UnitedHealthcare®

MEDICAL POLICY

HOME HEMODIALYSIS

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Related Policies:

- Skilled Care and Custodial Care Services
- Private Duty Nursing Services

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines 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.

BENEFIT CONSIDERATIONS

Home hemodialysis is subject to the terms and limitations indicated in the Coverage Determination Guidelines (CDGs) titled Custodial and Skilled Care Services and Private Duty Nursing Services.

COVERAGE RATIONALE

Home hemodialysis (HHD) is a proven therapy as an alternative to facility-based hemodialysis for patients with end-stage renal disease and medically necessary when the following criteria are met:

- Patient is stable on dialysis with no evidence of complex skilled interventions being necessary during treatments
- Patient or non-professional caregiver has the ability to perform and maintain home hemodialysis and has received comprehensive training regarding proper protocol.

- Absence of complications and significant concomitant disease that would cause home hemodialysis to be unsafe or unsuitable
- Presence of well-functioning vascular access

Professional staff-assisted home hemodialysis is medically necessary as an alternative to facility-based hemodialysis for patients with end-stage renal disease who meet ALL of the following criteria:

- Patient is stable on dialysis and not at increased risk as a result of having the procedure performed outside a dialysis center venue; and
- Patient has well-functioning vascular access; and
- Patient has medical contraindications to leaving home for hemodialysis; and
- Patient or non-professional caregiver is not capable of performing home hemodialysis
- Staff assisted home hemodialysis protocols generally match those provided in the hemodialysis center (i.e., at least 3 times per week, 3-4 hour treatments). The exact dialysis therapy employed is determined on an individual basis by the attending nephrologist.

See the Medicare Benefit Policy Manual Chapter 11, Section 30.2 Hemodialysis Training. Available at: https://www.cms.gov/manuals/Downloads/bp102c11.pdf Accessed December 2013.

APPLICABLE CODES

The Current Procedural Terminology (CPT®) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit 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 claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

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

CPT® Code	Description
99512	Home visit for hemodialysis
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

CPT® is a registered trademark of the American Medical Association.

DESCRIPTION OF SERVICES

For patients with end-stage renal disease (ESRD), hemodialysis (HD) is a convenient 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 a patient'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. On average, patients must receive HD treatment three times a week for a duration of three or more hours.

Home HD allows patients 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 also enables patients to perform dialysis more frequently or for longer durations, resulting in improved health, reduced symptoms, and a longer and higher quality of life. 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.

The most popular treatment regimens include:

- Conventional – three times a week for three to five hours, much like the regimen in a clinic
- Short daily – five to seven times a week for two to three hours each treatment
- Nocturnal – slow treatment, performed three or six times a week for six to eight hours. (ECRI, 2009)

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 HHD patients 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 immeasurably.

See the following Web sites for more information regarding access (accessed January 2014):

- Hemodialysis Access Fistula First: http://www.homedialysis.org/article/life_at_home/hemodialysis_access_fistula_first
- Arteriovenous Fistula First: http://www.fistulafirst.org/
- Home Dialysis Central: http://www.homedialysis.org/
- Buttonhole Cannulation: http://www.fistulafirst.org/HealthcareProfessionals/FFBIChangeConcepts/ChangeConcept8.aspx
- National Kidney Foundation Clinical Practice Guidelines for Vascular Access: http://www.kidney.org/professionals/kdoqi/guideline_upHD_PD_VA/index.htm

See the following Web Sites for more information regarding setting up a home hemodialysis program and information supporting more frequent home hemodialysis (accessed January 2014):

http://www.renalandurologynews.com/setting-up-a-home-hemodialysis-program/article/234862/
http://www.nxstage.com/homehemodialysis/clinical-evidence

CLINICAL EVIDENCE

The medical literature includes a number of studies that evaluated the relative effects on survival of home hemodialysis (HHD) compared to outpatient hemodialysis at a dialysis center. There are several observational studies that suggest that longer and more frequent dialysis sessions may result in significant improvements in selected clinical outcomes. Most studies were comprised of highly selected patients who had the ability to perform and maintain home hemodialysis. In some studies, patients were self-selected or were permitted to choose their preferred dialysis modality. Patients treated with HHD tended to be younger, to have fewer comorbidities, and to be at lower risk of morbidity and mortality compared with patients who were treated in hospitals or clinics.

