CORE DECOMPRESSION FOR AVASCULAR NECROSIS

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

Core decompression is unproven 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 quality and quantity of the evidence for core decompression for these conditions is limited and insufficient. Most studies involved a small number of patients and have lacked proper controls and therefore, there is insufficient data to allow conclusions regarding the safety and efficacy of core decompression in these patient populations.

Information Pertaining to Medical Necessity Review (When Applicable)
The above indications apply to medical necessity review.

Core Decompression for Avascular Necrosis: Medical Policy (Effective 11/01/2013)
BACKGROUND

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 corticosteroid, 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:

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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 radioluency 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 | Clinical Findings
--- | ---
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)

A systematic review regarding the use of Core decompression (CD) for the treatment of osteonecrosis of the hip, performed by Rajagopal (October 2012), noted that CD has been the surgical option since the 1960s. It was further noted that that the systematic review was done to evaluate CD with regard to pain relief, need for total hip arthroplasty (THA), and lesion size and Ficat stage. Only four articles of level IV evidence (139 total cases) met inclusion criteria. Three reported improvement in outcomes. Overall average outcomes were only "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 best outcomes with CD. Although CD may become a standard treatment option to prevent THA in early stages of ON, there are no rigorous studies that provide long-term outcome measures.

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. 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.

Von Stechow and Drees (2007) stated that osteonecrosis of the femoral head eventually leads to its destruction if it remains untreated. 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.

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.

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.

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.

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 earlier research: 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.

Core Decompression in the Shoulder, Knee, and Ankle

The clinical evidence was reviewed on September 16, 2013 with no additional information identified that would change the unproven conclusion.

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.

Humeral Head (Shoulder)

The clinical evidence was reviewed on September 16, 2013 with no additional information identified that would change the unproven conclusion.

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 clinical evidence was reviewed on September 16, 2013 with no additional information identified that would change the unproven conclusion.

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)**

The clinical evidence was reviewed on September 16, 2013 with no additional information identified that would change the unproven conclusion.

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
The clinical evidence was reviewed on September 16, 2013 with no additional information identified that would change the unproven conclusion.

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).

Additional Search Terms
Gaucher disease, Koehler disease, Legg-Calve'-Perthes disease, Legg-Perthes disease, sickle cell anemia, systemic lupus erythematosus

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/pmncfpmn.cfm Accessed September 11, 2013.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)
Medicare does not have a National Coverage Determination (NCD) for core decompression for avascular necrosis. Local Coverage Determinations (LCDs) do not exist at this time. (Accessed September 17, 2013)

APPLICABLE CODES
The codes listed in this policy are for reference purposes only. Listing of a service or device 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 benefit document. This list of codes may not be all inclusive.

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REFERENCES


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**POLICY HISTORY/REVISION INFORMATION**

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<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
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| 11/01/2013 | - Updated description of services to reflect most current clinical evidence and references; no change to coverage rationale or lists of applicable codes  
              - Archived previous policy version 2013T0240K |