Home Hemodialysis

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Instructions for Use

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Related Commercial/Individual Exchange Policies

- Home Health, Skilled and Custodial Care Services (for Commercial Only)
- Home Health, Skilled, and Custodial Care Services (for Individual Exchange Only)
- Private Duty Nursing Services

Community Plan Policy

- Home Hemodialysis

Application

UnitedHealthcare Commercial

This Medical Policy applies to all UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans in all states except for Colorado.

Coverage Rationale

Home hemodialysis without Skilled Care is proven and medically necessary as an alternative to facility-based hemodialysis for treating individuals with end-stage renal disease who meet all of the following criteria:

- Individual is stable on dialysis with no evidence of Skilled Care interventions being necessary during treatments; and
- Individual undergoing hemodialysis or non-professional caregiver has the ability to perform and maintain home hemodialysis and has received comprehensive training regarding proper protocol; and
- Absence of complications and significant concomitant disease that would cause home hemodialysis to be unsafe or unsuitable; and
- Presence of well-functioning vascular access

Home hemodialysis with Skilled Care is proven and medically necessary as an alternative to facility-based hemodialysis for treating individuals with end-stage renal disease who meet all of the following criteria:

- Individual is stable on dialysis and not at increased risk as a result of having the procedure performed outside a dialysis center venue; and
- Individual has well-functioning vascular access; and
- Individual has medical contraindications to leaving home for hemodialysis; and
- Individual undergoing hemodialysis or non-professional caregiver is not capable of performing home hemodialysis; and

- Staff assisted home hemodialysis protocols generally match those provided in the hemodialysis center (i.e., 3 times per week, 3-4-hour treatments). The exact dialysis therapy employed is determined on an individual basis by the attending nephrologist.

Definitions

The following definitions may not apply to all plans. Refer to the member specific benefit plan document for applicable definitions.

Skilled Care: Skilled nursing, skilled teaching and skilled rehabilitation services when all of the following are true:

- Must be delivered or supervised by licensed technical or professional medical personnel in order to obtain the specified medical outcome, and provide for the safety of the patient,
- Ordered by a physician,
- Not delivered for the purpose of helping with activities of daily living, including dressing, feeding, bathing or transferring from a bed to a chair,
- Requires clinical training in order to be delivered safely and effectively; and
- Not custodial care, which can safely and effectively be performed by trained non-medical personnel.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
90963	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents
90964	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents
90965	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents
90966	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older
90967	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients younger than 2 years of age
90968	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 2-11 years of age
90969	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 12-19 years of age
90970	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 20 years of age and older
90989	Dialysis training, patient, including helper where applicable, any mode, completed course
90993	Dialysis training, patient, including helper where applicable, any mode, course not completed, per training session
99512	Home visit for hemodialysis

HCPCS Code	Description
S9335	Home therapy, hemodialysis; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing services coded separately), per diem

Description of Services

For individuals with end-stage renal disease (ESRD), hemodialysis (HD) is an option for “renal replacement” therapy. HD includes two components, “ultrafiltration,” which is employed to remove extra fluid and “dialysis,” which relies on diffusion to remove small molecule waste products. In practice, these are delivered by channeling a portion of an individual’s blood flow into an extracorporeal circuit which includes an artificial kidney within which the critical therapeutic processes take place. Control and monitoring of these functions are regulated by features built into the dialysis machine. Conventional hemodialysis is performed three times a week for three to four hours or longer each time resulting, for some patients, in improved health, reduced symptoms, and a longer and higher quality of life.

Home HD allows individuals to conduct treatment in the convenience of a home environment. Treatment can be performed around one's daily activities in contrast to a clinic's available time slots. Home HD systems are similar to those used in the clinic, although they are more user-friendly and possess numerous safety features to minimize complications.
(National Kidney Foundation (NKF), home hemodialysis, 2015)

Individuals suitable for home hemodialysis (HHD) include those who:
- Have the ability and motivation to learn to carry out the process and the commitment to maintain treatment
- Are stable on dialysis
- Are free of complications and significant concomitant disease that would cause home hemodialysis to be unsafe or unsuitable
- Have a good functioning vascular access
- Have a caregiver who has made an informed decision to assist
- Have a suitable space that could be adapted within their home environment

(Rioux et al., 2015; Schatell, 2007; Walker et al., 2015; NICE, 2018)

In 2019, an Executive Order was signed and launched the Advancing American Kidney Health Initiative (AAKHI) to improve the lives of Americans suffering from kidney disease that directs the Department of Human Services (HHS) to take bold action to transform how kidney disease is prevented, diagnosed, and treated within the next decade. This initiative focused on specific strategies with one of its goals to improve Access to and Quality of Person-Centered Treatment Options. This goal was set with a vision to provide patients who have kidney failure with more options for treatment, from both today’s technologies and future technologies such as artificial kidneys, and make it easier for patients to receive care at home or in other flexible ways. The aim was to have 80 percent of new American ESRD patients in 2025 receiving dialysis in the home or receiving a transplant.

