UnitedHealthcare® Community Plan

UnitedHealthcare® Community Plan
Medical Policy

HOME HEMODIALYSIS

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Instructions for Use

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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., 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.

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;
- 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 federal, state or contractual requirements 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 Coverage Determination 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. On average, individuals must receive HD treatment three times a week for a duration of three or more hours.

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 also enables individuals 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 four hours or longer, much like the regimen in a clinic
- Short Daily: Five to seven times a week; treatments usually last about two hours each
- Nocturnal: Slow treatment, performed six nights a week or every other night for six to eight hours

(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**)

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 immeasurably.

See the following websites for more information regarding access:
- **Dialysis Access: Society for Vascular Surgeons: https://vascular.org/patient-resources/vascular-treatments/dialysis-access**
- Hemodialysis Access Fistula First: http://www.homedialysis.org/life-at-home/articles/hemodialysis-access-fistula-first
- Home Dialysis Central: http://www.homedialysis.org/
- Buttonhole Cannulation: https://www.kidney.org/atoz/content/buttonhole-technique
- National Kidney Foundation Clinical Practice Guidelines for Hemodialysis Adequacy (this document includes information regarding vascular access): https://www.kidney.org/professionals/guidelines/hemodialysis2015

(Accessed ~~October 28, 2018~~**February 3, 2020**)

See the following website for more information regarding setting up a home hemodialysis: http://www.renalandurologynews.com/setting-up-a-home-hemodialysis-program/article/234862/.
(Accessed ~~October 28, 2018~~**February 3, 2020**)

For information regarding home hemodialysis training, see the following:

- The Medicare Benefit Policy Manual Chapter 11, Section 30.2 Home Dialysis Training. Available at: https://www.cms.gov/manuals/Downloads/bp102c11.pdf
- National Kidney Foundation. Available at: https://www.kidney.org/atoz/content/homehemo

(Accessed ~~October 28, 2018~~**February 3, 2020**)

Most dialysis clinics require a person to train with a partner who will be in the home while the person receives treatment. See the following website for more information: https://www.niddk.nih.gov/health-information/kidney-disease/kidney-failure/hemodialysis. (Accessed ~~October 28, 2018~~**February 3, 2020**)

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.~~

Choi et al. (2020) examined a national cohort of incident end-stage renal disease patients 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.

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 peritoneal dialysis (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.

Mathew et al. (2018) conducted a systematic review and meta-analyses to compare the association of mortality and hospitalization in patients undergoing intensive hemodialysis (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 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, 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.

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 dialysis patients 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 maintenance dialysis patients 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.

Kasza et al. (2016) compared the survival of patients undergoing home hemodialyses (HD) with a permanent vascular access, facility HD with a permanent vascular access, facility HD with a central venous catheter and peritoneal dialysis. 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. Findings were robust to unmeasured confounding within plausible ranges. The authors 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.

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.)**

~~In an observational cohort study, Weinhandl et al. (2014) assessed if daily hemodialysis is associated with lower hospitalization risk. The study participants included Medicare-enrolled daily (5 or 6 sessions weekly) home hemodialysis (HHD) patients initiating NxStage System One use from January 1, 2006, through December 31, 2009, and contemporary thrice-weekly in-center hemodialysis patients, matched 5 to 1. For 3,480 daily HHD and 17,400 thrice-weekly in-center hemodialysis patients in intention-to-treat analysis, the HR of all-cause admission for daily HHD versus in-center hemodialysis was 1.01. Cause-specific admission HRs were 0.89 for cardiovascular disease, 1.18 for infection, 1.01 for vascular access dysfunction, and 1.02 for other morbidity. Regarding cardiovascular disease, first admission and readmission HRs for daily HHD versus in-center hemodialysis were 0.91 and 0.87, respectively. Regarding infection, first admission and readmission HRs were 1.35 and 1.03, respectively. Protective associations of daily HHD with heart failure and hypertensive disease were most pronounced, as were adverse associations of daily HHD with bacteremia/sepsis, cardiac infection, osteomyelitis, and vascular access infection. The authors concluded that all-cause hospitalization risk was similar in daily HHD and thrice-weekly in-center hemodialysis patients. However, risk of cardiovascular-related admission was lower with daily HHD, and risk of infection-related admission was higher. The authors stated that more attention should be afforded to infection in HHD patients.~~

~~The FREEDOM Study (Following Rehabilitation, Economics and Everyday-Dialysis Outcome Measurements) is a 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 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.~~

~~Kasza et al. (2016) compared the survival of patients undergoing home hemodialyses (HD) with a permanent vascular access, facility HD with a permanent vascular access, facility HD with a central venous catheter and peritoneal dialysis. 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. Findings were robust to unmeasured confounding within plausible ranges. The authors 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.~~

~~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.~~

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.

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.

Several registered trials relevant to home hemodialysis were identified on ClinicalTrials.gov. See the following website for more information: http://clinicaltrials.gov/ct2/results?term=home+hemodialysis&Search=Search. (Accessed ~~October 28, 2018~~**February 3, 2020**)

~~Sinclair et al. (2017) performed 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.~~

Professional Societies

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

The 2015 NKF/KDOQI clinical practice guidelines for hemodialysis adequacy state that 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. See the following website for more information: https://www.kidney.org/professionals/guidelines/hemodialysis2015. (Accessed ~~October 28, 2018~~**February 3, 2020**)

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~~ **clearances** are for home hemodialysis systems. See 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 ~~October 28, 2018~~**February 3, 2020**)

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 ~~October 28, 2018~~**February 3, 2020**)

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

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

Medicare covers home dialysis and associated items required for home dialysis, when criteria are met. Refer to the Medicare Benefit Policy Manual, Chapter 11, §30 – Home Dialysis and the Medicare Integrity Manual, Chapter 5, § 5.10- Period of Medical Necessity Home Dialysis Equipment.

(Accessed February 12, 2020)

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~~Medicare covers home dialysis and associated items required for home dialysis, when criteria are met. Refer to the Medicare Benefit Policy Manual, Chapter 11, §30 – Home Dialysis and the Medicare Integrity Manual, Chapter 5, § 5.10- Period of Medical Necessity Home Dialysis Equipment.~~
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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
Xx/01/2020	**Supporting Information** • **Updated *Description of Services, Clinical Evidence, FDA, CMS* and *References* sections to reflect the most current information** • **Archived previous policy version CS057.G**

INSTRUCTIONS FOR USE

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