Respiratory Assist Devices

Adopted from National Government Services website

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.

Respiratory assist devices require precertification and a physician face-to-face.

<table>
<thead>
<tr>
<th>CMS National Coverage Policy</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>DME Region LCD Covers</td>
<td>CGS Administrators, LLC Jurisdiction B and C</td>
</tr>
<tr>
<td>Revision/Review Effective Date</td>
<td>For service performed on or after 10/31/13</td>
</tr>
<tr>
<td></td>
<td>Reviewed/Revised: 07/01/17, 07/01/16, 10/01/15</td>
</tr>
<tr>
<td>The Health Plan</td>
<td>Will follow Coverage Determination posted on the CGS website across all lines of business unless otherwise indicated in sections of this policy, contractual agreements, or benefit documents.</td>
</tr>
</tbody>
</table>

DESCRIPTION

Respiratory assist devices (RAD) (BIPAP) provide administration of positive air pressure, using a nasal and/or oral mask interface that creates a seal, therefore avoiding the need to use more invasive interventions, i.e., tracheotomy.
COVERAGE GUIDELINES

INITIAL COVERAGE CRITERIA FOR E0470 and E0471 DEVICES FOR THE FIRST TWO MONTHS OF THERAPY:

For an E0470 or an E0471 RAD to be covered, the treating physician must perform a face-to-face and document symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc. Providers are expected to provide the correct testing required with precertification.

See Positive Airway Pressure policy and Oxygen policy for appropriate sleep testing requirements for member’s with OSA.

A RAD (E0470, E0471) is covered for the clinical disorder groups characterized as (I) restrictive thoracic disorders (i.e., progressive neuromuscular diseases or severe thoracic cage abnormalities), (II) severe chronic obstructive pulmonary disease (COPD), or (III) central sleep apnea (CSA), or complex sleep apnea (Comp SA), or (IV) hypoventilation syndrome, who meet the following criteria:

I. Restrictive Thoracic Disorders:

An E0470 or E0471 device is covered when criteria A - C are met:

A. There is a diagnosis documented in the medical record of a progressive neuromuscular disease (e.g., amyotrophic lateral sclerosis) or a severe thoracic cage abnormality (e.g., post thoracoplasty for TB), and

B. One of the following:
   1. An arterial blood gas PaCO2, done while awake and breathing the member’s usual FIO2 is greater than or equal to 45 mm Hg, or
   2. Sleep oximetry demonstrates oxygen saturation less than or equal to 88 percent for at least five minutes of nocturnal recording time (minimum recording time of two hours), done while breathing the member’s prescribed recommended FIO2, or
   3. For a neuromuscular disease (only), maximal inspiratory pressure is less than 60 cm H20 or forced vital capacity is less than 50 percent predicted.

C. COPD does not contribute significantly to the pulmonary limitation.

The Health Plan will authorize two initial months for either E0740 or E0471 if criteria is met. The above information is to be submitted with precertification.

If all of the above criteria are not met, then E0470 or E0471 and related accessories will be denied as not meeting coverage guidelines.

II. Severe COPD:

An E0740 device is covered if criteria A - C are met:

A. An arterial blood gas PaCO2, done while awake and breathing the member’s usual FIO2, is greater than or equal to 52 mm Hg, and
B. Sleep oximetry demonstrates oxygen saturation less than or equal to 88 percent for at least five minutes, done while breathing oxygen at 2 LPM or the member’s usual FIO2 (whichever is higher), and

C. Prior to initiating therapy, OSA and treatment with continuous positive airway pressure device (CPAP) has been considered and ruled out. See positive airway pressure policy for those guidelines.

**Note:** The 5 minutes does not have to be consecutive. The minimum recording time does have to be at least 2 hours.

**Note:** No facility testing required if there is sufficient documentation in the medical record that the member does not have some form of sleep apnea. This information must be submitted with precertification if no facility testing was performed.

