WATER PURIFICATION AND SOFTENING SYSTEMS USED IN CONJUNCTION WITH HOME DIALYSIS (NCD 230.7)

Guideline Number: MPG351.04
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POLICY SUMMARY

Overview

Water Purification Systems

Water used for home dialysis should be chemically free of heavy trace metals and/or organic contaminants which could be hazardous to the patient. It should also be as free of bacteria as possible but need not be biologically sterile. Since the characteristics of natural water supplies in most areas of the country are such that some type of water purification system is needed, such a system used in conjunction with a home dialysis (either peritoneal or hemodialysis) unit is covered by UnitedHealth Care.

There are two types of water purification systems which will satisfy these requirements:

- **Deionization** - The removal of organic substances, mineral salts of magnesium and calcium (causing hardness), compounds of fluoride and chloride from tap water using the process of filtration and ion exchange; or
- **Reverse Osmosis** - The process used to remove impurities from tap water utilizing pressure to force water through a porous membrane

Use of both a deionization unit and reverse osmosis unit in series, theoretically to provide the advantages of both systems, has been determined medically unnecessary since either system can provide water which is both chemically and bacteriologically pure enough for acceptable use in home dialysis. In addition, spare deionization tanks are not covered since they are essentially a precautionary supply rather than a current requirement for treatment of the patient.

Activated carbon filters used as a component of water purification systems to remove unsafe concentrations of chlorine and chloramines are covered when prescribed by a physician.

Water Softening System

Except as indicated below, a water softening system used in conjunction with home dialysis is excluded from coverage as not being reasonable and necessary within the meaning of §1862(a)(1) of the Act. Such a system, in conjunction with a home dialysis unit, does not adequately remove the hazardous heavy metal contaminants (such as arsenic) which may be present in trace amounts.

A water softening system may be covered when used to pretreat water to be purified by a reverse osmosis (RO) unit for home dialysis where:

- The manufacturer of the RO unit has set standards for the quality of water entering the RO (e.g., the water to be purified by the RO must be of a certain quality if the unit is to perform as intended);
- The patient's water is demonstrated to be of a lesser quality than required; and
- The softener is used only to soften water entering the RO unit, and thus, used only for dialysis. (The softener need not actually be built into the RO unit, but must be an integral part of the dialysis system.)
Developing Need When a Water Softening System is Replaced with a Water Purification Unit in an Existing Home Dialysis System

The medical necessity of water purification units must be carefully developed when they replace water softening systems in existing home dialysis systems. A purification system may be ordered under these circumstances for a number of reasons. For example, changes in the medical community’s opinions regarding the quality of water necessary for safe dialysis may lead the physician to decide the quality of water previously used should be improved, or the water quality itself may have deteriorated. Patients may have dialyzed using only an existing water softener previous to ESRD coverage because of inability to pay for a purification system. On the other hand, in some cases, the installation of a purification system is not medically necessary. Supporting documentation, such as the supplier’s recommendations or water analysis, may be required.

Guidelines

Cross Reference: See the Medicare Benefit Policy Manual, Chapter 15 §110.

Applicable Codes

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

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tr>
<td>A4680</td>
<td>Activated carbon filter for hemodialysis, each</td>
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<tr>
<td>E1610</td>
<td>Reverse osmosis water purification system, for hemodialysis</td>
</tr>
<tr>
<td>E1615</td>
<td>Deionizer water purification system, for hemodialysis</td>
</tr>
<tr>
<td>E1625</td>
<td>Water softening system, for hemodialysis</td>
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Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

References

CMS National Coverage Determinations (NCDs)

NCD 230.7 Water Purification and Softening Systems Used in Conjunction with Home Dialysis

CMS Benefit Policy Manual

Chapter 11 End Stage Renal Disease
Chapter 15; § 110 Covered Medical and Other Health Services

CMS Transmittals

Transmittal 171, Change Request 8261, Dated 06/07/2013 (Implementation of the End Stage Renal Disease (ESRD) Prospective Payment System (PPS))
Transmittal 2455, Change Request 7762, Dated 04/26/2012 (Hospital Dialysis Services for Patients with and without End Stage Renal Disease (ESRD))

MLN Matters

Article MM8120, Implementation of Changes in the End-Stage Renal Disease Prospective Payment System (ESRD PPS) for Calendar Year (CY) 2013
GUIDELINE HISTORY/REVISION INFORMATION

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

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<th>Date</th>
<th>Action/Description</th>
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<tr>
<td>04/01/2019</td>
<td>• Reorganized policy template; relocated Terms and Conditions and Purpose section</td>
</tr>
<tr>
<td>12/12/2018</td>
<td>• Annual review</td>
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TERMS AND CONDITIONS

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

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 member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use and distribution of this information are strictly prohibited.

*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.