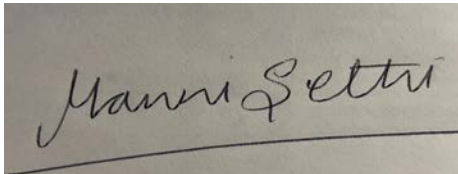


## Prior Authorization Review Panel

### MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.

Policies submitted without this form will not be considered for review.

<b>Plan: Keystone First Community Health Choices</b>	<b>Submission Date:</b> 1/1/2024
<b>Policy Number:</b> ccp.1442	<b>Effective Date:</b> 2/2020 <b>Revision Date:</b> December 1, 2023
<b>Policy Name:</b> Core decompression for avascular necrosis of the hip	
<b>Type of Submission – Check all that apply:</b>  New Policy <input checked="" type="checkbox"/> Revised Policy* Annual Review – No Revisions Statewide PDL	
<b>*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document.</b>  <b>Please provide any clarifying information for the policy below:</b>  See tracked changes below.	
<b>Name of Authorized Individual (Please type or print):</b>  Manni Sethi, MD, MBA, CHCQM	<b>Signature of Authorized Individual:</b>  



# Core decompression for avascular necrosis of the hip

Clinical Policy ID: CCP.1442

Recent review date: 12/2023

Next review date: 4/2025

Policy contains: Avascular necrosis, core decompression; femoral head; osteonecrosis.

*Keystone First Community HealthChoices has developed clinical policies to assist with making coverage determinations. Keystone First Community HealthChoices' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First Community HealthChoices when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First Community HealthChoices' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First Community HealthChoices will update its clinical policies as necessary. Keystone First Community HealthChoices' clinical policies are not guarantees of payment.*

## Coverage policy

Core decompression of the hip (femoral head and/or femoral neck) is clinically proven and, therefore, may be medically necessary for treating avascular necrosis when the following criterion is met (American Academy of Orthopaedic Surgeons, 2022; Hua, 2019; Zhao, 2020):

- Disease is in the early stage (pre-collapse stage 0, I and II).

Core decompression is investigational/not clinically proven and, therefore, not medically necessary for treating late stage avascular necrosis of the femoral head.

For any determinations of medical necessity for medications, refer to the applicable state-approved pharmacy policy.

### Limitations

No limitations were identified during the writing of this policy.

### Alternative covered services

- Anti-coagulants.
- Biophysical treatments.
- Bisphosphonates.
- Nonsteroidal anti-inflammatory drugs.
- Statins.

- Vascularized bone graft.
- Total hip arthroplasty.

## Background

Avascular necrosis, also known as osteonecrosis, aseptic necrosis, and ischemic necrosis, is caused by the loss of blood supply to the bone, leading to the bone deteriorating more quickly than it can regrow (Moya-Angeler, 2015; National Institute of Arthritis and Musculoskeletal and Skin Diseases, 2021). Various traumatic and atraumatic factors have been identified as risk factors for avascular necrosis. Atraumatic risk factors include corticosteroid use, alcohol abuse, dysbarism, coagulation disorders, hemoglobinopathies, and human immunodeficiency virus infection, but the etiology and pathogenesis are not well understood.

The prognosis for people with avascular necrosis varies depending on how much of the bone is affected, and how well the bone rebuilds itself. However, without treatment, the disease typically worsens, resulting in continued deterioration of the affected bone/s and joint/s. It is typical for people with the disease to have severe pain and limited movement within two years (National Institute of Arthritis and Musculoskeletal and Skin Diseases, 2021).

Plain anteroposterior and frog-leg lateral radiographs may provide images of cystic and sclerotic changes, but they are often insufficient for diagnosis of avascular necrosis. Magnetic resonance imaging is considered the best diagnostic method. Computerized tomography, magnetic resonance tomography, and scintigraphy are useful in determining disease progression (National Institute of Arthritis and Musculoskeletal and Skin Diseases, 2021).

Several classification systems are available to assist in staging avascular necrosis. The Association Research Circulation Osseous/Subcommittee of Nomenclature of the International Association on Bone Circulation and Bone Necrosis staging system, known as “ARCO,” is frequently used based on imaging findings, and was last revised in 2019 (Yoon, 2020). The stages are:

- Stage I: Patient may be symptomatic, radiography and computerized tomography scan findings are unremarkable, but there are evident changes on magnetic resonance imaging.
- Stage II: Magnetic resonance imaging findings are abnormal, and radiograph is abnormal.
- Stage IIIA (early): Subchondral fracture on radiograph or computed tomography, head collapse less than 2 millimeters.
- Stage IIIB (late): Subchondral fracture on radiograph or computed tomography, head collapse greater than 2 millimeters.
- Stage IV: Radiograph osteoarthritis of the hip joint with joint space narrowing, acetabular changes, and destruction.

