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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Dialysis Services

- Facility
- In Home
- Nocturnal
- Short Daily
- Ultrafiltration for the Treatment of Congestive Heart Failure

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefit Policy Manual, Chapter 8 - Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims
National Coverage Determinations (NCD)	Ultrafiltration, Hemoperfusion and Hemofiltration (110.15)
Local Coverage Determinations (LCD)	Frequency of Hemodialysis (L37504)
Local Coverage Article	Billing and Coding: Frequency of Hemodialysis (A55676)

For Non-Medicare Members

Service	Criteria
Hemodialysis	**Standard hemodialysis 3 days a week** is covered for members with end stage renal disease. For home dialysis the following additional criteria must be met: 1. The member is stable on dialysis. 2. The member is free of complications and significant concomitant disease that would render home dialysis unsuitable or unsafe. 3. The member or caregiver is capable of completing a home dialysis training program and adhering to a prescribed treatment regimen. 4. Adequate caregiver is available during dialysis 5. Back-up arrangements have been made with the facility-based dialysis center.
Frequent (Greater Than 3 Days a Week) Hemodialysis, Nocturnal or Short Daily, In Home or Facility	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.
Ultrafiltration for the Treatment of Congestive Heart Failure	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as

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	standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

End-stage renal disease (ESRD) is defined as an irreversible decline in kidney function that is severe enough to be fatal without treatment. In 2008, the prevalence of ESRD in the United States was 547,982 (Collins 2011). Treatment options for patients with ESRD include kidney transplantation and dialysis. Kidney transplantation is the preferred treatment for ESRD; however, the demand for kidney transplant exceeds the supply of transplantable organs (Pauly 2009). Of the 547,982 patients with ESRD, approximately 382,343 patients received dialysis (Collins 2011).

Dialysis filters blood to rid the body of harmful wastes, extra salt, and water. There are two types of dialysis peritoneal dialysis and hemodialysis. The majority of patients are treated using hemodialysis; however, there is no consensus on the optimal dose and frequency of hemodialysis. Difference hemodialysis regimens include: conventional hemodialysis, nocturnal hemodialysis, and short-daily hemodialysis (Toussaint 2010).

There are two types of dialysis: 1) Peritoneal dialysis: Removes waste products via the peritoneum, the membrane that lines the inside of the abdomen. The membrane is bathed in a special fluid called dialysate that is placed into the abdomen through a small tube, and after a designated period of time, the fluid is drained and replaced by new fluid. 2) Hemodialysis: Access is through surgical placement of an arteriovenous fistula, generally in the forearm, and less commonly by a venous catheter. After access is established, the fistula is connected to a hemodialysis machine that drains the blood, bathes it in dialysate solution and returns it to the bloodstream.

Conventional hemodialysis consists of three treatment sessions per week, with each session lasting 3 to 5 hours. Treatments can be performed in a dialysis center, hospital, or at home. Although this is a life-saving treatment, mortality in patients with ESRD is still remarkably high. Compared to the general population, mortality is four times higher in patients under 30 receiving dialysis and six times higher in patients over 65. Additionally, patients receiving dialysis often experience hypertension, fluid overload and the attendant cardiac sequelae, anemia, mineral and bone disorders, inflammation, poor nutritional status, poor functional status, and psychological disorders (Bayliss 2009, Ng 2010). Moreover, this approach to dialysis is inconvenient for patients receiving treatment in a dialysis center or hospital, who must travel to a dialysis unit several times a week.

Both nocturnal hemodialysis (typically 6-8 hours, 3-7 nights per week) and short-daily hemodialysis (typically 1.5-3 hours, 4-6 days per week) can take place at home or at a dialysis center. It is thought that increasing the frequency and duration of hemodialysis will lead to less fluid gain leading to improved blood pressure control, increased hemodynamic stability, and increased efficiency of solute clearance. A potential harm is an increased risk of vascular access complications due to more frequent use (Ng 2010, Toussaint 2010).