The FREEDOM (Following Rehabilitation, Economics and Everyday-Dialysis Outcome Measurements) Study is an ongoing prospective cohort study investigating the clinical and economic benefits of daily (6 times per week) at-home hemodialysis (HD). In an interim report, Jaber et al. (2010) examined the long-term impact of daily HD on depressive symptoms, measured using the Beck Depression Inventory (BDI) survey and postdialysis recovery time, measured using a previously validated questionnaire. The BDI survey and postdialysis recovery time question were administered at baseline, and changes were assessed at months 4 and 12. A total of 239 participants were enrolled (intention-to-treat cohort) and 128 completed the study (per-protocol cohort). The percentage of patients with depressive symptoms (BDI score>10) significantly decreased during 12 months. Similarly, in the per-protocol cohort, there was a significant decrease in postdialysis recovery time over 12 months. The intention-to-treat analysis yielded similar results. The percentage of patients experiencing prolonged postdialysis recovery time (>or=60 minutes) also significantly decreased. The investigators concluded that daily HD is associated with long-term improvement in depressive symptoms and postdialysis recovery time.

In an interim report for the ongoing FREEDOM prospective cohort study, Finkelstein et al. (2012) examined the long-term effect of at-home short daily hemodialysis on health-related quality of life, as measured by the SF-36 health survey. This was administered at baseline, 4 and 12 months after initiation of short daily hemodialysis to 291 participants (total cohort), of which 154 completed the 12-month follow-up (as-treated cohort). At the time of analysis, the mean age was 53 years, 66% were men, 58% had an AV fistula, 90% transitioned from in-center hemodialysis, and 45% had diabetes mellitus. In the total cohort analysis, both the physical- and mental-component summary scores improved over the 12-month period, as did all 8 individual domains of the SF-36. The as-treated cohort analysis showed similar improvements with the exception of the role-emotional domain. Significantly, in the as-treated cohort, the percentage of patients achieving a physical-component summary score at least equivalent to the general population more than doubled. According to the authors, at-home short daily hemodialysis is associated with long-term improvements in various physical and mental health-related quality of life measures.

Weinhandl et al. (2012) used a matched-cohort design to assess relative mortality in daily home hemodialysis and thrice-weekly in-center hemodialysis patients between 2005 and 2008. The authors matched 1873 home hemodialysis patients with 9365 in-center patients (i.e., 1:5 ratio) selected from the prevalent population in the US Renal Data System database. The cumulative incidence of death was 19.2% and 21.7% in the home hemodialysis and in-center patients, respectively. In the intention-to-treat analysis, home hemodialysis associated with a 13% lower risk for all-cause mortality than in-center hemodialysis. Cause-specific mortality hazard ratios (HRs) were 0.92 for cardiovascular disease, 1.13 for infection, 0.63 for cachexia/dialysis withdrawal, 1.06 for other specified cause, and 0.59 for unknown cause. Findings were similar using as-treated analyses. According to the authors, these data suggest that relative to thrice-weekly in-center hemodialysis, daily home hemodialysis is associated with a modest increase in survival. The authors stated that continued surveillance should better identify causes of mortality and determine whether treatment effects are homogeneous throughout the dialysis population.

The FHN Trial Group (2010) conducted a randomized clinical trial to determine whether increasing the frequency of in-center hemodialysis would result in beneficial changes in left ventricular mass, self-reported physical health, and other intermediate outcomes among patients undergoing maintenance hemodialysis. Patients were randomly assigned to undergo hemodialysis six times per week (frequent hemodialysis, 125 patients) or three times per week (conventional hemodialysis, 120 patients) for 12 months. The investigators concluded that frequent hemodialysis, as compared with conventional hemodialysis, was associated with favorable results with respect to the composite outcomes of death or change in left ventricular mass and death or change in a physical-health composite score but prompted more frequent interventions related to vascular access.

Marshall et al. (2011) performed an observational cohort study to evaluate dialysis modality (conventional facility hemodialysis (HD), conventional home HD, frequent/extended facility HD, frequent/extended home HD, and peritoneal dialysis (PD)). The study analyzed 26,016 patients with 856,007 patient-months of follow-up. Relative to conventional facility HD, adjusted mortality hazard ratios were 0.51 for conventional home HD, 1.16 for frequent/extended facility HD, 0.53 for frequent/extended home HD, and 1.10 for PD. According to the authors, this study supports a survival advantage of home HD without a difference between conventional and frequent/extended modalities.

