Coverage Summary

Dialysis Services

Policy Number: D-005 | Products: UnitedHealthcare Medicare Advantage Plans | Original Approval Date: 02/14/2008
Approved by: UnitedHealthcare Medicare Benefit Interpretation Committee | Last Review Date: 01/15/2019

Related Medicare Advantage Policy Guidelines:

- Laboratory Tests-CRD Patients (NCD 190.10)
- Levocarnitine-Treatment of Carnitine Deficiency in ESRD Patients (NCD 230.19)
- Medical Nutrition Therapy (NCD 180.1)
- Peridex CAPD Filter Set (NCD 230.13)
- Ultrafiltration Monitor (NCD 230.14)
- Ultrafiltration, Hemoperfusion and Hemofiltration (NCD 110.15)
- Water Purification and Softening Systems Used in Conjunction with Home Dialysis (NCD 230.7)

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The benefit information in this Coverage Summary is based on existing national coverage policy, however, Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable.

There are instances where this document may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG). In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

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II. DEFINITIONS
I. COVERAGE

Coverage Statement: Dialysis (peritoneal and hemodialysis) services are covered when Medicare criteria are met.

Guidelines/Notes:
1. Dialysis (peritoneal, hemofiltration, ultrafiltration and hemodialysis) services and all medically necessary equipment and supplies used to furnish dialysis in a Medicare certified ESRD Facility, member’s home or inpatient hospital facility are covered in accordance with Medicare coverage criteria.

See the Medicare Benefit Policy Manual, Chapter 11, §10- Definitions Relating to ESRD. (Accessed December 20, 2018)

Notes:
- All services must be done in home or at a Medicare Certified ESRD Facility.
- Medicare pays for one month’s emergency reserve supply for Method II home dialysis patients, once in a patient’s lifetime for each dialysis modality the patient receives. Refer to the Medicare Claims Processing Manual, Chapter 8, §90.3 - Amount of Payment by the DMERC. (Accessed December 20, 2018)

2. The following are examples of covered dialysis services and other related services, but are not limited to:
   a. Acute Dialysis - Dialysis given to patients who are not ESRD patients, but who require dialysis because of temporary kidney failure due to a sudden trauma; examples include but not limited to traffic accident or ingestion of certain drugs.

For billing and payment instructions of acute dialysis services furnished in the hospital, see the:
- Medicare Claims Processing Manual, Chapter 4, §200.2 - Hospital Dialysis Services For Patients with and without End Stage Renal Disease (ESRD). (Accessed December 20, 2018)

   b. Peridex CAPD Filter Sets are not covered. See the NCD for Peridex CAPD Filter Set (230.13). (Accessed December 20, 2018)

   c. Dialysis Furnished to Home Patients Who Are Traveling: Routine dialysis services may be covered when the member is temporarily absent from their service area. See the Medicare Benefit Policy Manual, Chapter 11, §30.1.B -In-facility Dialysis Sessions Furnished to Home Patients Who Are Traveling. (Accessed December 20, 2018)

   Also see the Medicare Claims Processing Manual, Chapter 8, §100 - Dialysis Sessions Furnished to Patients Who are Traveling. (Accessed December 20, 2018)

   d. Laboratory tests essential to monitor the progress of chronic renal dialysis patients are
covered. Any laboratory test in excess of frequency defined under “routine laboratory tests” or any test that is not listed above is covered only if there is documentation of medical necessity.

See NCD for Laboratory Tests – CRD Patients (190.10) (Accessed December 20, 2018)

Also see the Medicare Benefit Manual, Chapter 11, §20.2 – Laboratory Services. (Accessed December 20, 2018)

e. Drugs and biologicals used for the treatment of ESRD generally are covered in accordance with Medicare coverage criteria. For a comprehensive list of covered drugs and biologicals; See the Medicare Benefit Policy Manual, Chapter 11, §20.3-20.3.1-Drugs and Biologicals. (Accessed December 20, 2018)

Also see the Medicare Benefit Policy Manual Chapter 15, §50-Drugs and Biologicals. (Accessed December 20, 2018)

Ambulance transportation to or from dialysis facility is covered only when an ambulance level of transportation is medically necessary and other means of transportation are contraindicated or when the member is an inpatient in a skilled nursing facility (SNF) that cannot provide the services for the member. See the Medicare Benefit Policy Manual, Chapter 10 - Ambulance Services. (Accessed December 20, 2018)

Also refer to the Coverage Summary for Ambulance Services.

