided about treatment; and help patients reach decisions that are more aligned with their stated values."²⁸

Hip Disability and Osteoarthritis Outcome Score (HOOS)/HOOS, JR.

HOOS

The Hip disability and Osteoarthritis Outcome Score (HOOS) was developed as an instrument to assess the patient's opinion about their hip and associated problems and is intended to be used in an adult population with hip disability with or without OA.¹

The HOOS consists of 40 items arranged into 5 subscales. There are 10 items for pain, 5 items for other symptoms (3 for symptoms and 2 for stiffness), 17 items for function in ADL, 4 items for function in Sport/Rec, and 4 items for hip-related quality of life (QOL). Standardized answer options are given (5 Likert boxes) and each question is scored from 0 to 4. Scores are summarized for each subscale and transformed to a 0–100 scale (0 indicating extreme problems and 100 indicating no problems). The last week is taken into consideration when answering the questions.¹

Examples of Use

The HOOS has been used in subjects with hip disability with or without hip osteoarthritis²⁹ and in patients with hip OA pre- and postoperative total hip replacement (THR).^{30,31}

Reliability

The HOOS has been used in patients aged 42–89 years, including subjects with hip OA treated by medication only, subjects eligible for THR and postoperatively.^{29,30,32,33} The internal consistency ranged from 0.82 to 0.98 (Cronbach's alpha coefficient) in the different studies,^{29,32,33} with the highest value in the ADL subscale (0.94 – 0.98), which might indicate a redundancy of items. HOOS has high test–retest reproducibility, with the intraclass correlation coefficient ranging from 0.75 to 0.97 in the validation studies.^{29,32,33} The standard error of measurement published in the Dutch study ranged from 3.71 (QOL subscale) to 6.94 (pain subscale) for subjects with hip OA, and from 4.78 (ADL subscale) to 10.07 (Sport/Rec subscale) for subjects who had undergone THR.³²

Validity

The HOOS content validity was performed by asking patients to rate item importance in the 2 Swedish validation studies^{29,30} resulting in slightly different questionnaires where the LK 2.0 version has been translated into Dutch and French. HOOS construct validity has been tested by comparing it with the Short Form 36, the Oxford Hip Score, the Lequesne Index, and the visual analog scale for pain, and predetermined hypotheses were confirmed.^{30,32,33}

Ability to Detect Change

The HOOS responsiveness has been determined in 1 Swedish and in 1 French study (n=90 and n=30, respectively) after THR.^{30,33} The standardized response mean ranged from 1.29 –3.24.^{30,33}

Younger patients (age 66 years) showed larger responsiveness in all subscales compared with older subjects.³⁰ In the French sample, the effect size ranged from 1.97 (QOL subscale) to 3.24 (pain subscale) (18). The smallest detectable difference of the HOOS ranged from 9.6 for the ADL subscale to 16.2 for the QOL subscale.³³

Strengths

The HOOS is an extension of the WOMAC and is suggested to be valuable for younger and more active people due to added subscales. The HOOS has been included in 2 systematic reviews concerning psychometric evaluations of questionnaires assessing hip OA and yielded positive findings.^{34,35} The HOOS needs further psychometric testing in different cultures and in different groups of patients with hip disabilities.

The British Journal of Sports Medicine in 2009 published a review that looked to recommend the most suitable patient reported outcome (PRO) questionnaire for the assessment of hip and groin disability based on review of evidence of validity, reliability and responsiveness of the questionnaires. 12 different questionnaires designed for patients with hip disability were identified. The HOOS was found to contain adequate measurement qualities to evaluate patients with hip OA or THR. They concluded that the HOOS was recommended for evaluating patients with Hip OA undergoing non-surgical treatment and surgical interventions such as THR.³⁴

A study published in BMC Musculoskeletal Disorders in 2003 found that the HOOS to 2.0 appears to be useful for the evaluation of patient-relevant outcome after THR and is more responsive than the WOMAC LK 3.0. The added subscales sport and recreation function and hip related quality of life were highly responsive for this group of patients, with the responsiveness being highest for those younger than 66.³⁰

HOOS, JR.

