Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 11/1/24**
(See policy history boxes for previous effective dates)

Title: Ultrafiltration in Decompensated Heart Failure

Description/Background

Ultrafiltration is a technique being evaluated for removal of excess fluid from patients with volume overload and heart failure. Ultrafiltration removes fluid from the blood by using pressure differentials with dialysis equipment or similar filtration devices. Ultrafiltration is one of the most common approaches. It may be considered in those with diuretic resistance even if data about its effects on outcomes are unsettled. Ultrafiltration may be considered in refractory volume overload unresponsive to diuretic treatment.

Congestive heart failure (CHF) is a complex clinical syndrome characterized by inefficient myocardial performance, resulting in compromised blood supply to the body. CHF results from any disorder that impairs ventricular filling or ejection of blood to the systemic circulation. Individuals usually present with fatigue and dyspnea, reduced exercise tolerance, and systemic or pulmonary congestion. Heart failure is a relatively common problem and frequently results in hospitalizations and readmissions.

Heart failure is a condition with a variable natural history and multiple confounders of outcome. Clinical outcomes of interest in the treatment of heart failure include survival, hospitalization, complications, and quality of life; although removal of fluid and sodium, and weight loss, are important, they are surrogate outcomes that do not necessarily translate into clinical outcomes. Because ultrafiltration does not directly affect ventricular function, its effect on clinical outcomes is difficult to evaluate.[13]

Various approaches are being explored in treating this condition, especially when it is refractory (unresponsive) to conventional therapy. Ultrafiltration is one technique receiving increasing notice for a possible role in hospitalized patients with marked volume overload from heart failure. Ultrafiltration is a process utilized to remove fluid from the blood by using pressure differentials during treatment with a dialysis machine or similar filtration device.

It has been suggested that ultrafiltration may offer greater and more expeditious volume and sodium removal compared with conventional therapies, particularly in patients with decompensated heart failure whose fluid overload is unresponsive to medical management. In recent studies, this technique is also referred to as aquapheresis.

Newer devices that allow continuous ultrafiltration in ambulatory patients are under investigation to reduce volume overload.

Ultrafiltration
Ultrafiltration (UF) differs from dialysis in that it acts via convection rather than diffusion, which lowers the risk for induced metabolic abnormalities. Conventional UF devices required central venous access with a double lumen catheter, monitoring by a dialysis technician, and specialized hospital units. Devices have been developed that allow UF to be carried out via large peripheral venous catheters that potentially allow for continuous UF in ambulatory individuals. UF techniques are performed primarily in hospitalized individuals or in facility-based ambulatory settings, such as specialized dialysis clinics.[14]

Peripheral Ultrafiltration
Peripheral Ultrafiltration is a medical therapy that utilizes a portable machine that passes the patient's blood from a peripheral vein through a filter to remove excess fluid. The filtrate is then returned to the body. An advantage to this therapy is the requirement of only a small amount of blood to achieve relief of congestion without disrupting the body's electrolyte balance, heart rate, and blood pressure. Patients undergoing ultrafiltration will typically have an average hospital length of stay of three days.[14]

Peritoneal Ultrafiltration
Peritoneal dialysis (PD) removes fluid by ultrafiltration using the lining of the abdomen, the peritoneal membrane. Water moves from the blood to the PD solution through the peritoneal membrane. Ultrafiltration can be increased by increasing the amount of dextrose in the PD solution.[9]

Regulatory Status:

In June 2002, the Aquadex™ FlexFlow™ System (CHF Solutions, Brooklyn Park, MN) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. An updated/amended 510(k) approval (classified as a high permeability dialysis system) was given in September 2007 following modifications. The FDA determined that this device was substantially equivalent to existing devices for use in temporary (up to 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy, and for extended (longer than 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization. FDA product code: KDI.

In 2020, the FDA approved the Aquadex FlexFlow® System 2.0 for a slightly modified use: "Continuous ultrafiltration therapy for temporary (up to 8 hours) or extended (longer than 8 hours in patients who require hospitalization) use in adult and pediatric patients weighing 20 kilograms or more whose fluid overload is unresponsive to medical management, including diuretics. All treatments must be administered by a healthcare provider, within an outpatient or inpatient clinical setting, under physician prescription, both of whom having received training in extracorporeal therapies."