The Health Plan will authorize two initial months for E0470 if all the above criteria met. If all of the above criteria are not met, E0470 and related accessories will be denied as not meeting coverage guidelines.

**See Positive Airway Pressure and Oxygen Policies for coverage of concurrent oxygen with BIPAP.**

An **E0471** device will be covered for a patient with **COPD** in either of the two situations below, depending on the testing performed to demonstrate the need.

**Situation 1.** Member who qualified for an E0470 device, an E0471 started any time after a period of initial use of an E0470 device is covered if both criteria A and B are met:

A. An arterial blood gas PaCO2, done while awake and breathing the member’s prescribed FIO2, shows that the PaCO2 worsens ≥ 7 mm HG compared to the original result from criterion A, (above).

B. A facility-based PSG demonstrates oxygen saturation ≤88 percent for ≥ 5 minutes of nocturnal recording time (minimum recording time of two hours) while using an E0470 device that is not caused by obstructive upper airway events, i.e. AHI < 5.

**Situation 2.** Member who qualified for an E0470 device, an E0471 device will be covered if, at a time no sooner than 61 days after initial issue of the E0470 device, both of the following criteria **A and B** are met:

A. An arterial blood gas PaCO2 is done while awake and breathing the member’s prescribed FIO2, still remains ≥ 52 mm Hg.

B. Sleep oximetry while breathing with the E0470 device, demonstrates oxygen saturation ≤ 88 percent for ≥ five minutes of nocturnal recording time (minimum recording time of two hours), done while breathing oxygen at 2 LPM or the member’s prescribed FIO2 [whichever is higher].

If E0471 is billed but the criteria in either situation 1 or 2 are not met, it will be denied as not meeting coverage guidelines.
III. Central Sleep Apnea or Complex Sleep Apnea:

An E0470 or E0471 device is covered when, prior to initiating therapy, a complete facility-based, attended PSG is performed documenting the following: (A and B)

A. The diagnosis of CSA or CompSA 2 and
B. Significant improvement of the sleep-associated hypoventilation with the use of an E0470 or E0471 device on the settings that will be prescribed for initial use at home, while breathing the member’s prescribed FIO2.

If all of the above criteria are met, either an E0470 or an E0471 device will be covered for patients with documented CSA or CompSA for the first 2 months of therapy.

If all of the above criteria are not met, then E0470 or E0471 and related accessories will be denied as not meeting coverage guidelines.

IV. Hypoventilation Syndrome:

An E0470 device is covered if criteria 1, 2, and either 3 or 4 are met.

1. An initial arterial blood gas PaCO2, done while awake and breathing the member’s prescribed FIO2, is ≥ 45 mm Hg.
2. Spirometry shows an FEV1/FVC ≥ 70 percent.  
   (Refer to II. SEVERE COPD (above) for information about device coverage for members with FEV1/FVC < 70 percent).
3. Arterial blood gas PaCO2, done during sleep or immediately upon awakening, and breathing the member’s prescribed FIO2, shows the member’s PaCO2 worsened ≥ 7 mm Hg compared to the original result in criterion 1 (above).
4. A facility-based PSG demonstrates oxygen saturation ≤ 88 percent for ≥ five minutes of nocturnal recording time (minimum recording time of two hours) that is not caused by obstructive upper airway events – i.e., AHI < 5.

If the above criteria are not met, E0470 and related accessories will be denied as not meeting coverage guidelines.

An E0471 device is covered for a patient with hypoventilation syndrome if criteria A, B, and either C or D are met:

A. A covered E0470 device is being used.
B. Spirometry shows an FEV1/FVC ≥ 70 percent.  
   (Refer to II. SEVERE COPD (above) for information about device coverage for patients with FEV1/FVC < 70 percent).
C. An arterial blood gas PaCO2, done while awake, and breathing the member’s prescribed FIO2, shows that the member’s PaCO2 worsens ≥ 7 mm Hg compared to the ABG result performed to qualify the member for the E0470 device.
D. A facility-based PSG demonstrates oxygen saturation ≤ 88 percent for ≥ five minutes of nocturnal recording time (minimum recording time of two hours) that is not caused by obstructive upper airway events (i.e., AHI < 5) while using an E0470 device.
If the criteria above are not met, an E0471 device will be denied as not meeting coverage guidelines.

