Pleural Catheter Kits

For any item to be covered by The Health Plan, it must:

1. Be eligible for a defined Medicare or The Health Plan benefit category
2. Be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member
3. Meet all other applicable Medicare and/or The Health Plan statutory and regulatory requirements

For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity. Please refer to individual product lines certificates of coverage for possible exclusions of benefit.

For an item to be covered by The Health Plan, the supplier must receive a written, signed, and dated order before a claim is submitted to The Health Plan. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not reasonable and necessary.

Suppliers are to follow The Health Plan requirements for precertification as applicable.

Pleural catheter kits require precertification.

Items listed in this policy that are provided without first obtaining authorization may be denied for no precertification.

<table>
<thead>
<tr>
<th>CMS National Coverage Policy</th>
<th>None</th>
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<tbody>
<tr>
<td>DME Region LCD Covers</td>
<td>None</td>
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<tr>
<td>Effective Date</td>
<td>For service performed on or after 01/01/13</td>
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<tr>
<td>Revision/Review Date</td>
<td>07/01/17, 07/01/16, 02/01/15, 10/31/13</td>
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<tr>
<td>The Health Plan</td>
<td>The Health Plan criteria</td>
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DESCRIPTION

A tunneled drainage catheter has been successfully used for a long-term management of malignant pleural effusion. Tunneled drainage catheters have several advantages over other treatment options. Tunneled drainage catheter placement is safe, comfortable, and less expensive. It makes long-term outpatient management of symptoms caused by effusion and ascites possible.

COVERAGE GUIDELINES

The PLEURX was approved by the United States Food and Drug Administration in 1997 for the management of malignant pleural effusions.

1. The Centers for Medicare & Medicaid Services (CMS) has determined that the pleural catheter can be covered as a prosthetic device. CMS has determined that Pleurx pleural catheters are implanted prostheses.
2. Items in the drainage kit include vacuum drainage bottle and tubing, gauze, wound clamp and cup, gloves, evacuated bottle, foam catheter pad, valve cap, slide clamp, self-adhesive dressing, and CSR wrap.
3. HCPCS codes currently exist for some of the supplies (e.g., gauze, dressing, gloves), but some carriers may have these codes and the miscellaneous code A4649 set up in their systems. The Health Plan is using the following HCPCS code designation for pleural catheter supplies.

**CODING INFORMATION**

<table>
<thead>
<tr>
<th>COVERED DIAGNOSIS CODES</th>
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<tbody>
<tr>
<td>J90.0-J91.8 PLEURAL EFFUSION</td>
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<tr>
<td>R18.0 MALIGNANT ASCITES</td>
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<table>
<thead>
<tr>
<th>COVERED HCPCS CODES</th>
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<tr>
<td>A7048 VACUUM BOTTLE WITH DRAINAGE LINE, 500 ML</td>
</tr>
<tr>
<td>A4649 PLEURX DRAINAGE KITS- COME 10 PER CASE. 500 ML VACUUM BOTTLE, INCLUDES GAUZE PADS, ALCOHOL PADS, AND PAIR OF GLOVES</td>
</tr>
</tbody>
</table>

The provider should bill for a case of 10 bottles. The case includes some small accessories that are required to properly use the drainage kits, and this is how the manufacturer designs the product, and how doctors should prescribe. **Very rarely should additional supplies be requested or billed separately from the kit.**

For West Virginia Medicaid members the provider needs to bill A4649 for the kit. Do not bill A7048 as code A7048 is on the Non-Covered list. The vacuum bottle must be included and billed as a kit.

**DOCUMENTATION REQUIREMENTS**

For the purposes of this policy, it is expected that the medical record will support the need for the care provided. It is generally understood that the medical record includes the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports.

This documentation must be available with precertification.

Medicare has made changes to its requirements for dispensing orders, detailed written orders, and proof of delivery. The Health Plan will require the following:

1. Physician detailed written order. Order must include the following:
   a. Member’s name
   b. Date
   c. Order must include item being requested
   d. Order must include diagnosis code
   e. Physician signature with date. Date stamps are not appropriate
2. There must be documentation in the supplier’s records to support the medical necessity of that type of device. This information must be available upon request usually with precertification per The Health Plan policy. Documentation should include information as to the severity of the effusion, or ascites, frequency, past treatment and outcomes, and expected outcome with treatment.

3. Proof of delivery to be kept on file by the provider of the item.

**Note:** If templates or forms are submitted, (i.e., a Medicare Certificate of Medical Necessity, and/or a provider created form), The Health Plan reserves the right to request the medical record, that may include, but not limited to, the physician office notes, hospital and nursing facility records, and home health records.

**Note:** Template provider forms, prescriptions, and attestation letters are not considered part of the medical record, even if signed by the ordering physician. Information from the member’s medical record and the supplier must be available upon request.

**NOTE:** Providers may be held financially responsible if they furnish the above items without notifying the member, verbally and in writing, that the specific service being provided is not covered. This must be done prior to the dispensing of the device. The provider must submit the waiver or Advanced Beneficiary Notification (ABN) to The Health Plan with the claim showing the member agreed to pay for the device. Generalized statements on waivers or an ABN are not acceptable.

**KX, GA, and GZ MODIFIERS**

Suppliers may submit a claim with a KX modifier only if all the criteria for that item are met.

If the coverage criteria are not met, the GA or GZ modifier must be used. When there is an expectation of a medical denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN.

**ADVANCED BENEFICIARY NOTICE**

The Health Plan expects providers to follow the Medicare policy on ABN across all Medicare, Medicaid, and Commercial plans.

The Health Plan expects providers to follow the Medicare policy on the ABN with the Medicare Advantage/Med Select population and member’s where Medicare is primary and a The Health Plan Commercial plan is secondary.

**NOTE:** Providers may be held financially responsible if they furnish the above items without notifying the member, verbally and in writing, that the specific service being provided is not covered. This must be done prior to the dispensing of the device. The provider must submit the waiver or ABN to The Health Plan with the claim showing the member agreed to pay for the device. Generalized statements on waivers or ABN are not acceptable.
PRICING, DATA ANALYSIS, AND CODING (PDAC)

The Health Plan has implemented use of Medicare’s PDAC contractor for review of authorizations. Suppliers should contact the PDAC contractor for guidance on the correct coding of these items. 
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INTERNET LINKS AND SOURCES


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The Health Plan Provider Procedural Manual. Payment Voucher, Section 14, Page 11