There are several hemodialysis devices approved by the FDA for home use. Some are large, non-portable devices that require modifications to the home electrical and plumbing systems. These include the Fresenius 2008K and the B. Braun Dialog Plus. Others are smaller and portable. The NxStage System One is specifically designed for home use; it does not require infrastructure changes.

Medical Technology Assessment Committee (MTAC)

Frequent Home Dialysis

08/04/2008: MTAC REVIEW

Evidence Conclusion: on home nocturnal or short daily dialysis versus in-center dialysis 3 times a week:

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One RCT and two cohort studies were identified that compared nocturnal home dialysis to in-center dialysis 3 times a week. The RCT (Culleton et al., 2007) found statistically significant improvement in the primary outcome, LV mass, a surrogate marker for cardiovascular disease. Among other secondary outcomes, phosphate level was significantly lower in the nocturnal home dialysis group, and there was no significant between group differences in calcium level and anemia. Two cohort studies matched patients who received nocturnal dialysis to similar patients receiving conventional in-center dialysis 3 times a week. Bergman et al. (2008) found significantly lower dialysis-related or cardiovascular-related hospital admissions (the primary outcome) in the group converted to nocturnal dialysis, but no significant difference in all-cause hospitalization. Schwartz et al., (2005) also had significant findings for the primary study outcomes, increase in hemoglobin concentration and increase in the proportion of patients who were EPO-free after 12 months. None of the studies had mortality as an outcome.
There are fewer published studies on short-daily dialysis. A statistical analysis (Blagg et al., 2006) found a lower mortality rate in 117 patients who received short-daily dialysis either in-center or at home compared to national rates on patients receiving conventional hemodialysis (standardized mortality ratio=0.39). Patients who received short-daily dialysis may have differed from those in the national database, and there were financial links between the authors of this study and the home dialysis device used in the study.
Evidence on home nocturnal or short daily dialysis versus home dialysis 3 times a week:
No randomized controlled trials were identified, and there were no comparative studies with mortality as an outcome. The highest grade of evidence comparing different frequencies of home nocturnal dialysis is a retrospective cohort study by Mahadevan and colleagues (2006). The investigators evaluated biological parameters in 13 patients receiving nocturnal dialysis 6 nights a week and 21 patients receiving nocturnal dialysis every other night (3-4 times a week). After 3-6 months of follow-up, levels of urea, creatinine and PTH were all significantly lower in the group treated 6 nights/week, and there were no significant differences between groups in phosphate, calcium, albumin and homocysteine levels, or in use erythropoietin or phosphate binders. There were no significant differences at follow-up in the proportion of patients taking phosphate binders, calcitriol, blood pressure medications or erythropoietin. The evidence is limited due to lack of randomization (there may have been pre-existing differences between groups) and the small sample size (may be underpowered).
There is no high-grade evidence on health outcomes associated with short daily dialysis at home versus home hemodialysis 3 times a week.
Conclusions:
Objective 1:
- There is insufficient evidence that home nocturnal dialysis improves important health outcomes compared to in-center dialysis. An RCT found improvement in LV mass and phosphate level, intermediate outcomes, and mixed findings in QOL. There is weak evidence from a single cohort study that nocturnal dialysis lowers the rate of dialysis-related or cardiovascular-related hospitalizations. In this cohort study, all-cause hospitalizations did not decrease significantly.
- There is insufficient evidence that home short-daily dialysis improves health outcomes compared to in-center dialysis. One statistical analysis found a lower mortality rate with short daily dialysis compared to national rates, but patients may have differed in ways that affect outcomes, and there was potential financial bias.