CONTINUED COVERAGE CRITERIA FOR E0470 AND E0471 DEVICES BEYOND THE FIRST TWO MONTHS OF THERAPY

The Health Plan requests that the member be contacted near the 30th day and before the 60th day after initiation of RAD to assess for issues/problems with accessories (i.e., mask, and/or the device itself). The Health Plan will base a decision to continue coverage beyond this time based on the information submitted by the provider. The Health Plan may authorize an additional 30 days to re-evaluate compliance by the 90th day. The Health Plan advises that the member follow up with their physician within the trial period. The Health Plan will not continue coverage beyond the trial period unless this re-evaluation and the member’s compliance report are submitted for review.

**Note:** The provider is responsible to address compliance issues prior to the 61st day, as the device will not be capped until compliance is shown. Only one additional month to complete the 90-day trial period would be authorized if the member is not compliant within the first 2 trial months. If the member continues to show non-compliance, the device may not be authorized for succeeding months.

Compliance is shown as usage \( \geq 4 \) hours a night per 24 hours over 30 consecutive days. There must be documentation in the medical record about the progress of relevant symptoms and usage of the device up to that time. Failure to be consistently using the E0470 or E0471 device for an average of four hours per 24-hour period by the end of the three month trial period would represent noncompliant utilization for the intended purposes and expectations of benefit of this therapy. The Health Plan would deny continued coverage as not meeting the required compliance guidelines.

**REPLACEMENT**

If a RAD device is replaced during the five year RUL because of loss, theft, or irreparable damage due to a specific incident, there is no requirement for a new clinical evaluation, sleep test, or trial period.

If a RAD device is replaced following the five year RUL, there must be a face-to-face evaluation by their treating physician that documents that the beneficiary continues to use and benefit from the RAD device. There is no requirement for a new sleep test or trial period.

Replacement of a RAD prior to completion of five-year RUL for wear and tear is not covered. The Health Plan will reimburse repairs up to cost of machine but not replacement of the machine, in accordance with Medicare guidelines.

A precertification would be required in both situations.

**NONCOVERAGE STATEMENT**

Services of a respiratory therapist are not covered under the DME benefit.

For the purpose of this policy, the arterial blood gas, sleep oximetry study or polysomnogram may not be performed by a DME supplier. A DME supplier is not considered a qualified provider or supplier of these tests for purposes of this policy’s coverage and payment guidelines. This prohibition does not extend to the results of studies conducted by hospitals certified to do such tests.
If there is discontinuation of usage of an E0470 or E0471 device at any time, the supplier is expected to ascertain this, and stop billing for the equipment and related accessories and supplies.

A bi-level positive airway pressure device with back-up rate (E0471) is not medically necessary if the primary diagnosis is OSA. If E0471 is billed and primary diagnosis is OSA, it will be denied as not meeting coverage guidelines.

A liner is a device which is placed between the patient’s skin and the PAP mask interface. Liners used with a PAP mask are made of cloth, silicone or other materials. A liner used in conjunction with a PAP mask is considered a comfort/convenience item.

Ventilators described by codes E0450, E0460-E0466 are not covered when used for conditions described in this policy. Please refer to The Health Plan’s Ventilator policy for coverage guidelines.

**CODING INFORMATION**

CPT/HCPCS codes: The appearance of a code in this section does not necessarily indicate coverage.

