Home Hemodialysis

Policy Number: DIALYSIS 006.20
Effective Date: May 1, 2024

Instructions for Use

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Related Policies

- Private Duty Nursing Services
- Home Health, Skilled, and Custodial Care Services

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

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 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 hemodialysis (HHD) 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. HHD 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 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 HHD 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; 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.

A 2023 Hayes Evidence Analysis Research Brief summarized the volume of publications to determine whether there was adequate published peer-reviewed literature to evaluate the evidence related to home hemodialysis (HHD) with the Tablo Hemodialysis System (Outset Medical Inc.) for the treatment of patients with end-stage renal disease (ESRD). Two abstracts from 1 study evaluating the Tablo Hemodialysis System for HHD in patients with ESRD, including 1 comparative study was identified. The 2 abstracts reported patient-related outcomes for the same study population and compared at HHD with in-center hemodialysis. No single-arm studies addressing the Tablo Hemodialysis System were identified. The abstract review suggested that there currently is not enough published peer-reviewed literature to evaluate the evidence related to the Tablo Hemodialysis System (Outset Medical Inc.) for in-home dialysis of patients with ESRD in a full assessment. (Hayes, 2023)

A 2023 ECRI Clinical Evidence Assessment reviewed the full text of 2 nonrandomized comparison studies and 6 case series (1 reported in 3 publications) reporting on 12,536 patients that addressed HHD using NxStage and reported on hospitalization, QOL, conversion to in-center hemodialysis, and AEs. Studies may have some potential patient overlap, but it could not be confirmed from the available information. The report concluded that renal replacement therapy with NxStage System One in the home setting is safe and sustainable long term. NxStage appears to improve QOL and is associated with low hospitalization and low conversion rates to in-center hemodialysis through six-year follow-up, based on consistent findings of two comparison studies and six single-arm studies. Large, controlled trials comparing NxStage System One with other HHD devices and reporting on long-term patient-oriented outcomes are needed to address evidence gaps (Publication Weinhandl et al., 2015 is included in this report). (ECRI, 2023a)

A 2023 ECRI Clinical Evidence Assessment on the Tablo Hemodialysis System identified one study reported in two publications. The multicenter, prospective study (n = 30) assessed HHD using Tablo in patients with ESRD and reported on adherence to treatment protocol and AEs through 8-week follow-up. Time to recovery, QoL, and sleep quality through 8-week follow-up was reported. The study also compared Tablo HHD with Tablo in-center hemodialysis. The report concluded that the evidence indicates HHD with Tablo is feasible, but the evidence is insufficient to determine how well Tablo works for HHD in patients with kidney failure. The study did not report on some key patient-oriented outcomes (e.g., conversion-rates to in-center hemodialysis, hospitalization rates, all-cause mortality), and no published studies compare Tablo with other HHD systems or methods (peritoneal dialysis). Large controlled trials comparing Tablo with other HHD systems and reporting on long-term patient-oriented outcomes are needed to assess Tablo's safety and effectiveness. (Publications Plumb et al. (2020) and Chertow et al. (2020) are included in this report). (ECRI, 2023b)

In a multicenter study (Ok et al., 2023), thrice-weekly extended HHD was compared with in-center conventional HD (ICHD) in a large patient population with a long-term follow-up. Three hundred and forty-nine patients starting HHD were matched with 1047 concurrent patients on ICHD by using propensity scores. The primary outcome was overall survival. Secondary outcomes were technique survival; hospitalization; and changes in clinical, laboratory, and medication parameters. The mean duration of dialysis session was 418 ±54 minutes in HHD and 242 ±10 minutes in patients on ICHD. All-cause mortality rate was 3.76 and 6.27 per 100 patient-years in the HHD and the ICHD groups, respectively. In the intention-to-treat analysis, HHD was associated with a 40% lower risk for all-cause mortality than ICHD. In HHD, the 5-year technical survival was 86.5%. It was reported that HHD treatment provided better phosphate and blood pressure (BP) control, improvements in nutrition and inflammation, and reduction in hospitalization days and medication requirement. The authors concluded that these results indicated that extended HHD is associated with higher survival and better outcomes compared to ICHD.