Federal Register Volume 80, number 226, provided support for use of the shortened version of the HOOS, called the 'HOOS, JR.' (6 items).² A joint statement from multiple surgical specialty societies indicated there was new data validating the shortened versions of the HOOS instruments in THA patients. This shortened version is shown to be highly responsive in the THA patient population (standardized response means 1.7 to 2.4) and highly correlated with the Pain and Function, Daily Living subscales of the full HOOS and the WOMAC (Spearman's correlation .8-.94). They found that based on broad support in the orthopedic community, and a significantly smaller burden to complete, it was reasonable to replace the full HOOS with the HOOS, JR.

CollaboRATE

Patient-centered health care is a central component of current health policy agendas. Shared decision making (SDM) is considered to be the pinnacle of patient engagement and methods to promote this are becoming commonplace. However, the measurement of SDM continues to prove challenging. Reviews have highlighted the need for a patient-reported measure of SDM that is practical, valid, and reliable to assist implementation efforts. In consultation with patients, CollaboRATE was developed, a 3-item measure of the SDM process.³⁶ Barr et al (2014) completed a study identifying the need for scalable patient-reported measure of the SDM process. In the current project, the study assessed the psychometric properties of CollaboRATE. A representative sample of the US population was recruited online and was randomly allocated to view 1 of 6 simulated doctor-patient encounters in January 2013. Three dimensions of SDM were manipulated in the encounters: (1) explanation of the health issue, (2) elicitation of patient preferences, and (3) integration of patient preferences. Participants then completed CollaboRATE (possible scores 0-100) in addition to 2 other patient-reported measures of SDM: the 9-item Shared Decision Making Questionnaire (SDM-Q-9) and the Doctor Facilitation subscale of the Patient's Perceived Involvement in Care Scale (PICS). A subsample of participants was resurveyed between 7 and 14 days after the initial survey. This study assessed CollaboRATE's discriminative, concurrent, and divergent validity, intrarater reliability, and sensitivity to change. The final sample consisted of 1341 participants. CollaboRATE demonstrated discriminative

validity, with a significant increase in CollaboRATE score as the number of core dimensions of SDM increased from zero (mean score: 46.0, 95% CI: 42.4-49.6) to 3 (mean score 85.8, 95% CI: 83.2-88.4). CollaboRATE also demonstrated concurrent validity with other measures of SDM, excellent intrarater reliability, and sensitivity to change; however, divergent validity was not demonstrated. The fast and frugal nature of CollaboRATE lends itself to routine clinical use. Further assessment of CollaboRATE in real-world settings is required.³

Elwyn et al (2013) completed a study with an objective of measuring the process of shared decision making is a challenge, which constitutes a barrier to research and implementation. The aim of the study was to report the development of CollaboRATE, brief patient-reported measure of shared decision making. The following stages were utilized: (1) item formulation; (2) cognitive interviews; (3) item refinement; and (4) pilot testing of final items. Participants were over 18 years old and recruited from the public areas of the Dartmouth-Hitchcock Medical Center. The key finding of this study is that developing a brief patient-reported measure of shared decision making requires a move away from terms such as 'decisions', 'options' and 'preferences'. Although technically correct, these terms act as barriers. They are often unfamiliar, and they also implicitly assume that patients are willing to take active roles in decision making; whereas patients are often unaware that decisions are required, or have taken place, never mind feel that they could or should have participated in them. The outcome of this study concluded that these methods have allowed the development of a brief, patient-reported measure of shared decision making that is highly accessible to intended users.³⁷

The principles of shared decision making are well documented but there is a lack of guidance about how to accomplish the approach in routine clinical practice. The aim is to translate existing conceptual descriptions into a three-step model that is practical, easy to remember, and can act as a guide to skill development. Achieving shared decision making depends on building a good relationship in the clinical encounter so that information is shared, and patients are supported to deliberate and express their preferences and views during the decision making process. To accomplish these tasks, a model was proposed of how to do shared decision making that is based on choice, option and decision talk. The model has three steps: a) introducing choice, b) describing options, often by integrating the use of patient decision support, and c) helping patients explore preferences and make decisions. This model rests on supporting a process of deliberation, and on understanding that decisions should be influenced by exploring and respecting "what matters most" to patients as individuals, and that this exploration in turn depends on them developing informed preferences.³⁶

Total Hip Arthroplasty

Total hip arthroplasty (THA) and knee joint arthroplasty (TKA) are universally recommended in 14/14 existing treatment guidelines,⁴ and generally accepted as reliable and appropriate surgical procedures to restore function and improve health-related quality of life in patients with hip and knee OA who are not obtaining adequate pain relief and functional improvement with a combination of pharmacological and non-pharmacological treatments.⁴ The American Association of Hip and Knee Surgeons called the total hip arthroplasty the 'gold standard' for treating disabling hip pain.³⁸

There are multiple types of prostheses, including metal on polyethylene, metal on metal, ceramic on ceramic and hybrid prostheses. There are also cemented and uncemented prostheses. The risks and benefits of the different types of prostheses are beyond the scope of this policy.

