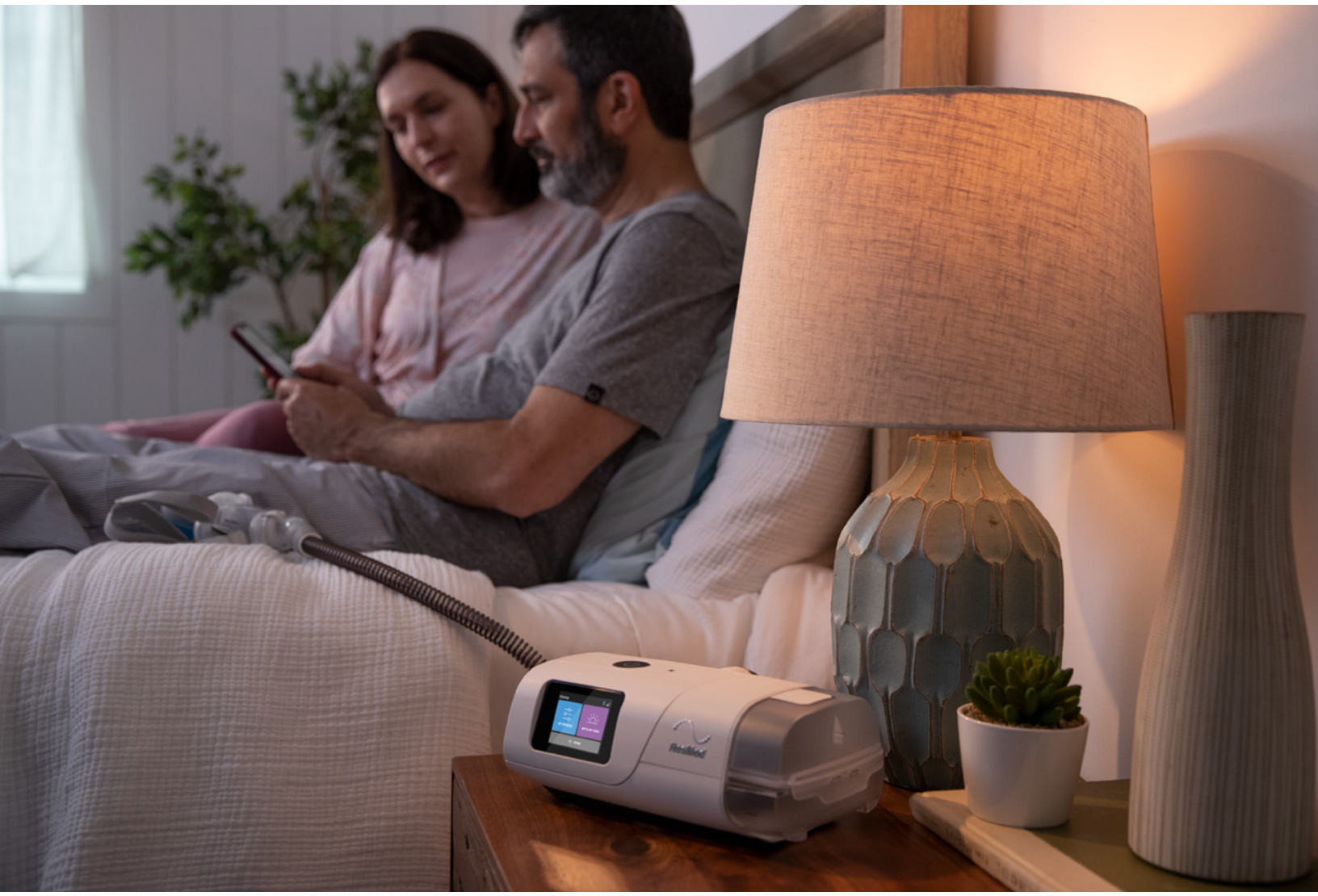
ResMed



Medicare respiratory assist device (RAD) coverage guidelines

For services performed on or after January 1, 2024

Initial coverage (first 3 months of therapy)

MEDICAL RECORDS* document:

- ☐ Symptoms characteristic of sleep-associated hypoventilation (e.g. daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc.) **and**
- ☐ Patient meets all coverage criteria for one (1) of the following disorders:

I. Restrictive thoracic disorders

Documentation of a neuromuscular disease (e.g. amyotrophic lateral sclerosis) or a severe thoracic cage abnormality (e.g. post-thoracoplasty for tuberculosis [TB]).

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One of the following:

- **Arterial blood gas (ABG)** $PaC0_2$, done while awake and breathing, the patient's prescribed Fi02 is ≥ 45 mm Hg.
- **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 prescribed recommended FiO_2.
- **For neuromuscular disease only,** maximal inspiratory pressure is < 60 cm H_2O, **or** forced vital capacity (FVC) is < 50% predicted.

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

E0470 or E0471
Based on the treating practitioner's judgment

II. Severe COPD

ABG $PaC0_2$ is ≥ 52 mm Hg while patient is awake and breathing the prescribed FiO_2.

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Sleep oximetry study demonstrates oxygen saturation ≤ 88% for ≥ 5 cumulative minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 liters per minute (LPM) or the patient's prescribed FiO_2 (whichever is higher).

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Prior to initiating therapy, sleep apnea and treatment with 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 [obstructive 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).

E0470

Situation 1 An E0471 started any time after a period of initial use of E0470 is covered if:

- An ABG $PaCO_2$, done while awake and breathing the patient's prescribed FiO_2, shows the patient's $PaCO_2$ worsens ≥ 7mm Hg compared to original ABG result above, **and**
- A facility-based polysomnogram (PSG) demonstrates oxygen saturation ≤ 88% for ≥ 5 cumulative minutes of nocturnal recording time (minimum recording time of 2 hours) while using an E0470 that is not caused by obstructive upper airway events (i.e. apnea–hypopnea index [AHI] < 5).