Also in February of 2020, the FDA approved the Aquadex SmartFlow, CHF Solutions. For the removal of excess fluid from patients with hypervolemia, otherwise known as fluid overload. The console is indicated for use of to 8 hours or more in hospitalized patients when hypervolemia is unresponsive to medical management or diuretics.

In January 4, 2024, the FDA approved a specialty catheter (Aquadex® Ultrafiltration System) that provides alternative peripheral access for ultrafiltration therapy across a greater range of patient physiologies. Aquadex is proven to simply, safely, and precisely remove excess fluid from patients suffering from fluid overload who have not responded to conventional medical management, including diuretics.[1]

Medical Policy Statement

The use of ultrafiltration in hospitalized individuals with acute decompensated heart failure is established when criteria are met. It may be considered a useful therapeutic option when indicated.

Peritoneal ultrafiltration is considered experimental/investigational. The results of this therapy for acute decompensated heart failure has not been shown to improve clinical outcomes.

Inclusionary and Exclusionary Guidelines

Inclusions:
The use of ultrafiltration for acute decompensated heart failure **in a hospitalized individual** may be considered established when the following criteria are met:

- Individual has dyspnea at rest or with minimal activity; **and**
- Individual has confirmed diuretic resistance defined as:
  - Dose escalation beyond previously recognized dose ceiling; **or**
  - Daily dose maximum is being reached without incremental improvement in diuresis.
- Use in patients who have a contraindication to diuretics.

Exclusions:

- Ultrafiltration used as a maintenance therapy for acute decompensated heart failure.
- Peritoneal ultrafiltration for acute decompensated heart failure.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

99199*					

*When used for ultrafiltration in decompensated heart failure in an acute setting according to the policy criteria.

Other codes (investigational, not medically necessary, etc.):

N/A

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

HEART FAILURE

Clinical Context and Therapy Purpose

The purpose of ultrafiltration in individuals with volume overload and heart failure is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following **PICO** was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with volume overload and heart failure.

Interventions

The therapy being considered is ultrafiltration. During ultrafiltration, a small catheter is placed in a vein, and the catheter transports blood to the ultrafiltration machine then back to the patient. After ultrafiltration is complete, the patient restarts on diuretics to keep fluid in balance.

Comparators

The following therapies are currently being used to manage patients with volume overload and heart failure: diuretics.

Outcomes
The general outcomes of interest are overall survival, quality of life, hospitalizations, and treatment-related morbidity.

Follow-up of at least 10 years would be preferable to determine outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought
- Studies with duplicative or overlapping populations were excluded.

Review of Literature
The UNLOAD trial was a non-blinded trial that involved 200 patients hospitalized for heart failure and hypervolemia randomly assigned during the first 24 hours of hospitalization to ultrafiltration or usual care (diuretics).[2] The study was conducted during 1 year at 28 U.S. centers. Primary efficacy endpoints were 48-hour weight loss and dyspnea score (1–7 Likert scale). Primary safety endpoints were changes in blood urea nitrogen, creatinine, and electrolyte levels throughout hospitalization and 90-day follow-up, and episodes of hypotension requiring therapeutic intervention at 48 hours. At least 13 secondary efficacy endpoints are also listed, including length of index hospitalization, quality-of-life assessments throughout follow-up, and resource utilization (rehospitalization for heart failure, unscheduled office and emergency department visits) during follow-up. Results showed a weight loss of 5.0 versus 3.1 kg from baseline at 48 hours (p=0.001) for the ultrafiltration and usual care groups, respectively, with no difference in dyspnea scores between treatment groups. There was no difference in the length of stay of the index hospitalization, but the ultrafiltration group had a smaller percentage of patients rehospitalized for heart failure at 90 days (18% and 32%, respectively, p=0.037). There were no differences between treatment groups for quality-of-life assessments and renal function, except for a greater likelihood of hypokalemia in the diuretic group (p=0.018). An additional subgroup analysis compared the outcomes of the ultrafiltration group versus standard intravenous (IV) diuretics by continuous infusion or bolus injection.[8] Despite similar fluid loss with ultrafiltration and continuous diuretic infusion, fewer heart failure rehospitalizations equivalents occurred only with the ultrafiltration group.

