Healthy Blue

Medical Policy

Subject:	Ultrafiltration in Decompensated Heart Failure		
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Description/Scope

This document addresses ultrafiltration, (also referred to as aquapheresis), a treatment for refractory congestive heart failure (CHF, also referred to as heart failure [HF]) that involves the removal of excess fluid. The technique utilizes pressure differentials during treatment with a dialysis machine or similar filtration device. Proponents suggest that this treatment may offer the potential for greater and more expeditious volume and sodium removal compared with conventional therapies for *hospitalized individuals.* Ultrafiltration is generally used for decompensated HF where fluid overload is unresponsive to conventional medical management with use of diuretics.

Position Statement

Investigational and Not Medically Necessary:

The use of ultrafiltration is considered **investigational and not medically necessary** for the treatment of heart failure.

Rationale

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. At the present time, UF techniques are performed primarily in hospitalized individuals or in facility-based ambulatory settings, such as specialized dialysis clinics.

Clinical studies of UF techniques on human subjects have been limited regarding the impact of this technology on survival, hospitalization, complication rates, and quality of life, compared to conventional treatment options. Studies of UF include small randomized trials (Bart, 2005; Bart, 2012; Costanzo, 2007; Costanzo, 2016; Rogers, 2008), case series (Costanzo, 2005; Dahle, 2006) and a retrospective case series (Jaski, 2008). Results of the UNLOAD trial (Ultrafiltration vs. Intravenous Loop Diuretics for Patients Hospitalized for Acute Decompensated Congestive Heart Failure) were published in 2007. A total of 200 individuals hospitalized for CHF at 28 sites were randomized to receive either UF or standard care. The primary endpoints included weight loss and dyspnea measured at 48 hours on a 7 point Likert scale. While the UF group reported a 30-40% greater fluid and weight loss, there was no difference in dyspnea between the two groups at 48 hours. Among the secondary outcomes,

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quality of life and other functional assessments were also similar between the two groups. However, the rehospitalization rates were lower in the UF group (18% vs. 32%). Study design and methodologic concerns have been raised and call into question the validity of the results from the UNLOAD trial. There were discrepancies between the improvement in intermediate outcomes, such as weight loss, and the key reported outcomes, such as dyspnea scores and walking distance, which did not differ between the two groups. The reduction in hospital admissions in the UF group was unexpected and is not explained by the intermediate measures of HF severity. Additional limitations included lack of blinding for subjects, investigators, and staff. In addition, there was inadequate reporting of recruitment and follow-up. Only 83 of 100 individuals randomized to the UF group and 84 of 100 individuals randomized to the standard care group were included in measures of the primary outcomes. This high rate of incomplete data at 48 hours after randomization of inpatient cohorts was unexplained. In addition, only 72 of the 100 individuals receiving UF had failed prior diuretic therapies, which is the U.S. Food and Drug Administration (FDA) labeled indication for peripheral UF in CHF (Costanzo, 2007).

Post-hoc analysis of the UNLOAD trial results investigated the primary outcomes of individuals randomized to UF (n=100), which were compared with those treated with continuous (n=32) or bolus (n=68) IV diuretics. In this analysis, the two primary outcome measures (dyspnea scores and weight loss at 48 hours) were compared across the three groups. Dyspnea scores at 48 hours did not differ between the three groups (p=0.608). Pair-wise comparisons showed the weight loss to be similar in the UF and IV continuous diuretic infusion groups (5 ± 3.1 vs. 3.6 ± 3.5 kg; p=0.145) but greater in the UF than in the IV bolus diuretic group (5 ± 3.1 vs. 2.9 ± 3.5 kg; p=0.001), although similar between the continuous IV diuretic infusion and bolus IV diuretic groups (3.6 ± 3.5 kg vs. 2.9 ± 3.5 kg; p=0.358). At 90 days, a secondary outcome measure of "rehospitalization equivalents" (rehospitalization plus unscheduled visits for HF) were fewer in the UF group (0.65 vs. 2.29; p=0.016) than in the continuous diuretic infusion group and the bolus diuretic group (0.65 vs. 1.31; p=0.05) (Costanzo, 2010).

