Core Decompression for Avascular Necrosis

Guideline Number: MMG027.M
Effective Date: November 1, 2023

Instructions for Use

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Related Policies
None

Coverage Rationale

Core decompression is proven and medically necessary for treating early (pre-collapse stage I and II) avascular necrosis of the femoral head.

Core decompression is unproven and not medically necessary for treating late avascular necrosis of the femoral head or for avascular necrosis elsewhere, including the humeral head, the distal femur, the talus, or the mandibular condyle due to insufficient evidence of efficacy.

Documentation Requirements

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

Required Clinical Information
Core Decompression for Avascular Necrosis
Medical notes documenting the following, when applicable: • Radiographic reports • Condition requiring procedure • Associated co-morbidities • Medical/surgical therapies tried and failed • Member's degree of pain and functional disability • Proposed procedure

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health

service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
21299	Unlisted craniofacial and maxillofacial procedure
23929	Unlisted procedure, shoulder
27299	Unlisted procedure, pelvis or hip joint
27599	Unlisted procedure, femur or knee
27899	Unlisted procedure, leg or ankle

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HCPCS Code	Description
S2325	Hip core decompression

Description of Services

Avascular necrosis (AVN), also known as osteonecrosis, aseptic necrosis and ischemic bone necrosis, is a common disease characterized by death of cellular elements of bone or marrow. AVN occurs when the blood flow to the bone has been interrupted leading to the death of bone. As the bone tissue dies, the bone structure collapses which results in pain and loss of joint function. This condition occurs most often in the femoral head but can affect other bones and joints. There are many risk factors for the disease including hemoglobinopathies, dislocation of the hip, alcoholism, fracture of the femoral neck, use of corticosteroids, as well as collagen vascular disease. AVN is a progressive disorder that often results in the eventual collapse of the bone and the need for joint replacement or other arthroplasty.

Core decompression of the hip is usually employed before collapse and fracture of the femoral head and/or neck to delay or avoid reconstructive surgery of the affected joint. It is generally carried out to preserve the function and the structure of the hip as well as to relieve pain associated with AVN. Core decompression consists of drilling one or more small channels into the dead bone (necrotic lesion) to create a channel for new blood vessels. The procedure is designed to decrease pressure within the bone and restore blood flow to the bone. Bone grafting may or may not be used with core decompression.

Severity of avascular necrosis is determined by the staging system based on the consensus of the Subcommittee of Nomenclature of the International Association on Bone Circulation and Bone Necrosis (Patel, 2018). Staging is as follows:

Stage	Clinical Findings
Stage 0	• Patient is asymptomatic • Radiography findings are normal • Histology findings demonstrate osteonecrosis
Stage I	• Patient may or may not be symptomatic • Radiography and CT scan findings are unremarkable • AVN is considered likely based on MRI and bone scan results [may be subclassified by extent of involvement (see below)] • Histology findings are abnormal
Stage II	• Patient is symptomatic • Plain radiography findings are abnormal and include osteopenia, osteosclerosis, or cysts • Subchondral radiolucency is absent • MRI findings are diagnostic

Stage	Clinical Findings

Stage III	• Patient is symptomatic
	• Radiographic findings include subchondral lucency (crescent sign) and subchondral collapse
	• Shape of the femoral head is generally preserved on radiographs and CT scans
	• Subclassification depends on the extent of crescent, as follows:
	  ○ Stage IIIa: Crescent is less than 15% of the articular surface
	  ○ Stage IIIb: Crescent is 15-30% of the articular surface
	  ○ Stage IIIc: Crescent is more than 30% of the articular surface

Stage IV	• Joint space may be irregular
	• CT scanning is more sensitive than radiography
	• Subclassification depends on the extent of collapsed surface, as follows:
	  ○ Stage IVa: Less than 15% of surface is collapsed
	  ○ Stage IVb: Approximately 15-30% of surface is collapsed
	  ○ Stage IVc: More than 30% of surface is collapsed

Stage V	• Radiography findings include narrowing of the joint space, osteoarthritis with sclerosis of acetabulum, and marginal osteophytes
Stage VI	• Findings include extensive destruction of the femoral head and joint