Objective 2:
- There is insufficient evidence that home nocturnal dialysis 6 nights a week improves important health outcomes compared to home hemodialysis 3 times a week.
- There is insufficient evidence that home short-daily dialysis 5 or more times a week improves important health outcomes compared to home hemodialysis 3 times a week

Articles: Assessment objectives:
1) To determine whether frequent home nocturnal or home short daily dialysis leads to better health outcomes in patients with end-stage renal disease compared to conventional in-center dialysis 3 times a week.
2) To determine whether frequent home nocturnal or home short daily dialysis leads to better health outcomes in patients with end-stage renal disease compared to home dialysis 3 times a week.

Important health outcomes are survival, hospitalizations and quality of life.
Objective 1: Comparison with in-center hemodialysis One randomized controlled trial (Culleton et al., 2007) and two cohort studies (Bergman et al., 2008; Schwartz et al., 2005) comparing frequent nocturnal home hemodialysis to in-center hemodialysis were identified and critically appraised. Case series were not reviewed due to the availability of higher-grade evidence. The studies on short-daily hemodialysis were all case series. Most were small (<15 patients) and or included patients who primarily received dialysis in-center and thus were not suitable for critical appraisal. The strongest study identified compared outcomes in 117 patients on short-daily dialysis (84% at home) to outcomes of patients from a national database receiving conventional dialysis (Blagg et al., 2006). The Blagg study was critically appraised. *Objective 2: Comparison with home hemodialysis 3 times a week*
One comparative study was identified, and critically appraised (Mahadevan et al., 2006). This was a small retrospective cohort study comparing outcomes in patients who received home nocturnal dialysis either six nights per week or on alternate nights (3-4 times a week). An RCT by the Frequent Hemodialysis Network (FHN) is
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underway comparing nocturnal home hemodialysis 3 versus 6 times a week. The study is currently recruiting patients; the estimated completion date is January 2010 (Clinicaltrials.gov). *Studies reviewed include:*
Blagg CR, Kjellstrand CM, Ting GO, Young BA. Comparison of survival between short-daily hemodialysis and conventional hemodialysis using the standardized mortality ratio. Hemodialysis International 2006; 10: 371-374. See Evidence Table Culleton BF, Walsh M, Klarenbach SW et al. Effect of frequent nocturnal hemodialysis vs conventional hemodialysis on left ventricular mass and quality of life. JAMA 2007; 298: 1291-1299. See Evidence Table Bergman A, Fenton SSA, Richardson RMA, Chan CT. Reduction in cardiovascular related hospitalization with nocturnal home hemodialysis. Clin Nephrol 2008; 69: 33-39. See Evidence Table Schwartz DI, Pierratos A, Richardson RMA et al. Impact of nocturnal home hemodialysis on anemia management in patients with end-stage renal disease. Clin Nephrol 2005; 63: 202-208. See Evidence Table Mahadevan K, Pellicano R, Reid A et al. Comparison of biochemical, hematological and volume parameters in two treatment schedules of nocturnal home hemodialysis. Nephrology 2006; 11: 413-418. See Evidence Table.

The use of home dialysis in the treatment of kidney disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Nocturnal Dialysis