In 2010, an assessment of UF for HF was conducted by the Veterans Health Administration Technology Assessment Program in the United Kingdom (UK), which found no recently published evidence to materially change conclusions from a previous report by the Centre for Evidence-based Purchasing (CEP) of the UK National Health Services, that noted, "CEP finds that ultrafiltration has significant potential to become a routine therapy for excess fluid removal in patients with congestive heart failure. However, further work is needed to establish the patient groups who would benefit most" (Flynn, 2010).

Results of the Effectiveness of Ultrafiltration in Treating People With Acute Decompensated Heart Failure (ADHF) and Cardiorenal Syndrome (CARRESS-HF) trial were published in 2012, which was a large, multicenter study sponsored by the National Heart Lung and Blood Institute (NHLBI) of the National Institutes of Health (NIH) and Duke University, in collaboration with CHF Solutions®, Inc. The primary purpose of this trial was to investigate the safety and effectiveness of UF versus standard medical drug therapy in improving renal function and relieving fluid buildup in people hospitalized with ADHF and cardiorenal syndrome. Subjects with ADHF, worsening renal function, and persistent congestion were randomized to a strategy of stepped pharmacologic therapy (n=94) or UF (n=94). The primary endpoint was the bivariate change from baseline in the serum creatinine level and body weight, as assessed 96 hours after random assignment. Study subjects were followed for 60 days. The results showed that UF was inferior to pharmacologic therapy with respect to the bivariate endpoint of the change in the

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serum creatinine level and body weight at 96 hours after enrollment (p=0.003), owing primarily to an increase in the creatinine level in the UF group. At 96 hours, the mean change in the creatinine level was -0.04 ± 0.53 mg per deciliter (-3.5 ± 46.9 μmol per liter) in the pharmacologic-therapy group, as compared with +0.23 ± 0.70 mg per deciliter (20.3 ± 61.9 μmol per liter) in the UF group (p=0.003). There was no significant difference in weight loss at 96 hours after enrollment between subjects in the pharmacologic-therapy group and those in the UF group (a loss of 5.5 ± 5.1 kg [12.1 ± 11.3 lb] and 5.7 ± 3.9 kg [12.6 ± 8.5 lb], respectively; p=0.58). A higher percentage of subjects in the UF group than in the pharmacologic-therapy group had a serious adverse event (72% vs. 57%, p=0.03). The investigators concluded that the use of a stepped pharmacologic-therapy algorithm was superior to UF for the preservation of renal function at 96 hours, with similar amounts of weight loss for both approaches. UF was associated with a higher rate of adverse events (Bart, 2012).

Results of a retrospective, single center review included 63 consecutive adult subjects with ADHF who were admitted to the Heart Failure Intensive Care Unit at the Cleveland Clinic from 2004 through 2009 and who required slow continuous ultrafiltration (SCUF) because of congestion that had been refractory to hemodynamically guided intensive medical therapy. The mean creatinine level was 1.9 ± 0.8 mg/dl on admission and 2.2 ± 0.9 mg/dl at SCUF initiation. After 48 hours of SCUF, there were significant improvements in hemodynamic variables (mean pulmonary arterial pressure: 40 ± 12 mm Hg vs. 33 ± 8 mm Hg, p=0.002; central venous pressure: 20 ± 6 mm Hg vs. 16 ± 8 mm Hg, p=0.007; mean pulmonary wedge pressure: 27 ± 8 mm Hg vs. 20 ± 7 mm Hg, p=0.02; Fick cardiac index: 2.2 l/min/m^2 [interquartile range: 1.87 to 2.77 l/min/m^2] vs. 2.6 l/min/m^2 [interquartile range: 2.2 to 2.9 l/min/m^2], p=0.0008); and weight loss (102 ± 25 kg vs. 99 ± 23 kg, p=0.0001). However, there were no significant improvements in serum creatinine levels (2.2 ± 0.9 mg/dl vs. 2.4 ± 1 mg/dl, p=0.12) and blood urea nitrogen (60 ± 30 mg/dl vs. 60 ± 28 mg/dl, p=0.97). Fifty-nine percent of study participants receiving SCUF required conversion to continuous hemodialysis during their hospital course and 14% were dependent on dialysis at hospital discharge. Thirty percent died during hospitalization, and 6 individuals were discharged to hospice care. The authors concluded that SCUF after admission for ADHF refractory to standard medical therapy was associated with high incidence of subsequent transition to renal replacement therapy and high in-hospital mortality, despite significant improvement in hemodynamics (Patarroyo, 2012).