As ethical and methodological considerations have precluded evaluation of total joint replacement with RCTs, evidence to support their efficacy is based substantially on numerous uncontrolled observational studies and a very small number of cohort studies where outcomes have been compared with standard medical care (LoE III). These are well summarized in a 2004 qualitative and systematic review of the scientific literature relating to health-related quality of life outcomes following THA and TKA.⁴

Avascular Necrosis

Total hip arthroplasty (THA) is a highly successful surgery for the management of both osteoarthritis (OA) and avascular necrosis (AVN) of the hip.³⁹ While a majority of THA is performed for OA, a significant portion is performed in the setting of AVN. Multiple studies demonstrate positive outcomes with THA for AVN.⁴⁰⁻⁴²

Recent studies have shown 96.6% survivorship with revision as an endpoint with an average of 16 year follow up.³⁹ THA for AVN has shown to have superior outcomes when compared to hemiarthroplasty with lower rates of groin pain and migration.⁴³ When compared to OA, THA for AVN has been found to have similar functional outcomes but worse long term pain outcomes.⁴⁴

One hundred twenty-three total hip arthroplasties were performed in 85 patients with osteonecrosis of the femoral head. There were 51 males and 34 females with an average age of 45 years. The average follow-up time was 4.6 years with a range of 2 to 10 years. All femoral stems and 71 sockets were fixed with acrylic cement. Fifty-two of the sockets used were placed without cement. The average Harris hip score improved from 45 points preoperatively to 92 points at the time of last follow-up. Using modern cement techniques and components, total hip arthroplasty can give excellent results in the young patient with avascular necrosis and may be the treatment of choice when reconstructive surgery is required.⁴¹

A study was conducted to evaluate the role of total hip replacement in cases of advanced avascular necrosis of the head of femur in patients admitted to two tertiary care military hospitals. 20 patients reporting with avascular necrosis of femoral head were taken for study. Out of 20 patients, 16 were males and 4 were females. They were evaluated pre-operatively and total hip replacement was done in all twenty cases. Patients were evaluated using Harris hip score and showed improvement of the score in all cases. The authors concluded that total hip replacement is beneficial for patients of advanced avascular necrosis of femoral head.⁴⁵

Chang *et al* evaluated 74 hips in 52 patients who underwent THR for ONFH after kidney transplantation with cementless THRs. They reported 96.6% cumulative implant survivorship at a mean follow-up of 10.2 years, which is comparable with survivorship due to other causes of THR. In the light of these findings, the outcomes of THR even in these high-risk patients are improving, potentially due to improved medical and surgical management, as well as the use of modern prosthetic designs, including cementless acetabular and femoral fixation.⁴⁶

Unstable Fracture

Sidhu *et al* studied postoperative complications, mortality rate, functional outcome using the Harris hip score, time to return to normal activities, and radiographic evidence of healing. Two patients died on the third and fifth postoperative days. Seven more patients died within one year. The Harris hip score at one month was 66 ± 7 (mean \pm standard deviation); at three months 72 ± 6 ; at one year 74 ± 5 ; at three years 76 ± 6 and in the 27 patients who completed five year follow-up it was 76 ± 8 . Mobilization and weight-bearing was started immediately in the post-operative period. Average time taken to return to normal daily activities was 28 days (range 24-33). No loosening or infection of the implants was observed. Total hip arthroplasty is a valid treatment option for mobile and mentally healthy elderly patients with intertrochanteric fractures. This procedure offers quick recovery with little risk of mechanical failure, avoids the risks associated with internal fixation and enables the patient to maintain a good level of function immediately after surgery.⁴⁷

Simko *et al* performed a study to evaluate the clinical and functional outcomes of THAs in patients with acetabular fractures due to low energy injury. They concluded that acute primary THA with the use of an antiprotusion cage and bone grafting for acetabular fractures in elderly patients allows us to employ only one surgical technique for definitive repair. It provides primary stability and immediate pain relief, permits graded weight-bearing and early pain-free mobilization, and may also treat hip arthritis, if it exists. This technique has also good prospects for

a selected group of younger patients in whom the treatment of acetabular fractures has a poor prognosis.⁴⁸

