MASSACHUSETTS

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Medical Policy

Ultrafiltration in Decompensated Heart Failure

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Policy Number: 542

BCBSA Reference Number: 2.02.22
NCD/LCD: NA

Related Policies

None

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

The use of ultrafiltration is considered **INVESTIGATIONAL** in patients with heart failure.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is **not** a covered service.
Commercial PPO and Indemnity	This is **not** a covered service.
Medicare HMO Blue℠	This is **not** a covered service.
Medicare PPO Blue℠	This is **not** a covered service.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes
There is no specific CPT code for this service.

Description
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.

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. 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."[1.]

Summary
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.

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 randomized controlled trials did not find significant differences in adverse events in groups receiving ultrafiltration or diuretics, some RCTs (eg, 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 (eg, unblinded outcome assessment, incomplete information on patient status). Moreover, long-term outcomes (ie, >1 year) have not been reported. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
7/2021	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
7/2020	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
6/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
6/2017	New references added from BCBSA National medical policy.
7/2016	New references added from BCBSA National medical policy.
8/2015	New references added from BCBSA National medical policy.
9/2014	New references added from BCBSA National medical policy.
8/2013	New references from BCBSA National medical policy.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
4/2011	Reviewed - Medical Policy Group – Cardiology and Pulmonology. No changes to policy statements.
10/20/2010	New medical policy effective 10/ 20/2010 describing ongoing non-coverage.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

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