Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

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
Latest Review Date: April 2023
Category: Medicine
ARCHIVED EFFECTIVE 11/1/2023

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** and as **investigational** for patients with heart failure.

****Note - 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 April 11, 2023.

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 Heart Association, American College of Cardiology, and Heart Failure Society of America

In 2022, the AHA, ACC, and HFSA published a joint guideline for the Management of Heart Failure. There was no specific recommendation for ultrafiltration, but the following was stated:

> "Bedside ultrafiltration initiated early after admission increased fluid loss, with decreased rehospitalizations in some studies when compared with use of diuretics without systematic escalation and was also associated with adverse events related to the intravenous catheters required. Many aspects of ultrafiltration including patient selection, fluid removal rates, venous access, prevention of therapy-related complications, and cost require further investigation."

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:

0692T	Therapeutic ultrafiltration (Effective 1/1/2022)

Prior to 1/1/22, there were no specific CPT codes for this procedure.

37799	Unlisted procedure, vascular surgery
90999	Unlisted dialysis procedure, inpatient or outpatient

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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.
Medical Policy Group, September 2021: Added unlisted codes 37799 and 90999 to Current Coding.
Medical Policy Group, November 2021: 2022 Coding Update. Added CPT code 0692T to Current Coding.
Medical Policy Group, April 2022: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, April 2023: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, November 2023: Archived effective 11/1/2023.