Clinical Evidence

Core Decompression of the Femoral Head (Hip)

DeFeo et al. (2022) performed a prospective study to describe functional outcomes and gait quality among a young population with hip osteonecrosis (ON) before and after hip core decompression (CD). The study included participants with hip ON secondary to treatment for hematologic malignancy or sickle cell disease, between 8 and 29 years old. At one-year follow-up, 13 participants completed the Functional Mobility Assessment (FMA), range of motion, and GAITRite® testing. The results reported that participants demonstrated improved mobility and endurance on the FMA at 1-year post-operatively compared to pre-operatively, with higher scores for time on the Timed Up and Go, time on the Timed Up and Down Stairs, and 9-Minute Walk Test scores for distance walked and heart rate. GAITRite® analysis also showed improvements in many gait parameters at. At 1-year follow-up, patients reporting feeling better, with 92% reporting that they had no need for an assistive device and 76.9% reporting only minimal to no pain. The average pain score was 4.38 (only minimal pain) at the 1-year assessment, indicating that pain scores did not worsen over time and no further surgery was required. The authors concluded that young patients with hip ON demonstrated improvements in functional mobility, endurance, and gait quality one year following hip CD. Longer-term follow-up studies would be warranted to determine the longevity of hip CD surgery and functional outcomes in this population.

Andronic et al. (2021) conducted a systematic review to assess the outcomes and time to total hip replacement (THR) following CD of the femoral head without any augmentation for non-traumatic (AVN). Studies reporting the outcome of CD for AVN were assessed. Studies using additional implants, vascularized grafts or any type of augmentation were excluded. Quality assessment was performed using the Joanna Briggs Institute Critical Appraisal Checklist (JBI CAC) tool. A total of 49 studies describing 2540 hips were included. The mean weighted follow-up time was 75.1 months and the mean age at surgery was 39 years. Twenty-four of 37 studies reported improvement in all outcome scores, whilst 9/37 studies report only partial improvement post-operatively. Four studies (4/37) described poor clinical outcomes following intervention. Data was pooled from 20 studies, including 1134 hips with a weighted mean follow-up of 56 months. The percentage of hips undergoing THR averaged 38%. The time to THR had a weighted mean of 26 months after CD. Limitations included heterogeneity of the data and restrictions within the included studies. Future studies should report outcome by results based on preoperative stages as proposed by the ARCO group and post-collapse stages of ON should be omitted. Despite limitations, CD alone achieved short-term clinical improvements in most cases. Pooled results from 1134 hips and of these nearly 80% with early stage of ON, showed that about 38% of patients ended up having a total hip replacement at an average of 26 months following CD without augmentation.

A systemic review and meta-analysis by Hua et al., (2019) observed the treatment of ON of the femoral head (ONFH) with CD. Thirty-two studies included 1865 patients (2,441 hips). These were mostly case series with six comparative studies, but that all included CD in both comparison arms. Twenty-one studies (1,301 hips) using Ficat staging standard, 7 studies (338 hips) using Association Research Circulation Osseous (ARCO) staging standard, and University of Pennsylvania system for staging avascular necrosis (UPSS) staging criteria for 4 studies (802 hips). All the studies recorded the treatment, 22 studies (1,379

hips) were treated with CD alone, and 7 studies (565 hips) were treated with CD combined with autologous bone (CD Autologous bone). Some subjects (497 hips) were treated with CD combined with autologous bone marrow (CD Marrow). Twenty-seven studies (2,120 hips) documented the number of conversions to total hip replacement (THA), and 26 studies (1,752 hips) documented the number of radiographic progression (RP).The random-effect model was used for meta-analysis, and the results showed that the overall success rate was 65%. The rate of success was better for the earlier stages of necrosis. Although differing staging systems are used in assessing avascular necrosis (this publication did not use the Subcommittee of Nomenclature of the International Association on Bone Circulation and Bone Necrosis staging system), the findings suggest that potential candidates for CD are patients with ON but no femoral head collapse. The rate of success, conversion to THA, and radiographic progression showed significant difference on the outcomes of ONFH using different treatments. The authors concluded that CD was safe and effective for treating ON of the femoral head, however it should be used with caution for advanced femoral head necrosis.