Jayanti et al. (2013) evaluated home hemodialysis (HHD) in a study that included 166 patients. All patients were followed up prospectively until a switch to alternative modality, to include 4528 patient-months of follow-up and about 81 508 HHD sessions during an 8-year period (January 2004-December 2011). Twenty-four patients switched to an alternative modality during the period. Combined technique survival (HHDc) as a composite of training (HHDtr) and at home (HHDhome) was analyzed and clinical predictors of HHD modality failure since the commencement of the program were calculated using Cox regression analysis. Technology-related interruptions to dialysis over a 12-month period and patient-reported reasons for quitting the program were analyzed. Technique survival at 1, 2 and 5 years was 90.2, 87.4, 81.5% (HHDc) and 98.4, 95.4 and 88.9% (HHDhome) when censored for training phase exits, death and transplantation. The combined HHDc modality switch rate is 1 in 192 patient-months of dialysis follow-up. Age >60 years, diabetes, cardiac failure, unit decrease in Hb and increasing score of age-adjusted Charlson--comorbidity index were significantly associated with technique failure. Significant clinical predictors of HHD technique failure in a multivariate model were diabetes and cardiac failure. The majority (61%) switched to an alternative modality for non-medical reasons. The composite of operator error and mechanical breakdown resulting in temporary HHD technique failure was 0.7% per year. The authors concluded that HHD training and technique failure rate are low. Technical errors are infrequent too. Diabetes and cardiac failure are associated with significant risk of technique failure. Although absolute rates are low, training failure is proportionally quite significant, highlighting the importance of reporting the composite technique failure rate (to include early HHD training phase) in HHD programs.
Kjellstrand et al. (2010) studied the influence of time and dialysis and the dose (Kt/V) on survival in 262 patients on short-daily hemodialysis (SDHD) In Cox proportional hazard analysis, 4 factors were independently associated with survival: age in years Hazard Ratio (HR)=1.05, weekly dialysis hours HR=0.84, home dialysis HR=0.50, and secondary renal disease HR=2.30. Based on the study results, the investigators concluded that with SDHD, longer time and dialysis at home were independently associated with improved survival, while Kt/V was not.

Lockridge and Kjellstrand (2011) studied the association of survival in a 12-year study of 87 nightly home hemodialysis (NHHD) patients and compared the survival of the these patients with that reported by the United States Renal Data System (USRDS) using standardized mortality rate (SMR). The cumulative survival was 79% at 5 years and 64% at 10 years. Using Cox proportional hazards univariate analysis, 7 of 26 factors studied were associated with mortality: less than high school education, hour of each dialysis, comorbidities, secondary renal disease, congestive heart failure, Leypoldt's eKt/V, and Daugirdas Kt/V. In backward stepwise Cox analysis, education and

hour of dialysis were the only factors independently associated with survival. The standardized mortality rate was only 0.30 of that reported by the United States Renal Data System for patients on thrice-weekly hemodialysis adjusted for age, gender, race, and diagnosis. The influence of education was the most significantly associated with survival, and the duration of each dialysis treatment was important. According to the authors, the survival rate of NHHD patients appeared to be superior to intermittent hemodialysis.

In a six month randomized trial (n=51) comparing frequent nocturnal hemodialysis (5-6 times/week) to conventional hemodialysis (3 times/week), researchers reported that frequent nocturnal hemodialysis improved left ventricular mass, reduced the need for blood pressure medications, improved some measures of mineral metabolism and improved selected health-related quality of life measures. Anemia control was not affected by nocturnal hemodialysis (Culleton, 2007).

In a retrospective analysis to determine if clinical effects previously associated with short-daily dialysis were also seen using the NxStage System One™ portable hemodialysis device, Kraus et al. (2007), conducted a prospective, 2-treatment, 2-period, open-label, crossover study of in-center hemodialysis vs. home hemodialysis in 32 patients treated at 6 U.S. centers. The 8-week In-Center Phase (6 days/week) was followed by a 2-week transition period and then followed by the 8-week Home Phase (6 days/week). Twenty-six out of 32 patients (81%) successfully completed the study. Successful delivery of at least 90% of prescribed fluid volume (primary endpoint) was achieved in 98.5% of treatments in-center and 97.3% at home. Total effluent volume as a percentage of prescribed volume was between 94% and 100% for all study weeks. The composite rate of intradialytic and interdialytic adverse events per 100 treatments was significantly higher for the In-Center Phase (5.30) compared with the Home Phase (2.10; p=0.007). Compared with the period immediately preceding the study, there were reductions in blood pressure, antihypertensive medications, and interdialytic weight gain. Daily home hemodialysis with a small, easy-to-use hemodialysis device is a viable dialysis option for end-stage renal disease patients capable of self/partner-administered dialysis.

Pauly et al. (2010) assessed patient-specific predictors of mortality or technique failure associated with nocturnal home hemodialysis (NHD). The study included 247 NHD patients. A total of 14.6% of the cohort experienced death or technique failure. Unadjusted 1- and 5-year adverse event-free survival was 95.2 and 80.1%, respectively. Significant predictors of a composite of mortality and technique failure included advanced age, diabetes, central venous catheter use, and inability to perform NHD independently. Weekly frequency of NHD was not predictive. Age and diabetes remained significant factors with multivariable analysis. The authors concluded that NHD is associated with excellent adverse event-free survival.