04/18/2011: MTAC REVIEW

Evidence Conclusion: *Short-daily dialysis compared to conventional dialysis*: A recent RCT that included 245 patients and evaluated whether short-daily dialysis (1.5 to 2.75 hours, six times per week) would improve patient outcomes compared to conventional dialysis (2.5 to 4 hours, three times per week). There were two composite primary outcome variables: death or 12-month change in left ventricle mass as assessed by cardiac MRI, and death or 12-month change in physical-health composite score from the RAND 36-item health survey. Compared to conventional dialysis, frequent dialysis was associated with favorable changes in both of the primary composite outcomes. As the mortality rate in both groups was low, the bulk of the treatment effect was seen in intermediate outcomes. The sample size was insufficient to determine the effects of frequent versus conventional dialysis on overall mortality, cause-specific mortality, or hospitalizations (FHN Trial Group 2010). *Nocturnal dialysis compared to conventional dialysis*: There is no high-quality evidence on health outcomes associated with nocturnal dialysis versus conventional dialysis. The majority of studies identified assessed intermediate outcomes such as mineral metabolism. Very few studies had mortality as an outcome. Results from these studies are inconsistent due to the low-quality of the studies. Conclusion: There is insufficient evidence to determine whether nocturnal dialysis leads to better health outcomes in patients with end-stage renal disease compared to conventional dialysis 3 times a week. There is fair evidence that short-daily dialysis leads to improvements in intermediate outcomes such as left ventricle mass and physical-health composite score compared to conventional dialysis 3 times a week. **Articles:** Studies were selected for review if they included at least 25 subjects and assessed the effect of nocturnal or short-daily dialysis on health outcomes. The majority of studies identified were non-randomized, observational studies. As these studies are more prone to bias, they were not selected for review. An RCT that compared the quality of life of patients receiving nocturnal dialysis to conventional dialysis was not selected for review as it did not have adequate power. A recent RCT comparing short-daily dialysis to conventional dialysis was selected for review.
The following study was critically appraised: FHN Trial Group. In-center hemodialysis six times per week versus three times per week. *N Engl J Med 2010;* 363:2287-2300. See Evidence Table

The use of nocturnal dialysis in the treatment of kidney disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Frequent Home Dialysis

08/20/2012: MTAC REVIEW

Evidence Conclusion:

Survival – There is lower quality evidence upon which to draw conclusions about survival with home versus in-center hemodialysis. Three observational studies specifically reported on death or measures of mortality and survival with home hemodialysis compared to in-center hemodialysis. One study had no deaths and therefore found no difference. The two other studies favored home hemodialysis but were either small or had a higher likelihood of residual confounding (Kaiser 2011).
Since the Kaiser review, a recent matched-cohort study was identified that included 11,508 subjects assessed the relative mortality between daily home hemodialysis and thrice-weekly in-center hemodialysis. Results from this study suggest that home hemodialysis may be associated with a reduction in all-cause mortality compared to thrice-weekly in-center hemodialysis (HR 0.87, 95% CI 0.78-0.97, P=0.01). Limitations of the study include: residual confounding, approximately 1 in 4 home hemodialysis patients switched to in-center hemodialysis, more patients in the in-center treatment group were dually eligible for Medicare and Medicaid, and the cause of death was unknown in 10-20% of cases (Weinhandl 2012).

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Hospitalizations – There is lower quality evidence upon which to draw conclusions about hospitalizations with home versus in-center hemodialysis. One nested-case control study favored home hemodialysis in terms of hospitalizations per patients and two additional studies appeared to possibly favor home hemodialysis but were underpowered (Kaiser 2011).
Quality of life – The evidence is of insufficient quantity and quality to draw conclusions on quality of life with home versus in-center hemodialysis. Two small observational studies did not find differences in quality of life with home versus in-center hemodialysis. One study reported that both groups had about the same number of subjects working (Kaiser 2011).
Change in left ventricular mass – No studies were identified that evaluated this outcome (Kaiser 2011).
Blood pressure control – There is lower quality evidence upon which to draw conclusions. Two studies reported significant decreases in blood pressure measures with home hemodialysis compared to in-center hemodialysis. One study also appeared to favor home hemodialysis in terms of need for antihypertensive medications (Kaiser 2011).
Nutritional status and serum albumin – There are lower quality evidence upon which to draw conclusions. Three observational studies reported mixes results on measures of serum albumin, with one study significantly favoring home as compared to in-center hemodialysis. One study found no difference in intradialytic weight gain with home versus in-center hemodialysis (Kaiser 2011).
Vascular access complications/ Safety – The studies evaluating vascular access complications have been very small and the results were somewhat mixed. One study evaluated the operations (per patient) due to vascular access and found no significant difference, but the data tended toward favoring home hemodialysis. Another small study appeared to favor in-center, but the study was not adequately powered to evaluate this outcome. In terms of other safety reports, one small study appeared to have more machine malfunctions with home hemodialysis, another study reported that a composite measure of intradialytic adverse events appeared to favor home hemodialysis, but this was not significant (Kaiser 2011).
Articles: In March 2011, Kaiser reviewed alternative approaches to hemodialysis. Since the Kaiser review three observational studies were identified. Two studies were excluded as they did not compare in-center hemodialysis to home hemodialysis. The remaining observational study was selected for review.
Several studies were identified that reanalyzed results from the FHN trial; however, they were not selected for review since the FHN trial evaluated whether short-daily in-center hemodialysis improved patient outcomes compared to conventional in-center hemodialysis, and whether nocturnal home hemodialysis improved patient outcomes compared to conventional home hemodialysis. The following article and medical technology assessment were selected for review: Kaiser Permanente. Alternative approaches to hemodialysis: short “daily” and nocturnal. March 2011. The committee voted to accept the Kaiser technology assessment. The studies were insufficient to draw conclusions on clinical benefit as compared to standard forms of dialysis.

