BlueCross BlueShield of Alabama

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

Name of Blue Advantage Policy:

Ultrafiltration in Decompensated Heart Failure

Policy #: 435
Category: Medicine

Latest Review Date: May 2020
Policy Grade: A

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:

Effective for dates of service on or after August 14, 2010:

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 March 9, 2020.

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 have 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 the effects of the technology on 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.

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CODING:
CPT Codes:

There are no specific CPT codes for this procedure

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POLICY HISTORY:

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Medical Policy Group, January 2012
Medical Policy Group, July 2012
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