### HCPCS MODIFIERS

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>EY</td>
<td>NO PHYSICIAN OR OTHER LICENSED HEALTH CARE PROVIDER ORDER FOR THIS ITEM OR SERVICE</td>
</tr>
<tr>
<td>GA</td>
<td>WAIVER OF LIABILITY STATEMENT ISSUED AS REQUIRED BY PAYOR POLICY, INDIVIDUAL CASE.</td>
</tr>
<tr>
<td>GZ</td>
<td>ITEM OR SERVICE EXPECTED TO BE DENIED AS NOT REASONABLE AND NECESSARY</td>
</tr>
<tr>
<td>KX</td>
<td>REQUIREMENTS SPECIFIED IN THE MEDICAL POLICY HAVE BEEN MET</td>
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### HCPCS CODES

#### EQUIPMENT

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>E0470</td>
<td>RESPIRATORY ASSIST DEVICE, BI-LEVEL PRESSURE CAPABILITY, WITHOUT BACKUP RATE FEATURE, USED WITH NONINVASIVE INTERFACE, E.G., NASAL OR FACIAL MASK (INTERMITTENT ASSIST DEVICE WITH CONTINUOUS POSITIVE AIRWAY PRESSURE DEVICE)</td>
</tr>
<tr>
<td>E0471</td>
<td>RESPIRATORY ASSIST DEVICE, BI-LEVEL PRESSURE CAPABILITY, WITH BACK-UP RATE FEATURE, USED WITH NONINVASIVE INTERFACE, E.G., NASAL OR FACIAL MASK (INTERMITTENT ASSIST DEVICE WITH CONTINUOUS POSITIVE AIRWAY PRESSURE DEVICE)</td>
</tr>
</tbody>
</table>
## HCPCS CODES

### ACCESSORIES

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A4604</td>
<td>TUBING WITH INTEGRATED HEATING ELEMENT FOR USE WITH POSITIVE AIRWAY PRESSURE DEVICE</td>
</tr>
<tr>
<td>A7027</td>
<td>COMBINATION ORAL/NASAL MASK, USED WITH CONTINUOUS POSITIVE AIRWAY PRESSURE DEVICE, EACH</td>
</tr>
<tr>
<td>A7028</td>
<td>ORAL CUSHION FOR COMBINATION ORAL/NASAL MASK, REPLACEMENT ONLY, EACH</td>
</tr>
<tr>
<td>A7029</td>
<td>NASAL PILLOWS FOR COMBINATION ORAL/NASAL MASK, REPLACEMENT ONLY, PAIR</td>
</tr>
<tr>
<td>A7030</td>
<td>FULL FACE MASK USED WITH POSITIVE AIRWAY PRESSURE DEVICE, EACH</td>
</tr>
<tr>
<td>A7031</td>
<td>FACE MASK INTERFACE, REPLACEMENT FOR FULL FACE MASK, EACH</td>
</tr>
<tr>
<td>A7032</td>
<td>CUSHION FOR USE ON NASAL MASK INTERFACE, REPLACEMENT ONLY, EACH</td>
</tr>
<tr>
<td>A7033</td>
<td>PILLOW FOR USE ON NASAL CANNULA TYPE INTERFACE, REPLACEMENT ONLY, PAIR</td>
</tr>
<tr>
<td>A7034</td>
<td>NASAL INTERFACE (MASK OR CANNULA TYPE) USED WITH POSITIVE AIRWAY PRESSURE DEVICE, WITH OR WITHOUT HEAD STRAP</td>
</tr>
<tr>
<td>A7035</td>
<td>HEADGEAR USED WITH POSITIVE AIRWAY PRESSURE DEVICE</td>
</tr>
<tr>
<td>A7036</td>
<td>CHINSTRAP USED WITH POSITIVE AIRWAY PRESSURE DEVICE</td>
</tr>
<tr>
<td>A7037</td>
<td>TUBING USED WITH POSITIVE AIRWAY PRESSURE DEVICE</td>
</tr>
<tr>
<td>A7038</td>
<td>FILTER, DISPOSABLE, USED WITH POSITIVE AIRWAY PRESSURE DEVICE</td>
</tr>
<tr>
<td>A7039</td>
<td>FILTER, NON DISPOSABLE, USED WITH POSITIVE AIRWAY PRESSURE DEVICE</td>
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<tr>
<td>A7044</td>
<td>ORAL INTERFACE USED WITH POSITIVE AIRWAY PRESSURE DEVICE, EACH</td>
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<tr>
<td>A7045</td>
<td>EXHALATION PORT WITH OR WITHOUT SWIVEL USED WITH ACCESSORIES FOR POSITIVE AIRWAY DEVICES, REPLACEMENT ONLY</td>
</tr>
<tr>
<td>A7046</td>
<td>WATER CHAMBER FOR HUMIDIFIER, USED WITH POSITIVE AIRWAY PRESSURE DEVICE, REPLACEMENT, EACH</td>
</tr>
<tr>
<td>E0561</td>
<td>HUMIDIFIER, NON-HEATED, USED WITH POSITIVE AIRWAY PRESSURE DEVICE</td>
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<tr>
<td>E0562</td>
<td>HUMIDIFIER, HEATED, USED WITH POSITIVE AIRWAY PRESSURE DEVICE</td>
</tr>
</tbody>
</table>