Frequent Home Dialysis

10/12/2020: MTAC REVIEW

Evidence Conclusion:

- There is a lack of high-quality randomized controlled trials assessing the effectiveness of frequent home hemodialysis versus conventional in-center hemodialysis in patients with ESRD.

- The available evidence is of low quality, mainly from uncontrolled studies, and suggests:
    - Home hemodialysis may decrease mortality compared to in-center hemodialysis
    - No difference between groups in terms of all-cause mortality, hospitalization, cardiovascular mortality, access survival, and transplantation rate
    - Mixed findings regarding quality of life and adverse events.
    - Home hemodialysis may be comparable to in-center dialysis in patients with ESRD

The use of frequent home dialysis in the treatment of kidney disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Ultrafiltration in the Treatment of Congestive Heart Failure

08/07/2006: MTAC REVIEW

Evidence Conclusion: The RAPID-CHF trial (Bart 2005) was a randomized, controlled, non-blinded trial that compared usual care vs. usual care plus ultrafiltration (UF) in 40 patients admitted to hospital with acute decompensated heart failure and fluid overload. Patients randomized to the usual care group received the conventional heart failure therapy. Those in the UF group received an 8 hour UF treatment with a maximum fluid removal rate of 500 cc/hour. Diuretics were administered after the 8 hours of UF, and additional courses of UF were allowed after 24 hours. The results of the trial show that the weight loss (primary endpoint of the trial) was not significantly different between the two study groups. The average volume removal of fluid was significantly

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higher in the UF group at 24 and 48 hours. Patients in the two treatment groups experienced improvement in their symptoms during the treatment period. The improvement observed was significantly greater in the UF group compared to the usual care group at 48 hours but not at 24 hours. The significant difference may be due to the greater fluid removal or due to chance as the trial was small, un-blinded, and the outcome measure was subjective. Costanzo et al (2005) reported their experience with early initiation of UF in 20 selected HF patients admitted to hospital with manifest signs and symptoms of fluid overload. The patients underwent UF which was continued until the acute decompensation heart failure symptoms were resolved. The removal of fluid was aggressive (8,654 + 4,205 ml) and resulted in a mean decrease of 6 kg of weight at discharge, and improvement in the clinical signs of symptoms of fluid overload that seem to have lasted for the 90 days of follow-up. This was only an observational case series with no comparison or control group and subject to selection and observation bias. The results of the UNLOAD (or UltrafiltrationN versus IV diuretics for patients hospitalized for Acute Decompensated congestive heart failure) trial was presented at the 2006 ACC conference in Atlanta, but have not been published in a peer reviewed journal to date. The trial randomized 200 patients from 28 centers to receive the standard intravenous diuretic drug therapy or IV diuretics plus ultrafiltration to treat fluid overload. The study was not blinded, the primary outcomes were weight loss and dyspnea score at 48 hours, and the patients were followed up for 90 days. The unpublished results of the trial indicate that both treatments were associated with significant improvement in the dyspnea score at 48 hours, but with no significant difference between the two treatment groups. Patients in the UF group had significantly greater net fluid and weight loss at 48 hours, and a lower incidence of hypokalemia. The results also show that the hospital readmission rate, during the 3 months of follow-up, was significantly lower in the UF group, vs. the IV diuretic group. All three studies were funded or supported by the manufacturer of the device CHF Solutions, Brooklyn Park, Minnesota, which may introduce bias. In conclusion, there is insufficient evidence to date to determine the efficacy and long-term safety of ultrafiltration versus standard care in acute decompensated heart failure, or to determine who would benefit most from the intervention.