In 2010, Giglioli et al studied the effects of ultrafiltration vs. diuretics on clinical, biohumoral, and hemodynamic variables in patients with decompensated heart failure, the ULTRADISCO study.[3] Thirty patients with decompensated HF were randomly assigned to diuretics or ultrafiltration. Haemodynamic variables, including several novel parameters indicating the overall performance of the cardiovascular system, were continuously assessed with the Pressure Recording Analytical Method before, during, at the end of treatment (EoT) and 36 h after completing treatment. Aldosterone and N-terminal pro-B-type natriuretic peptide (NT-proBNP) plasma levels were also measured. Patients treated with ultrafiltration had a more pronounced reduction in signs and symptoms of HF at EoT compared with baseline, and a significant decrease in plasma aldosterone (0.24+0.25 vs. 0.86+1.04 nmol/L; P , 0.001) and

NT-proBNP levels (2823+2474 vs. 5063+3811 ng/L; P , 0.001) compared with the diuretic group. The ultrafiltration group showed a significant improvement (% of baseline) in a number of hemodynamic parameters, including stroke volume index (114.0+11.7%; P , 0.001), cardiac index (123.0+20.8%; P , 0.001), cardiac power output (114.0+13.8%; P , 0.001), dP/dtmax (129.5+19.9%; P , 0.001), and cardiac cycle efficiency (0.24+0.54 vs. 20.14+0.50 units; P , 0.05), and a significant reduction in systemic vascular resistance 36 h after the treatment (88.0+10.9%; P , 0.001), which was not observed in the diuretic group.

Hanna et al (2012) compared ultrafiltration with conventional diuretic (CD) therapy, and found ultrafiltration is associated with greater weight loss and fewer rehospitalizations in patients admitted with decompensated heart failure (HF).[4] Concerns have been raised regarding its safety and efficacy in patients with more advanced heart failure. The authors conducted a single center, prospective, randomized controlled trial in patients with advanced HF admitted to an intensive care unit for hemodynamically guided therapy, comparing UF (n=17) with CD (n=19) at admission. The primary end point was the time required for pulmonary capillary wedge pressure (PCWP) to be maintained at a value of 18 mm Hg for at least 4 consecutive hours. Secondary end points included levels of cytokines and neurohormones, as well as several clinical outcomes. In our study cohort, the time to achieve the primary end point was lower in the UF group but did not reach statistical significance (P = .08). UF resulted in greater weight reduction, higher total volume removed, and shorter hospital length of stay. There were no differences in kidney function, biomarkers, or adverse events. In patients with advanced HF under hemodynamically tailored therapy. The authors concluded that UF can be safely performed to achieve higher average volume removed than CD therapy without leading to adverse outcomes.

Marenzi et al published findings of the CUORE trial in 2014.[5] Fifty-six patients with congestive HF were randomized to receive standard medical therapy (control group; n = 29) or ultrafiltration (ultrafiltration group; n = 27). The primary end point of the study was rehospitalizations for congestive HF during a 1-year follow-up. Despite similar body weight reduction at hospital discharge in the 2 groups (7.5 ± 5.5 and 7.9 ± 9.0 kg, respectively; P = .75), a lower incidence of rehospitalizations for HF was observed in the ultrafiltration-treated patients during the following year (hazard ratio 0.14, 95% confidence interval 0.04-0.48; P =.002). Ultrafiltration-induced benefit was associated with a more stable renal function, unchanged furosemide dose, and lower B-type natriuretic peptide levels. At 1 year, 7 deaths (30%) occurred in the ultrafiltration group and 11 (44%) in the control group (P = .33).

Hu et al (2020) investigated the efficacy and safety of early ultrafiltration in acute decompensated heart failure (ADHF) patients.[6] One hundred patients with ADHF within 24 h of admission were randomly assigned into early ultrafiltration (n = 40) or torasemide plus tolvaptan (n = 60) groups. The primary outcomes were weight loss and an increase in urine output on days 4 and 8 of treatment. Patients who received early ultrafiltration for 3 days achieved a greater weight loss (kg) (-2.94 ± 3.76 vs - 0.64 ± 0.91, P < 0.001) and urine increase (mL) (198.00 ± 170.70 vs 61.77 ± 4.67, P <0.001) than the torasemide plus tolvaptan group on day 4. From days 4 to 7, patients in the early ultrafiltration group received sequential therapy of torasemide and tolvaptan. Better control of volume was reflected in a greater weight loss (- 3.72 ± 3.81 vs - 1.34 ± 1.32, P < 0.001) and urine increase (373.80 ± 120.90 vs 79.5 ± 52.35, P < 0.001), greater reduction of B-type natriuretic peptide(BNP) (pg/mL) (- 1144 ± 1435 vs - 654.02 ± 889.65, P = 0.037), NYHA (New York Heart Association) functional class (- 1.45 ± 0.50 vs - 1.17 ± 0.62, P = 0.018), jugular venous pulse (JVP) score (points) (-1.9 ± 1.13 vs -