Marti-Carvajal et al. (2014, updated 2019) conducted a systematic review to compare the effect of surgical treatments with non-surgical treatment of avascular necrosis (AVN) in individuals with sickle cell disease (SCD). Only 1 randomized clinical trial was identified and included 46 participants. Eight patients withdrew after randomization as they declined to participate in the trial. The remaining 38 patients were randomized to receive either hip CD and physical therapy or physical therapy alone. After a mean follow-up of 3 years, the surgical group (hip CD and physical therapy) showed no clinical improvement compared with the non-surgical group. There were also no significant differences between the study groups in terms of major complications (hip pain; vaso-occlusions; and acute chest syndrome). This study did not report patient-relevant centered outcomes, such as mortality or quality of life (QOL).The authors concluded that the addition of CD to physical therapy did not improve outcomes for patients with SCD and AVN. Additional studies, preferably RCTs, are necessary to evaluate the role of hip-core depression in patients with SCD. A new 2019 search of the Cochrane Cystic Fibrosis and Genetic Disorders Haemoglobinopathies Trials Register did not identify any potentially eligible trials for inclusion in the review.

Roth et al. (2016) conducted a systematic review based on the published literature from January 1, 1970 to April 31, 2013 for the treatment of adult non-traumatic avascular necrosis of the femoral head (AVN; N-ANFH). Inclusion criteria were systematic reviews, meta-analyses and relevant peer review publications. Systematic literature search was done using the databases of the US National Library of Medicine National Institutes of Health and the Cochrane Library and a total of 159 articles were included for detailed evaluation. The authors concluded that CD is indicated and should be offered in early and potential reversible stages of N-ANFH, Association Research Circulation Osseous (ARCO) stage 1, but also stage 2 if the area of necrosis is medial or central and < 30%. According to the authors, in ARCO stage 3 and 4, CD is not indicated and total hip replacement (THR) should be discussed.

Sadile et al. (2016) conducted a meta-analysis to assess the efficacy of CD compared with all other joint preserving treatments (JPT) in delaying the natural ON evolution to hip osteoarthritis (HOA). Medline and Scopus databases were searched for 15- to 70-year-olds with ON of the femoral head (ONFH) with a minimum follow-up of 24 months. The outcomes evaluated were patient clinical status, radiographic progression and total hip arthroplasty or further surgery need. A total of 12 studies which included randomized controlled trials, controlled clinical trials and prospective studies (776 patients) met the inclusion criteria. Clinical outcome, radiographic progression and the need for total hip arthroplasty/further surgery suggested a slight superiority of other JPT compared with CD. The authors identified that high heterogeneity of the primary investigations was the main limitation of the study. They concluded that the efficacy and effectiveness of CD for ONFH are, at best, no better than other joint preserving strategies. The more recent scientific evidence seems to suggest that such procedure is less successful than other joint preserving strategies. According to the authors further studies are needed to identify the best therapeutic approach to the ONFH.

Yu et al. (2015) conducted a case series to review the outcomes of using synthetic bone graft substitute (calcium sulfate and calcium phosphate) for the treatment of late-stage ON of the femoral head. The study consisted of 19 hips in 18 patients with ON of the femoral head [6 hips in Association Research Circulation Osseous (ARCO) stage IIC and 13 hips in stage IIIA] who were treated with CD combined with PRO-DENSE™ (Injectable Regenerative Graft). The clinical failure was defined as conversion to total hip arthroplasty or progression in head collapse. At the conclusion of the study, 3 in the 6 stage IIC hips and 8 in the 13 stage IIIA hips were converted to total hip arthroplasty postoperatively. Advanced collapse of the femoral head waiting for total hip arthroplasty was observed in the other six hips. Of the 19 hips, only 2 hips survived without further collapse in the 5-year follow-up. This resulted in 89.5% failure rate. The authors concluded that CD combined with an injectable (PRO-DENSE) were associated with high failure rates in the early postoperative period. It is not recommended for the treatment of ARCO stage IIC and IIIA ON of the femoral head.