Water purification and softening systems used in conjunction with home dialysis are covered when criteria are met. See the NCD for Water Purification and Softening Systems Home Dialysis (230.7). (Accessed December 20, 2018)

Also see the Medicare Benefit Policy Manual, Chapter 11, §30.1 - Home Dialysis Items and Services. (Accessed December 20, 2018)

Medical Nutritional Therapy (MNT) is covered when criteria are met; see the NCD for Medical Nutrition Therapy (180.1) for coverage criteria. (Accessed December 20, 2018)

Notes:
- MNT services are not covered for members receiving maintenance dialysis
- A member cannot receive MNT if they have received initial Diabetic Self-Management Training (DSMT) within the last 12 months unless:
  - The need for a reassessment and additional therapy has been documented by the referring physician as a result of a change in diagnosis or medical condition; or
  - The beneficiary receiving DSMT is subsequently diagnosed with renal disease

Also see the Medicare Benefit Policy Manual, Chapter 11, §40 I - Nutritional Services and Services. (Accessed December 20, 2018)

Intravenous levocarnitine for those ESRD patients who have been on dialysis for a minimum of three (3) months are covered. Patients must have documented carnitine deficiency along with signs and symptoms of:
1) Erythropoietin–resistant anemia, or
2) Hypotension on hemodialysis that interferes with delivery of the intended dialysis

Note: Continued use of levocarnitine will not be covered if improvement has not been demonstrated within 6 months of initiation of treatment. All other indications for levocarnitine are non-covered in the ESRD population. For more specific criteria, see the

j. Epogen (epoetin alfa) and Aranesp (darbepoetin alfa) are covered for dialysis patients who meet criteria. See the Medicare Benefit Policy Manual, Chapter 11, §20.3 - Drugs and Biologicals. (Accessed December 20, 2018)

Also see the Coverage Summary for Medications/Drugs (Outpatient/Part B).

k. Home and Self-dialysis Training: Training of a home dialysis member and/or family member/ significant other, including review of family and home status, environment, and counseling and training of family members are covered. See the Medicare Benefit Manual Chapter 11, §30.2 - Home Dialysis Training. (Accessed December 20, 2018)

l. Ultrafiltration, hyperperfusion and hyperfiltration procedures are covered only when criteria are met. See the NCD for Ultrafiltration, Hemoperfusion and Hemofiltration (110.15). Also see the NCD for Ultrafiltration Monitor (230.14). (Accessed December 20, 2018)

3. **Period of Medical Necessity - Home Dialysis Equipment**

The following situations may occur causing temporary non-use of equipment:

- Beneficiary requires in-facility treatment for re-stabilization or as a result of some acute condition. The beneficiary is expected to return to home dialysis;
- Beneficiary is temporarily without a suitable home dialysis assistant;
- Beneficiary is away from home but expects to return; or
- Beneficiary is a transplant candidate and is taken off home dialysis preparatory to transplant. (If the transplant cannot occur, or if the transplant is not successful, the patient will very likely resume home dialysis and an evaluation can be made whether it will be within the immediate or foreseeable future.)

Under such circumstances, DME MACs, DME PSCs or ZPICs determine that medical necessity exists and pay for a period of up to 3 months after the month home dialysis equipment was last used. This does not eliminate the necessity for periodic reevaluation of medical necessity. It provides a tolerance to avoid frequent reevaluation in renal dialysis situations and provides for continuity of payments where economically advantageous.