Agraharkar et al. (2002a) presented data on 28 patients with severe debilitating and terminal illnesses. These patients were receiving dialysis at their home administered by a registered nurse according to a dialysis prescription provided by an attending nephrologist. According to the authors, end stage renal disease (ESRD) patients with severe disability can continue dialysis at home. The authors concluded that certain patients, such as those with terminal illnesses or severe debilities who require ambulance transportation, staff-assisted home hemodialysis (SAHD) can be an efficacious modality of dialysis. Conclusions reached are limited by small sample size.

Agraharkar et al. (2000b) describe 4 patients that have had problems receiving in-center hemodialysis (ICHD) for various reasons. When these patients were switched to staff-assisted home hemodialysis (SAHD), the dialysis core indicators improved compared with ICHD and the patients needed significantly fewer hospitalization days. The authors indicated that in patients who cannot be easily transferred and in patients with neuropsychiatric disorders, SAHD can be a more efficacious modality of dialysis. The authors concluded that SAHD is safe for selected patients. The authors recommend that SAHD be considered as a viable option for patients who

may face significant difficulty in receiving ICHD. Conclusions reached are limited by small sample size.

Several registered trials relevant to home hemodialysis were identified on ClinicalTrials.gov. See the following Web site for more information: http://clinicaltrials.gov/ct2/results?term=home+hemodialysis&Search=Search Accessed December 2013.

National Institute for Health and Care Excellence (NICE) (2005): A review was performed by the National Institute for Clinical Excellence to provide guidance on the location where hemodialysis is carried out. The recommendations note that patients suitable for home hemodialysis will 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 render home hemodialysis 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

*For additional information on vascular access click here.

Professional Societies:

National Kidney Foundation (NKF)/KDOQI: The 2006 NKF/KDOQI clinical practice guidelines for hemodialysis adequacy suggest that the minimally adequate dose of dialysis can be reduced among patients with residual kidney function of greater than 2 mL/min per 1.73 m^2. These guidelines also state that serum phosphorus level appears to be a predictor of mortality in dialysis patients, as well as patients with chronic kidney disease. Phosphorus control is dependent on phosphorus intake, compliance with phosphorus-binder intake, and hemodialysis prescription. According to the NKF, an increase in total weekly hours of dialysis, probably more than 24 hours per week, distributed over at least 3 treatments per week appears to be needed to control phosphorus levels in most dialysis patients. In the Tassin experience (8 hours/week × 3 = 24 hours), approximately one third of patients no longer required phosphate binders. Using an "every-other-night" nocturnal dialysis strategy (~28 hours per week) should give results similar to those in the Tassin experience. According to the NKF, nocturnal dialysis given 5 to 6 times per week appears to remove the need for phosphorus binders, adequately controls phosphorus levels in almost all patients, and often requires the addition of phosphorus to the dialysate to prevent hypophosphatemia.
See the following Web site for more information: http://www.kidney.org/professionals/kdoqi/guideline_upHD_PD_VA/hd_rec4.htm Accessed December 2013.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Dialysis systems are classified under the product codes FII, FKT, KDI and ONW. There were numerous 510(k) approvals for codes FII, FKT, and KDI and not all of these approvals are for home hemodialysis systems. 510(k) clearances for products that have been identified as home hemodialysis systems mentioned in this policy include:

- Fresenius 2008K@ Home (Fresenius Medical Care, Walnut Creek, CA)-March 16, 2000
- NxStage System One™ (NxStage Medical, Inc., Lawrence, MA) - June 24, 2005

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 2013)

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does cover home dialysis and other medically necessary items for home dialysis, when reasonable and necessary for patients with end-stage renal disease. Refer to the Medicare Benefit Policy Manual Chapter 11- End-Stage Renal Disease (ESRD) at http://www.cms.hhs.gov/manuals/Downloads/bp102c11.pdf and the Medicare Integrity Manual Chapter 5 § 5.10- Period of Medical Necessity Home Dialysis Equipment at http://www.cms.hhs.gov/manuals/downloads/pim83c05.pdf for coverage and billing information.

Medicare does not have a National Coverage Determination (NCD) for home dialysis. Local Coverage Determinations (LCDs) do not exist at this time.

(Accessed December 13, 2013)

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
09/01/2014	• Updated related policies reference link; o Replaced Custodial and Skilled Care Services (title changed 09/01/14) with Skilled Care and Custodial Care Services
04/01/2014	• Reorganized policy content • Revised coverage rationale: o Reformatted and clarified medical necessity criteria o Updated/expanded medical necessity criteria for *professional staff-assisted home hemodialysis*; added language to indicate staff assisted home hemodialysis protocols generally match those provided in the hemodialysis center (i.e. at least 3 times per week, 3-4 hour treatments); the exact dialysis therapy employed is determined on an individual basis by the attending nephrologist • Updated supporting information to reflect the most current description of services, clinical evidence and references • Archived previous policy version 2013T0476J