A non-randomized prospective multicenter study compared osteosynthesis by trochanteric nailing ($n = 113$) to hip arthroplasty ($n = 134$) in unstable trochanteric fracture (AO types 31 A2.2 and 3 and A3.3) in 247 patients over the age of 75 years. They found that three-month mortality was identical in the two groups (21.2% versus 21%). General complications did not differ, although mechanical complications were more frequent in the nailing group (12.5% versus 2.8%). Functional results (Parker and PMA scores) were better in the implant than in the nail group. They concluded that their study validated hip arthroplasty in these indications. Cemented stems associated to a dual-mobility acetabular component gave the best results.⁴⁹

Revision Total Hip Arthroplasty

Revision hip arthroplasty, which constitutes close to one quarter of all arthroplasties performed in the U.S., places immense financial burden on healthcare and has a less favorable outcome than primary total hip arthroplasty.⁵⁰

A study published in the *Journal of Bone and Joint Surgery America* noted that the most common type of revision THA procedure was an all component revision (41.1%). The most common causes of revision were instability/dislocation (22.5%), mechanical loosening (19.7%) and infection (14.1%) The average length of hospital stay for all types of revision arthroplasties was 6.2 days.⁵¹

Slif et al found that potential reasons for hip revisions can be stratified into three groups: patient-related factors, implant-related factors, and failures related to inadequate surgical technique.⁵²⁻⁵⁴ Osteolysis and aseptic loosening, resulting from the failure of bearing surfaces, are considered to be the most common reasons for revision hip arthroplasty.^{52,55} These are failures that occur relatively long after the primary implantation. Other causes of failure which occur at earlier times include implant-related problems, such as periprosthetic fractures,^{56,57} delamination of the porous coating,⁵⁴ or other manufacturing problems. Patient-related factors leading to the failure of total hip arthroplasty include co-morbidities such as sickle cell anaemia,⁵⁸ poor bone quality,⁵⁹ or other variables that may predispose the patient to infections or dislocation. Surgical technique may also affect the outcome of total hip arthroplasty. This technical influence may be greater than previously believed as many revisions are required because of recurrent dislocation, malpositioning of components, or other technical problems.⁶⁰⁻⁶² Various other factors, such as high body mass index, use of non-steroidal anti-inflammatory drugs (NSAIDs) and smoking, are still subject to controversy in terms of being potential causes of prosthetic failure.⁶³⁻⁶⁷

Fink noted in the *International Journal of Medical Science* in 2009 that many concepts have been devised for the treatment of late periprosthetic infections of total hip prostheses. A two-stage revision with a temporary antibiotic-impregnated cement spacer and a cemented prosthesis appears to be the most preferred procedure although, in recent times, there seems to be a trend towards cementless implants and a shorter period of antibiotic treatment. Because of the differences in procedure, not only between studies but also within studies, it cannot be decided which period of parenteral antibiotic treatment and which spacer period is the most suitable. The fact that comparable rates of success can be achieved with different treatment regimens emphasizes the importance of surgical removal of all foreign materials and the radical debridement of all infected and ischemic tissues and the contribution of these crucial procedures to the successful treatment of late periprosthetic infections.⁶⁸

Springer et al noted that revision THA is indicated for most periprosthetic fractures that occur around the stem of the femoral implant. Their study noted that revision THA for the treatment of a periprosthetic fracture around the stem of the femoral implant was successful in restoring function for most patients. The greatest long-term problems were prosthetic loosening and fracture nonunion. Better results were seen when an uncemented, extensively porous-coated stem was used.⁶⁹

Summary of Evidence

Total hip arthroplasty (THA), also known as total hip replacement, for osteoarthritis (OA), is supported with sufficient clinical evidence in the published scientific literature as safe and effective in relieving pain and improving joint function and mobility in patients who have failed nonsurgical medical management. Despite the potential benefits, THA it is an elective procedure and should only be considered after extensive discussion of the risks, benefits, and alternatives. There is insufficient evidence to support the safety, efficacy, and improved long-term outcomes for all other indications outside of the medical necessity indications.