Articles: The search yielded around 280 articles most of which were review articles, opinion pieces, or dealt with the technical aspects of the procedures. There was one RCT, and several small case series, many of which dated back in the 1980s and 1990s. The RCT and the relevant case series using the new UF device (System 100, CHF Solutions, Minneapolis, Minnesota) were selected for critical appraisal: Bart BA, Boyle A, Bank AJ, et al. Ultrafiltration versus usual care for hospitalized patients with heart failure. The Relief for Acutely fluid-overloaded Patients with Decompensated Congestive Heart Failure (RAPID-CHF) trial. J Am Coll Cardiol 2005; 46:2043-2046. **See** Evidence Table. MR, Saltzberg M, O'sollivan J, et al. Early ultrafiltration in patients with decompensated heart failure and diuretic resistance. J Am Coll Cardiol 2005;46:2047-2051. **See** Evidence Table.

The use of ultrafiltration in the treatment of congestive heart failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/17/2013: MTAC REVIEW

Ultrafiltration in the Treatment of Congestive Heart Failure

Evidence Conclusion: All published trials on the use of ultrafiltration in patients with acute decompensated heart failure with or without renal dysfunction compared UF with IV diuretic-based therapy. No published RCT, to date, examined the efficacy and safety of ultrafiltration in patients with ADHF who refractory to diuretics were. This latter indication of ultrafiltration was only evaluated in a one retrospective study with no control group.

Ultrafiltration as a first line therapy The UNLOAD (ultrafiltration versus Intravenous Diuretics for Patients Hospitalized for Acute Decompensated Congestive Heart Failure) trial compared ultrafiltration to diuretic therapy in patients hospitalized for acute decompensated heart failure. The trial examined UF as a first-line early therapy not as a rescue therapy (i.e. patients did not have to fail an initial diuretic therapy to be included in the trial). 200 patients were randomized to receive early UF (within 24 hours of hospitalization) or intravenous diuretic drug therapy. The co-primary outcomes were weight loss and patient self-assessed dyspnea score at 48 hours. The results show that both the UF and IV diuretic therapies were associated with significant improvement in the dyspnea score at 48 hours, with no statistically significant difference between the two treatment groups. Patients in the UF group had significantly greater fluid and weight loss at 48 hours, and a lower incidence of hypokalemia. This however, did not have an impact on the length of the index hospital stay. The rates of rehospitalization and unscheduled visits during the 90 days of follow-up were significantly lower in the UF group, vs. the IV diuretic group. The results also show a higher rise in serum creatinine levels in the UF group vs. the IV diuretic group (twice as many patients in the UF arm experienced an increase in sCr level >0.3 ml/dL during the first 24 hours of therapy) but the difference did not reach a statistically significant level. The authors considered the lack of significant difference between the two groups for this as well as other outcomes, as similar effects when the trial was not designed as equivalent study, and the lack of significant differences could results from insufficient statistical power. The study was a multicenter RCT but had several limitations many of which were acknowledged by the authors. The trial had a relatively small size and short follow-up duration, excluded patients with hypotension or hemodynamic instability, and used suboptimal dose and mode of administration of loop diuretics.