Diagnoses and ICD-10 codes that are covered if criteria above are met. Not an all-inclusive list.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>B91, G14</td>
<td>LATE EFFECTS OF ACUTE POLIOMYELITIS</td>
</tr>
<tr>
<td>G47.31</td>
<td>PRIMARY CENTRAL SLEEP APNEA</td>
</tr>
<tr>
<td>G47.33</td>
<td>OBSTRUCTIVE SLEEP APNEA (ADULT) (PEDIATRIC)</td>
</tr>
<tr>
<td>G47.37</td>
<td>CENTRAL SLEEP APNEA IN CONDITIONS CLASSIFIED ELSEWHERE</td>
</tr>
<tr>
<td>ICD-10 Code Range</td>
<td>Description</td>
</tr>
<tr>
<td>---------------------------</td>
<td>--------------------------------------------------------------</td>
</tr>
<tr>
<td>G12.0-G12.9</td>
<td>ANTERIOR HORN CELL DISEASE</td>
</tr>
<tr>
<td>G54.0-G54.9</td>
<td>NERVE ROOT AND PLEXUS DISORDERS</td>
</tr>
<tr>
<td>G72.9</td>
<td>MYONEURAL DISORDERS, MUSCULAR DYSTROPHIES, AND OTHER MYOPATHIES</td>
</tr>
<tr>
<td>J40-J43.9, J44.9-J47.9</td>
<td>CHRONIC OBSTRUCTIVE PULMONARY DISEASE AND ALLIED CONDITIONS</td>
</tr>
<tr>
<td>J96.00, J96.90-J98.4</td>
<td>OTHER DISEASES OF LUNG</td>
</tr>
<tr>
<td>J39.8, J98.09</td>
<td>OTHER DISEASES OF TRACHEA AND BRONCHUS [TRACHEOMALACIA]</td>
</tr>
<tr>
<td>M41.20-M41.80, M41.9</td>
<td>KYPHOSCOLIOSIS AND SCOLIOSIS</td>
</tr>
<tr>
<td>M95.4</td>
<td>ACQUIRED DEFORMITY OF CHEST AND RIB</td>
</tr>
<tr>
<td>Q31.1-Q31.3, Q31.8-Q32.4</td>
<td>OTHER CONGENITAL ANOMALY OF LARYNX, TRACHEA, AND BRONCHUS [TRACHEOMALACIA]</td>
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<tr>
<td>R06.81</td>
<td>APNEA</td>
</tr>
<tr>
<td>R06.00-R06.89</td>
<td>OTHER DYSPNEA AND RESPIRATORY ABNORMALITIES</td>
</tr>
<tr>
<td>R09.02</td>
<td>HYPOXEMIA</td>
</tr>
<tr>
<td>S14.1095, S24.1095-S34.1095, S34.1395, S14.2XX5-S34.9XX5</td>
<td>LATE EFFECT OF SPINAL CORD INJURY OR INJURY TO NERVE ROOT(S), SPINAL PLEXUS(ES), AND OTHER NERVES OF TRUNK</td>
</tr>
<tr>
<td>G47.01-G47.36, G47.39-G47.8</td>
<td>ORGANIC SLEEP DISORDERS (OTHER THAN CENTRAL AND OBSTRUCTIVE)</td>
</tr>
<tr>
<td>G47.9-G47.8</td>
<td>SLEEP DISTURBANCES</td>
</tr>
</tbody>
</table>

