Clinical Policy: Ultrafiltration for Heart Failure

Reference Number: HNCA.CP.MP.456

Coding Implications
Revision Log

Last Review Date: 11/23

See Important Reminder at the end of this policy for important regulatory and legal information.

Medicare	NCD 110.15	Ultrafiltration, Hemoperfusion and Hemofiltration

Description

During ultrafiltration therapy, blood is withdrawn from the body, pumped through a filter, and returned to the body. The pump produces a pressure gradient across a semi-permeable membrane, which expels an isotonic solution of water and salts from the blood, before returning the filtered blood to the patient. Ultrafiltration is proposed to treat patients with fluid overload from heart failure.

Policy/Criteria

I. It is the policy of Health Net of California that ultrafiltration may be considered medically necessary for patients who are hospitalized with acute decompensated heart failure (ADHF) refractory to maximum recommendations related to medical and pharmaceutical therapy (i.e., diuretics).

II. It is the policy of Health Net of California that ultrafiltration (including peritoneal) is **investigational** for all other indications, including but not limited to, initial therapy of ADHF.

Background

ADHF is a common and potentially fatal cause of acute respiratory distress. Heart failure (HF) may be new or an exacerbation of chronic disease. The clinical syndrome is characterized by the development of acute dyspnea associated with the rapid accumulation of fluid within the lung's interstitial and alveolar spaces, which is the result of elevated cardiac filling pressures (cardiogenic pulmonary edema).

Patients with ADHF who fail to adequately respond to diuretic therapy are initially treated by medical management (adjustment and addition of diuretic medications and diet). If these measures are not sufficient to effectively reduce volume overload, ultrafiltration is suggested. Traditionally ultrafiltration was carried out with hemodialysis machines in hospital dialysis units, however, newer portable machines allow ultrafiltration to take place in a variety of patient settings and are not limited to dialysis suites (e.g., Aquadex FlexFlow system).

In the UNLOAD trial, 200 patients hospitalized for ADHF were randomly assigned to ultrafiltration or to standard care, including intravenous diuretics during the admission. At 48 h, weight and net fluid loss were greater in the ultrafiltration group. Dyspnea scores were similar. At 90 days, the ultrafiltration group had fewer HF rehospitalizations, rehospitalization days per

patient, and unscheduled visits. No serum creatinine differences occurred between groups. Nine deaths occurred in the ultrafiltration group and 11 in the diuretics group.[2] In the CARRESS-HF trial, 188 patients with ADHF, worsened renal function, and persistent congestion were randomly assigned to either stepped pharmacology therapy or ultrafiltration. The use of a stepped pharmacologic-therapy algorithm was superior to a strategy of ultrafiltration for the preservation of renal function at 96 hours, with a similar amount of weight loss with the two approaches. Ultrafiltration was associated with a higher rate of adverse events.

Peritoneal Ultrafiltration as an Adjunctive Therapy in End-Stage Heart Failure (PUF)
Grossekettler et al (2020) reported that peritoneal ultrafiltration (pUF) for refractory HF reduces the incidence, which is of important because as each episode adds to mortality risk. The authors did not that there are insufficient data regarding which patient cohort benefits the most and the finding of this study warrant further investigational with larger cohorts to clarify the different effects on outcomes in end stage HF. The studies included 143 refractory HF patients who were treated with PUF. Outcomes compared eGRF, NNYHA classifications, body weight, C reactive protein, ejection fraction, lung function improvement, hospitalization episodes.

The authors concluded that pUF offered various benefits in HFpEF and HFrEF, however, there were also substantial differences. In particular, hospitalization rates were found to be significantly reduced in HFpEF patients, indicating a greater medical and economical advantage. However, LVEF was only found to be improved in HFrEF patients. These researchers stated that the findings of this study warrant larger controlled studies to elaborate the differential effects of pUF as an adjunct palliative therapy in end-stage HF. The authors stated that this study had several drawbacks. This study had a relatively small patient cohort, while cardio-renal patients were included from 18 different centers. Thus, this all-comers population may have resulted in a highly heterogeneous collective that did not allow the exclusion of potential biases. Furthermore, the fact that pUF patients received a rather close monitoring might have resulted in an improved outcome on its own.

Dunlay, et al states in UpToDate (2022) Management of refractory heart failure with reduced ejection fraction: "For patients who fail to respond to adequately to an aggressive diuretic regimen, extracorporeal ultrafiltration or hemodialysis can be used to remove intravascular fluid."

American College of Cardiology Foundation (ACC)/American Heart Association (AHA) Task Force (2013, updated 2022)
Per the ACC/AHA Guideline on the management of heart failure, ultrafiltration may be considered for patients with obvious volume overload to alleviate congestive symptoms and fluid weight. Ultrafiltration may be considered for patients with refractory congestion not responding to medical therapy.

European Society of Cardiology (ESC)
The European Society of Cardiology (ESC) Task Force guidelines developed with contribution from the Heart Failure Association (HFA) (Ponilowski, 2016) on the diagnosis and treatment of acute and chronic heart failure note that there is "no evidence favouring ultrafiltration over loop

diuretics as first-line therapy in patients with AHF. At the present time, routine use of ultrafiltration is not recommended and should be confined to patients who fail to respond to diuretic-based strategies."

National Institute for Health and Care Excellence (2022)
The National Institute for Health and Care Excellence's clinical guideline on "Ultrafiltration in Acute Decompensated Heart Failure"(Sarsam, 2022) stated that "The standard treatment for volume overload in patients with ADHF is usually pharmacologic, involving intravenous (IV) diuresis, mainly with loop diuretics. Extracorporeal ultrafiltration (UF) is an emerging alternative therapy for treating volume overload in acutely decompensated heart failure patients. This activity describes the indications for ultrafiltration in acutely decompensated heart failure patients and highlights the role of the interprofessional team in the management of these patients."

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2015, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes	Description
37999	Unlisted procedure, vascular surgery

HCPCS Codes	Description
S9007	Ultrafiltration monitor

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
I50.1- I50.9	Heart failure

Reviews, Revisions, and Approvals	Date	Approval Date
Policy adopted from Health Net NMP456 Ultrafiltration for Heart Failure	11/16	
Update – no changes, references added	11/17	
References updated – no change	12/18	
Added references, no changes	12/19	

Reviews, Revisions, and Approvals	Date	Approval Date
Added peritoneal to II as investigational as well as background and references	12/20	12/20
Update- no changes	12/21	12/21
No change. Added references	11/22	11/22
No change – added Medicare NCD	11/23	11/23

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,

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This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.