Using the United States Renal Data System, Shah et al. (2023) retrospectively evaluated an observational cohort of 42,849 patients who started HHD. The association of sex and race/ethnicity with the outcome of all-cause mortality was evaluated. In the study cohort, 40.4% were women, and 57.4% were White. Women on HHD had higher unadjusted death rates (26.9 versus 22.4) compared with men. There was no difference in adjusted all-cause mortality between men and women, but women had an 8% higher adjusted risk of all-cause mortality at 1 year after initiating HHD. Hispanic, White, and Black patients had higher unadjusted death rates compared with Asians and Native Americans (25.1 versus 24.8 versus 23.2 versus 17.4 versus 16.6 per 100 person-years). There was no difference in adjusted all-cause mortality in Black, Hispanic, and Native Americans compared with White patients, while Asians had a lower risk of all-cause mortality than did White patients. There was no difference in adjusted 1-year mortality for Asian, Black, Hispanic, and Native American patients compared with White patients. The results concluded that women had higher adjusted 1-year mortality than did men; however, they had comparable survival on long-term follow-up after adjusting for socioeconomic status and other covariates in the home dialysis population. There were no racial/ethnic differences in adjusted mortality in the home dialysis population in the long-term follow up, except for Asians who had lower mortality than did White patients. Residing in midwestern geographical region was associated with a higher adjusted risk of mortality in the HHD population.

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 (HHD). Secondary outcomes included independent hemodialysis, quality of life (QoL), symptoms, patient activation and hospitalization. There were 586 hemodialysis patients recruited. The proportion performing 5 or more tasks or HHD increased from 45.6% to 52.3%, however after analysis by step the adjusted odds ratio for the intervention was 1.63. 28.3% of patients doing less than 5 tasks at baseline performed 5 or more at the end of the study . Independent or HHD increased from 7.5% to 11.6%, 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 HHD as well as an increase in the number of tasks among patients who were doing fewer than 5 at baseline.

The Agency for Healthcare Research and Quality (2020) performed a technology assessment to study effects of more frequent or longer hemodialysis on clinical outcomes, QoL, and symptoms in patients with 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 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. 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 QoL 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 QoL or patient-reported symptom measures.

A prospective, multicenter, open-label, crossover trial (n = 30) comparing in-center and in HHD using Tablo was conducted (Plumb et al., 2020). There were 4 treatment periods during which hemodialysis was prescribed 4 times per week: 1-week Run-In, 8-week In-Center, 4-week Transition, and 8-week In-Home. Adherence to the protocol requirement of 4 treatments per week was 96% in-center and 99% in-home. The average prescribed and delivered session lengths were 3.4 hours for both the In-Center and the In-Home periods. The primary efficacy endpoint for the intention-to-treat cohort was achieved in 199/200 (99.5%) of measurements during the In-Center period and 168/171 (98.3%) In-Home. The average weekly standard Kt/Vurea was 2.8 in both periods. The secondary efficacy UF endpoint was achieved in the ITT cohort in 94% in both in-center and in-home. Two prespecified adverse events (AEs) occurred during the In-Center period and 6 in the In-Home period. None of the AEs were deemed by investigators as related to Tablo. The median resolution time of alarms was 8 seconds in-center and 5 seconds in-home. Primary and secondary efficacy and safety endpoints were achieved during both In-Center and In-Home trial periods. The authors concluded that this study confirms that Tablo is safe and effective for HHD use. Study limitations included small sample size and brief study period.

Chertow et al. (2020) reviewed the data in the prospective, multicenter, open-label, crossover trial study on several parameters of health-related quality of life, including time to recovery (TTR), the EQ-5D-5L, and the quality of sleep and related symptoms, to further assess the safety of HHD with Tablo. Results obtained during the in-center and in-home phases of the trial were compared. Median TTR was 1.5 hours (10th, 90th percentile range 0.17 to 12, mean TTR 3.68 ±5.88 hours) during the in-center and 2 hours (10th, 90th percentile range 0 to 6.0, mean TTR 3.04 ±5.14 hours) during the at-home phase. Median index values on the EQ-5D-5L were similar during the in-center (0.832, 10th, 90th percentile range 0.617 to 1, mean 0.817 ±0.165) and in-home (0.826, 10th, 90th percentile range 0.603 to 1, mean 0.821 ±0.163) trial phases. Patients reported feeling alert or well-rested with little difficulty falling or staying asleep or feeling tired and worn out when using Tablo in either environment. The authors concluded that when using Tablo in-home, patients reported similar TTR, general health status, and sleep quality and related symptoms compared to using Tablo in-center.

