Hip Resurfacing

Policy # 00119
Original Effective Date: 09/18/2002
Current Effective Date: 05/10/2021

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider metal-on-metal (MoM) total hip resurfacing (THR) with a Food and Drug Administration (FDA)-approved device system to be **eligible for coverage**** as an alternative to total hip replacement.

Patient Selection Criteria

Coverage eligibility for the use of metal-on-metal (MoM) total hip resurfacing (THR) with a Food and Drug Administration (FDA)-approved device system as an alternative to total hip replacement will be considered when all of the following criteria are met:

- Is a candidate for total hip replacement; and
- Is likely to outlive a traditional prosthesis; and
- Does not have a contraindication for total hip resurfacing (THR) (see Contraindications for Total Hip Resurfacing below).

Based on review of available data, the Company may consider partial hip resurfacing with a Food and Drug Administration (FDA)-approved device in patients with osteonecrosis of the femoral head who have one or more contraindications for metal-on-metal (MoM) implants and meet all of the following criteria to be **eligible for coverage****:

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Patient Selection Criteria

Coverage eligibility for the use of partial hip resurfacing with an Food and Drug Administration (FDA)-approved device in patients with osteonecrosis of the femoral head who have one or more contraindications for metal-on-metal (MoM) implants will be considered when all of the following criteria are met:

- The patient is a candidate for total hip replacement; and
- Is likely to outlive a traditional prosthesis; and
- The patient has no known or suspected metal sensitivity or concern about potential effects of metal ions; and
- There is no more than 50% involvement of the femoral head; and
- There is minimal change in acetabular cartilage or articular cartilage space identified on radiography.

Contraindications for Total Hip Resurfacing:

The Food and Drug Administration (FDA) lists several contraindications for total hip resurfacing (THR). These contraindications include (not a complete listing) the following:

- Bone stock inadequate to support the device due to:
    - Severe osteopenia or a family history of severe osteoporosis or severe osteopenia;
    - Osteonecrosis or avascular necrosis with more than 50% involvement of the femoral head;
    - Multiple cysts of the femoral head (more than 1 cm);
- Skeletal immaturity;
- Vascular insufficiency, muscular atrophy, or neuromuscular disease severe enough to compromise implant stability or postoperative recovery;
- Known moderate to severe renal insufficiency;
- Severely overweight;
- Known or suspected metal sensitivity;
- Immunosuppressed or receiving high doses of corticosteroids;
- Females of child bearing age due to unknown effects on the fetus of metal ion release.

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers all other types and applications of total hip resurfacing (THR) to be **investigational.***

The use of hip resurfacing when patient selection criteria are not met is considered to be **investigational.***

Policy Guidelines

The U.S. Food and Drug Administration (FDA) lists several contraindications for total hip resurfacing. These contraindications include, but are not limited to, the following:

- Bone stock inadequate to support the device due to:
  - severe osteopenia or a family history of severe osteoporosis or severe osteopenia
  - osteonecrosis or avascular necrosis with more than 50% involvement of the femoral head
  - multiple cysts of the femoral head (>1 cm)
- Skeletal immaturity
- Vascular insufficiency, muscular atrophy, or neuromuscular disease severe enough to compromise implant stability or postoperative recovery
- Known moderate-to-severe renal insufficiency
- Severely overweight
- Known or suspected metal sensitivity
- Immunosuppressed or receiving high doses of corticosteroids
- Females of child bearing age due to unknown effects on the fetus of metal ion release.

A 2012 FDA advisory panel of experts identified young males with larger femoral heads as the best candidates for hip resurfacing systems. The FDA has advised that a metal-on-metal hip implant should be selected only after determining that the benefit-risk profile of using a metal-on-metal hip implant outweighs that of using an alternative hip system. Factors to consider include the patient's age, sex, weight, diagnosis, and activity level. Patients should be informed about the benefits and

risks of metal-on-metal hip implants, including the risk that the hip implant may need to be replaced. Patient expectations and the potential complications of surgery with a metal-on-metal hip implant should be discussed.