Vascular access is necessary to provide adequate blood flow to accomplish treatment for hemodialysis. There are a variety of options available to achieve vascular access. Arteriovenous fistulas (AVFs) are the "gold standard" since they are associated with far fewer complications than arteriovenous grafts (AVG; a piece of synthetic “blood vessel” is interposed between artery and vein), and indwelling dialysis catheters (generally inserted into a large vein in the neck). Although individuals performing HHD are sometimes intimidated by the needle sticks necessary to obtain access through an AVF or an AVG, they should be encouraged to learn to perform them. While indwelling dialysis catheters require no skin puncture, they increase the infection risk.

Clinical Evidence

Evidence suggests that there might be a health outcomes and quality of life benefit of home vs. in-center hemodialysis (HD) in selected patients. The quality of this evidence is, however, low and mostly derived from observational studies. Furthermore, data are mixed on the benefit of routine more frequent vs. thrice weekly HD.

Fotheringham et al. (2021) conducted a stepped-wedge cluster randomized trial looking at a collaborative series approach to increase the patient’s ability to perform five or more tasks while completing hemodialysis at home. This study included 12 UK renal centers who recruited in-center hemodialysis patients with sites randomized into early and late participation in a 12-month

invention series of collaboration that included data collection, learning events, Plan-Study-Do-Act cycles, and teleconferences repeated every 6 weeks, supported by a faculty, co-production, materials and a nursing course. The primary outcome was the proportion of patients undertaking five or more hemodialysis-related tasks or home hemodialysis. Secondary outcomes included independent hemodialysis, quality of life, symptoms, patient activation and hospitalization. There were 586 hemodialysis patients recruited. The proportion performing 5 or more tasks or home hemodialysis increased from 45.6% to 52.3% (205 to 244/449, difference 6.2%, 95% CI 1.4 to 11%), however after analysis by step the adjusted odds ratio for the intervention was 1.63 (95% CI 0.94 to 2.81, p = 0.08). 28.3% of patients doing less than 5 tasks at baseline performed 5 or more at the end of the study (69/244, 95% CI 22.2-34.3%, adjusted odds ratio 3.71, 95% CI 1.66-8.31). Independent or home hemodialysis increased from 7.5% to 11.6% (32 to 49/423, difference 4.0%, 95% CI 1.0-7.0), but the remaining secondary endpoints were unaffected. The intervention did not increase dialysis related tasks being performed by in-center based patients, but there was an increase in home hemodialysis as well as an increase in the number of tasks among patients who were doing fewer than 5 at baseline. Ongoing research is needed to examine interventions to engage people who dialyze at centers in their own care to promote home hemodialysis.

