Respiratory assist devices (RADs) are used to deliver adjustable, variable levels of positive air pressure (PAP) 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. RADs may also include a timed backup feature to deliver air pressure whenever sufficient spontaneous inspiratory efforts fail to occur. ResMed bilevel devices combine increased comfort with a high level of clinical control to help meet the unique needs of every patient. Bilevel to treat obstructive sleep apnea (OSA) and noncompliant continuous positive airway pressure (CPAP) is addressed in a separate Medicare coverage policy and summarized in the ResMed PAP for OSA Reimbursement fast facts: PN 1013493. For Life support ventilator, see Ventilator reimbursement fast facts: PN 1017230.

Billing criteria for RADs

Medicare has specified coverage criteria for patients with the following groups of clinical conditions. Please refer to the local coverage policy for additional details.2

**Restrictive thoracic disorders**

An E0470 or E0471 device is covered for the first three months of therapy when the following criteria are met:

A. There is documentation in the patient’s medical record of a neuromuscular disease (e.g. amyotrophic lateral sclerosis) or a severe thoracic cage abnormality (e.g. post-thoracoplasty for TB).

B. One of the following:
   a. An arterial blood gas (ABG) PaCO₂ done while awake and breathing the patient’s prescribed FiO₂ is ≥ 45 mm Hg, OR
   b. Sleep oximetry demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing the patient’s recommended FiO₂, or
   c. For a neuromuscular disease only, either:
      i. Maximal inspiratory pressure is < 60 cmH₂O, or
      ii. Forced vital capacity is < 50% predicted.

C. Chronic obstructive pulmonary disease (COPD) does not contribute significantly to the patient’s pulmonary limitation.

**Severe COPD**

An E0470 device is covered for the first three months of therapy if the following criteria are met:

A. An ABG PaCO₂, done while awake and breathing the patient’s prescribed FiO₂, is ≥ 52 mm Hg.

B. Sleep oximetry demonstrates oxygen saturation ≤ 88% for ≥ a cumulative 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the patient’s prescribed FiO₂ (whichever is higher).

C. Prior to initiating therapy, sleep apnea and treatment with a CPAP has been considered and ruled out. (Note: Formal sleep testing is not required if there is sufficient information in the medical record to demonstrate that the patient does not suffer from some form of sleep apnea [OSA, central sleep apnea (CSA) and/or complex sleep apnea (CompSA)] as the predominant cause of awake hypercapnia or nocturnal arterial oxygen desaturation).

An E0471 device will be covered for a patient with COPD if additional criteria are met. Refer to the RAD Local Coverage Determination (LCD) at www.cms.gov/medicare-coverage-database.

**Central sleep apnea or complex sleep apnea**

An E0470 or E0471 device is covered for the first three months of therapy when, prior to initiating therapy, a complete facility-based, attended PSG is performed documenting the following:

A. The diagnosis of CSA or CompSA, and

B. Significant improvement of the sleep-associated hyperventilation with the use of an E0470 or E0471 device on the settings that will be prescribed for initial use at home, while breathing the patient’s prescribed FiO₂.2

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**Device** | **Description** | **HCPCS** | **Medicare Jan 2019 former Competitive Bid Area monthly rate** | **Medicare Jan 2019 non-CBA non-rural monthly rate** | **Medicare Jan 2019 non-CBA rural monthly rate**
--- | --- | --- | --- | --- | ---
Bilevel without a backup rate | ResMed bilevel device examples (e.g. ResMed AirCurve™ 10 VAuto, AirCurve 10 S, VPAP™ COPD) | E0470 | $123 – $94 | $107 – $101 | $186 – $166
Bilevel with a backup rate | ResMed bilevel device examples (e.g. AirCurve 10 ST, AirCurve 10 ST-A, AirCurve 10 ASv) | E0471 | $300 – $236 | $271 – $253 | $463 – $415
Hypventilation syndrome

An E0470 device is covered for the first three months of therapy if the following criteria are met for both A & B, and either C or D:

A. An initial ABG PaCO₂, done while awake and breathing the patient's prescribed FiO₂, is ≥ 45 mm Hg, and

B. Spirometry shows an FEV1/FVC ≥ 70% (refer to Severe COPD section for information about device coverage for patients with FEV1/FVC < 70%), and either

C. An ABG PaCO₂, done during sleep or immediately upon awakening, and breathing the patient's prescribed FiO₂, shows the patient's PaCO₂ worsened ≥ 7 mm Hg compared to the original result in criterion A (above), or

D. A facility-based PSG or HST demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events, i.e. AHI < 5.

An E0471 device is covered for the first three months of therapy if the following criteria are met for both A & B, and either C or D:

A. A covered E0470 device is being used, and

B. Spirometry shows an FEV1/FVC ≥ 70%, (refer to Severe COPD section for information about device coverage for patients with FEV1/FVC < 70%), and either

C. An ABG PaCO₂, done while awake, and breathing the patient's prescribed FiO₂, shows the patient's PaCO₂ worsens ≥ 7 mm Hg compared to the ABG result performed to qualify the patient for the E0470 device (criterion A under E0470), or

D. A facility-based PSG or HST demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events, i.e. AHI < 5 while using an E0470 device.

Follow-up documentation requirements

Documentation requirements for billing E0470 or E0471 beyond the first three months of therapy

- Patient’s medical record documents:
  - that the patient was re-evaluated by the treating practitioner on or after the 61st day after initiation of therapy
  - the progress of relevant symptoms
  - patient usage (avg. 4 hours per 24-hour period) of the device up to the time of reevaluation.

- Documentation in supplier’s records includes:
  - a signed and dated statement completed by the treating practitioner no sooner than 61 days after initiating use of the device that the patient consistently uses the device (an average of 4 hours per 24-hour period) and is benefiting from its use.

FAQs

Q: What is the appropriate diagnosis code for complex sleep apnea?

Complex sleep apnea (CompSA) is a form of central sleep apnea (CSA) and is may be billed using ICD-10 diagnosis code G4737 (central sleep apnea in conditions classified elsewhere) when performing a full diagnostic polysomnography or G4731 (primary central sleep apnea) when performing a split-night polysomnography.

Q: Can an HST or portable monitoring device be used to diagnose CSA or CompSA?

No. A complete facility-based, attended PSG is required.