CORE DECOMPRESSION FOR AVASCULAR NECROSIS

Policy Number: 065.E
Effective Date: September 1, 2015

INSTRUCTIONS FOR USE
This Coverage Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Coverage Policy is based. In the event of a conflict, the enrollee’s specific benefit document supersedes this Coverage Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Coverage Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Coverage Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care 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.

BENEFIT CONSIDERATIONS

Essential Health Benefits for Individual and Small Group:
For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such,
when using this guideline, it is important to refer to the enrollee specific benefit document to determine benefit coverage.

**COVERAGE RATIONALE**

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

Core decompression is unproven and not medically necessary for the treatment of 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.

The available evidence for core decompression for these conditions is limited and of low quality. Most clinical studies involve a small number of patients and lack proper controls. Therefore, there is insufficient data to allow conclusions regarding the safety and efficacy of core decompression for these indications.

**APPLICABLE CODES**

The Current Procedural Terminology (CPT®) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit 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 claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

<table>
<thead>
<tr>
<th>CPT® Code</th>
<th>Description</th>
<th>Coverage Status</th>
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<tbody>
<tr>
<td>27299</td>
<td>Unlisted procedure, pelvis or hip joint</td>
<td>Requires manual review</td>
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<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
<th>Coverage Status</th>
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<tr>
<td>S2325</td>
<td>Hip core decompression</td>
<td>Requires preauthorization</td>
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**DESCRIPTION OF SERVICES**

Avascular necrosis (AVN), also known as osteonecrosis, aseptic necrosis and ischemic bone necrosis, is a relatively common disease characterized by death of cellular elements of bone or marrow.

Avascular necrosis (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). 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.
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 (Tofferi, 2008). Staging is as follows:

<table>
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<th>Stage</th>
<th>Clinical Findings</th>
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| 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 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:  
  o Stage IIIa: Crescent is less than 15% of the articular surface  
  o Stage IIIb: Crescent is 15-30% of the articular surface  
  o 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:  
  o Stage IVa: Less than 15% of surface is collapsed  
  o Stage IVb: Approximately 15-30% of surface is collapsed  
  o 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)**

A systematic review regarding the use of core decompression for the treatment of osteonecrosis of the hip, noted that core decompression has been the surgical option since the 1960s (Rajagopal et al., 2012). The study authors noted that the systematic review was performed to evaluate core decompression with regard to pain relief, need for total hip arthroplasty (THA), lesion size, and Ficat stage. Only 4 articles of level IV evidence (139 total cases) met inclusion criteria. Three studies reported improvement in outcomes. Overall outcomes were “good” in one study and either “fair” or “poor” in the others. One-fourth (25.8%) of patients required THA. Patients with necrotic lesion size <50% had the best outcomes with core decompression. Although core decompression may become a standard treatment option to prevent THA in early stages of osteonecrosis, there are currently no rigorous studies that provide data regarding long-term health outcomes.
In 2014, Marti-Carvajal et al. (2009) conducted a systematic review to compare the effect of surgical treatment to non-surgical treatment of avascular necrosis (AVN) in individuals with sickle cell disease (SCD). Only 1 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 core decompression and physical therapy or physical therapy alone. After a mean follow-up of 3 years, the surgical group showed no clinical improvement compared to the non-surgical group. There were also no significant differences between the study groups in terms of major complications (hip pain; vasocclusions; and acute chest syndrome). This study did not report patient-relevant outcomes, such as mortality or quality of life (QOL). The author’s concluded that the addition of core decompression to physical therapy did not improve outcomes for patients with SCD and AVN. Additional studies, preferably randomized controlled trials, are necessary to evaluate the role of hip core depression in patients with SCD.