The Agency for Healthcare Research and Quality (2020) performed a technology assessment to study effects of more frequent or longer hemodialysis on clinical outcomes, quality of life (QOL), and symptoms in patients with end-stage renal disease (ESRD). They defined usual care as in center hemodialysis three times per week with less than 4 hours per treatment, more frequent hemodialysis as four or more treatments per week, and longer hemodialysis as 4 or more hours per treatment. This systematic review consisted of 3 RCTs (Chertow 2010 Rocco 2010 and Culleton 2007 included below), 1 non-randomized trial, and 13 observational studies. Compared to the U.S. hemodialysis population, study populations were younger, healthier, and had a longer life expectancy. Two RCT's included the FHN Daily Trial (Chertow, 2010) and FHN Nocturnal trial (Rocco 2010) concluded that the pre-dialysis systolic blood pressure and antihypertensive medication use were lower in the active treatment groups. However, the intervention was not blinded, blood pressure measurements were not standardized, and antihypertensive medication use was based on self-report, all of which can bias these results. Culleton et al. (2007 included below) randomized 52 patients from two Canadian university centers to either nocturnal hemodialysis treatments performed six times per week at home or usual care in-center hemodialysis treatments provided three times per week. When taking all the studies together, the strength of evidence (SOE) was low that more frequent hemodialysis compared to usual care: lowered mortality, the composite outcome of risk of death or increase in left ventricular (LV) mass, and risk of death or decrease in physical health; lowered LV mass and heart rate variability; and improved quality of life and patient reported symptom measures, blood pressure, and metabolic measures. The SOE was low that more frequent and longer hemodialysis compared to usual hemodialysis: improved blood pressure; and shortened time to recovery after hemodialysis. The SOE was low that vascular access complications were more frequent with either more frequent or more frequent and longer hemodialysis, compared to usual care. The overall strength of evidence is low that selected widespread hemodialysis patients with low expected mortality and minimal residual kidney function may benefit from more frequent hemodialysis with a lower risk of death, lowering of blood pressure, reduction in antihypertensive medication use, and lowering of LV mass. Nevertheless, these benefits need to be balanced with an increased risk of vascular access complications and doubt about the effect on total mortality. Some of the studies of more frequent hemodialysis were conducted among in-center hemodialysis whereas most patients receiving frequent hemodialysis in the U.S. are treated at home using hemodialysis systems not tested in all the RCTs. Therefore, the authors' conclusion is limited to this setting: More frequent in-center hemodialysis may improve clinical outcomes, mortality, and quality of life or patient-reported symptom measures.

In an observational cohort study, Choi et al. (2020) examined a national cohort of patients with incident end-stage renal disease that was comprised of 1,993 and 16,514 patients transitioning to HHD and peritoneal dialysis (PD), respectively, from 2007 to 2011. The HHD patients were matched with PD patients. PD patients who transitioned within 12 months of starting dialysis had similar mortality risks, while PD patients who transitioned > 12 months after starting dialysis had an 83% higher risk for mortality (hazard ratio 1.83; 95% CI 1.33-2.52). The authors noted there was no meaningful survival difference in the first 12 months between HHD and PD, but patients who transitioned to PD after 12 months of dialysis had worse survival than their HHD counterparts. It was concluded that additional studies are warranted to investigate clinical implications of these differences.

In another cohort study, Rydell et al. (2019) analyzed the long-term effects of HHD on patient survival and on subsequent renal transplantation, compared with institutional hemodialysis (IHD) and PD, taking age and comorbidity into account. Patients starting HHD as initial renal replacement therapy (RRT) were matched with patients on IHD or PD, according to gender, age, Charlson Comorbidity Index and start date of RRT, using the Swedish Renal Registry. Survival analyses were performed as intention-to-treat (disregarding changes in RRT) and per-protocol (as on initial RRT). A total of 152 patients with HHD as initial RRT were matched with 608 IHD and 456 PD patients, respectively. Median survival was longer for HHD in intention-to-treat

analyses: 18.5 years compared with 11.9 for IHD ($p < 0.001$) and 15.0 for PD ($p = 0.002$). The difference remained significant in per-protocol analyses omitting the contribution of subsequent transplantation. Patients on HHD were more likely to receive a renal transplant compared with IHD and PD, although treatment modality did not affect subsequent graft survival ($p > 0.05$). The authors concluded that HHD as initial RRT showed improved long-term patient survival compared with IHD and PD. This survival advantage persisted after matching and adjusting for a higher transplantation rate. Dialysis modality had no impact on subsequent graft survival. The findings are limited by the observational nature of the study.

Mathew et al. (2018) conducted a systematic review and meta-analyses to compare the association of mortality and hospitalization in patients undergoing intensive HD, compared with conventional HD or PD. The review included cohort studies with comparator arm and randomized controlled trials (RCTs) with > 50% of adult patients (≥ 18 years) comparing any form of intensive HD (> 4 sessions/wk. or > 5.5 h/session) with any form of chronic dialysis (PD, HD ≤ 4 sessions/wk or ≤ 5.5 h/session), that reported at least 1 predefined outcome (mortality or hospitalization). Twenty-three studies, including two RCTs, with a total of 70,506 patients were included. The authors noted that the overall quality of evidence was low or very low for critical outcomes. Outcomes such as quality of life, transplantation, and vascular access outcomes were not included in the review. The authors stated that compared with conventional HD, nocturnal home HD, nocturnal in-center HD, and short daily home HD were all significantly associated with decreased mortality.