Total hip resurfacing should be performed by surgeons adequately trained and experienced in the specific techniques and devices used.

Background/Overview

Hip resurfacing is an alternative to total hip arthroplasty (THA; also known as total hip replacement) for patients with advanced arthritis of the hip. Total hip resurfacing describes the placement of a shell that covers the femoral head together with implantation of an acetabular cup. Partial hip resurfacing is considered a treatment option for avascular necrosis with collapse of the femoral head.

Total hip resurfacing has been investigated in patients with osteoarthritis, rheumatoid arthritis, and advanced avascular necrosis as an alternative to total hip arthroplasty (THA), particularly in young active patients who would potentially outlive a total hip prosthesis. Therefore, hip resurfacing could be viewed as a time-buying procedure to delay the need for a total hip arthroplasty (THA). Proposed advantages of total hip resurfacing compared with THA include preservation of the femoral neck and femoral canal, thus facilitating revision or conversion to a total hip resurfacing, if required. In addition, the resurfaced head is more similar in size to the normal femoral head, thus increasing the stability and decreasing the risk of dislocation compared with THA.

Total hip resurfacing has undergone various evolutions, with modifications in prosthetic design and composition and implantation techniques. For example, similar to total hip prostheses, the acetabular components of total hip resurfacing have been composed of polyethylene. However, over time it became apparent that device failure was frequently related to the inflammatory osteolytic reaction to polyethylene debris wear particles. Metal acetabular components have since been designed to improve implant longevity. Sensitivity to wear particles from metal-on-metal chromium and cobalt implant components are of increasing concern.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2006, the Birmingham Hip Resurfacing system (Smith & Nephew Orthopaedics), a metal-on-metal resurfacing system, was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process for use in patients requiring primary hip resurfacing arthroplasty for noninflammatory or inflammatory arthritis. This decision was primarily based on a series of 2,385 patients who received this device by a single surgeon in England. A number of post approval conditions were required, including the following items:

- Study longer term safety and effectiveness through 10-year follow-up of the initial 350 patients in the patient cohort that was part of the premarket approval.
- Study the "learning curve" and the longer term safety and effectiveness of the Birmingham Hip Resurfacing system in the United States by studying 350 patients at up to 8 sites where clinical and radiographic data will be assessed annually through 5 years and at 10 years. Also, determine cobalt and chromium serum concentration and renal function in these patients at 1, 4, and 10 years.
- Implement a training program to provide clinical updates to investigators.

Two additional metal-on-metal hip resurfacing systems have been approved: in 2007, the Cormet™ Hip Resurfacing System (Corin) and, in 2009, the Conserve® Plus Total Hip Resurfacing System (MicroPort Orthopedics). Both implants were approved for skeletally mature patients with either: noninflammatory degenerative arthritis (eg, osteoarthritis and avascular necrosis); or inflammatory arthritis (eg, rheumatoid arthritis). (Note: patients with the latter arthritis might be individuals who, due to younger age or increased activity level, may not be suitable for traditional THA because it would increase the possibility of requiring ipsilateral hip joint revision.)

Various devices have been cleared for marketing by the FDA through the 510(k) process for partial hip (femoral) resurfacing. Some surgeons may be using a femoral resurfacing component together with an acetabular cup (total arthroplasty component) as an off-label application.

FDA product code: NXT.

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Rationale/Source

Hip resurfacing is an alternative to total hip arthroplasty (also known as hip replacement) for patients with advanced arthritis of the hip. Total hip resurfacing describes the placement of a shell that covers the femoral head together with implantation of an acetabular cup in patients with painful hip joints. Partial hip resurfacing is considered a treatment option for avascular necrosis with collapse of the femoral head. Available prostheses are metal-on-metal devices.