0.78 ± 0.69, P < 0.001), inferior vena cava (IVC) diameter (mm) (- 15.35 ± 11.03 vs - 4.98± 6.00, P < 0.001) and an increase in the dyspnea score (points) (4.08 ± 3.44 vs 2.77 ± 2.03, P = 0.035)in the early ultrafiltration group on day 8. No significant differences were found in the re-admission and mortality rates in the 2 patient groups at the 1-month and 3-month follow-ups. Both groups had a similar stable renal profile. The authors concluded that early UF may be superior to diuretics for volume overload treatment initiation of ADHF patients.

In a meta-analysis, Wobbe et al (2020) intended to assess the impact of UF therapy in ADHF patients.[7] The authors searched the medical literature to identify well-designed studies comparing UF with the usual diuretic therapy in this setting. Systematic evaluation of 8 randomized controlled trials enrolling 801 participants showed greater fluid removal (difference in means 1372.5 mL, 95% CI 849.6 to 1895.4 mL; $p < 0.001$), weight loss (difference in means 1.592 kg, 95% CI 1.039 to 2.144 kg; $p < 0.001$) and lower incidences of worsening heart failure (OR 0.63, 95% CI 0.43 to 0.94, $p = 0.022$) and rehospitalization for heart failure (OR 0.54, 95% CI 0.36 to 0.82, $p = 0.003$) without a difference in renal impairment (OR 1.386, 95% CI 0.870 to 2.209; $p = 0.169$) or all-cause mortality (OR 1.13, 95% CI 0.75 to 1.71, $p = 0.546$).

In a multicenter feasibility study, Morpurgo et al (2017), evaluated the feasibility of a new ultrafiltration device, the CHIARA (Congestive Heart Impairment Advanced Removal Approach) system, that utilizes a single-lumen cannula (17G, multi-hole) inserted in a peripheral vein of the arm.[8] In this prospective feasibility study, consecutive ultrafiltration treatments (lasting ≥6 hours and with an ultrafiltration rate ≥100ml/h) with the CHIARA device and a single peripheral venous approach were performed at 6 Italian hospitals. For each session, the authors evaluated the performance of the venous access, the ultrafiltrate volume removed, and the cause of its interruption. One-hundred-three ultrafiltration sessions were performed in 55 patients with AHF (average 1.9±1.7 treatment/patient). The overall median length of ultrafiltration treatment was 14h (interquartile range 7-21) with removal of 3266±3088ml of fluid (183±30ml/hour). The treatment was successfully completed in 92 (89%) sessions and in 80% of patients. The mean suction flow rate from the vein was 70±20ml/min, while the mean re-injection flow rate was 98±26ml/min. There were no clinically relevant complications related to the venous access and/or to the anticoagulant therapy with heparin.

Peritoneal Ultrafiltration

In 2015, Viglino et al performed a systematic review of literature to highlight which patients peritoneal ultrafiltration (PUF) has been used in, how and with what results.[9] Consideration was given to 14 papers for a total of 471 patients. (1) Characteristics of the patients. Average age 71.6 years; diabetes mellitus (DM) 47%; New York Heart Association (NYHA) class III 38.9%-class IV 59.8%; ischemic cardiopathy 67.8%; mean LVEF 35%. (2) PUF modality. Only continuous ambulatory peritoneal dialysis (CAPD) in ten studies, only APD in two studies, both in two studies. Overall CAPD was used in 56.2% of the pts. A single exchange of icodextrin was used to treat 51% of patients on CAPD. The volume of ultrafiltration obtained varied between 390 and 1,180 ml/die. (3) Effects of PUF. Significant improvement in NYHA class and reduction in hospitalizations. Survival at 12 months varying between 47 and 95%. Mortality seems to be associated with DM, higher basal glomerular filtration rate, less change in ejection fraction after PUF and less use of ICOs. The main limitation of the selected studies, mostly retrospective and with a limited number of patients, remains the lack of clarity and uniformity of the selection criteria used. For this reason, extrapolations about survival require extreme caution and are not currently possible.