OR

Situation 2 An E0471 will be covered no sooner than 61 days after initial issue of the E0470 if:

- An ABG $PaCO_2$, done while awake and breathing the patient's prescribed FiO_2, still remains ≥ 52 mm Hg, **and**
- Sleep oximetry while breathing with the E0470 demonstrates oxygen saturation ≤ 88% for ≥ 5 cumulative minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the patient's prescribed FiO_2 (whichever is higher).

E0471

* The patient's medical records include the treating practitioner's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports

III. Central or complex sleep apnea

Prior to initiating therapy, a complete facility-based, attended PSG was performed documenting:

- ☐ Diagnosis of either CSA or CompSA, **and**
- ☐ Significant improvement of the sleep-associated hypoventilation with use of an E0470 or E0471 on the settings that will be prescribed for initial use at home while breathing the patient's prescribed FiO_2.

E0470 or E0471
Based on the treating practitioner's judgment

IV. Hypoventilation

An initial ABG $PaCO_2$, done while awake and breathing the patient's prescribed FIO_2, is ≥ 45 mm Hg.

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Spirometry shows an FEV1/FVC ≥ 70%.

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- **An ABG** $PaCO_2$, done during sleep or immediately upon awakening, and while breathing the patient's prescribed FiO_2, shows the patient's $PaCO_2$ worsened ≥ 7mm Hg compared to the initial ABG result, **or**
- **A facility-based PSG or home sleep testing (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).

E0470

Covered E0470 is being used.

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Spirometry shows an FEV1/FVC ≥ 70%.

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- **An ABG** $PaCO_2$, done while awake and breathing the patient's prescribed FiO_2, shows the patient's $PaCO_2$ worsens ≥ 7 mm Hg compared to the ABG result performed to qualify the patient for the E0470 device, **or**
- **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).

E0471

ResMed E0470 and E0471 Devices

E0470–Bilevel without a backup rate:
- AirCurve™ VAuto

E0471–Bilevel with a backup rate:
- AirCurve ST
- AirCurve ST-A
- AirCurve ASV*

*ASV therapy is contraindicated in patients with chronic, symptomatic heart failure (NYHA 2-4) with reduced left ventricular ejection fraction (LVEF ≤ 45%) and moderate to severe predominant central sleep apnea.

Continued coverage (beyond the first 3 months of therapy)

MEDICAL RECORDS† document:
- ☐ Patient was re-evaluated by the treating practitioner on/after the 61st day of therapy
- ☐ Progress of relevant symptoms
- ☐ Patient usage of the device (average 4 hours per 24 hours) by the time of the re-evaluation

and

SUPPLIER RECORDS‡ documentation includes:
- ☐ Signed and dated physician statement completed no sooner than 61 days after initiating use of the device declaring:
  - ☐ Patient is compliantly using device (an average of 4 hours per 24 hour period), **and**
  - ☐ Patient is benefiting from its use.

* Not all types of HST are appropriate for the evaluation of CSA or CompSA as necessary parameters are not monitored

† The patient's medical records include the practitioner's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports

‡ The signed practitioner statement must be obtained and kept on file by the supplier (not sent in with the claim)

Glossary

AHI. Apnea–hypopnea index is the average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device.

Apnea. The cessation of airflow for at least 10 seconds.

CAHI. For diagnosis of CSA, the 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 positive airway pressure device. For CompSA, the CAHI is determined during the use of a positive airway pressure device after obstructive events have disappeared. If the AHI or CAHI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events used to calculate the AHI or CAHI must be at least the number of events that would have been required in a 2-hour period (i.e. greater than or equal to 10 events).

CompSA. Complex sleep apnea is a form of central apnea specifically identified by all of the following:

1. With use of a positive airway pressure device without a backup rate (E0601 or E0470), the polysomnogram (PSG) shows a pattern of apneas and hypopneas that demonstrates the persistence or emergence of central apneas or central hypopneas upon exposure to CPAP (E0601) or a bilevel device without backup rate (E0470) when titrated to the point where obstructive events have been effectively treated (obstructive AHI less than 5 per hour).
2. After resolution of the obstructive events, the sum total of central apneas plus central hypopneas is greater than 50% of the total apneas and hypopneas; and
3. After resolution of the obstructive events, a CAHI greater than or equal to 5 per hour.

CSA. Central Sleep Apnea is defined by all of the following:

1. An apnea-hypopnea index (AHI) greater than or equal to 5; and
2. The sum total of central apneas plus central hypopneas is greater than 50% of the total apneas and hypopneas; and
3. A central apnea–central hypopnea index (CAHI) is greater than or equal to 5 per hour; and
4. The presence of at least one of the following:
   - Difficulty initiating or maintaining sleep, frequent awakenings, or non-restorative sleep
   - Awakening short of breath
   - Sleepiness
   - Snoring
   - Witnessed apnea
5. There is no evidence of daytime or nocturnal hypoventilation.

FEV1. Forced expired volume in 1 second.

FiO_2. The fractional concentration of oxygen delivered to the patient for inspiration. The patient's prescribed FiO_2 refers to the oxygen concentration the patient normally breathes when not undergoing testing to qualify for coverage of a respiratory assist device (RAD). That is, if the patient does not normally use supplemental oxygen, their prescribed FiO_2 is that found in room air.

Hypopnea. An abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% decrease in oxygen saturation.

OSA. Obstructive sleep apnea

TB. Tuberculosis

Reference:
U.S. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): Respiratory Assist Devices (L33800), retrieved January 09, 2024 from https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33800&ver=29&keywordtype=starts&keyword=respira&bc=0

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