For individuals who have an indication for hip replacement who would outlive a traditional prosthesis and have no contraindication for hip resurfacing who receive a metal-on-metal total hip resurfacing device or a partial hip resurfacing device, the evidence includes 2 randomized controlled trials, numerous large observational studies, large registry studies, and systematic reviews. Relevant outcomes are symptoms, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related morbidity. The efficacy of total hip resurfacing performed with current techniques is similar to that for total hip arthroplasty over the short-to-medium term, and total hip resurfacing may permit easier conversion to a total hip arthroplasty for younger patients expected to outlive their prosthesis. Based on potential ease of revision of total hip resurfacing compared with total hip arthroplasty, current evidence supports conclusions that hip resurfacing presents a reasonable alternative for active patients who are considered too young for total hip arthroplasty when performed by surgeons experienced in the technique. The literature on adverse events (eg,metallosis, pseudotumor formation, implant failure) is evolving as longer follow-up becomes available. Due to the uncertain risk with metal-on-metal implants, the risk-benefit ratio needs to be considered carefully on an individual basis. In addition, emerging evidence has suggested an increased risk of failure in women, possibly due to smaller implant size. Therefore, these factors should also be considered in the overall patient evaluation for total hip resurfacing, and patients should make an informed choice with their treating physicians. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have an indication for hip replacement who would outlive a traditional prosthesis and have no contraindication for hip resurfacing who receive partial hip resurfacing device, the evidence includes a comparative study. Relevant outcomes are symptoms, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related morbidity. Although evidence has shown better outcomes with total hip resurfacing than with partial hip resurfacing, partial hip resurfacing would be appropriate in younger patients with osteonecrosis

who have contraindications for a metal-on-metal prosthesis. These factors should be considered in the overall patient evaluation for total hip resurfacing, and patients should make an informed choice with their treating physicians. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 1 physician specialty society and 1 academic medical center while this policy was under review in 2013. Input was mixed, although both reviewers agreed that evidence is not sufficient to conclude that the potential for harm with metal-on-metal hip resurfacing outweighs the benefit for all patients. One reviewer noted that current cross-linked polyethylene total hip components may last 20 to 30 years, limiting the number of patients who would outlive a total hip prosthesis and be considered an appropriate candidate for total hip resurfacing.

Practice Guidelines and Position Statements

Hip Society

In 2012, the Hip Society published an algorithmic approach to the diagnosis and management of metal-on-metal arthroplasty (total hip arthroplasty [THA], total hip resurfacing). The review indicated that adverse local tissue reactions to metal debris are escalating and that all arthroplasty patients returning for follow-up should be queried for pain, discomfort, or compromise of function. Symptomatic patients should be evaluated for all intra-articular and extra-articular causes of pain, including aseptic loosening, sepsis, component malposition, or fluid collections and/or masses about the hip. The Hip Society stated that there is still a role for metal-on-metal resurfacing arthroplasty in select patients groups. The ideal candidate is a man younger than age 55 with osteoarthritis and a femoral head size larger than 50 mm. Another relative indication is the need or desire to return to a very high activity level at work or in recreation. Contraindications to metal-on-metal resurfacing

include known or suspected metal sensitivity; moderate or worse renal function; women who may become pregnant; osteoporosis; large cysts; and avascular necrosis more than 50%.

California Technology Assessment Forum
In 2011, the California Technology Assessment Forum concluded there was no evidence that the potential benefits of metal-on-metal hip resurfacing outweighed the potential risks. Revision rates appeared to be higher in patients receiving total hip resurfacing procedures than in those receiving THA, which is of particular importance because the total hip resurfacing procedure targets young people. This risk may be particularly high in women. In addition, the elevated levels of metal ions were concerning. Although the clinical significance of these elevated ion levels is still uncertain, they are implicated in the development of aseptic lymphocytic vasculitis-associated lesions, often seen in aseptic failure of total hip resurfacing. Pseudotumors appear to be a more severe manifestation of aseptic lymphocytic vasculitis-associated lesions. It was recommended that metal-on-metal hip resurfacing using the Birmingham Hip Resurfacing, Cormet 2000, or Conserve Plus devices did not meet California Technology Assessment Forum criteria for safety, efficacy, or improvement in health outcomes for patients as an alternative to THA.