Miller et al. (2018) conducted a systematic review to compare home hemodialysis (HHD) and in-center HD (ICHD) outcomes for survival, hospitalization, cardiovascular (CV), nutrition, and quality of life (QoL). Regarding mortality, 10 of 13 trials reported 13-52% reduction; three trials found no differences. According to 6 studies, blood pressure and left ventricular size measurements were generally lower in HHD patients compared to similar measurements in ICHD patients. Regarding nutritional status, conflicting results were reported (8 studies); some found improved muscle mass, total protein, and body mass index in HHD vs. ICHD patients, while others found no significant differences. There were no significant differences in the rate of hospitalization between HHD and ICHD in the 6 articles reviewed. Seven studies on QoL demonstrated positive trends in HHD vs. ICHD populations. The authors concluded that despite limitations in the current data, 66% of the publications reviewed (29/44) demonstrated improved clinical outcomes in patients who chose HHD. Even though HHD may not be preferred in all patients, the authors concluded that a review of the literature suggests that HHD should be provided as a modality choice for substantially more than the current 1.8% of HHD patients in the United States.

An RCT known as “The Frequent Hemodialysis Network (FHN) Daily Trial” was a multicenter, randomized trial that included 245 patients assigned to either in center frequent hemodialysis (six times weekly) or conventional in center hemodialysis (three times weekly). Several publications resulted from this trial. The main findings were reported in Chertow, et al. (2010). Inclusion criteria into the study were fairly broad, including end-stage renal disease requiring chronic renal replacement therapy, age 13 years or above, weight above 30 kg, and achieved mean eKt/V > 1.0 for last two baseline hemodialysis sessions. Two primary composite outcomes were determined at one year, including death or one-year change from baseline in left ventricular (LV) mass, as assessed by cardiac resonance imaging, and death or one-year change in physical health, as assessed by a RAND heath survey. Both composite outcomes showed significant benefit of the frequent-dialysis group compared with the conventional-dialysis group (HR 0.61, 95% CI, 0.46-0.82 for death or change in LV mass and HR 0.70, 95% CI, 0.53-0.92 for death or change in physical health). This study also showed benefits in predetermined secondary outcomes to the frequent dialysis group, such as a decrease in LV mass, improved blood pressure control, and phosphate balance but not on cognitive performance, depression, serum albumin concentration, or use of erythropoiesis-stimulating agents (ESAs). Kotanko, et al. (2015) further analyzed the results of this intervention and found that frequent HD reduces blood pressure and the number of prescribed antihypertensive medications. It was found that frequent in-center dialysis led to improved self-reported general mental health and aspects of health-related quality of life including a shorter recovery time after a dialysis session. In this analysis, frequent dialysis reduced LV end-diastolic volume, LV end-systolic volume, and right ventricular (RV) end-diastolic volume but did not affect the ratio between LV mass/LV end-diastolic volume, which is a marker for LV remodeling. The primary clinical benefit of the FHN Daily trial appeared to be better volume control, which contributed to better blood pressure control and lower LV mass. Adverse effects included more arteriovenous access interventions and increased intradialytic hypotensive events. The study also has several limitations. One being the sample size was insufficient to determine the effects of frequent in-center hemodialysis on death, cause-specific death, hospitalization, or other events. Chertow, et al. (2016) then examined the effects of randomization to the 12-month intervention of frequent versus conventional in–center hemodialysis on mortality during extended follow-up and found that frequent in–center hemodialysis intervention reduced long-term mortality (hazard ratio: 0.54, 95%CI: 0.31 to 0.93), suggesting that frequent hemodialysis may benefit selected patients with ESRD. These latest findings are however limited by crossover to different renal replacement approaches after the randomization. Frequent Hemodialysis Network: Daily Trial ClinicalTrials.gov Identifier: NCT00264758.

