Policy Number	**MED202.062**
Policy Effective Date	**12/15/2025**

Ultrafiltration in Decompensated Heart Failure

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

The use of ultrafiltration **is considered experimental, investigational and/or unproven** in individuals with heart failure.

NOTE: This policy does not apply to individuals with renal failure being treated using dialysis.

Policy Guidelines

None.

Description

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, also known as congestive heart failure, is a complex clinical syndrome characterized by the heart's inability to pump blood effectively due to structural or functional impairments. The most common cause of heart failure is ischemic heart disease, but other factors, such as hypertension, valvular disease, and myocarditis, also contribute to its development. (1)

An estimated 6.7 million adults in the United States 20 years of age and older had heart failure between 2017 to 2020. (2) The prevalence continues to increase over time with the aging of the population. Prevalence of disease is higher in women than men 80 years of age and older. Overall prevalence is especially high in Black individuals. A 2008 study demonstrated that Black individuals had the highest risk of developing heart failure, followed by Hispanic, White, and Chinese individuals in the United States. (3) Higher risk reflected differential prevalence of hypertension, diabetes, and lower socioeconomic status. Black individuals also had the highest proportion of incident heart failure not preceded by myocardial infarction (75%). Additionally, Black individuals have a greater 5-year case fatality rate associated with heart failure compared to White individuals. (4)

Common symptoms of heart failure include shortness of breath, fatigue, fluid retention, and edema. Management depends on the classification and staging of the disease. The New York Heart Association (NYHA) classification stratifies and defines the functional capacity and severity of heart failure symptoms (See Table 1 below). (1)

Table 1. New York Heart Association Functional Classification (5)

Class	Patient Symptoms
I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation or shortness of breath.
II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, shortness of breath or chest pain.
III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, shortness of breath or chest pain.
IV	Symptoms of heart failure at rest. Any physical activity causes further discomfort.

Treatment

While heart failure can't be cured, it can be treated. The main goal of treatment is to improve symptoms and help the patient achieve a higher quality of life. Management can be as simple as making healthy lifestyle changes and taking medications, to more involved treatments with devices and surgery. 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.

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

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. FDA 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." (6)

Rationale

This policy is based on a review of relevant professional association recommendations.

American Heart Association et al.
In 2013, the American Heart Association and American College of Cardiology Foundation published joint guidelines on the diagnosis and management of heart failure in adults (under Recommendations for Hospitalized Patient) that list ultrafiltration as a class IIb recommendation (benefit greater than or equal to risk, additional studies needed). (7) The recommendations indicated that 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. (8)

The American Heart Association, in conjunction with the American College of Cardiology, and the Heart Failure Society of America released updated guidelines (2022) on the management of

heart failure, which offered the following in regard to ultrafiltration as renal replacement therapy in hospitalized individuals: “Bedside ultrafiltration initiated early after admission increased fluid loss, which 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.” (9)

European Society of Cardiology and Heart Failure Association

In 2021, the European Society of Cardiology and Heart Failure Association released joint guidelines on the diagnosis and treatment of acute and chronic heart failure. (10) The guidelines indicate that renal replacement therapies (e.g., ultrafiltration) should be considered in patients who fail to respond to diuretic-based strategies, specifically stating “It [ultrafiltration] may be considered in those with diuretic resistance even if data about its effects on outcomes are unsettled.” (Class of recommendation: IIb, Level of evidence: C)

In 2023 the European Society of Cardiology and Heart Failure Association published a “Focused Update” on the previous (2021) guidelines, the new guidelines did not include recommendations relevant to the use of ultrafiltration in heart failure. (11)

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member’s benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	0692T
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
12/15/2025	Document updated. Coverage unchanged. Added references 1-5 and 11.
06/15/2025	Reviewed. No changes.
03/15/2024	Document updated with literature review. Coverage unchanged. References 1 and 22 added.
06/01/2023	Reviewed. No changes.
12/01/2022	Document updated with literature review. Coverage unchanged. Added references 1, 9, 10, 14, 17, 18, 21 and 22.
08/01/2021	Reviewed. No changes.
08/15/2020	Document updated with literature review. Coverage unchanged. Added references 14 and 16.
08/01/2019	Reviewed. No changes.
01/15/2019	Document updated with literature review. Coverage unchanged. Added References 4-5. Document title changed from “Ultrafiltration in Heart Failure”.
09/01/2017	Reviewed. No changes.
09/01/2016	Document updated with literature review. Coverage unchanged.
08/15/2015	Reviewed. No changes.
09/15/2014	Document updated with literature review. No change in coverage statement.
05/01/2012	Document updated with literature review. No change in coverage statement. CPT/HCPCS code(s) updated.
11/15/2010	Document updated with literature review. No change in coverage statement.
12/01/2008	New medical document