Other staging systems include the Ficat (1985) staging criteria and the University of Pennsylvania system (Steinberg, 2014). The use of different staging criteria complicates the comparative analysis of treatment effects across studies.

Treatment options include medications such as bisphosphonates and statins, biophysical treatments, and surgery. Surgery to treat avascular necrosis of the femoral head may be either femoral head sparing or femoral head replacement. Femoral head sparing procedures are indicated at pre-collapse stages when the patient has minimal symptoms, while femoral head replacement procedures are indicated when the joint has collapsed. Core decompression consists of drilling one or more small channels into the dead bone. The procedure is designed

to decrease pressure within the bone by restoring blood flow to the bone. Bone grafting may or may not be used with core decompression (National Institute of Arthritis and Musculoskeletal and Skin Diseases, 2021).

In the United States from 2010 to 2020, a nationwide survey ( $n = 64,739$ ) of trends in the surgical management of osteonecrosis of the femoral head found 94.1% were arthroplasty procedures and 5.9% were joint-preserving procedures. The use of core decompression significantly increased from 4.2% to 4.6% ( $P = .017$ ) and was performed more often among patients younger than 50 years than among older cohorts (10.2% versus 2.4%). However, the investigators were unable to correlate disease stage with operative management (Ng, 2023).

## Findings

Effective early intervention, when the deterioration of the femoral head has not yet advanced to collapse, could prevent further damage to the head and joint. However, identifying the appropriate treatment to effectively manage avascular necrosis of the femoral head is challenging due to the paucity of Level 1 evidence.

Core decompression can be performed in various locations including the femoral head, and can use autologous bone marrow cell injection, vascular fibular grafting, or electric stimulation adjunctively. However, overall efficacy of core decompression at preventing eventual articular collapse remains controversial (American College of Radiology, 2022).

Core decompression is sometimes successful for early-stage osteonecrosis in preventing collapse of the femoral head and the development of arthritis. Core decompression is often combined with bone and cartilage grafting to help regenerate healthy bone and support cartilage at the hip joint (American Academy of Orthopaedic Surgeons, 2022).

Surgical guidelines from a collaboration of three Chinese groups (Microsurgery Department of the Orthopedics Branch of the Chinese Medical Doctor Association, 2017) indicate that core decompression is currently the most common procedure used in the early stages of avascular necrosis of the femoral head, while vascularized bone grafting is the recommended treatment for early stage III avascular necrosis of the femoral head.

The evidence for the safety and efficacy of core decompression is based primarily on the systematic review of 32 studies in which 1,865 individuals participated. A total of 2,441 hips were included. In 22 studies, a total of 1,379 hips were treated with core decompression alone. In seven studies, 565 hips were treated with core decompression combined with autologous bone, while nine studies (497 hips) were treated with core decompression combined with autologous bone marrow (Hua, 2019).

The outcome measures included overall surgical success rate (successful surgery defined as: during follow-up, Harris hip score  $\geq 70$ , no further total hip replacement surgery required, no radiographic progression), rate of conversion to total hip replacement, rate of radiographic progression, rate of success with participants in different preoperative stages, and complications (e.g., fracture, surgical site pain, hematoma, deep vein thrombosis, and infection). Outcomes were reported as effect size (95% confidence interval) (Hua, 2019):

- The overall pooled success rate was 0.65. Success rates according to treatment were 0.57 (0.50 to 0.61) for core decompression alone, 0.74 (0.66 to 0.83) for core decompression plus bone marrow, and 0.81 (0.69 to 0.92) for core decompression and autologous bone marrow.
- Conversion to total hip replacement was documented in 27 studies (2,120 hips) with a pooled overall conversion rate of .28 (0.22 to 0.34). Subgroup analyses according to treatment showed conversion rates of 0.34 (0.26 to 0.42), 0.16 (0.08 to 0.24), and 0.18 (0.02 to 0.34) for core decompression alone, core decompression plus bone marrow, and core decompression plus autologous bone marrow, respectively ( $P < .05$ ).

- Radiographic progression was documented in 26 studies (1,752 hips). Three of the 26 studies were randomized clinical trials. Follow-up periods ranged from 16 to 132 months. Twenty-one studies reported complications (69 total cases). In subgroup analysis by treatment, the conversion rates were 0.43 (0.32 to 0.54) for core decompression alone, 0.27 (0.17 to 0.32) for core decompression plus bone marrow, and 0.18 (0.02 to 0.35) in for core decompression plus autologous bone marrow.
- The overall success rate, conversion to total hip replacement, and radiographic progression showed significant differences in outcomes based on use of combined treatments. More data are needed in order to determine which combination of treatment is most useful and in which population.
- This meta-analysis included studies using Ficat (n = 21), ARCO (n = 7), and University of Pennsylvania (n = 4) staging. In a subgroup analysis, the success rate among those staged in Ficat I (78.29%) was superior to the success rate in Ficat II (59.38%), which was itself superior to the success rate Ficat III (27.44%) (differences statistically significant).
- Hua recommends avoiding alcohol and corticosteroids, both risk factors for osteonecrosis, during treatment (Hua, 2019).