Cheng and colleagues (2015) published a systematic review and meta-analysis of seven randomized controlled trials (RCTs) (total n=569 participants) that evaluated UF in decompensated HF with renal insufficiency. A pooled analysis of five of these trials did not find a significant difference between groups in all-cause mortality (odds ratio [OR] 0.95; 95% confidence interval [CI], 0.58 to 1.55; p=0.83). There was significantly more 48-hour weight loss (WMD 1.59; 95% CI, 0.32 to 2.86; p=0.01; I2=68%) and 48-hour fluid removal (WMD 1.23; 95% CI, 0.63 to 1.82; p<0.0001; I2=43%) in the UF group. Serum creatinine and serum creatinine changes were similar between the UF and control groups. All-cause mortality (OR 0.95; 95% CI, 0.58 to 1.55; p=0.83; I2=0.0%) and all-cause rehospitalization (OR 0.97; 95% CI, 0.49 to 1.92; p=0.94; I2=52%) were also similar between the UF and control groups. Adverse events, such as anemia, infection, hemorrhage, worsening HF, and other cardiac disorders did not differ significantly between the UF and control groups.

Siddiqui and colleagues (2017) performed a systematic review and meta-analysis to determine the role of ultrafiltration for individuals with ADHF. The authors analyzed nine RCTs (n=820) that compared UF (n=403) to

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conventional diuretics (n=417). The primary endpoints were cumulative heart failure readmissions, cumulative heart failure readmissions at 90 days, and cumulative all-cause admissions. Cumulative hospital readmissions secondary to heart failure were less in the UF group than the diuretic group (77 vs.111, risk ratio [RR] 0.71; 95% CI, 0.49 to 1.02; p=0.07). Likewise, at 90 days there were less readmissions in the UF group than the diuretic group (43 vs. 67, RR 0.65; 95% CI, 0.47 to 0.90; p=0.01). However, there were no differences between the UF group and the diuretic group for all-cause readmissions (56 vs. 58, RR 0.65; 95% CI, 0.18 to 2.38; p=0.52). Hypotension was more common in the UF group than the diuretic group (24 vs. 13, OR 2.06; 95% CI, 0.98 to 4.32; p=0.06). The cumulative mortality, length of hospital stay, and renal function between the two groups was similar. The study was limited by the heterogeneity of the RCTs. The authors concluded that ultrafiltration "remains a plausible treatment option" for ADHF and larger RCTs with extended follow-up are needed.

Kabach and colleagues (2017) performed a meta-analysis to compare UF to conventional diuretic therapy for ADHF. They used pooled data from nine RCTs (n=605) and compared UF to diuretics in a 1:1 ratio. They found that UF was associated with a reduced risk of clinical worsening (OR 0.57; 95% CI, 0.38 to 0.86; p=0.007) and better clinical decongestion (OR 2.32; 95% CI, 1.09 to 4.91; p=0.03). However, they did not find that UF improved the risk of re-hospitalization (OR 0.92; 95% CI, 0.62 to 1.38; p=0.70) or mortality (OR 0.99; 95% CI, 0.60 to 1.62; p=0.97). The authors noted that the study was limited by the heterogeneity of the RCTs. They concluded that although UF improves symptoms, "many questions concerning the indications of UF, as a unique decision-making tool in ADHF are still unanswered."