See the Medicare Integrity Manual, Chapter 5, §5.10 - Period of Medical Necessity - Home Dialysis Equipment. (Accessed December 20, 2018)

### II DEFINITIONS

**Continuous Ambulatory Peritoneal Dialysis (CAPD):** A form of peritoneal dialysis that was developed as an alternative method of dialysis for home dialysis members. It is a continuous dialysis process that uses the member’s peritoneal membrane as a dialyzer and requires the implanting of an indwelling catheter to provide access to the peritoneum. Medicare Benefit Policy Manual, Chapter 11, §10 – Definitions Relating to ESRD. (Accessed December 20, 2018)

**Dialysis:** The process in which waste products are removed from the body by diffusion from one fluid compartment to another through a semi-permeable membrane. There are two types of renal dialysis procedures in common clinical usage: hemodialysis and peritoneal dialysis. Medicare Benefit Policy Manual, Chapter 11, §10 – Definitions Relating to ESRD. (Accessed December 20, 2018)

**End Stage Renal Disease (ESRD):** The final stage of kidney disease where kidney function is irreversible and permanent and requires a regular course of dialysis or a kidney transplantation to

**Hemodialysis:** The most widely used type of dialysis, hemodialysis filters the blood through a kidney machine, where wastes are removed before the blood is returned to the body. *Medicare Benefit Policy Manual, Chapter 11, §10 – Definitions Relating to ESRD.* (Accessed December 20, 2018)

**Home Dialysis:** Peritoneal dialysis or hemodialysis performed by an ESRD member after completion of an approved training program. *Medicare Benefit Policy Manual, Chapter 11, §10 – Definitions Relating to ESRD.* (Accessed December 20, 2018)

**Peritoneal Dialysis:** A type of dialysis where the filtering takes place within the member’s abdominal cavity without the blood leaving the body. There are 3 types of Peritoneal Dialysis: (1) Continuous Ambulatory Peritoneal Dialysis (CAPD); (2) Continuous Cycling Peritoneal Dialysis (CCPD) and (3) Intermittent Peritoneal Dialysis (IPD). *Medicare Benefit Policy Manual, Chapter 11, §10 – Definitions Relating to ESRD.* (Accessed December 20, 2018)

**Self-Dialysis:** Dialysis performed with little or no professional assistance by an ESRD member who has completed an appropriate training course. This treatment may be performed on an inpatient or outpatient basis. *Medicare Benefit Policy Manual, Chapter 11, §30.2 Home Dialysis Training.* (Accessed December 20, 2018)

### III. REFERENCES

See above

### IV. REVISION HISTORY

**04/01/2019** Updated policy introduction; added language to clarify:
- There are instances where [the Coverage Summary] may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG)
- In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*)

**01/15/2019** Annual review with the following updates:

**Guideline 2.c –**
- Updated language to reflect changes in Medicare Benefit Policy Manual, Chapter 11, §30.1.B -In-facility Dialysis Sessions Furnished to Home Patients Who Are Traveling from “Dialysis Furnished to Home Patients Who Are Traveling: Routine dialysis services may be covered when the member is temporarily absent from their the service area for a period of 6 months or less” to “Dialysis Furnished to Home Patients Who Are Traveling: Routine dialysis services may be covered when the member is temporarily absent from their service area.”
- Added reference link to the “*Medicare Claims Processing Manual, Chapter 8, §100 - Dialysis Sessions Furnished to Patients Who are Traveling*”.

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01/16/2018  Annual review; no updates.

01/17/2017  
- Guideline 1 - Dialysis
  - Updated language to reflect changes in the Medicare Benefit Policy Manual Pub.100-2, Chapter 11 - End Stage Renal Disease (ESRD), Section 10-Definitions Relating to ESRD by adding the verbiage “hemofiltration, ultrafiltration” and by replacing “dialysis center” with “ESRD Facility”
  - Updated CMS reference to include the section title “Section 10- Definitions Relating to ESRD”
- Guideline 2 a Examples of Covered Dialysis Services and Other Related Services – Removed reference to the Medicare Benefit Policy Manual Pub.100-2, Chapter 11 - End Stage Renal Disease (ESRD), Section 10 - Definitions Relating to ESRD (does not mention “acute dialysis”)
- Guideline 2.e Drugs and biologicals – Updated language to reflect changes in the Medicare Benefit Manual, Chapter 11- End Stage Renal Disease (ESRD) Section 20.3-20.3.1 - Drugs and Biologicals by adding the verbiage “used for the treatment of ESRD. For a comprehensive list of covered drugs and biologicals; see the” and removing “or home dialysis such as Epoetin, Heparin, and local anesthetics”
- Guideline 2.g – Water purification – Added CMS reference to the Medicare Benefit Policy Manual Chapter 11- End Stage Renal Disease (ESRD), Section 30.1 – Home Dialysis Items and Services
- Guideline 2.h - Medical Nutritional Therapy - Added CMS reference to the Medicare Benefit Policy Manual Chapter 11- End Stage Renal Disease (ESRD), Section 40 I – Nutritional Services and Services

01/19/2016  Annual review; no updates.

