MEDICAL POLICY

POLICY TITLE	ULTRAFILTRATION IN DECOMPENSATED HEART FAILURE
POLICY NUMBER	MP 2.078

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☐ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**3/1/2024**

I. POLICY

Ultrafiltration in decompensated heart failure may be considered **medically necessary** in the inpatient setting when **ALL** of the following are met:

- Fluid volume overload; **AND**
- Dyspnea at rest or with minimal activity; **AND**
- Confirmed diuretic resistance defined as:
  - Dose escalation beyond previously recognized dose ceiling; **OR**
  - Dose approaching the maximum recommended daily dose without incremental improvement in diuresis

Ultrafiltration in decompensated heart failure is considered **not medically necessary** for all other indications not outlined above.

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO – Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

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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.

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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 is used to remove fluid from the blood via 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 than conventional therapies, particularly in patients with decompensated heart failure whose fluid overload is unresponsive to medical management. Reducing fluid overload by ultrafiltration is a not a new technique, but has not been widely used as a first line treatment for patients in heart failure. Ultrafiltration is now receiving attention once again, as technological advances have resulted in ultrafiltration systems that are portable, easy to use, and which can be used with peripheral vessel access. It is felt that fluid removal by ultrafiltration safely and effectively reduces circulatory preload and afterload while minimizing electrolyte imbalance, neurohormonal activation, and hypotension

Ultrafiltration differs from hemodialysis in that it acts via convention rather than diffusion, thereby lowering the risk for induced metabolic abnormalities. 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.

Regulatory Status

In 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 2007 following system 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. FD 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."

IV. RATIONALE

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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 these controlled trials 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 found no 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, 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., greater than 1 year) have not been reported.

Clinical trials evidence in the literature is limited and suggests only that UF may be appropriate for patients with acute decompensated heart failure (ADHF) who are unresponsive to pharmacologic treatment.

The American College of Cardiology Foundation and American Heart Association published joint guidelines (2013) on the diagnosis and management of heart failure in adults (under Recommendations for Hospitalized Individual) that list ultrafiltration as a class IIb recommendation (benefit greater than or equal to risk, additional studies needed). The recommendations indicated that ultrafiltration "may be considered for individuals with obvious volume overload to alleviate congestive symptoms and fluid weight" (level of evidence B: conflicting evidence) and "for individuals 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.

V. DEFINITIONS

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N/A

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the

applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary for ultrafiltration to remove excess fluid from patients with volume overload and heart failure:

Procedure Codes								
90999	37799	0692T						

ICD-10-CM Diagnosis Codes	Description
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure

ICD-10-CM Diagnosis Codes	Description
I50.811	Acute right heart failure
I50.812	Chronic right heart failure
I50.813	Acute on chronic right heart failure
I50.814	Right heart failure due to left heart failure
I50.82	Biventricular heart failure
I50.84	End stage heart failure

IX. REFERENCES

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X. POLICY HISTORY

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MP 1.060	**2/14/20** Consensus review. No changes to policy statement. Coding reviewed. References updated.
	11/12/2021 Minor Review. Policy statement changed from investigation to not medically necessary. FEP language updated. Background and References updated.
	12/02/2021 Administrative update. New code 0692T added.
	11/23/2022 Major Review. Ultrafiltration may be considered medically necessary when criteria is met. Background, Rationale and References updated.
	11/29/2023 Consensus review. No change to policy statement. References added.

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