Supplemental Information

Practice Guidelines and Position Statements

Several societies have established guidelines for the treatment of osteoarthritis. These include the American College of Rheumatology (ACR) and The Osteoarthritis Research Society International (OARSI). These groups recommend that, before turning to surgery, patients try non-surgical options that have been shown to have some success, such as weight loss, exercise, activity modification, or the use of walking aids or orthotics.

American College of Rheumatology

The American College of Rheumatology has developed Recommendations for the use of Non-pharmacologic and Pharmacologic therapies in Osteoarthritis of the Hand, Hip, and Knee. This summary of recommendations includes those recommendations specific to the hip.⁷⁰

ACR Recommendations for the Use of Non-Pharmacologic and Pharmacologic Therapies in OA.

Recommendation	Action
Non-Pharmacologic Recommendations for the Management of Hip Osteoarthritis (OA):	
We strongly recommend that patients with hip OA should do the following:	<ul style="list-style-type: none"> Participate in cardiovascular and/or resistance land-based exercise Participate in aquatic exercise Lose weight (for persons who are overweight) Participate in self-management programs Receive manual therapy in combination with supervised exercise
We conditionally recommend that patients with hip OA should do the following:	<ul style="list-style-type: none"> Receive psychosocial interventions Be instructed in the use of thermal agents Receive walking aids, as needed Participation in balance exercises, either alone or in combination with strengthening exercises
We have no recommendations regarding the following:	<ul style="list-style-type: none"> Participation in tai chi Receiving manual therapy alone
Pharmacologic Recommendations for the Initial Management of Hip OA*	
We conditionally recommend that patients with hip OA should use one of the following:	<ul style="list-style-type: none"> Acetaminophen Oral NSAIDs Tramadol Intraarticular corticosteroid injections
We conditionally recommend that patients with hip OA should not use the following:	<ul style="list-style-type: none"> Chondroitin sulfate Glucosamine
We have no recommendation regarding the use of the following:	<ul style="list-style-type: none"> Topical NSAIDs Intraarticular hyaluronate injections Duloxetine Opioid analgesics

* No strong recommendations were made for the initial pharmacologic management of hip osteoarthritis (OA). For patients who have an inadequate response to initial pharmacologic management, please see the Results for alternative strategies. NSAIDs=nonsteroidal anti-inflammatory drugs.

Osteoarthritis Research Society International

The Osteoarthritis Research Society International (OARSI) has offered consensus guidelines for the treatment/management of hip and knee osteoarthritis. The OARSI performed a literature review and consulted a panel of 16 experts from four medical disciplines.

The Osteoarthritis Research Society International (OARSI) Recommendations for the Management of Hip and Knee Osteoarthritis, Part II for Hip OA.⁴