Core Decompression in the Shoulder, Knee, and Ankle

While available evidence indicates that CD is effective in treating early stages of AVN of the hip, there is currently insufficient evidence that this procedure is effective in treating AVN of the shoulder, knee or ankle. The majority of studies involved a small number of patients and lacked appropriate control groups. Prospective, well-designed, randomized, controlled trials are needed to ascertain the clinical value of CD for joints other than the hip.

Humeral Head (Shoulder)

Dubin et al. (2023) conducted a systematic review to compare the results of CD versus nonoperative modalities for the treatment of ON of the humeral head, including success rate defined as lack of progression to further procedures (shoulder arthroplasty) and no need for further intervention clinical results (patient reported pain and functional scores); as well as radiological outcomes. Nine studies included individuals who underwent CD of the shoulder (N-291) and were analyzed at a mean follow-up of 8.1 years. There were six studies that examined 359 shoulders that underwent nonoperative management at a mean follow-up of 8.1 years. The mean success rate of CD for avoiding further procedures was 76.6% in stage I through stage III. Stage III shoulders avoided shoulder arthroplasty in 63%. Nonoperative management resulted in a success rate of 13%. In the CD studies, 7 of 9 showed improvements in clinical outcome measurements compared to 1 of 6 of the nonoperative studies. Radiographically, there was less progression in the CD group (39 out of 191 shoulders (24.2%)) versus the nonoperative group (39 out of 74 shoulders (52.3%)). The authors concluded that CD is an effective method for management, especially when compared to nonoperative treatment methods for stage I to III ON of the humeral head. Most of the literature was of very small cohort size and have limited follow-up time.

Alkhateeb et al. (2021) conducted a systematic study to review the outcomes of surgical intervention for humeral head avascular necrosis for patients with sickle cell disease. Outcome parameters were pain, range of motion, specific shoulder outcome scores, and complications. Six studies, three retrospective cohorts (2 level III and 1 level IV) and three case series (level IV), were included in this review. A total of forty-three patients comprising forty-nine shoulders, underwent different surgical procedures. Surgical procedures were CD, arthroscopic intervention, humeral head resurfacing, shoulder hemiarthroplasty, and total shoulder arthroplasty. The authors agreed that shoulder hemiarthroplasty and total shoulder arthroplasty yielded significant benefits in terms of pain, ROM, function, and patient satisfaction. Described complications included progression of ON, septic loosening, glenoid wear, scapular insufficiency, and joint stiffness. The authors concluded that for patients with SCD suffering from early stages of HHAVN, CD has not yet been confirmed to prevent or delay natural progression of the disease. There was a low level of evidence for this review and larger high-quality prospective and comparative trials to further evaluate the effectiveness of surgery in treating humeral head ON in the SCD population are needed. (Authors Harreld et al. (2009) and Kennon et al. (2016) which were previously cited in this policy, are included in this systematic review)

Franceschi et al., (2016) performed a systematic review to identify published studies and analyze clinical evidence available related to the surgical management of ON of the humeral head. Twelve studies were included: five prospective case series and seven retrospective case series. A total of 309 patients, comprising 382 shoulders, were included. Three main surgical procedures were evaluated: CD, hemi-arthroplasty and total shoulder arthroplasty. The authors concluded that based on the current available data, CD is a safe and effective option for treating low-grade ON of the humeral head, while hemi-arthroplasty and total shoulder arthroplasty should be considered for high-grade ON. According to the authors more studies and better-designed trials are needed and the level of evidence had poor reference standard, analyses with no sensitivity analyses. The findings are limited by the lack of comparison group.

Femoral Condyle or Distal Femur (Knee)

One retrospective cohort study (n = 248 knees) (Mont et al., 2000) of participants undergoing nonoperative treatment, CD, arthroscopic debridement, or total knee arthroplasty provided weak but positive evidence of the long-term effectiveness of CD in delaying secondary surgery in the early stages of AVN of the femoral condyle. A second CD procedure was performed in 16% of patients; the criteria for repeat CD were not reported. Only 7 knees were at stage III at the time of diagnosis. The overall survival rate for knees included in the 2000 report (stages I through III) was 79%, based on a mean of 7 years of follow-up (minimum of 2 years).

