Clinical Policy: Ultrafiltration for Heart Failure
Reference Number: HNCA.CP.MP.456

Last Review Date: 12/20

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

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During ultrafiltration therapy, blood is withdrawn from the body, pumped through a filter, and returned to the body.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)\(^1\)

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
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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.3

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.

American College of Cardiology Foundation (ACC)/American Heart Association (AHA) Task Force (2013)

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
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The National Institute for Health and Care Excellence’s clinical guideline on “Acute heart failure: Diagnosing and managing acute heart failure in adults” (NICE, 2014) stated that “Do not routinely offer ultrafiltration to people with acute heart failure. Consider ultrafiltration for people with confirmed diuretic resistance. Diuretic resistance is defined as dose escalation beyond a person's previously recognized dose ceiling or a dose approaching the maximum recommended daily dose without incremental improvement in diuresis”.

**Heart Failure Society of America**

The Heart Failure Society of America’s comprehensive heart failure practice guidelines (2010) indicated that ultrafiltration may be considered for the treatment of acute decompensated heart failure fluid overload in lieu of diuretics (level B evidence: cohort or smaller studies) and that ultrafiltration may be considered when congestion continues despite diuretic therapy (level C evidence: opinion).

**Coding Implications**

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Reviews, Revisions, and Approvals

| Added peritoneal to II as investigational as well as background and references | 12/20 | 12/20 |

References

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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.

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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.

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