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The dose of the diuretic, duration, and rate of UF were all based on the discretion of the attending physician who was not blinded to the randomization groups and could be a source of bias. In addition, the authors did not present any data on low-salt diet compliance, or criteria for hospitalization. The study was supported by CHF Solution Inc., and the primary author as well as a number of other authors had financial ties to the manufacturer of the device CHF Solutions, Brooklyn Park, Minnesota. The Cardiorenal Rescue Study in Acute Decompensated Heart Failure (CARRESS-HF, sponsored by the NHLBI) investigated the role of UF as a treatment for patients with persistent congestion and worsening of kidney function (increase in serum creatinine ≥0.3 mg/dL within 12 weeks before or 10 days after index admission). 188 patients were randomized to undergo ultrafiltration (fluid removal at a rate of 200 ml/hour using Aquadex System 100; CHF Solutions), or to receive stepped pharmacological therapy involving increasing the doses of loop diuretics (with or without metolazone), vasodilators and inotropes (based on an algorithm that aimed at achieving urine output of 3-5 liters/ day). The assigned treatment was continued in the two groups until signs and symptoms of congestion were improved as possible. The primary endpoint was bivariate (simultaneous) change in serum creatinine level and body weight in 96 hours after randomization. The trial was not blinded, and the patients were followed-up for 60 days. Recruitment for the trial was stopped early before reaching the planned size of 200 subjects based on the advice of the data and safety monitoring board due to lack of benefit and excess adverse events with ultrafiltration. The results of CARRESS-HF show that stepped pharmacological therapy was superior to UF when the primary end point was assessed at 96 hours after randomization. There was a statistically significant reduction the serum creatinine (sCr) in the pharmacologic therapy group compared to the UF group. There was no significant difference between the groups in weight loss at 96 hours. At the 60 days of follow-up, there were no statistically significant differences in weight loss, or rate of hospitalization due to heart failure. There was a nonsignificant increase in the all-cause readmission rate in the UF group. UF, was also associated with a significantly higher rate of serious adverse events including kidney failure, bleeding complications, and catheter– related complications. The sixty-day mortality was17% for the UF group and 13% for the pharmacological therapy group with no significant difference between the groups, however, as indicated earlier, a lack of significant difference does not indicate equivalence due to the study design. These results should be interpreted with caution and cannot be generalized to patients with ADHF with better renal function than those included in the trial.
Other published trials Two other very small published RCTs (ULTRADISCO (Giglioli et al 2011), and Hanna and colleagues' trial (2012) also compared ultrafiltration versus intravenous diuretics inpatients hospitalized for ADHF. The trials had intermediate outcomes (hemodynamic variables in the ULTRADISCO trials, and time for pulmonary wedge pressure to be maintained at >18 mmHg for ≥4 consecutive hours in Hanna and colleagues' study). Their overall results showed greater fluid loss with UF vs. diuretic therapy with no significant difference between the groups in the serum creatinine levels. Ultrafiltration as a rescue therapy for patients with ADHF who are refractory to IV diuretic therapy The literature search did not identify any published RCT to date, that examined the efficacy and safety of ultrafiltration in patients with ADHF who were refractory to diuretics. In a retrospective observational study with no comparison group, Patarroyo and colleagues (2012) analyzed data from hospital records for adult patients with ADHF admitted to one heart failure intensive care unit in Cleveland Ohio ((2004-2009) and who required slow continuous ultrafiltration therapy (SCUF). The study population was a highly selected group of 63 adult patients with advanced HF, worsening renal function, and congestion refractory to hemodynamically guided intensive medical therapy. Their median age was 58 years, mean LV ejection fraction 26 ±15%, baseline serum creatinine (sCr) 1.9 ± 0.8 mg/dL and hemodynamics consistent with cardiogenic shock. SCUF was initiated after a mean of 8 days from admission, was performed at a rate of 200ml/hr. and for a mean duration of 8 days. At the initiation of SCUF therapy the sCr level was 2.2 ± 0.9 mg/dL. The mean duration of the UF therapy was 3+2 days, and the primary endpoint of the study was all-cause mortality and the secondary endpoint included number of readmissions for ADHF and dialysis-dependent status at time of discharge. The results of the analysis showed that after 48 hours of SCUF the overall cohort lost weight significantly compared to baseline (mean 4.4 kg). This was associated with significant improvement in hemodynamic variables but with no improvements in sCr levels or blood urea. 37 patients (59%) required conversion to continuous hemodialysis during their hospital stay and 9 (14%) were dependent on hemodialysis at hospital discharge. 34/37 (93%) of these patients were readmitted to the hospital within 60 days form discharge.19/63 patients (30%) died during the index hospitalization, and 4 were discharged to terminal care in hospice. The overall 1-year all-cause mortality was 70% and 2 of the surviving patients underwent heart transplantation. The results of the study should be interpreted with caution due to the study design and its inclusion of severely ill patients. Conclusion: There is insufficient evidence to support the use of ultrafiltration as a first-line treatment in hospitalized ADHF with volume overload. There is insufficient evidence to determine the safety and efficacy of ultrafiltration in patients with ADHF who are refractory to diuretic therapy. Results from UNLOAD trial, suggest, but do not provide good evidence, that ultrafiltration may provide better correction of volume overload than IV diuretics (given at the dose used in the trial) in patients hospitalized ADHF who are not resistant to diuretic therapy. The trial had its limitations and does not provide any evidence on the safest and most effective rates of fluid removal, duration of treatment, or the conditions for termination of ultrafiltration. There is evidence from the CARRESS-HF that IV loop diuretic-based therapy adding distal-acting diuretics, IV vasodilator and inotropic agents as needed is superior to ultrafiltration in patients with acute
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decompensated heart failure and worsening renal function. CARESS-HF results show increased incidence of worsening kidney function in the ultrafiltration group versus the stepped pharmacologic therapy group.
A large ongoing trial (AVOID-HF) (NCT01474200) involving 810 patients in 40 US centers is examining the effect of UF vs. intravenous diuretics in reducing hospitalization in patients with ADHF before worsening renal function.
Articles: UNLOAD trial (Costanzo et al 2007, evidence table 1) See Evidence Table. CARRESS-HF (Bart yet al 2012, evidence table 2) See Evidence Table