Rocco et al. (2011) reported the main results of a companion study to the FHN Daily Trial, a randomized controlled trial known as "The Frequent Hemodialysis Network (FHN) Nocturnal Trial". The FHN Nocturnal Trial randomly assigned 87 individuals to 6-times weekly night home dialysis (NHD) or 3-times-weekly HD (primarily at home) for 1-year. Inclusion criteria were similar as in the FHN Daily Trial, except that participants were all adults and willing to perform hemodialysis at home. Participants were enrolled starting in March 2006 and follow-up was completed by May 2010. The investigators randomized 87 patients to three times per week conventional hemodialysis or to nocturnal hemodialysis six times per week, all with single-use high-flux dialyzers. The 45 patients in the frequent nocturnal arm had a 1.82-fold higher mean weekly stdKt/V(urea), a 1.74-fold higher average number of treatments per week, and a 2.45-fold higher average weekly treatment time than the 42 patients in the conventional arm. There was not a significant effect of nocturnal hemodialysis for either of the two coprimary outcomes (death or left ventricular mass (measured by MRI) with a hazard ratio of 0.68, or of death or RAND Physical Health Composite with a hazard ratio of 0.91). Possible explanations for the left ventricular mass result include limited sample size and patient characteristics. Secondary outcomes included cognitive performance, self-reported depression, laboratory markers of nutrition, mineral metabolism and anemia, blood pressure and rates of hospitalization, and vascular access interventions. Participants in the nocturnal arm had improved control of hyperphosphatemia and hypertension, but no significant benefit among the other main secondary outcomes. There was a trend for increased vascular access events in the nocturnal arm. The authors were unable to demonstrate a definitive benefit of more frequent nocturnal hemodialysis for either co-primary outcome. ClinicalTrials.gov Identifier: NCT00271999. Rocco et al. (2015): after the 1-year trial concluded, study participants were free to modify their HD prescription. The authors obtained dates of death and kidney transplantation through July 2011 using linkage to the USRDS and queries of study centers and used log-rank tests and Cox regression to relate mortality to the initial randomization assignment. Median follow-up for the trial and post-trial observational period was 3.7 years. In the nocturnal arm, there were 2 deaths during the 12-month trial period and an additional 12 deaths during the extended follow-up. In the conventional arm, the numbers of deaths were 1 and 4, respectively. In the NHD group, the overall mortality HR (hazard ratio) was 3.88 (95% CI, 1.27-11.79; p = 0.01). Using as-treated analysis with a 12-month running treatment average, the HR for mortality was 3.06 (95% CI, 1.11-8.43; p = 0.03). Six-month running treatment data analysis showed an HR of 1.12 (95% CI, 0.44-3.22; p = 0.7). These results should be interpreted cautiously due to a surprisingly low (0.03 deaths/patient-year) mortality rate for individuals randomly assigned to conventional HHD, low statistical power for the mortality comparison due to the small sample size, and the high rate of HD prescription changes. Adverse effects included more arteriovenous vascular access interventions and accelerated loss of residual renal function. The trial concluded that patients randomly assigned to NHD had a higher mortality rate than those randomly assigned to conventional HD. The authors concluded that the implications of this result require further investigation.

Several additional analysis combined data from the Frequent Hemodialysis Network Daily and the Frequent Hemodialysis Network Nocturnal Trial comparing frequent vs. conventional therapy (three times per week).

- Garg et al. (2017) examined whether participants receiving frequent hemodialysis had better health-related quality of life compared to patients receiving conventional hemodialysis. After one year in the Daily Trial, patients assigned to frequent in-center hemodialysis reported a higher feeling thermometer score, better general health, and a shorter recovery time after a dialysis session compared to standard thrice-weekly dialysis. After one year in the Nocturnal Trial, patients assigned to frequent home hemodialysis also reported a shorter recovery time after a dialysis session, but no statistical difference in their feeling thermometer or general health scores compared to standard home dialysis schedules. Participants receiving day or nocturnal hemodialysis on average recovered approximately one hour earlier from a frequent compared to conventional hemodialysis session. Participants treated in an in-center dialysis facility reported better HRQoL with frequent compared to conventional hemodialysis.
- Chan et al. (2013) examined the impact of frequent in center and home nocturnal dialysis on LV and right ventricular (RV) volumes, LV remodeling and global systolic function and explore which if any baseline patient characteristics modified these effects. In the daily trial, frequent hemodialysis resulted in significant reductions in left ventricular end diastolic volume left ventricular end systolic volume right ventricular end diastolic volume, and a trend for right ventricular end systolic volume compared with conventional therapy. The magnitude of reduction in left and right ventricular end diastolic volumes with frequent hemodialysis was accentuated among patients with residual urine output < 100 ml/d. In the nocturnal trial, there were no significant changes in left or right ventricular volumes. The frequent dialysis interventions had no substantial effect on the ratio of left ventricular mass/left ventricular end diastolic volume in either trial. Frequent in-center hemodialysis reduced left and right ventricular end systolic and diastolic ventricular volumes as well as left ventricular mass, but it did not affect left ventricular remodeling.
- Unruh et al. (2013) assessed the impact of in-center and nocturnal hemodialysis frequency on depressive symptoms and self-reported mental health. The authors noted that frequent in-center hemodialysis, as compared with conventional in-center hemodialysis, improved self-reported general mental health. Changes in self-reported