In an observational cohort study, Choi et al. (2020) examined a national cohort of patients with incident ESRD 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. 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 a 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 and 15.0 for PD. 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. 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 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 QoL, transplantation, and vascular access outcomes were not included in the review. The authors stated that compared with conventional HD, nocturnal HHD, nocturnal in-center HD, and short daily HHD were all significantly associated with decreased mortality.

Miller et al. (2018) conducted a systematic review to compare HHD and in-center HD (ICHD) outcomes for survival, hospitalization, cardiovascular (CV), nutrition, and 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). Inclusion criteria into the study were fairly broad, including ESRD 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 QoL 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. 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 RCT 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. After the 1-year trial concluded, study participants were free to modify their HD prescription. Rocco et al. (2015) 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). Using as-treated analysis with a 12-month running treatment average, the HR for mortality was 3.06 (95% CI). Six-month running treatment data analysis showed an HR of 1.12 (95% CI). 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 QoL 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 HHD 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.

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 HHD with a permanent vascular access, facility HD with a permanent vascular access, facility HD with a central venous catheter and PD, 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 HHD 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. 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.

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 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. (Publications Weinhandl et al. (2015), Weinhandl et al. (2012), and Jayanti et al. (2013), which were previously cited in this policy, are included in this systematic review.)

Slinin et al. (2015) conducted 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 . 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 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. 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.

Clinical Practice Guidelines

American Heart Association (AHA)

A 2022 scientific statement from the AHA states that emerging evidence supports a more physiological approach to administering dialysis therapy, including in the home through HHD or peritoneal dialysis, may lead to improvement in several cardiovascular risk factors and cardiovascular outcomes compared with thrice-weekly in-center hemodialysis. They concluded that incorporation of interdisciplinary care models to increase the use of home dialysis therapies in an equitable manner will contribute to the ultimate goal of improving outcomes for patients with kidney failure and cardiovascular disease. (Sarnak et al., 2022)

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 QoL 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 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.

National Institute for Health and Care Excellence (NICE)

A 2018 NICE guideline on renal replacement therapy and conservative management made the following recommendations:

- Offer a choice of dialysis modalities at home or in center ensuring that the decision is informed by clinical considerations and patient preferences.
- There was no evidence to suggest clear differences between home and in-center HD/HDF. The committee acknowledged that these treatments could have very different effects on lifestyle and recommended patient choice.

(NICE, 2018)

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, FPI, 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 December 29, 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 December 29, 2023)

Devices that have been developed to be used for hemodialysis at home include:

- NxStage System One™ (NxStage Medical, Inc., Lawrence, MA) received U.S. Food and Drug Administration (FDA) 501(k) clearance for use in the home. It is indicated for the treatment of acute and chronic renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration, in an acute or chronic care facility. The system is also indicated for home hemodialysis, including home nocturnal hemodialysis and solo home hemodialysis during waking hours. All treatments must be administered under physician's prescription and must be performed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.
- Fresenius Medical Care received FDA 501(k) clearance for the Fresenius 2008K@home™ (Fresenius Medical Care, Waltham, MA). It is indicated for acute and chronic dialysis therapy in an acute or chronic facility and for hemodialysis in the home. It must be administered under physician's prescription and observed by a trained individual who is considered competent in the use of the device.
- Tablo® Hemodialysis System (Outset Medical, Inc, San Jose, CA) received U.S. Food and Drug Administration (FDA) 501(k) clearance and is indicated for use in patients with acute and/or chronic renal failure, with or without ultrafiltration, in an acute or chronic care facility, and for use in the home. It must be administered under physician's prescription and observed by a trained individual who is considered competent in the use of the device.

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The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2024T0476V]

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Policy History/Revision Information

Date	Summary of Changes
05/01/2024	**Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Removed *Definitions* section • Archived previous policy version DIALYSIS 006.19

Instructions for Use

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford 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 Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Oxford Clinical 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.