The use of ultrafiltration in the treatment of congestive heart failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Standard Hemodialysis - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Frequent (Greater Than 3 Days a Week) Hemodialysis, Nocturnal or Short Daily, In Home or Facility - Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
99512	Home visit for hemodialysis
90999	Unlisted dialysis procedure, inpatient or outpatient
E1629	Tablo hemodialysis system for the billable dialysis service

Ultrafiltration for the Treatment of Congestive Heart Failure
Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Considered Not Medically Necessary

CPT® or HCPC Codes	Description
0692T	Therapeutic ultrafiltration

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Creation Date	Review Dates	Date Last Revised
08/04/2008	07/06/2010 MDCRPC, 05/03/2011 MDCRPC, 03/06/2012 MDCRPC, 10/02/2012MDCRPC, 08/06/2013MPC, 06/30/2014MPC, 04/07/2015MPC, 02/02/2016MPC, 12/06/2016MPC, 10/03/2017MPC ,08/07/2018MPC, 08/06/2019MPC, 08/04/2020MPC, 08/03/2021MPC, 08/02/2022MPC, 08/01/2023MPC, 03/12/2024MPC	04/17/2024

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
12/09/2015	Added Medicare and Noridian links
10/29/2018	Updated the Medicare links
08/04/2020	Added Medicare LCA A55676; Added CPT codes 90999 and 99512
08/03/2021	Added the October 12, 2020 MTAC review
10/26/2022	Updated applicable codes, including new codes released 01/01/22 and 04/01/22.
04/17/2024	Merged “Ultrafiltration for the Treatment of Congestive Heart Failure” criteria and retitled to Dialysis

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	Services

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