depressive symptoms were not statistically significant. They were unable to conclude whether nocturnal hemodialysis yielded similar effects. As trial interventions were not blinded, this could have introduced a bias in the findings. The authors concluded that more rigorous studies are needed to determine if more frequent hemodialysis is warranted.

- Chan et al. (2012) examined the associations with left ventricular mass with HD frequency and explored which if any factors influenced the therapeutic response to frequent hemodialysis. In the Daily Trial, frequent hemodialysis resulted in a significant reduction in LVM, LVM index, and percent change in geometric mean of LVM. Similar trends were noted in the Nocturnal Trial but did not reach statistical significance compared to conventional therapy. In the Daily Trial, a more pronounced effect of frequent hemodialysis on LVM was evident among patients with left ventricular hypertrophy at baseline. Changes in LVM were associated with changes in blood pressure (conventional hemodialysis: $r = 0.28$, $p = 0.01$, daily hemodialysis: $r = 0.54$, $p < 0.001$) and were not significantly associated with changes in other parameters. Frequent in-center hemodialysis reduced LVM. There was no statistical difference in nocturnal. The authors concluded that the benefit of frequent in-center hemodialysis on LVM may be mediated by valuable effects on blood pressure.
- Hall et al. (2012) compared the studies looking at effects of frequency versus conventional related to measures of physical performance, health and functioning. The authors noted that frequent in-center hemodialysis compared with conventional in-center hemodialysis improved self-reported physical health and functioning but had no significant effect on objective physical performance. There were no significant effects of frequent nocturnal hemodialysis on the same physical metrics.
- Daugirdas et al. (2012) reviewed the effects of frequent hemodialysis on measures of CKD mineral and bone disorders. Results indicate that frequent hemodialysis did not have major effects on calcium or parathyroid hormone concentrations in either trial. They also observed that frequent hemodialysis facilitated control of hyperphosphatemia and extended session lengths could allow more liberal diets and freedom from phosphorus binders.

Ramar et al. (2017) conducted a systematic review that included comparative randomized controlled trials or observational studies with no restriction on language, published from 2000 to 2014, involving at least 5 adult patients on dialysis who received a minimum of 6 months of follow-up. The effect size was pooled and stratified by intervention strategy (multidisciplinary care, home dialysis, alternate dialysis settings, and electronic health record implementation). Heterogeneity (I^2) was used to assess the variability in study effects related to study differences rather than chance. Twenty-five international studies with 74,833 patients on maintenance dialysis were included. Interventions with multidisciplinary care or home dialysis were associated with a lower mortality and hospitalizations. The findings are however limited by the inclusion of observational studies.

Sinclair et al. (2017) completed a health technology assessment (HTA) evaluating dialysis modalities for the treatment of end-stage kidney disease (ESKD). The aim of the HTA was to inform policy questions regarding the optimal treatment for eligible patients and effective methods of implementation support for the various dialysis options reviewed through an assessment of the clinical effectiveness patient experiences and perspectives, ethical issues, and implementation issues of dialysis modalities for the treatment of ESKD. The authors concluded that home-based hemodialysis is an appropriate modality option for the treatment of ESKD. They however noted that the evidence is dominated by non-randomized studies.

Kasza et al. (2016) compared the survival of patients undergoing home HD with a permanent vascular access, facility HD with a permanent vascular access, facility HD with a central venous catheter and peritoneal dialysis, using a cohort study design. There were 20,191 patients who underwent ≥ 90 days of dialysis (median 2.25 years, interquartile range 1-3.75 years). There were significant differences in age, gender, comorbidities and other variables between treatment groups at baseline. Thirty per cent of patients had at least one treatment change. Relative to facility HD with permanent access, the risk of death for home HD patients with a permanent access was lower in the first year. The authors indicated that the findings were robust to unmeasured confounding within plausible ranges. They concluded that relative to facility HD with permanent vascular access, home HD conferred better survival prospects, while peritoneal dialysis was associated with a higher risk and facility HD with a catheter the highest risk, especially within the first year of dialysis.