Comparability of these results with those of future studies may be limited. First, patients were selected for CD only after 3 months of conservative treatment failed to relieve symptoms. This is a reasonable selection process but not one reported by other authors. Results from CD might have been more favorable in patients whose symptoms had not already been shown to be

unresponsive to conservative treatment. Secondly, 16% of patients had two, rather than one, CD procedures for AVN in the knee, which may have inflated results. The findings are limited by lack of randomization to assigned treatment approaches.

Talus (Ankle)

A systematic review which included forty-one studies was conducted by Dhillon et al. (2018) to identify and summarize the available evidence in the literature for the treatment of talar avascular necrosis (AVN). They concluded that the literature was inconclusive regarding the ideal modality of treatment of the talar AVN, and the factors that should guide such treatment have not been well explained. They summarized that early talar AVN seems best treated with protected weight bearing and possibly in combination with extracorporeal shock wave therapy. If that fails, CD can be considered. Arthrodesis should be saved as a salvage procedure in late cases with arthritis and collapse, and a tibiotalocalcaneal fusion with bone grafting may be needed in cases of significant bone loss. Future prospective, randomized studies are necessary to guide the conservative and surgical management of talar AVN, as the findings were based on Level IV evidence only.

Beck et al., (2016) conducted a prospective case series to assess the effectiveness of endoscopic CD (ECD) in the treatment of osteochondral lesions of the talus (OLT). All patients suffered from chronic ankle pain due to an OLT of the medial talar dome and had undergone non-operative treatment for at least 3 months without improvement of their symptoms. The diagnosis was confirmed by plain radiographs and an MRI of the ankle joint. Seven patients underwent CD of the lesion. Outcome and patient satisfaction were evaluated according to the American Orthopedic Foot and Ankle Society Score (AOFAS) and the Foot and Ankle Disability Index (FADI) preoperatively and after a mean follow-up of 24.1 months. Remodeling of the OLT and bone ingrowth into the graft substitute were evaluated by means of radiographs of the ankle joint, as well as an MRI 1year after treatment. The authors found that the AOFAS significantly improved from 71.0 ±2.4 to 90.3 ±5.9, and the FADI improved from 71.8 ±11.1 to 91.7 ±4.8. The radiographic controls showed good bone remodeling with invisibility of the bone graft substitute in x-ray within 8–12 weeks. The ECD led to a good restoration of the medial talar dome contour with an almost complete resection of the OLT. MRI imaging showed an alteration of the bony signal in the treated OLT and drill meatus for more than 12 months. This is an uncontrolled study with a small sample size.

Gross and colleagues (2014) conducted a systematic review evaluating various interventions for talar avascular necrosis, including hind foot fusion, conservation treatment approaches, bone grafts, CD, and talar replacement. A total of 19 studies (321 ankles) were included for detailed review. All individual studies were considered poor quality, and the overall body of evidence was considered very low quality due to study limitations, such as imprecise and sparse data and possible reporting bias. Study author concluded that additional randomized studies are needed to inform and guide specific treatments for avascular necrosis of the talus.

Mandibular Condyle

ON of the mandibular condyle has only recently been reported, and there is limited information on the efficacy of CD. In 8 of 9 patients (16 joints) with histologically confirmed ON of the mandible, CD resulted in substantial pain reduction over a mean follow-up period of 34 months. (Chuong et al., 1995) In a second group of 8 patients (15 joints) with more severe lesions, CD with bone grafting resulted in significant clinical improvement in 11 joints during the follow-up period (mean 28 months).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Core decompression is a surgical procedure and is not regulated by FDA. The procedure is performed with ordinary surgical instruments. The FDA has not approved any devices specifically for core decompression. Approval has been granted to numerous bone graft substitutes (product code LYC), some of which may be used in conjunction with core decompression. Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed July 22, 2023)

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Guideline History/Revision Information

Date	Summary of Changes
11/01/2023	**Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information • Archived previous policy version MMG027.L

Instructions for Use

This Medical Management Guideline provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs.

Before using this guideline, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Management Guideline is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare West Medical Management Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

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