

Core Decompression for Avascular Necrosis (for Ohio Only)

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Related Policies
None

Application

This Medical Policy only applies to the state of Ohio.

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 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

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). The procedure is designed to decrease pressure within the bone and 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 (Patel, 2018).

Staging is as follows:

Stage	Clinical Findings
Stage 0	<ul style="list-style-type: none"> • Patient is asymptomatic • Radiography findings are normal • Histology findings demonstrate osteonecrosis
Stage I	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Patient is symptomatic • Plain radiography findings are abnormal and include osteopenia, osteosclerosis, or cysts • Subchondral radiolucency is absent • MRI findings are diagnostic
Stage III	<ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ 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	<ul style="list-style-type: none"> • Joint space may be irregular • CT scanning is more sensitive than radiography • Subclassification depends on the extent of collapsed surface, as follows: <ul style="list-style-type: none"> ○ 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	Clinical Findings
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 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 1865 patients (2441 hips). These were mostly case series with six comparative studies, but that all included core decompression in both comparison arms: Twenty-one studies (1301 hips) using Ficat staging standard, 7 studies (338hips) 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 (1379 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 (2120 hips) documented the number of conversions to total hip replacement (THA), and 26 studies (1752hips) 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. High quality randomized controlled trials and prospective studies are needed to further clarify the effects of differing etiology factors and treatments. The findings are limited by lack of comparison group that did not undergo core decompression.

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 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 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.

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.

Marti-Carvajal and colleagues (2014, updated 2016) 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 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; vasocclusions; 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 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 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.

Wei et al. (2011, included in the Hua meta-analysis cited above) conducted a case series 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 pre-collapse stage.

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)

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. A search was performed using the PubMed (MEDLINE), EMBASE and Cochrane Library databases. 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.

Kennon and colleagues (2016) evaluated radiographic and functional outcomes after procedures for humeral head atraumatic avascular necrosis (HAAVN), decompression efficacy in chronic steroid-induced (CSI) and sickle cell disease (SCD) populations. Twenty-five shoulders were treated surgically for HAAVN. Stage I/II disease received core decompression and ultrasound bone stimulation. Stage III received surface replacement or hemiarthroplasty, and arthroplasty was performed for stage IV/V. Radiographs and clinical scores were recorded preoperatively and postoperatively. Eleven shoulders (stage I/II disease) underwent core decompression. Seven of 8 shoulders (88%) progressed to stage III/IV after decompression. All SCD patients progressed to collapse. The procedure in 19 shoulders was surface replacement, hemiarthroplasty, or total shoulder arthroplasty (TSA). Constant, American Shoulder and Elbow Surgeons, Simple Shoulder Test-12, and University of California Los Angeles Shoulder scores were significantly higher at 1- and 2-year follow-up with arthroplasty; 13 of 16 arthroplasty patients (81%) had satisfactory to excellent results. One surface replacement was revised to reverse TSA. The authors concluded that the results suggest core decompression for AVN in SCD patients does not alter osteonecrosis progression and humeral head collapse. They suggest that resurfacing and hemiarthroplasty are viable treatment options for stage III, whereas shoulder replacement for stage IV/V disease appears to offer better functional results.

Harreld et al. (2009) conducted a small case series with historical controls 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, lack of contemporary controls, and small sample size.

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, 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 tibiototalcalcaneal 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 1 year 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 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 October 13, 2020)

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Policy History/Revision Information

Date	Summary of Changes
02/01/2023	<ul style="list-style-type: none">Created state-specific policy version
05/01/2021	Template Update <ul style="list-style-type: none">Replaced content sub-heading titled “Professional Societies” with “Clinical Practice Guidelines” in <i>Clinical Evidence</i> sectionRemoved <i>CMS</i> sectionReplaced reference to “MCG™ Care Guidelines” with “InterQual® criteria” in <i>Instructions for Use</i>
02/01/2021	Application <ul style="list-style-type: none">Reformatted content
12/01/2020	Template Update <ul style="list-style-type: none">Reformatted policy; transferred content to new template Supporting Information <ul style="list-style-type: none">Updated <i>Clinical Evidence</i>, <i>CMS</i>, and <i>References</i> sections to reflect the most current informationArchived previous policy version CS025.H

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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