Recommendation	Strength of Recommendation (SOR)
General Recommendations	
Optimal management of OA requires a combination of non-pharmacological and pharmacological modalities.	SOR: 96% (95% CI: 93-99)
Non-Pharmacological Modalities of Treatment	
All patients with hip and knee OA should be given information access and education about the objectives of treatment and the importance of changes in lifestyle, exercise, pacing of activities, weight reduction, and other measures to unload the damaged joint(s). The initial focus should be on self-help and patient-driven treatments rather than on passive therapies delivered by health professionals. Subsequently emphasis should be placed on encouraging adherence to the regimen of non-pharmacological therapy.	SOR: 97% (95% CI: 95-99)
The clinical status of patients with hip or knee OA can be improved if patients are contacted regularly by phone.	SOR: 66% (95% CI: 57-75)
Patients with symptomatic hip and knee OA may benefit from referral to a physical therapist for evaluation and instruction in appropriate exercises to reduce pain and improve functional capacity. This evaluation may result in provision of assistive devices such as canes and walkers, as appropriate.	SOR: 89% (95% CI: 82-96)
Patients with hip and knee OA should be encouraged to undertake, and continue to undertake, regular aerobic, muscle strengthening and range of motion exercises. For patients with symptomatic hip OA, exercises in water can be effective.	SOR: 96% (95% CI: 93-99)
Patients with hip and knee OA, who are overweight, should be encouraged to lose weight and maintain their weight at a lower level. Walking aids can reduce pain in patients with hip and knee OA.	SOR: 96% (95% CI: 92-100)
Patients should be given instruction in the optimal use of a cane or crutch in the contralateral hand. Frames or wheeled walkers are often preferable for those with bilateral disease.	SOR: 90% (95% CI: 84-96)
Every patient with hip or knee OA should receive advice concerning appropriate footwear. In patients with knee OA insoles can reduce pain and improve ambulation. Lateral wedged insoles can be of symptomatic benefit for some patients with medial tibio-femoral compartment OA.	SOR: 77% (95% CI: 66-88)
Some thermal modalities may be effective for relieving symptoms in hip and knee OA.	SOR: 64% (95% CI: 60-68)
Transcutaneous electrical nerve stimulation (TENS) can help with short-term pain control in some patients with hip or knee OA.	SOR: 58% (95% CI: 45-72)
Pharmacological Modalities of Treatment	
Acetaminophen (paracetamol) (up to 4 g/day) can be an effective initial oral analgesic for treatment of mild to moderate pain in patients with knee or hip OA. In the absence of an adequate response, or in the presence of severe pain and/or inflammation, alternative pharmacologic therapy should be considered based on relative efficacy and safety, as well as concomitant medications and comorbidities.	SOR: 92% (95% CI: 88-99)
In patients with symptomatic hip or knee OA, non-steroidal anti-inflammatory drugs (NSAIDs) should be used at the lowest effective dose but their long-term use should be avoided if possible. In patients with increased GI risk, either a COX-2 selective agent or a non-selective NSAID with co-prescription of a proton pump inhibitor (PPI) or misoprostol for gastroprotection may be considered, but NSAIDs, including both non-selective and COX-2 selective agents, should be used with caution in patients with cardiovascular (CV) risk factors.	SOR: 93% (95% CI: 88-99)
Intra-articular (IA) injections with corticosteroids can be used in the treatment of hip or knee OA, and should be considered particularly when patients have moderate to severe pain not responding satisfactorily to oral analgesic/anti-inflammatory agents and in patients	SOR: 78% (95% CI: 61-95)

Recommendation	Strength of Recommendation (SOR)
with symptomatic knee OA with effusions or other physical signs of local inflammation.	
Injections of IA hyaluronate may be useful in patients with knee or hip OA. They are characterized by delayed onset, but prolonged duration, of symptomatic benefit when compared to IA injections of corticosteroids.	SOR: 64% (95% CI: 43-85)
In patients with symptomatic knee OA glucosamine sulphate and chondroitin sulphate may have structure-modifying effects while diacerein may have structure-modifying effects in patients with symptomatic OA of the hip.	SOR: 41% (95% CI: 20-62)
The use of weak opioids and narcotic analgesics can be considered for the treatment of refractory pain in patients with hip or knee OA, where other pharmacological agents have been ineffective, or are contraindicated. Stronger opioids should only be used for the management of severe pain in exceptional circumstances. Non-pharmacological therapies should be continued in such patients and surgical treatments should be considered.	SOR: 82% (95% CI: 74-90)
Surgical Modalities of Treatment	
Patients with hip or knee OA who are not obtaining adequate pain relief and functional improvement from a combination of non-pharmacological and pharmacological treatment should be considered for joint replacement surgery. Replacement arthroplasties are effective, and cost-effective interventions for patients with significant symptoms, and/or functional limitations associated with a reduced health-related quality of life, despite conservative therapy.	SOR: 96% (95% CI: 94-98)
Osteotomy and joint preserving surgical procedures should be considered in young adults with symptomatic hip OA, especially in the presence of dysplasia. For the young and physically active patient with significant symptoms from unicompartmental knee OA, high tibial osteotomy may offer an alternative intervention that delays the need for joint replacement some 10 years.	SOR: 75% (95% CI: 64-86)

Medicare National Coverage

Medicare does not have a National Coverage Determination, but does have a Local Coverage Determination (LCD) for Total Hip Arthroplasty (L34163) and Total Knee Arthroplasty (L36575).^{8,71}

Noridian will not consider a total hip replacement or total knee replacement medically necessary when the following contraindications are present:

- Active infection of the hip or knee joint or active systemic bacteremia
- Active urinary tract or dental infection
- Active skin infection (exception recurrent cutaneous staph infections) or open wound within the planned surgical site of the hip or knee
- Rapidly progressive neurological disease except in the clinical situation of a concomitant displaced femoral neck fracture

