Core Decompression for Avascular Necrosis

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Instructions for Use

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Application

This Medical Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

State	Policy/Guideline
Indiana	Core Decompression for Avascular Necrosis (for Indiana Only)
Kentucky	Core Decompression for Avascular Necrosis (for Kentucky Only)
Louisiana	Core Decompression for Avascular Necrosis (for Louisiana Only)
New Jersey	Core Decompression for Avascular Necrosis (for New Jersey Only)
Ohio	Core Decompression for Avascular Necrosis (for Ohio Only)
Pennsylvania	Core Decompression for Avascular Necrosis (for Pennsylvania Only)
Tennessee	Core Decompression for Avascular Necrosis (for Tennessee Only)

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.

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 policy 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 federal, state, or contractual requirements and applicable laws that may

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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 relatively 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 (refer to the following)] • 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

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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)

Andronic et al. (2021) conducted a systematic review to assess the outcomes and time to total hip replacement (THR) following core decompression (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 2,540 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 1,134 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 osteonecrosis should be omitted. Despite limitations, core decompression alone achieved short-term clinical improvements in the majority of cases. Pooled results from 1,134 hips and of these nearly 80% with early stage of osteonecrosis, showed that about 38% of patients ended up having a total hip replacement at an average of 26 months following core decompression without augmentation.

A systemic review and meta-analysis by Hua et al. (2019) observed the treatment of osteonecrosis of the femoral head (ONFH) with core decompression. Thirty-two studies included 1,865 patients (2,441 hips). These were mostly case series with six comparative studies, but that all included core decompression 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 core decompression (CD) alone, and 7 studies (565 hips) were treated with core decompression combined with autologous bone (CD Autologous bone). Some subjects (497 hips) were treated with core decompression 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 core decompression are patients with osteonecrosis 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 core decompression was safe and effective for treating osteonecrosis of the femoral head, however, it should be used with caution for advanced femoral head necrosis.

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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 core decompression and physical therapy or physical therapy alone. After a mean follow-up of 3 years, the surgical group (hip core decompression 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; vasoocclusions; 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 core decompression 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.

Miyahara et al. (2018) evaluated the effect of core decompression on patients' perception of pain, and progression of disease to femoral head collapse and total hip arthroplasty. Thirty hips in early stage osteonecrosis were evaluated using clinical, radiological, risk factor maintenance, and by the functional Merle D'Aubigné and Postel score. At six months, 83.3% showed symptom improvement. However, 73.3% evolved to femoral head collapse, with total hip arthroplasty indicated for 50%. The authors concluded that core decompression improved patients' pain early in the disease but did not alter their ultimate prognosis.

A network meta-analysis was conducted by Yoon et al. (2018) to assess the efficacy of various core decompression (CD) modalities and non-operative treatment. Nine randomized controlled trials with a minimum two-year follow-up were included. A total of 453 hips were included in the meta-analysis, 151 hips in CD, 70 hips in CD combining bone grafting (BG), 116 hips in CD combining bone marrow mononuclear cells (BMMC), 25 hips in CD combining BG and BMMC, and 91 hips in non-operative treatment. The rate of conversion to total hip arthroplasty (THA) and the radiologic progression were compared among the five treatments. The pooled risk ratio compared with non-operative treatment for THA conversion was 0.92 in traditional CD; 4.10 in CD combining BG; 0.30 in CD combining BMMC; and 1.78 in CD combining BG and BMMC. No significant differences were found in terms of the radiologic progression and the rates of THA conversion across all CD modalities and non-operative treatment. The authors concluded that these results question the assumption that CD changes the natural course of osteonecrosis of the femoral head. If the size of necrotic portion is the major determinant of future collapse of the necrotic femoral head and the collapse does not occur in small lesions even without any treatment, a large-scale randomized controlled trial is necessary to confirm the effectiveness of CD. The study is limited by the inherently indirect nature of network meta-analyses as evidence.

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 U.S. 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 core decompression 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, core decompression is not indicated and total hip replacement (THR) should be discussed.

Sadile et al. (2016) conducted a meta-analysis to assess the efficacy of core decompression (CD) compared with all other joint preserving treatments (JPT) in delaying the natural osteonecrosis evolution to hip osteoarthritis (HOA). Medline and Scopus databases were searched for 15- to 70-year-olds with osteonecrosis 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 core decompression 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.

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Shah et al. (2015) undertook a case series (n = 20) to analyze the clinical, functional and radiological outcome of core decompression and bone grafting in patients with osteonecrosis of the femoral head (ONFH) up to stage IIB. The procedure adopted in 26 hips was core decompression and cancellous bone grafting. Two hips were treated with core decompression and fibular grafting. Functional outcome was assessed by Harris hip score, wherein 19 hips had good or excellent outcome; 1 hip had fair outcome and 8 hips showed poor result. For stage I, 12/13 hips improved, whereas for Stage IIA, 6/11 hips showed improvement and for stage IIB, only 2/4 hips showed improvement. Core decompression procedures showed improvement in patients who had abduction more than 30 degrees and adduction more than 108 degrees. It also showed more improvement for internal rotation in comparison with external rotation. Out of the 28 hips, a majority had pain relief immediately following operation but as time passed deterioration was seen. At 3 months, 22 hips had pain relief but only 19 hips had pain relief at final follow-up. Less than 25% of the hips required a replacement or salvage procedure. The success rate was 92.3% for grade I, 100% for grade IIA and 50% for grade IIB. The authors concluded that core decompression and bone grafting provide satisfactory outcome when patients are carefully selected in early stages of the disease before the stage of collapse.

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 osteonecrosis of the femoral head. The study consisted of 19 hips in 18 patients with osteonecrosis of the femoral head [6 hips in Association Research Circulation Osseous (ARCO) stage IIC and 13 hips in stage IIIA] who were treated with core decompression 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 core decompression 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 osteonecrosis of the femoral head.

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, included in the Hua meta-analysis cited above). The study authors also noted that that their 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 their 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.

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)

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 core decompression, 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 osteonecrosis, septic loosening, glenoid wear, scapular insufficiency, and joint stiffness. The authors concluded that for patients with SCD suffering from early stages of HHAVN, core decompression 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

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osteonecrosis 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 osteonecrosis 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: core decompression, hemi-arthroplasty and total shoulder arthroplasty. The authors concluded that based on the current available data, core decompression is a safe and effective option for treating low-grade osteonecrosis of the humeral head, while hemi-arthroplasty and total shoulder arthroplasty should be considered for high-grade osteonecrosis. 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) of participants undergoing nonoperative treatment, core decompression, arthroscopic debridement, or total knee arthroplasty, 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. 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, core decompression 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 core decompression (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 core decompression 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 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

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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 case series 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 control and small sample size.

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).

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 21, 2022)

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Policy History/Revision Information

Date	Summary of Changes
04/01/2023	Supporting Information • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information • Archived previous policy version CS025.K

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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