Wei et al. (2011) conducted a study on the effect of core decompression combined with an allogeneic, antigen-extracted, autolysed fibular allograft and autologous impacted bone grafting for the treatment of osteonecrosis of the femoral head. The study included 162 patients (223 hips; 61 females, 101 males; mean age 33.5 years, range 19-54 years) with stage II-III avascular necrosis of the femoral head. The outcome was determined by changes in the Harris hip score, by progression in radiographic stages, and by the need for hip replacement. The mean follow-up was 24 months. Excellent and good results were obtained in 93.3% of cases in stage II, and 87% in stages III with a survivorship of 81% in all cases. According to the authors, core decompression combined with an allogeneic, antigen-extracted, autolysed fibular allograft and autologous impacted bone grafting may be the treatment of choice, particularly in the precollapse stage.

Von Stechow and Drees (2007) stated that untreated osteonecrosis will eventually destroy the affected femoral head. Depending on the location and the extent of the osteonecrosis, several surgical options are available. For early small and medium-sized pre-collapse lesions, core decompression is the treatment of choice.

Simank et al. (2001) found that patients treated with core decompression (94 hips) were 67% more likely than patients treated with osteotomy (83 hips) to require subsequent total hip replacement over a mean follow-up of 9 years, although the relative risk calculation was not significant. This may not be a useful comparison for a number of reasons. As the authors acknowledge, osteotomy patients may be more likely to postpone further surgery, having already endured the morbidity associated with a more complicated procedure. Another bias potentially in favor of the osteotomy results was that about half of the patients treated with osteotomy also had a core decompression procedure although the authors do report that the relative risk of failure did not differ significantly between patients treated only with osteotomy and those who received the double procedure. Furthermore, core decompression is not generally considered to be an alternative to osteotomy, or partial joint arthroplasty; rather, it is intended to delay both osteotomy and complete arthroplasty.

Two studies calculated Kaplan-Meier survivorship curves, which take into account the follow-up time for each hip. Bozic et al. (1999) studied 37 hips and compared Kaplan-Meier curves between hips that were at stage I or precystic stage IIA with hips in all other more advanced stages (cystic IIA, IIB, IIC, and III) and found a statistically significant difference, with survival of 166 months for the first group and 57 months for the second. Simank et al. (2001) (n=94 hips) demonstrated Kaplan-Meier probabilities of joint survival of 84% at 4 years and 78% at 6 years for patients with hips at stage I or II, excluding patients who had a history of corticosteroid use because it was shown to be predictive of failure. Those probabilities dropped to 63% at 4 years and 56% at 6 years for patients with hips at stage III, IV, or V.
A few studies afford some evidence that, within a given stage, larger lesions and lesions in a central or lateral, as opposed to medial, position are less likely to be treated successfully with core decompression. Bozic et al. (1999) found that hips in the precystic phase of stage II were dramatically more likely to survive than hips with stage II lesions that were cystic or sclerocystic.

**Core Decompression in the Shoulder, Knee, and Ankle**

While available evidence indicates that core decompression 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. Furthermore, several of the studies were published by the same group of investigators. Prospective, well-designed, randomized, controlled trials are needed to ascertain the clinical value of core decompression for joints other than the hip.

**Humeral Head (Shoulder)**

Harreld et al. (2009) conducted a small study to evaluate humeral head core decompression involving percutaneous perforations. During this study, shoulder arthroplasty was avoided in all 15 patients (26 shoulders) for a mean follow-up of 32 months. Of the 26 shoulders, 25 had successful clinical and functional outcomes, and 1 showed radiographic progression of the disease but has not needed further operative treatment. Decompression results were compared with those of a nonoperative historical control group, identified through a literature search. There was a 48% (143/299) rate of progression to arthroplasty in the control group at a follow-up ranging from 2 to 4.5 years. According to the authors, percutaneous decompression appears to be a low-morbidity method for relieving symptoms and deferring shoulder arthroplasty in patients with symptomatic osteonecrosis of the humeral head. This study is limited by lack of randomization, and small sample size.