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
 - Clinical records indicating pain and functional disability that interferes with ADLs
 - Documentation of limited range of motion if applicable
 - Reason for surgical intervention
 - Treatment plan (i.e., surgical intervention)
- Prior conservative treatments, duration, and response
- Past and present diagnostic testing and results
- Pertinent past procedural and surgical history
- Radiology report(s) (i.e., MRI, CT)
- Completed and signed Total Hip Arthroplasty Decision Aid by the member and physician
- Completed and signed Hip dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR.) by the member
- Completed and signed CollaboRATE survey by the member

Post Service (in addition to the above, please include the following):

- Results/reports of tests performed
- Procedure report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may

include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	27125	Hemiarthroplasty, hip, partial (e.g., 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	Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft
	27138	Revision of total hip arthroplasty; femoral component only, with or without allograft
HCPCS	S2118	Metal-on-metal total hip resurfacing, including acetabular and femoral components

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
04/01/2016	Custom Policy
07/01/2016	Policy revision without position change
12/01/2017	Policy revision without position change
09/01/2018	Policy revision without position change
03/01/2019	Policy revision without position change
10/01/2019	Administrative update
05/01/2020	Annual review. Policy statement and guidelines updated.
11/01/2020	Administrative update. Policy statement and guidelines updated.
05/01/2021	Annual review. No change to policy statement.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	AFTER
<p>Total Hip Arthroplasty for Adults BSC7.11</p> <p>Policy Statement: Total hip arthroplasty may be considered medically necessary when ALL of the following criteria are met:</p> <ol style="list-style-type: none"> I. The reason for the arthroplasty is osteoarthritis (OA), rheumatoid arthritis, avascular necrosis (osteonecrosis), or post-traumatic arthritis of the hip joint II. The member and physician have reviewed, completed, and signed the Total Hip Arthroplasty Decision Aid ensuring shared decision making has occurred III. The member has reviewed, completed, and signed the Hip Dysfunction & Osteoarthritis Outcome Score (HOOS), JR. survey, with submission of the score with the clinical documentation IV. The member has reviewed, completed, and signed the CollaboRATE survey, with submission of the score with the clinical documentation V. It is NOT for a customized hip replacement, including all of the following: <ol style="list-style-type: none"> A. It does NOT use customized templates, and/or instrumentation B. It does NOT use customized hip implant C. It does NOT use a "Gender specific" implant D. It does NOT use Pre-operative imaging studies (e.g., CT scans, MRI) associated with the customization and/or utilized as part of intraoperative navigation (e.g., MAKOplasty) VI. There is NO active infection of the joint or active systemic bacteremia (that has not been treated) VII. There is NO skin infection (exception recurrent cutaneous staph infections) or open wound within the planned surgical site of the hip VIII. There is NO allergy to components of the implant (e.g., cobalt, chromium or alumina) IX. There is NO skeletal immaturity X. There is NO paraplegia or quadriplegia, permanent or irreversible muscle weakness (in the absence of pain) that prevents 	<p>Total Hip Arthroplasty for Adults BSC7.11</p> <p>Policy Statement: Total hip arthroplasty may be considered medically necessary when ALL of the following criteria are met:</p> <ol style="list-style-type: none"> I. The reason for the arthroplasty is osteoarthritis (OA), rheumatoid arthritis, avascular necrosis (osteonecrosis), or post-traumatic arthritis of the hip joint II. The member and physician have reviewed, completed, and signed the Total Hip Arthroplasty Decision Aid ensuring shared decision making has occurred III. The member has reviewed, completed, and signed the Hip Dysfunction & Osteoarthritis Outcome Score (HOOS), JR. survey, with submission of the score with the clinical documentation IV. The member has reviewed, completed, and signed the CollaboRATE survey, with submission of the score with the clinical documentation V. It is NOT for a customized hip replacement, including all of the following: <ol style="list-style-type: none"> A. It does NOT use customized templates, and/or instrumentation B. It does NOT use customized hip implant C. It does NOT use a "Gender specific" implant D. It does NOT use Pre-operative imaging studies (e.g., CT scans, MRI) associated with the customization and/or utilized as part of intraoperative navigation (e.g., MAKOplasty) VI. There is NO active infection of the joint or active systemic bacteremia (that has not been treated) VII. There is NO skin infection (exception recurrent cutaneous staph infections) or open wound within the planned surgical site of the hip VIII. There is NO allergy to components of the implant (e.g., cobalt, chromium or alumina) IX. There is NO skeletal immaturity X. There is NO paraplegia or quadriplegia, permanent or irreversible muscle weakness (in the absence of pain) that prevents