American Academy of Orthopaedic Surgeons
In 2010, the American Academy of Orthopaedic Surgeons published a technology overview on metal-on-metal hip resurfacing. To compare revision rates between metal-on-metal hip resurfacing and THA, the Academy analyzed 3 joint registries, which indicated that patients who received total hip resurfacing were at greater risk for revision than patients who received THA. One registry suggested that younger men may have a lower revision rate after total hip resurfacing than THA, although the available data were not found to clearly establish an advantage for this subgroup. There was no conclusive evidence on predictors of successful or unsuccessful outcomes.

National Institute for Health and Care Excellence
In 2014, the National Institute for Health and Care Excellence (NICE) updated its guidance on THA and total hip resurfacing for end-stage arthritis of the hip. NICE concluded that both THA and total hip resurfacing were options for treating end-stage arthritis of the hip, although clinicians may be more likely to offer resurfacing arthroplasty to men than to women because of higher revision rates observed in women. NICE concluded that THA was more effective and less costly than total hip resurfacing in all analyses, that the revision rate was the most important key driver of costs and quality-adjusted life years, and that because the predicted revision rate of THA was less than 5% at

10 years in the population for whom both THA and total hip resurfacing were suitable, the revision rate standard for total hip resurfacing should be the same as that for THA. NICE recommended specific prostheses for THA and total hip resurfacing only if the prostheses have revision rates of 5% or less at 10 years.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in February 2020 did not identify any ongoing or unpublished trials that would likely influence this review.

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Policy History

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09/04/2002 Medical Policy Committee review
09/18/2002 Managed Care Advisory Council approval
11/02/2004 Medical Director review
11/16/2004 Medical Policy Committee review. Format revision. Clinical criteria revised.
11/29/2004 Managed Care Advisory Council approval
07/07/2006 Format revision including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
12/06/2006 Medical Director review
12/20/2006 Medical Policy Committee approval. Coverage eligibility unchanged.
06/13/2007 Medical Director review
06/20/2007 Medical Policy Committee approval. Policy updated with TEC Assessment; metal-on-metal total hip resurfacing with an FDA-approved device system now may be considered medically necessary as an alternative to total hip replacement in patients who are candidates for total hip replacement and who are likely to outlive a

	traditional prosthesis. All other types and applications of total hip resurfacing remain investigational.
08/06/2008	Medical Director review
08/20/2008	Medical Policy Committee approval. Eligible for coverage with added contraindications. Updated rationale.
08/06/2009	Medical Policy Committee approval
08/26/2009	Medical Policy Implementation Committee approval. No change to coverage eligibility.
08/05/2010	Medical Policy Committee review
08/18/2010	Medical Policy Implementation Committee approval. Statement added for partial resurfacing; considered medically necessary in specific conditions. Title changed to Hip Resurfacing.
08/04/2011	Medical Policy Committee review
08/17/2011	Medical Policy Implementation Committee approval. No change to coverage.
08/02/2012	Medical Policy Committee review
08/15/2012	Medical Policy Implementation Committee approval. No change to coverage.
09/05/2013	Medical Policy Committee review
09/18/2013	Medical Policy Implementation Committee approval. No change to coverage.
11/06/2014	Medical Policy Committee review
11/21/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed
10/29/2015	Medical Policy Committee review
11/16/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/03/2016	Medical Policy Committee review
11/16/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
11/02/2017	Medical Policy Committee review
11/15/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/08/2018	Medical Policy Committee review

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11/21/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/07/2019	Medical Policy Committee review
11/13/2019	Medical Policy Implementation Committee approval. Added a Policy Guidelines section. Coverage eligibility unchanged.
04/02/2020	Medical Policy Committee review
04/08/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/01/2021	Medical Policy Committee review
04/14/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 04/2022

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2020 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	27299
HCPCS	S2118
ICD-10 Diagnosis	M15.0, M15.4-M15.9, M16.0-M16.9, M87.051-M87.059, M87.150-M87.159, M87.251-M87.256, M87.350-M87.353, M87.850-M87.859, M90.551-M90.559

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment,

would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and 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 that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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