Grodin and colleagues (2018) performed a per-protocol analysis on the CARESS-HF study (Bart, 2012) to better understand the effect of UF on clinical biomarkers and neurohormonal activation. They included participants who were randomized to the UF group and had UF output collected or were randomized to the pharmacological group and had urine but not UF collected. A total of 106 participants were included at 96 hours. The researchers found that UF was associated with higher cumulative fluid loss, net fluid loss, and relative reduction in weight. Additionally, UF was associated with higher serum creatinine and blood urea nitrogen by 72 hours, lower serum sodium by 48 hours, and increased plasma renin activity by 96 hours. The pharmacological group was associated with higher serum bicarbonate after 24 hours. The two 60-day composite endpoints ([i] death, heart failure hospitalization, or unscheduled emergency department or clinic visit; and [ii] death, any hospitalization, or unscheduled emergency department or clinic visit) were not significantly different between the UF and pharmacological groups. The researchers concluded that UF was associated with more efficient decongestion compared to the pharmacological group, but the UF group had a rise in serum creatinine and neurohormonal activation. The study was limited by the per-protocol design.

A 2009 focused update from the American College of Cardiology Foundation (ACCF), American Heart Association (AHA) Task Force on Practice Guidelines has been incorporated into the ACC/AHA 2005 Guidelines for the Diagnosis and Management of Heart Failure in Adults (Hunt, 2005). Within this focused update, the following recommendation was given a Class IIa, Level of Evidence: B – "Ultrafiltration is reasonable for patients with refractory congestion not responding to medical therapy" (Jessup, 2009). This recommendation was repeated in another 2009 update to the ACC/AHA Guidelines for the Diagnosis and Management of Heart Failure in Adults (Hunt, 2009). Additional excerpted comments from these documents are as follows:

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> If all diuretic strategies are unsuccessful, ultrafiltration or another renal replacement strategy may be reasonable. Ultrafiltration moves water and small- to medium-weight solutes across a semipermeable membrane to reduce volume overload. Because the electrolyte concentration is similar to plasma, relatively more sodium can be removed than by diuretics…Consultation with a kidney specialist may be appropriate before opting for any mechanical strategy to affect diuresis. (Hunt, 2009; Jessup, 2009).

An updated 2013 ACCF/AHA Guideline for the Management of Heart Failure downgraded its recommendations to Class IIb for UF as renal replacement therapy *in hospitalized individuals* based on the limited evidence demonstrating safety/efficacy as follows:

- Ultrafiltration may be considered for patients with obvious volume overload to alleviate congestive symptoms and fluid weight.(Level of Evidence: B);
- Ultrafiltration may be considered for patients with refractory congestion not responding to medical therapy (Level of Evidence: C) (Yancy, 2013).

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 state the following:

> 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.

The Heart Failure Society of America's 2010 Comprehensive Heart Failure Practice Guideline states, "When individuals have acute decompensated HF and evidence of fluid overload, they should initially be treated with loop diuretics but that UF may be considered in lieu of diuretics" (strength of evidence 5 B [derived from cohort studies or smaller clinical trials, diverse in design and prospective or retrospective in nature]) (Lindenfeld, 2010).

At the present time, the published evidence is insufficient to show net improvement in health outcomes through the use of UF (aquapheresis) techniques for the treatment of refractory ADHF, as compared to conventional treatment modalities. Although recent reviews and meta-analyses have shown favorable clinical results from use of UF in ADHF, most investigators concur that additional large, well-designed trials are needed to establish the role of UF in refractory ADHF (DeVecchis, 2014; Ebrahim, 2015; Kwong, 2014; Wen, 2013; Zhi, 2013).