Piccoli et al. (2016) conducted a systematic review to analyze the relationship between dialysis schedule and pregnancy outcomes in pregnancies with chronic dialysis to clarify the major risks, outcomes and treatment suggestions and to identify optimal regimens associated with the best pregnancy outcomes, with the least adverse effects for the mother and neonate. Medline-PubMed, Embase and the Cochrane library were searched (1 January 2000-31 December 2014); separate analysis was performed for case series (more than five cases) and case reports. Meta-regression was performed in case series dealing with the larger subset of HD patients; case reports were analyzed separately (according to PD versus HD; conception before or during dialysis). 190 full texts and 25 congress abstracts from 2048 references were obtained. The authors selected 101 full

papers and 25 abstracts (36 series; 90 case reports), for a total of 681 pregnancies in 647 patients. In the case series (574 pregnancies in 543 patients), preterm delivery was extremely frequent (83%). Meta-regression analysis showed a relationship between hours of dialysis per week in HD and preterm delivery and was significant for preterm deliveries (< 37 gestational weeks:) and for small for gestational age (SGA). SGA was closely associated with the number of dialysis sessions per week. Case report analysis suggests a lower incidence of SGA on HD versus PD. No evidence of an increased risk of congenital abnormality was found in the retrieved papers. The overall conclusion noted that data on pregnancy on dialysis are mixed but rapidly accumulating; the main determinant of outcomes on HD is the dialysis schedule. The differences between PD and HD should be further analyzed.

A systematic review conducted by Ishani et al. (2015) compared the effectiveness of home-based kidney dialysis versus in-center or other outpatient kidney dialysis locations. The report was based on research conducted by the Evidence-based Synthesis Program (ESP) Center funded by the Department of Veterans Affairs, Veterans Health Administration. The authors of the systematic review concluded that low-strength evidence suggests that home-based dialysis may provide similar health outcomes and at similar or lower costs for many patients compared to in-center hemodialysis. Therefore, home-based dialysis may be an acceptable and sometimes preferred alternative to in-center hemodialysis. According to the authors, information is limited on factors important in addressing selection of and barriers to home-based dialysis and remains an area of important research and health policy. (Weinhandl et al. (2015), Weinhandl et al. (2012), and Jayanti et al. (2013), which were previously cited in this policy, are included in the Ishani et al. (2017) systematic review.).

Slinin et al. (2015) in a systematic review to determine whether clinical and patient centered outcomes in patients with advanced chronic kidney disease (CKD) were improved by the following, earlier hemodialysis therapy initiation, more frequent or longer duration hemodialysis or use of low-flux compared to high-flux membrane. The authors included patients with advanced chronic kidney disease receiving hemodialysis. The review consisted of 32 articles from 19 trials from 2000 to March 2014. The interventions comprised, early versus late dialysis therapy initiation; more frequent (> 3 times a week) or longer duration (> 4.5 hours) compared to conventional hemodialysis; low- versus high-flux dialyzer membranes. Frequency and duration of hemodialysis included two RCTs, Culleton et al., 2007 and Rocco et al., 2011 (that are described above) looking at more frequent dialysis (4-7 sessions per week) was compared to dialysis 3 times per week. Although none of the studies was powered to assess mortality, moderate-quality evidence indicated that earlier dialysis therapy initiation (at estimated creatinine clearance [eCl_{cr}] of 10-14 mL/min) did not reduce mortality compared to later initiation (eCl_{cr} of 5-7 mL/min). More than thrice-weekly hemodialysis and extended-length hemodialysis during a short follow-up did not improve clinical outcomes compared to conventional hemodialysis and resulted in a greater number of vascular access procedures (very low-quality evidence). Hemodialysis using high-flux membranes did not reduce all-cause mortality, but reduced cardiovascular mortality compared to hemodialysis using low-flux membranes (moderate-quality evidence). Limitation indicated that few studies were adequately powered to evaluate mortality. Heterogeneity of study designs and interventions precluded pooling data for most outcomes. The overall findings among patients with advanced CKD without uremic symptoms found that initiating dialysis later did not lead to worse clinical outcome, nor did more frequent or extended dialysis improved clinical outcomes compared to conventional hemodialysis. The studies did not assess all-cause mortality or other clinical outcomes, but more frequent dialysis is associated with greater risk or vascular access related procedures.