Villa's (2016) analysis of 12 randomized controlled trials compared core decompression with bone marrow to core decompression alone and bisphosphonate treatment in osteonecrosis of the femoral head. Numerous limitations did not allow a determination of which treatment improved functional or radiologic outcome.

Core decompression along with bone marrow aspirate concentrate was studied in later (post collapse) stages of avascular necrosis of hip. A systematic review and meta-analysis compared radiographic progression along with the need for total hip replacement and core decompression alone. The review included 12 studies. Out of the 270 hips, 196 were treated with core decompression combined with bone marrow aspirate concentrate. Of these, 39.8% worsened from stage three to four, with an overall incidence of total hip replacement of 38.3% in stages three and four. Core decompression can be considered in the younger population to delay total hip replacement, with (late) stage three avascular necrosis before severe femoral head distortion or arthritis sets in (Jindal, 2021).

In a meta-analysis of four randomized controlled trials and two controlled clinical trials involving 323 hips, compared to conservative treatments, core decompression was effective for preventing femoral collapse within a short-term (24 to 48 months) follow-up, but an even higher successful rate was found after biophysical stimulations (Hong, 2015). Larger, well-designed studies with longer follow-up periods are necessary to determine the long-term outcomes.

In 2020, we removed the coverage statement and references relating to other therapies to focus the policy on core decompression. We added one guideline update (Zhao, 2020, update of Microsurgery Department of the Orthopedics Branch of the Chinese Medical Doctor Association, 2017) and one meta-analysis of the efficacy of bone marrow stem cells combined with core decompression in the treatment of osteonecrosis of the femoral head (Wang, 2020). The results confirm previous findings and warrant no additional policy changes.

In 2021 we updated the literature search to include studies of treatment in the younger population for late stage avascular necrosis of the hip to possibly offset need for total hip replacement in this age group (Jindal, 2021).

In 2022, we added three systematic reviews of core decompression for osteonecrosis of the femoral head. In the literature, biological augmentation consists of bone marrow stem cells and, to a lesser extent, bone morphogenic protein and platelet-rich plasma. Two systematic reviews found low-to-moderate quality evidence suggesting a mixed beneficial effect of bone marrow stem cells added to core decompression, in terms of radiographic disease progression and conversion to arthroplasty in adults with at least 24 months of follow-up. The overall rates of complications were generally low, mild, and self-limiting (Andronic, 2021; Saini, 2023).

Liu (2021) analyzed randomized controlled trials of core decompression augmented with bone graft, tantalum rod implantation, cell therapies, and vascularized bone graft, as well as nonsurgical and conservative treatment. The meta-analysis demonstrated that, while core decompression with cell therapy showed a superior outcome in terms of radiographic progression compared to nonsurgical treatment, there were no statistically significant differences in radiographic progression or conversion to total hip arthroplasty among any of the other treatments. No policy changes are warranted.

In 2023, we added two guidelines (American College of Radiology, 2022; American Academy of Orthopaedic Surgeons, 2022), one systematic review/meta-analysis, and one randomized trial to the policy. No policy changes are warranted. Results of the systematic review suggest cell therapy combined with core decompression may be more effective in preventing collapse, radiographic progression, and conversion to total hip arthroplasty than core decompression alone in the short term. Long-term results were mixed, and adequately powered trials with long-term follow-up were lacking (Li, 2023).

A double-blind, randomized, placebo-controlled trial (n = 49) compared the efficacy of core decompression combined with autologous osteoblastic cell transplantation core decompression with placebo implantation for treatment of early-stage osteonecrosis of the femoral head. The follow-up period was 24 months post-treatment. The results did not support any improvement in outcomes with the addition of autologous osteoblastic cells in terms of treatment response, clinical response, and radiologic response at 12 months, or the percentage of patients undergoing total hip arthroplasty at 24 months. The investigators did not recommend the combination of osteoblastic cells and core decompression in this patient population (Jayankura, 2023).

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On October 2, 2023, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “decompression, surgical (MeSH),” “osteonecrosis (MeSH),” “osteonecrosis,” “femoral head,” and “avascular necrosis”. We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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## Policy updates

12/2019: initial review date and clinical policy effective date: 2/2020

12/2020: Policy references updated. Coverage modified.

12/2021: Policy references updated.

12/2022: Policy references updated.

12/2023: Policy references updated.