The presence of an ICD-10 code listed in above section is not sufficient by itself to assure coverage.

**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. Description of item. The medical record must contain the information that supports the request for each item, and must be submitted with the precertification, if the item requires precertification, or with the claim, if no precertification was required.

d. Order must include diagnosis code

e. Physician signature with date. Date stamps are not appropriate.

f. Quantity of items required and duration: A new order is required if there is an increase in the quantity of the supply used per month and/or the type of supply used.

The supplier is to contact The Health Plan in this instance to update referral.

2. There must be documentation in the supplier’s records to support the medical necessity of that item. This information must be available upon request usually with precertification per The Health Plan policy.

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

Physicians shall document the face-to-face clinical evaluations and re-evaluations in a detailed narrative note in their charts in the format that they use for other entries. For the initial evaluation, the report should document pertinent information.

The Health Plan will accept the following items of documentation submitted by the supplier for continued coverage:

1. A signed and dated statement completed by the treating physician no sooner than 61 days after initiating use of the device, declaring that the patient is compliantly using the device (an average of four hours per 24-hour period) and that the member is benefiting from its use, or

2. The computer readout from the machine itself and a statement from the member certifying that the submitted readout is correct. This is the preferred method of determining machine usage compliance and providers may be asked to submit this in certain cases, even if physician statement provided. (If RAD is being used for OSA the computer download is required.)
RESPIRATORY ASSIST DEVICES

RAD DEVICES PROVIDED TO A MEMBER WHILE IN A PART A FACILITY STAY

Reimbursement for a RAD provided to a member while the member is covered in a Part A facility is based on specific contract information with the individual facility. RAD therapy is usually included in the per diem for Part A facilities.

NEW MEMBER’S WITH EXISTING RAD

For those members who are new to The Health Plan but are in a current rental period through their previous insurance, The Health Plan requires a review of testing done, compliance download, and the face-to-face visit with physician that qualified the member for the device.

The Health Plan will reimburse the remainder of The Health Plan’s rental period up to the contracted purchase amount of the device.

BILLING GUIDELINES

ACCESSORIES

Accessories are separately reimbursable when used with E0470 or E0471.

Accessories should be authorized initially with device. Once the RAD has been capped out, the supplies do not require authorization and will be reimbursed per the chart below.

Precertification is required if providing supplies greater than the allowable.

Initial precertification is required for supplies if the member obtained the machine his/herself, or with another insurer, as The Health plan would have no record of the device being authorized or that the member met criteria for the device.

The following table represents the usual maximum amount of accessories expected to be medically necessary:

<table>
<thead>
<tr>
<th>ACCESSORY</th>
<th>MAXIMUM AMOUNT</th>
<th>ACCESSORY</th>
<th>MAXIMUM AMOUNT</th>
</tr>
</thead>
<tbody>
<tr>
<td>A4604</td>
<td>1 per 3 months</td>
<td>A7034</td>
<td>1 per 3 months</td>
</tr>
<tr>
<td>A7027</td>
<td>1 per 3 months</td>
<td>A7035</td>
<td>1 per 6 months</td>
</tr>
<tr>
<td>A7028</td>
<td>2 per 1 month</td>
<td>A7036</td>
<td>1 per 6 months</td>
</tr>
<tr>
<td>A7029</td>
<td>2 per 1 month</td>
<td>A7037</td>
<td>1 per 3 month</td>
</tr>
<tr>
<td>A7030</td>
<td>1 per 3 months</td>
<td>A7038</td>
<td>2 per 1 month</td>
</tr>
<tr>
<td>A7031</td>
<td>1 per 1 month</td>
<td>A7039</td>
<td>1 per 6 months</td>
</tr>
<tr>
<td>A7032</td>
<td>2 per 1 month</td>
<td>A7046</td>
<td>1 per 6 months</td>
</tr>
<tr>
<td>A7033</td>
<td>2 per 1 month</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Precertification is required when billing for quantities of supplies greater than those described in this policy as the usual maximum amounts. There must be a clear medical reason supported and documented by the physician’s record, and submitted to The Health Plan for review.
Liners are not interfaces for use with a PAP mask. They should be billed A9270 (non covered item or service). They should not be billed as replacement features of a PAP mask such as A7031 (face mask interface, replacement for full face mask, each) or A7032 (cushion for use on nasal mask interface, replacement only, each). There is no additional payment for liners used with a PAP mask.

Code A7033 is used for a replacement nasal cannula-type interface. This interface extends a short distance into the nostrils. The unit of service for this code is “pair”. For some products, there are two physically separate cushions or “pillows” – one for each nostril. Two cushions/pillows equal one unit of service of A7033. For other products, the interface is a single piece with two protrusions that extend into the nostrils. One of these interfaces equals one unit of service of A7033.

Please note that code E0472 was removed from the RAD policy in 2008- do not bill accessories (A7027, A7028, A7029, A7030, A7031, A7032, A7033, A7034, A7035, A7036, A7044) for noninvasive interfaces with this base code.

**DISPENSING SUPPLIES**

A beneficiary or their caregiver must specifically request refills of PAP accessories before they are dispensed. The supplier must not automatically dispense a quantity of supplies on a predetermined regular basis, even if the beneficiary has "authorized" this in advance. The Health Plan is following Medicare guidelines for supplies provided on a reoccurring basis:

Providers are required to contact members prior to dispensing supplies and or medications, and not automatically ship supplies. Contact with member must not take place prior to 14 calendar days of delivery and delivery is to be no sooner than 10 calendar days of end of usage. (Refer to the CMS Program Integrity Manual, Internet-Only Manual, CMS Pub. 100-8, Chapter 5, section 5.2.6 for more information.)

**Note to The Health Plan providers:** Shipments of supplies in greater quantity than what is being used by member will not be reimbursed.

**KX, GA, and GZ MODIFIERS**

Proper uses of modifiers are required. The provider is to use the appropriate modifier as indicated.

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.

Claim reimbursement is based on contract and timely filing policies of The Health Plan.

**ADVANCED BENEFICIARY NOTICE**

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

**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. [dmepdac.com/](http://dmepdac.com/)

**MEDICARE DEFINITIONS AND DESCRIPTION**

FIO2 is the fractional concentration of oxygen delivered to the patient for inspiration. For the purpose of this policy, the patient’s usual FIO2 refers to the oxygen concentration the patient normally breathes when not undergoing testing to qualify for coverage of a RAD. That is, if the patient does not normally use supplemental oxygen, their usual FIO2 is that found in room air.

FEV1 is the forced expired volume in one second.

FVC is forced vital capacity.

Polysomnography is the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep with a physician review, interpretation, and report. It must include sleep staging, which is defined to include a 1-4 lead electroencephalogram (EEG), and electro-oculogram (EOG), and a submental electromyogram (EMG). It must also include at least the following additional parameters of sleep: airflow, respiratory effort, and oxygen saturation by oximetry. It may be performed as either a whole night study for diagnosis only or as a split night study to diagnose and initially evaluate treatment.