01/20/2015  Annual review with the following updates:
Guideline 1 [Dialysis (peritoneal and hemodialysis services)]
  - Added “and all medically necessary equipment and supplies used to furnish dialysis”
Guideline 2.a (Acute Dialysis)
  - Added reference link to the following:
    - Medicare Benefit Policy Manual, Chapter 1, Section 10 - Covered Inpatient Hospital Services Covered Under Part A
    - Medicare Claims Processing Manual, Chapter 4, Section 200.2 - Hospital Dialysis Services For Patients with and without End Stage Renal Disease (ESRD)
Guideline 2.b [CAPD (Continuous Ambulatory Peritoneal Dialysis) home dialysis support services]
  - Removed guideline; no longer in the referenced Medicare Benefit Policy Manual
• Retained Peridex CAPD Filter Set under Guideline 2.b

Guideline 2.c (Maintenance dialysis services)

• Removed language pertaining to maintenance dialysis services and supplies
  (language no longer in the referenced Medicare Benefit Policy Manual)

• Changed title to Dialysis Furnished to Home Patients who are Traveling

• Reference link updated

Guideline 2.d Laboratory tests

• Added reference link to the *Medicare Benefit Manual, Chapter 11- End Stage Renal Disease (ESRD)*, 20.2 – Laboratory Services

Guideline 3 (Period of Medical Necessity – Home Dialysis Equipment

• Added to Guideline Section (from the Definition section)

Definitions

• Added reference link to the definition of:
  
  o Continuous Ambulatory Peritoneal Dialysis (CAPD) (*Medicare Benefit Policy Manual Pub.100-2, Chapter 11 - End Stage Renal Disease (ESRD), Section 10 – Definitions Relating to ESRD*)
  
  o Dialysis (*Medicare Benefit Policy Manual Pub.100-2, Chapter 11 - End Stage Renal Disease (ESRD), Section 10 – Definitions Relating to ESRD*)
  
  o End Stage Renal Disease (ESRD (CMS.gov on End-Stage Renal Disease )
  
  o Hemodialysis (*Medicare Benefit Policy Manual Pub.100-2, Chapter 11 - End Stage Renal Disease (ESRD), Section 10 – Definitions Relating to ESRD*)
  
  o Home Dialysis (*Medicare Benefit Policy Manual Pub.100-2, Chapter 11 - End Stage Renal Disease (ESRD), Section 10 – Definitions Relating to ESRD*)
  
  o Peritoneal Dialysis (*Medicare Benefit Policy Manual Pub.100-2, Chapter 11 - End Stage Renal Disease (ESRD), Section 10 – Definitions Relating to ESRD*)
  
  o Self-Dialysis (*Medicare Benefit Manual Chapter 11- End Stage Renal Disease (ESRD), Section -30.2 Home Dialysis Training*)

• Removed the definition of:
  
  o Maintenance Dialysis (No CMS reference available)
  
  o Medical Nutritional Therapy (No CMS reference available)
  
  o Nutritional Professional (Not used within this policy)
  
  o Peritoneal Membrane (Not used within this policy)
  
  o Renal Disease (Not used within this policy)
  
  o Routine Laboratory Tests (Defined in detail in the referenced NCD)

• Moved the definition of Period of Medical Necessity Home Dialysis Equipment to the Guideline section

02/18/2014 Annual review; no updates.

06/24/2013 Guidelines #2.a (Acute Dialysis) - Added applicable coverage language (new to policy)

02/19/2013 Annual review; no updates.

02/27/2012 Annual review; no updates.

02/21/2011 Annual review; no updates.