POLICY STATEMENT

(No changes)

BEFORE	AFTER
<p>ambulation, or rapidly progressive neurological disease (except in the clinical situation of a concomitant displaced femoral neck fracture)</p> <p>XI. A patient has any of the following conditions:</p> <p>A. Degenerative joint disease when all of the following exist:</p> <ol style="list-style-type: none"> 1. Documentation of failure of conservative therapy (non-surgical medical management) or documentation of rationale if conservative therapy is considered inappropriate 2. Documentation of limited range of motion, antalgic gait, and pain in hip joint with passive range of motion on physical examination 3. Radiographic evidence of any of the following: <ol style="list-style-type: none"> a. Severe osteoarthritis of hip joint as evidenced by two or more of the following: <ol style="list-style-type: none"> i. Subchondral cysts ii. Subchondral sclerosis iii. Periarticular osteophytes iv. Joint subluxation v. Bone on bone articulation vi. Joint space narrowing b. Avascular necrosis (osteonecrosis) with greater than stage II with collapse and in stage II avascular necrosis with severe recalcitrant hip pain in spite of treatment with medications c. Rheumatoid arthritis (joint space narrowing) d. Post traumatic conditions not amenable to hip preservation (even in the absence of severe osteoarthritis), including but not limited to femoral head fractures or some acetabular fractures e. Synovitic and tumorous conditions that do not respond to conservative therapy or hip preservation surgery, including but not limited to synovial osteochondromatosis and pigmented villonodular synovitis <p>B. Tumor involving proximal femur or acetabulum</p> <p>C. Unstable fracture of the femoral neck or acetabulum</p>	<p>ambulation, or rapidly progressive neurological disease (except in the clinical situation of a concomitant displaced femoral neck fracture)</p> <p>XI. A patient has any of the following conditions:</p> <p>A. Degenerative joint disease when all of the following exist:</p> <ol style="list-style-type: none"> 1. Documentation of failure of conservative therapy (non-surgical medical management) or documentation of rationale if conservative therapy is considered inappropriate 2. Documentation of limited range of motion, antalgic gait, and pain in hip joint with passive range of motion on physical examination 3. Radiographic evidence of any of the following: <ol style="list-style-type: none"> a. Severe osteoarthritis of hip joint as evidenced by two or more of the following: <ol style="list-style-type: none"> i. Subchondral cysts ii. Subchondral sclerosis iii. Periarticular osteophytes iv. Joint subluxation v. Bone on bone articulation vi. Joint space narrowing b. Avascular necrosis (osteonecrosis) with greater than stage II with collapse and in stage II avascular necrosis with severe recalcitrant hip pain in spite of treatment with medications c. Rheumatoid arthritis (joint space narrowing) d. Post traumatic conditions not amenable to hip preservation (even in the absence of severe osteoarthritis), including but not limited to femoral head fractures or some acetabular fractures e. Synovitic and tumorous conditions that do not respond to conservative therapy or hip preservation surgery, including but not limited to synovial osteochondromatosis and pigmented villonodular synovitis <p>B. Tumor involving proximal femur or acetabulum</p> <p>C. Unstable fracture of the femoral neck or acetabulum</p>

POLICY STATEMENT (No changes)	
BEFORE	AFTER
<p>D. Symptomatic findings of FemoroAcetabular Impingement (FAI) in the presence of significant (advanced) osteoarthritis</p> <p>E. Previous arthroplasty or resurfacing revision, indicated by one or more of the following conditions:</p> <ol style="list-style-type: none"> 1. Joint instability 2. Implant failure 3. Infection 4. Irreducible or recurrent dislocation 5. Displaced fracture at prosthesis site 6. Allergy to implant material <p>Total hip arthroplasty is considered investigational for all other indications due to insufficient evidence of effectiveness.</p>	<p>D. Symptomatic findings of FemoroAcetabular Impingement (FAI) in the presence of significant (advanced) osteoarthritis</p> <p>E. Previous arthroplasty or resurfacing revision, indicated by one or more of the following conditions:</p> <ol style="list-style-type: none"> 1. Joint instability 2. Implant failure 3. Infection 4. Irreducible or recurrent dislocation 5. Displaced fracture at prosthesis site 6. Allergy to implant material <p>Total hip arthroplasty is considered investigational for all other indications due to insufficient evidence of effectiveness.</p>