Culleton et al. (2007) conducted a randomized controlled trial known as the “Alberta trial” investigating the effects of frequent home nocturnal hemodialysis compared with conventional in-center hemodialysis on left ventricular mass, HRQOL, blood pressure and mineral metabolism on 52 participants from 2 centers. Frequent home nocturnal hemodialysis significantly improved the primary outcome in their left ventricular mass after 6 months of treatment, compared to those remaining on 3 days per week in-center (mean left ventricular mass difference between groups, 15.3 g, 95% confidence interval [CI], 1.0 to 29.6 g; p = .04). Frequent nocturnal hemodialysis did not significantly improve quality of life. However, frequent nocturnal hemodialysis was associated with clinically and statistically significant improvements in selected kidney-specific domains of quality of life. Frequent nocturnal hemodialysis was also associated with improvements in systolic blood pressure and mineral metabolism, including a reduction in or discontinuation of antihypertensive medications (16/26 patients in the nocturnal hemodialysis group vs 3/25 patients in the conventional hemodialysis group) and oral phosphate binders (19/26 patients in the nocturnal hemodialysis group vs 3/25 patients in the conventional dialysis group). No benefit in anemia management was seen with nocturnal hemodialysis. The authors concluded that in this study, compared with conventional hemodialysis (3 times weekly), frequent nocturnal home hemodialysis improved left ventricular mass, reduced the need for blood pressure medications, improved some measures of mineral metabolism, and improved selected measures of quality of life. Study limitations included small sample size, limited follow up, and lack of masking. Second, the intervention was at home with self-care patients likely enriching the sample with patients who were less likely to have serious problems.

Clinical Practice Guidelines

National Kidney Foundation Kidney/Disease Outcomes Quality Initiative (NKF/KDOQI)

The 2015 NKF/KDOQI clinical practice guidelines for hemodialysis adequacy state the following among other conclusions and recommendations:

- We suggest that patients with end-stage kidney disease be offered in-center short frequent hemodialysis as an alternative to conventional in-center thrice weekly hemodialysis after considering individual patient preferences, the potential quality of life and physiological benefits, and the risks of these therapies.
- Home long hemodialysis (6-8 hours, 3 to 6 nights per week) should be considered for patients with end-stage kidney disease who prefer this therapy for lifestyle considerations.
- The guideline recommends a target single pool Kt/V (spKt/V) of 1.4 per hemodialysis session for patients treated thrice weekly, with a minimum delivered spKt/V of 1.2. In patients with significant residual native kidney function (Kru), the dose of hemodialysis may be reduced provided Kru is measured periodically to avoid inadequate dialysis.
- Consider additional hemodialysis sessions or longer hemodialysis treatment times for patients with large weight gains, high ultrafiltration rates, poorly controlled blood pressure, difficulty achieving dry weight, or poor metabolic control (such as hyperphosphatemia, metabolic acidosis, and/or hyperkalemia).

They also note that:

- Conventional HD remains the most common treatment for end-stage renal disease (ESRD) worldwide and is usually performed for 3 to 5 hours, 3 days per week.
- The Work Group is unaware of any randomized trials of home short frequent HD and thus the group developed guideline statements only for in-center short frequent HD.
- Given inconclusive data regarding efficacy, and potentially increased risk of harm and mortality, no firm recommendations regarding home long frequent HD could be made by the Work Group.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Dialysis systems are classified under the product codes FII, FKT, KDI and ONW. There were numerous 510(k) clearances for codes FII, FKT, and KDI and not all of these clearances are for home hemodialysis systems. Refer to the following website for more information (enter product code FII, FKT, KDI or ONW): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed January 10, 2023)

Additional product information on other home dialysis products may be found using product codes: FJK (set, tubing, blood, with and without anti-regurgitation valve [hemodialysis system and accessories]); FKP (system, dialysate delivery, single patient); FKR (subsystem, proportioning [hemodialysis system and accessories); KOC (accessories, blood circuit, hemodialysis) KPO (dialysate concentrate for hemodialysis (liquid or powder), available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed January 10, 2023)

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Policy History/Revision Information

Date	Summary of Changes
10/01/2023	**Application** ***Individual Exchange Plans*** • Removed language indicating this Medical Policy does not apply to Individual Exchange benefit plans in the states of Massachusetts, Nevada, and New York **Supporting Information** • Archived previous policy version 2023T0476T

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.