Dukka et al (2019) discusses peritoneal ultrafiltration for heart failure and lessons learned from a randomized controlled trial.[10] The Peritoneal Dialysis for Heart Failure (PDHF) study was a multicenter prospective randomized controlled trial which aimed to investigate this issue. The trial stopped early due to inadequate recruitment. We describe methods, trial activity, and lessons learned. The trial aimed to recruit 130 participants with severe diuretic-resistant HF (New York Heart Association [NYHA] 3/4) and chronic kidney disease (CKD) stage 3/4 on optimal medical treatment for ≥ 4 weeks from 6 UK centers. Participants were randomized to either continuation of conventional HF treatment or to additionally receiving PuF (1 overnight exchange using Icodextrin dialysate). Primary outcome was change in 6-minute walk test (6MWT) between baseline and 28 weeks (end of trial). Secondary outcomes were changes in patient reported quality of life as assessed by the Kansas City Cardiomyopathy Questionnaire, short form 36 (SF 36) health survey results, hospitalization, and mortality. Over a 2-year period, 290 patients were screened from which only 20 met inclusion criteria and 10 were recruited. Reasons for ineligibility were fluctuating estimated glomerular filtration rate (eGFR), suboptimal HF treatment, frailty, and patients being too unwell for randomization. Barriers to recruitment included patient frailty, with some participants considered only when they were at end of life, unwillingness to engage in an invasive therapy, and suboptimal coordination between cardiology and renal services. This is a challenging patient group in which to perform research, and lessons learned from the peritoneal dialysis (PD)-HF trial will be helpful in the planning of future studies in this area.

Wojtaszek et al (2019) explored the efficacy of PUF with a nightly 12-h exchange in the long-term treatment of refractory HF.[11] The study included patients with chronic HF resistant to updated HF therapy (pharmacological and devices if applicable), who had experienced at least three hospitalizations due to HF during the preceding year and were disqualified from heart transplantation. All of them were treated with nightly 12-h 7.5% icodextrin exchange. There were 15 patients (13 men), aged 72 ± 9 years, with charlson comorbidity index (CCI) 9 ± 1.2, NYHA class IV (11 patients) or III (4 patients), and eGFR 32 ± 11 ml/min/1.73m^2. They were followed up for 24 ± 8 months (range 12-43, median 26 months). During the 1st year, all patients improved their NYHA functional class from 3.7 ± 0.5 to 2.6 ± 0.5; P = 0.0005, with stable (34.3 ± 12.4, and 35.6 ± 16.5%, respectively) left ventricular ejection fraction (LVEF), and inferior vena cava (IVC) diameter decreased from 27.8 ± 2.7 to 24.4 ± 3.4 mm; P = 0.09. Daily diuresis increased from 867 ± 413 to 1221 ± 680 ml; P = 0.25, while the dose of furosemide could be reduced from 620 ± 256 to 360 ± 110 mg/d; P = 0.0005, however, the kidney function deteriorated, with eGFR drop from 32 ± 11 to 25.6 ± 13 ml/min/1.73m^2; P = 0.01). HF-related hospitalizations decreased from 8.9 ± 2.8 days/month to 1.5 ± 1.2 days/month (P = 0.003). Mechanical peritoneal dialysis complications occurred in five patients and infectious complications in four (peritonitis rate 1 per 72 patient-month). Patient survival was 93% at 1 year and 73% at 2 years. Technique survival was 100%.

SUMMARY OF EVIDENCE

For individuals who have decompensated heart failure who receive ultrafiltration, the evidence consists of randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are overall survival, quality of life, hospitalizations, and treatment-related morbidity. most published RCTs reported beneficial effects of ultrafiltration on physiologic measures and intermediate outcomes such as weight loss, and/or reductions in intensive care unit stay or readmissions for heart failure. Studies have shown greater fluid removal, a reduction in systemic vascular resistance, fewer cardiovascular events, stable renal function and fewer

rehosptializations. The evidence is sufficient to determine that the technology results in an improvement in the net health outcomes.