For the purpose of this policy, polysomnographic studies must be performed in a sleep study laboratory, and not in the home or in a mobile facility. It must comply with all applicable state regulatory requirements.

Central sleep apnea (CSA) is defined as:

1. An apnea-hypopnea index (AHI) greater than five, and
2. Central apneas/hypopneas greater than 50 percent of the total apneas/hypopneas, and
3. Central apneas– hypopneas index ≥ five times per hour, and
4. Symptoms of either excessive sleepiness or disrupted sleep must be documented.
5. No evidence of daytime or nocturnal hypoventilation.

Complex sleep apnea (CompSA) is a form of central apnea specifically identified by the persistence or emergence of central apneas or hypopneas upon exposure to CPAP or an E0470 device where obstructive events have been effectively treated. The obstructive AHI is < 5/hr. The sum total of central apneas plus central hypopneas is > 50% of the total apneas and hypopneas. The central apnea-central hypopnea index is ≥ 5/hr. The CAHI is determined during the use of a PAP device after obstructive events have disappeared.

Central apnea-central hypopnea index (CAHI) is the average number of episodes of central apnea and central hypopnea per hour of sleep without the use of a PAP device.

Apnea is defined as the cessation of airflow for at least 10 seconds.
Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds associated with at least a 30 percent reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4 percent decrease in oxygen saturation.

The AHI is defined as the average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device.

If the AHI is calculated based on less than two hours of continuous recorded sleep, the total number of recorded events used to calculate the AHI must be at least the number of events that would have been required in a two-hour period (i.e., ≥ 10 events).

Either a non-heated (E0561) or heated (E0562) humidifier is covered and paid separately when ordered by the treating physician for use with a covered E0470 or E0471 RAD.

A RAD without backup rate (E0470) delivers adjustable, variable levels (within a single respiratory cycle) of positive air pressure by way of tubing and a noninvasive interface (such as a nasal, oral, or facial mask) to assist spontaneous respiratory efforts and supplement the volume of inspired air into the lungs (i.e., NPPRA). A respiratory cycle is defined as an inspiration, followed by expiration.

A RAD with backup rate (E0471) delivers adjustable, variable levels (within a single respiratory cycle) of positive air pressure by way of tubing and a noninvasive interface (such as a nasal or oral facial mask) to assist spontaneous respiratory efforts and supplement the volume of inspired air into the lungs (i.e., NPPRA). In addition, it has a timed backup feature to deliver this air pressure whenever sufficient spontaneous inspiratory efforts fail to occur.

A4604 describes tubing used with a heated humidifier and has a heated wire running the length of the tubing. It is designed for use with a positive airway pressure device and a non-invasive interface, i.e., nasal or face mask, nasal cannula, or oral interface.

Code A7032 is used for a replacement nasal mask interface that goes around the nose, but not into the nostrils. The unit of service for this code is “each.”

Code A7033 is used for a replacement nasal cannula-type interface. This interface extends a short distance into the nostrils. The unit of service for this code is “pair.” For some products, there are two physically separate cushions or “pillows” – one for each nostril. Two cushions/pillows equal one unit of service of A7033. For other products, the interface is a single piece with two protrusions that extend into the nostrils. One of these interfaces equals one unit of service of A7033.

A7027 (combination oral/nasal mask, used with continuous positive airway pressure device, each) is a two-piece system with separate elements for oral and nasal use.

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INTERNET LINKS AND SOURCES


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

Section 6407 of the Affordable Care Act (ACA) Established a Face-to-Face Encounter Requirement for Certain Items of DME


Noridian Healthcare Solutions PDAC. Medicare Pricing Data Analysis and Coding. Advisory Articles dmpdac.com/resources/advisory_articles.html

Medicare Benefit Policy Manual 100-2, Chapter 15, Section 110.1

Noridian PDAC Updates [pdac@noridian.com] Tuesday 2/25/14. General announcement email