



BlueCross BlueShield  
of Alabama

**This policy does not apply to patients with renal failure being treated using dialysis.**

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**Name of Blue Advantage Policy:**

**Ultrafiltration in Decompensated Heart Failure**

Policy #: 435  
Category: Medicine

Latest Review Date: May 2021  
Policy Grade: **Effective July 1, 2021: Active policy but no longer scheduled for regular literature reviews or updates.**

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**BACKGROUND:**

*Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational\*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
  - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
  - *Furnished in a setting appropriate to the patient's medical needs and condition;*
  - *Ordered and furnished by qualified personnel;*
  - *One that meets, but does not exceed, the patient's medical need; and*
  - *At least as beneficial as an existing and available medically appropriate alternative.*

*\*Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare** for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

## **POLICY:**

**Blue Advantage** will treat the **use of ultrafiltration** as a **non-covered benefit** in **patients with heart failure** and as **investigational**.

**This policy does not apply to patients with renal failure being treated using dialysis.**

*Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

## **DESCRIPTION OF PROCEDURE OR SERVICE:**

Ultrafiltration is used to remove excess fluid from patients with volume overload and heart failure. It removes fluid from the blood by using pressure differentials with dialysis equipment or similar filtration devices.

### **Heart Failure**

Heart failure is a relatively common condition that frequently results in hospitalizations and readmissions.

### **Treatment**

Various treatment approaches are being explored, especially when the condition is refractory to conventional therapy. Ultrafiltration, also referred to as aquapheresis, is a technique being investigated for a possible role in hospitalized patients with marked volume overload from heart failure.

It has been suggested that ultrafiltration may offer greater and more expeditious volume and sodium removal than conventional therapies, particularly in patients with decompensated heart failure whose fluid overload is unresponsive to medical management.

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

### **Outcome Measures**

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.

## **KEY POINTS:**

The most recent literature review is through February 11, 2021.

### **Summary of Evidence**

For individuals who have decompensated heart failure who receive ultrafiltration, the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are overall survival, quality of life, hospitalizations, and treatment-related morbidity. A number of RCTs and meta-analyses of RCTs have been published. Meta-analyses did not find significant differences in all-cause mortality in patients receiving ultrafiltration or diuretics, and nearly all meta-analyses did not find significant between-group differences in rehospitalization rates. RCTs and meta-analysis found that patients undergoing ultrafiltration had significantly greater weight loss and more fluid removal than diuretic therapy. Although pooled analyses of RCTs did not find significant differences in adverse events in groups receiving ultrafiltration or diuretics, some RCTs (e.g., CARESS and, AVOID-HR) have reported higher rates of adverse events after ultrafiltration including significant worsening of renal function and treatment-related serious adverse events. The available trials have several methodologic limitations (e.g., unblinded outcome assessment, incomplete information on patient status). Moreover, long-term outcomes (i.e., >1 year) have not been reported. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

### **Practice Guidelines and Position Statements**

#### **American College of Cardiology Foundation and American Heart Association**

In 2013, the American College of Cardiology Foundation and American Heart Association published joint guidelines on the diagnosis and management of heart failure in adults (under Recommendations for Hospitalized Patient) lists ultrafiltration as a Class IIb recommendation (benefit greater than or equal to risk, additional studies needed). The recommendations stated ultrafiltration “may be considered for patients with obvious volume overload to alleviate congestive symptoms and fluid weight” (level of evidence B: conflicting evidence) and “for patients with refractory congestion not responding to medical therapy” (level of evidence C: recommendation less well established).

A 2017 update from the American College of Cardiology, the American heart Association Task Force on Clinical Practice Guidelines, and the Heart Failure Society of America did not mention ultrafiltration.

#### **European Society of Cardiology and Heart Failure Association**

In 2012, the European Society of Cardiology Heart Failure Association released joint guidelines on the diagnosis and treatment of acute heart failure stated that “ultrafiltration is sometimes used to remove fluid in patients with HF [heart failure], although is usually reserved for those unresponsive or resistant to diuretics.” In 2016, an update noted that “ultrafiltration is not recommended and should be confined to patients who fail to respond to diuretic-based strategies” was added.

#### **Heart Failure Society of America**

In 2010, the Heart Failure Society of America’s (HFSA) 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)

**U.S. Preventive Services Task Force**

Not applicable

**KEY WORDS:**

Ultrafiltration, Aquapheresis, Aquadex, FlexFlow, CHF Solutions, Congestive Heart Failure, CHF

**APPROVED BY GOVERNING BODIES:**

In June 2002, the Aquadex FlexFlow™ System (Baxter, acquired by CHF Solutions in 2016) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. An 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 (≤8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy, and for extended (> 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization.

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.”

**BENEFIT APPLICATION:**

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

**CURRENT CODING:**

**CPT Codes:**

There are no specific CPT codes for this procedure

## REFERENCES:

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## **POLICY HISTORY:**

Adopted for Blue Advantage, June 2010

Available for comment June 30-August 13, 2010

Medical Policy Group, January 2012

Medical Policy Group, July 2012

Medical Policy Group, September 2013

Medical Policy Group, October 2013

Medical Policy Group, June 2014

Medical Policy Group, January 2015

Medical Policy Group, June 2015

Medical Policy Group, May 2016

Medical Policy Group, May 2017

Medical Policy Group, May 2018

Medical Policy Group, May 2019

Medical Policy Group, May 2020

Medical Policy Group, May 2021

Medical Policy Group, July 2021: Policy retired. Effective July 1, 2021: Active policy but no longer scheduled for regular literature reviews or updates.

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*This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.*

*This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.*