Background/Overview

In February 2020, the Aquadex FlexFlow® System 2.0 (CHF Solutions, Inc., Eden Prairie, MN) received clearance from the FDA through the 510(k) clearance process, as substantially equivalent to prior predicate devices that perform UF/aquapheresis techniques. The current FDA approved indications for use are as follows:

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- Temporary (up to 8 hours) UF treatment of patients with fluid overload who have failed diuretic therapy, and
- Extended (longer than 8 hours) UF treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization.

"All treatments must be administered by a health care provider, under physician prescription, both of whom having received training in extracorporeal therapies" (FDA, 2020).

Definitions

Aquapheresis™: The trademarked term for removal of salt and water with the Aquadex FlexFlow System which was classified by the FDA as a high permeability dialysis system.

Heart failure (HF; [also referred to as congestive heart failure {CHF}]): The term used for a clinical syndrome characterized by systemic perfusion that is inadequate to meet the body's metabolic demands as a result of impaired cardiac pump function. The heart is unable to pump sufficient oxygenated blood to vital organs and there is congestion/pooling of blood in the extremities and lungs with resultant symptoms, such as dyspnea (shortness of breath).

New York Heart Association (NYHA) Definitions:
The NYHA classification of heart failure is a 4-tier system that categorizes based on subjective impression of the degree of functional compromise. The four NYHA functional classes are as follows:

- Class I - individuals with cardiac disease but without resulting limitation of physical activity; ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain; symptoms only occur on severe exertion;
- Class II - individuals with cardiac disease resulting in slight limitation of physical activity; they are comfortable at rest; ordinary physical activity, (for example, moderate physical exertion, such as carrying shopping bags up several flights of stairs) results in fatigue, palpitation, dyspnea, or anginal pain;
- Class III - individuals with cardiac disease resulting in marked limitation of physical activity; they are comfortable at rest; less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain;
- Class IV - individuals with cardiac disease resulting in inability to carry on any physical activity without discomfort; symptoms of heart failure or the anginal syndrome may be present even at rest; if any physical activity is undertaken, discomfort is increased.

Ultrafiltration (UF): A term for a technique that moves water and small-to-medium weight solutes across a semi-permeable membrane to reduce volume overload.

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The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:

CPT

37799	Unlisted procedure, vascular surgery [when specified as ultrafiltration, aquapheresis]

ICD-10 Procedure

6A550Z3	Pheresis of plasma, single [when specified as ultrafiltration, aquapheresis]

ICD-10 Diagnosis

I09.81	Rheumatic heart failure
I11.0	Hypertensive heart disease with heart failure
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
I50.1-I50.9	Heart failure
I97.130-I97.131	Postprocedural heart failure

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	02/11/2021	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale, Background, References and Websites sections.
Reviewed	02/20/2020	MPTAC review. Updated Rationale, References and Websites sections.
Reviewed	03/21/2019	MPTAC review. Description/Scope, Rationale, References and Websites sections updated.
Reviewed	05/03/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." The Rationale, References, and Websites sections updated.
Reviewed	05/04/2017	MPTAC review. The Rationale and References sections were updated.
Reviewed	05/05/2016	MPTAC review. The Rationale and References were updated. Removed ICD-9 codes from Coding section.
Reviewed	05/07/2015	MPTAC review. The Rationale and References were updated.
Reviewed	05/15/2014	MPTAC review. The Rationale, Definitions and References were updated.
Reviewed	05/09/2013	MPTAC review. The Rationale and References were updated.
Reviewed	05/10/2012	MPTAC review. The Rationale and References were updated.
Reviewed	05/19/2011	MPTAC review. Rationale, Background/Overview, References and Index updated.
Reviewed	05/13/2010	MPTAC review. The Rationale and References were updated.
New	05/21/2009	MPTAC review. Initial document development.

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