For individuals who have decompensated heart failure who receive peritoneal ultrafiltration, The evidence includes one RCT and a review of literature. In the randomized study the following barriers where encountered: patient frailty, with some participants considered only when they were at end of life, unwillingness to engage in an invasive therapy, and suboptimal coordination between cardiology and renal services. Wojtaszek et al (2019) explored the efficacy of PUF with a nightly 12-h exchange in the long-term treatment of refractory HF. Wojtaszek et al (2019) explored the efficacy of PUF with a nightly 12-h exchange in the long-term treatment of refractory HF. In this study, mechanical peritoneal dialysis complications occurred in many patients. Further studies are needed on the safety and efficacy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03994874	Peritoneal ultrafiltration in cardio-renal syndrome (PURE)	84	Apr 2026
NCT05318105	Ultrafiltration vs. IV diuretics in worsening heart failure (REVERSE-HF)	372	Oct 2025
Unpublished			
NCT02829450	Home-based ultrafiltration for congestive heart failure impact on survival, hospitalizations rate, quality of life, peritoneal membrane characteristics and residual renal function with different treatment modes	40	Oct 2020 (status unknown)
NCT02829450	Peritoneal ultrafiltration to treat congestive heart failure	40	Oct 2020
NCT02846337	Ultrafiltration vs. medical therapies in the management of the cardio renal syndrome (UR-CARE)	154	Sept 2021

NCT: national clinical trial

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

American College of Cardiology Foundation and American Heart Association

The 2013 ACCF/AHA Guidelines for the Diagnosis and Management of Heart Failure in Adults (under Recommendations for Hospitalized Patient) lists ultrafiltration as a Class IIb recommendation (benefit greater than risk, additional studies needed).[13] The recommendations state ultrafiltration “may be considered for patients with obvious volume overload to alleviate congestive symptoms and fluid weight (Level of Evidence of B-conflicting evidence), and “for patients with refractory congestion not responding to medical therapy” (Level of Evidence C: recommendation less well established).

The 2022 updated guidelines for the diagnosis and management of heart failure state “Many aspects of ultrafiltration including patient selection, fluid removal rates, venous access, prevention of therapy-related complications, and cost require further investigation.”

European Society of Cardiology and Heart Failure Association

In 2021 (updated 2023), the European Society of Cardiology and Heart Failure Association released joint guidelines on the diagnosis and treatment of acute heart failure, which stated "Ultrafiltration is one of the most common approaches. It may be considered in those with diuretic resistance even if data about its effects on outcomes are unsettled.” They also state ultrafiltration may be considered in refractory volume overload unresponsive to diuretic treatment (class IIb, level C rating)“[14]

Heart Failure Society of America

The Heart Failure Society of America’s (HFSA) 2010 Comprehensive Heart Failure Practice Guidelines indicate 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) The HFSA guidelines also indicate ultrafiltration may be considered when congestion continues despite diuretic therapy. (Level C evidence - opinion)[15]

Government Regulations
National/ Local:

There is no national or local coverage determination specifically addressing ultrafiltration as a treatment for decompensated heart failure.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through July 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/07	5/14/07	6/7/07	Joint policy established
11/1/10	8/28/10	8/17/10	Routine maintenance
11/1/12	8/21/12	8/21/12	Routine maintenance; policy reformatted to mirror BCBSA policy.
11/1/13	8/20/13	9/3/13	Routine maintenance. Policy status unchanged. References 4, 10-11 and 15 added.
3/1/15	12/12/14	12/29/14	Routine maintenance. Policy status unchanged.
5/1/16	2/16/16	2/16/16	Routine maintenance. Change in policy title, added references.
5/1/17	2/21/17	2/21/17	Routine policy maintenance. Changes in policy title, updated references and rationale.
5/1/18	2/20/18	2/20/18	Routine policy maintenance. Added references 4 and 5. No change in policy status.
5/1/19	2/19/19		Routine policy maintenance. No change in policy status.
5/1/20	2/18/20		Routine policy maintenance, added references 16 & 17. No change in policy status.
5/1/21	2/16/21		Routine policy maintenance, no change in policy status.
5/1/22	2/15/22		Routine policy maintenance, no change in policy status.
5/1/23	2/21/23		Routine policy maintenance, no change in policy status. (ds)
2/20/24			Policy tabled at JUMP. Vendor status N/A (ds)
11/1/24	8/26/24		Policy status changed to mixed, added E/I statement to MPS. Inclusion section with criteria. Old references removed, new references added. Rationale rewritten. Code

			99199 moved to established. Vendor managed: N/A (ds)

Next Review Date: 3rd Qtr. 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: ULTRAFILTRATION IN DECOMPENSATED HEART FAILURE

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Per policy criteria
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

N/A