Continuous positive airway pressure (CPAP) and bilevel devices are indicated for patients with obstructive sleep apnea (OSA). ResMed’s CPAP and bilevel devices are designed to deliver effective therapy as quietly and comfortably as possible.

Billing Criteria
Medicare has specific criteria for coverage of CPAP and bilevel devices for treatment of OSA. Please refer to the local coverage policy for additional details.

Key Coverage Criteria Required for All CPAP Claims
A single-level CPAP device (E0601) is covered for the treatment of OSA if criteria A-C are met:

A. The patient has face-to-face clinical evaluation by treating physician prior to the sleep test to assess the patient for OSA.
   NOTE: Physicians shall document the face-to-face evaluation and re-evaluation in a detailed narrative note in their charts. For the initial evaluation, the report would commonly document pertinent information (ie, history and physical exam), but may include other details.

B. The patient has a Medicare-covered sleep test that meets either of the following criteria:
   1. The apnea-hypopnea index (AH1) or respiratory disturbance index (RDI)* is ≥ 15 events per hour with minimum of 30 events; or
   2. The AH1 or RDI is ≥ 5 and ≤ 14 events per hour with minimum of 10 events and documentation of:
      a. Excessive daytime sleepiness, impaired cognition, mood disorders or insomnia; or
      b. Hypertension, ischemic heart disease or history of stroke.

C. The patient and/or their caregiver has received instruction from the supplier of the CPAP device and accessories in the proper use and care of the equipment.

* The RDI is defined as the average number of apneas plus hypopneas per hour of recording without the use of a positive airway pressure (PAP) device.

Key Coverage Criteria Required for All Bilevel Claims
A bilevel without backup rate (E0470) is covered for those patients with OSA who meet criteria A-C above, in addition to:

D. A single-level (E0601) CPAP device has been tried and proven ineffective based on a therapeutic trial conducted in either a facility or a home setting.

Treating physician must document both of the following issues were addressed prior to changing a patient from an E0601 to an E0470 device due to ineffective therapy:

A. Interface fit and comfort. An appropriate interface has been properly fit and the beneficiary is using it without difficulty. This properly fit interface will be used with the E0470 device; and

B. E0601 pressure settings. The current pressure setting of the E0601 prevents the beneficiary from tolerating the therapy, and lower pressure settings of the E0601 were tried but failed to:
   1. Adequately control the symptoms of OSA; or
   2. Improve sleep quality; or
   3. Reduce the AH1/RDI to acceptable levels.

Device Description HCPCS Medicare Reimbursement1

<table>
<thead>
<tr>
<th>Device</th>
<th>Description</th>
<th>HCPCS</th>
<th>Medicare Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPAP</td>
<td>CPAP devices (eg, S9 Elite™, S9 Escape™). Includes automatic positive airway pressure (APAP) devices (eg, S9 AutoSet™, S9 Escape Auto)</td>
<td>E0601</td>
<td>$103.42 – 87.912 (monthly rate)</td>
</tr>
<tr>
<td>Bilevel</td>
<td>Bilevel devices without a backup rate (eg, VPAP™ Auto)</td>
<td>E0470</td>
<td>$237.56 – 201.932 (monthly rate)</td>
</tr>
</tbody>
</table>

This tool will assist you in understanding Medicare coding and coverage for CPAP and bilevel devices to treat OSA.
**Key Coverage Criteria for Sleep Tests**

- Covered sleep tests include Type I, II, III or IV devices
- Beneficiaries must receive face-to-face demonstration, or video or telephonic instruction on HST device prior to test
- Education on HST device must be provided by entity performing the test (not by DME supplier)
- No aspect of HST, including, but not limited to, delivery and/or pickup of the device, may be performed by a DME supplier
- All sleep tests must be interpreted by a physician who holds either (required as of 11/1/08 for interpretation of home sleep tests and as of 1/1/10 for facility-based tests):
  1. Current certification in sleep medicine by the American Board of Sleep Medicine (ABSM); or
  2. Current subspecialty certification in sleep medicine by member board of American Board of Medical Specialists (ABMS); or
  3. Completed training by ABMS member board and completed all requirements for subspecialty certification in sleep except exam itself; or
  4. Active staff of a sleep center or lab accredited by the AASM, ACHC or The Joint Commission.

**Q & A**

For additional questions, please reference the “Positive Airway Pressure (PAP) Devices – Supplier Frequently Asked Questions” posted by the four Medicare DMACs.

**Q: What if a patient fails the initial trial?**

A patient is eligible to requalify if they have another face-to-face clinical evaluation by the treating physician and a repeat sleep test in a facility-based setting (Type I study).

**Q: Does the treating physician who completes the initial face-to-face exam have to write the order for the PAP therapy?**

No, the treating physician who does the initial face-to-face exam does not have to be the same physician who orders the PAP. For example, the PAP device can be ordered by a physician from the sleep lab.

**Q: Explain the term visual inspection as it relates to adherence monitoring. What does this mean and how can it be documented?**

Visual inspection is determining adherence by looking at information on the PAP device’s display screen and documenting the values in a written report. The supplier may contact the beneficiary via telephone and ask them to read values from their device (ie, phone-in compliance), or the supplier or physician may read the values during a home/office visit. The values must document that the patient is using the device for four or more hours per night for 70% of the nights in a consecutive 30-day period.

**Q: If a patient was diagnosed with OSA and received a PAP device paid for by private insurance, and the patient is now enrolled in Fee-For-Service (FFS) Medicare and needs a replacement device, what is required for coverage?**

Prior to FFS Medicare enrollment, the patient must have a sleep test that meets the FFS Medicare AH1 coverage criteria in effect at the time that the beneficiary seeks a replacement PAP device and/or accessories. Following enrollment, the patient must also have a face-to-face evaluation by their treating physician that documents a diagnosis of OSA and that the patient continues to use the PAP device.

**Continued Coverage Beyond the First Three Months of Therapy**

Continued coverage documented between 31st and 91st day after initiation of therapy

1. Face-to-face clinical re-evaluation by treating physician and documentation of improved symptoms of OSA; and
2. Physician review of objective evidence of adherence (defined as use of PAP ≥4 hours per night on 70% of nights during a consecutive 30-day period) via direct download or visual inspection of usage data.

**Continued Coverage Documentation for Bilevel Devices:**

- Switch to bilevel day 1–60 following CPAP setup
  Obtain Rx for E0470 device (clinical re-evaluation must occur between 31st and 91st day following initiation of CPAP)
- Switch to bilevel day 61–90 following CPAP setup
  Obtain Rx for E0470 device (clinical re-evaluation must occur before 120th day following initiation of CPAP)
- Switch to bilevel post day 90 following CPAP setup
  Obtain Rx for E0470 device and new initial face-to-face clinical evaluation (clinical re-evaluation must occur between 31st and 91st day following initiation of bilevel)

The information provided with this notice is general reimbursement information only as of January 1, 2012. It is not legal advice, nor is it advice about how to code, complete or submit any particular claim for payment. Although we supply this information to the best of our current knowledge, it is always the provider’s responsibility to determine and submit appropriate codes, charges, modifiers and bills for the services that were rendered. This information is provided as of the date listed above, and all coding and reimbursement information is subject to change without notice.

1 The rates listed are based on the Medicare 2012 DMEPOS National Fee Schedule. Competitive bidding rates may be applicable in certain CBAs; please reference the single payment amounts for these areas.
2 2011 Medicare ceiling and floor rates; rate reduces by 25% after the third month; payment over 13 months. Actual allowables vary by state.