One small (n=46 patients, 67 shoulders), retrospective, uncontrolled study, (LaPorte et al., 1998) provided weak but positive evidence of the long-term effectiveness of core decompression in delaying secondary surgery for AVN of the humeral head, not only in the precollapse stages but also in stage III. Joint survival rates for stages I, II, III, and IV were 94%, 88%, 70%, and 14%, respectively, after a mean follow-up of 10 years. Early experience by Mont et al. (1993) with core decompression in the humeral head concluded that because the glenoid is shallower and less conforming than the acetabulum and the shoulder is not a weight-bearing joint, deterioration of shoulder function may not occur until advanced stages of AVN. They postulated that core decompression for stage III or even stage IV AVN may be more appropriate for the shoulder than for the hip (Mont et al., 1993).

**Femoral Condyle or Distal Femur (Knee)**

The knee is the second most common location for osteonecrosis with about a 10 % incidence of the disease in the hip.

One retrospective, uncontrolled study (n=248 knees), provided weak but positive evidence of the long-term effectiveness of core decompression in delaying secondary surgery in the early stages of AVN of the femoral condyle. A second core decompression procedure was performed in 16% of patients; the criteria for repeat core decompression 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) (Mont et al., 2000).

Comparability of these results (Mont et al., 2000) with those of future studies may be limited. First, patients were selected for core decompression 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 core decompression 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, core decompression procedures for AVN in the knee, which may have inflated results.

**Talus (Ankle)**

Gross and colleagues (2014) conducted a systematic review evaluating various interventions for talar avascular necrosis, including hindfoot fusion, conservation treatment approaches, bone grafts, core decompression, 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.

Marulanda et al. (2010) conducted a non-randomized study to examine the results of percutaneous drilling to treat osteonecrosis of the ankle in 31 patients (44 ankles). At a mean follow-up duration of 45 +/- 12 months, 40 (91%) ankles had achieved a successful clinical outcome. There were no perioperative complications, although 3 ankles subsequently collapsed and required arthrodesis. According to the authors, the percutaneous drilling technique appears to be a useful method for the relief of symptomatic ankle osteonecrosis. This study is limited by lack of randomization, control and small sample size.

A retrospective analysis of 32 ankles provides weak but positive evidence of effectiveness in treating AVN of the talus. The rate of joint survival over a mean follow-up period of 7.3 years was 91%. Five ankles were at stage III AVN at the time of diagnosis; the remainder was at stage II. As in the knee studies, comparability with future studies is limited because core decompression was performed only in patients who had not responded to conservative treatment. However, because AVN in the talus appears to be rare, the authors had to start the time frame for their retrospective review in 1974, which may make it difficult to study this condition (Delanois et al, 1998).

**Mandibular Condyle**

Osteonecrosis of the mandibular condyle has only recently been reported, and there is limited information on the efficacy of core decompression. In 8 of 9 patients (16 joints) with histologically confirmed osteonecrosis of the mandible, core decompression 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, core decompression with bone grafting resulted in significant clinical improvement in 11 joints during the follow-up period (mean 28 months).

**Summary**

Although the majority of the studies have a weak study design with a lack of controlled comparisons and small sample sizes, results were consistent and support the conclusions of preliminary research that core decompression is safe, and may result in prevention or deferral of partial or complete arthroplasty if performed in hips with AVN at stage I or II, with a substantially higher likelihood of success at stage I. Joint survival rates for hips at stage I were quite high (92% to 100%). In all studies, joint survival declined with increasing baseline disease stage.

However, the available evidence for core decompression for other conditions, such as late avascular necrosis of the femoral head, or avascular necrosis of the humeral head, distal femur, talus, or mandibular condyle is limited and low quality. Most clinical studies involve a small number of patients and lack proper controls. Hence, definitive conclusions regarding the safety and efficacy of these other indications cannot be drawn.

**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

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 August 14, 2015.

REFERENCES

The foregoing Unitedhealthcare of the River Valley policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by the UnitedHealthcare Medical Technology Assessment Committee [2015T0219N].


**POLICY HISTORY/REVISION INFORMATION**

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<th>Date</th>
<th>Action/Description</th>
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<tr>
<td>09/01/2015</td>
<td>• Updated coverage rationale; clarified language pertaining to clinical evidence/study findings</td>
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<tr>
<td></td>
<td>• Updated supporting information to reflect the most current clinical evidence, and references</td>
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