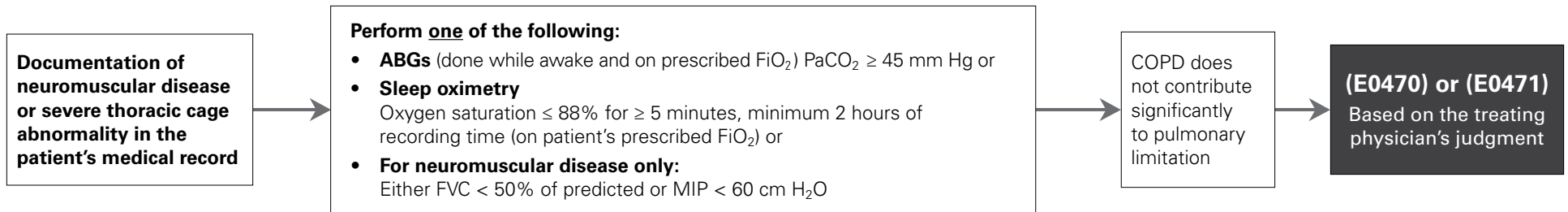




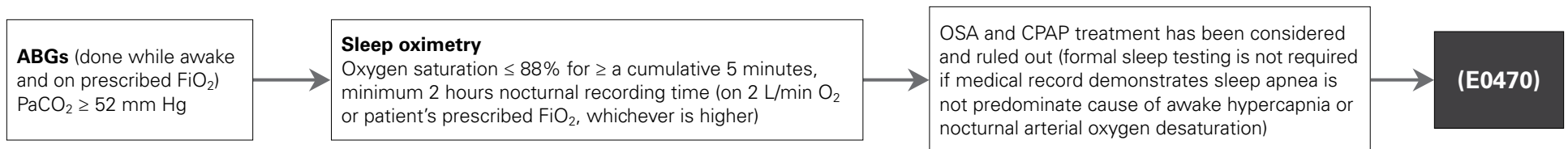
Respiratory Assist Device (RAD) Qualifying Guidelines

CMS revision effective date: December 2014

I. Restrictive Thoracic Disorders



II. COPD



For COPD patients to qualify for a RAD with backup rate (E0471):

Situation 1 After period of initial use of an E0470; **ABG** (done while awake and on prescribed FiO_2) shows $PaCO_2$ worsens ≥ 7 mm Hg compared to original ABG result; **facility-based PSG** demonstrates oxygen saturation $\leq 88\%$ for \geq a cumulative 5 minutes, minimum 2 hours nocturnal recording time while on an E0470 and not caused by obstructive upper airway events (ie, $AHI < 5$).

Situation 2 No sooner than 61 days after initial issue of E0470; **ABG** (done while awake and on prescribed FiO_2) shows $PaCO_2 \geq 52$ mm Hg; **Sleep oximetry** on an E0470 demonstrates oxygen saturation $\leq 88\%$ for \geq a cumulative 5 minutes, minimum 2 hours nocturnal recording time (on 2 L/min O_2 or patient's prescribed FiO_2 , whichever is higher).

Respiratory Assist Device (RAD) Documentation Requirements for Continued Coverage Beyond First 3 Months

Patients on an E0470 or E0471 device must be reevaluated no sooner than 61 days after initiating therapy.

Required Documentation

- Progress of relevant symptoms
- Signed and dated statement by treating physician declaring patient using average 4 hours per 24-hour period and patient benefiting from use

ResMed E0470 and E0471 Devices

E0470–Bilevel without a backup rate:

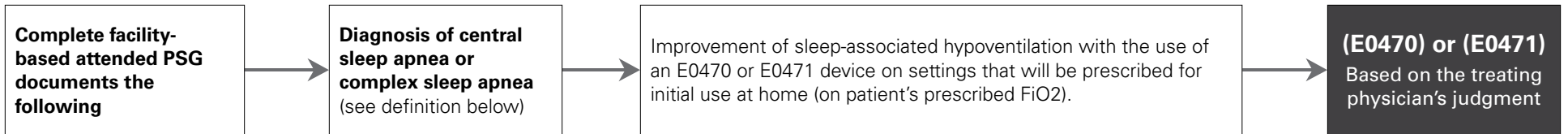
- AirCurve™ 10 VAuto
- AirCurve™ 10 S
- VPAP™ COPD

E0471–Bilevel with a backup rate:

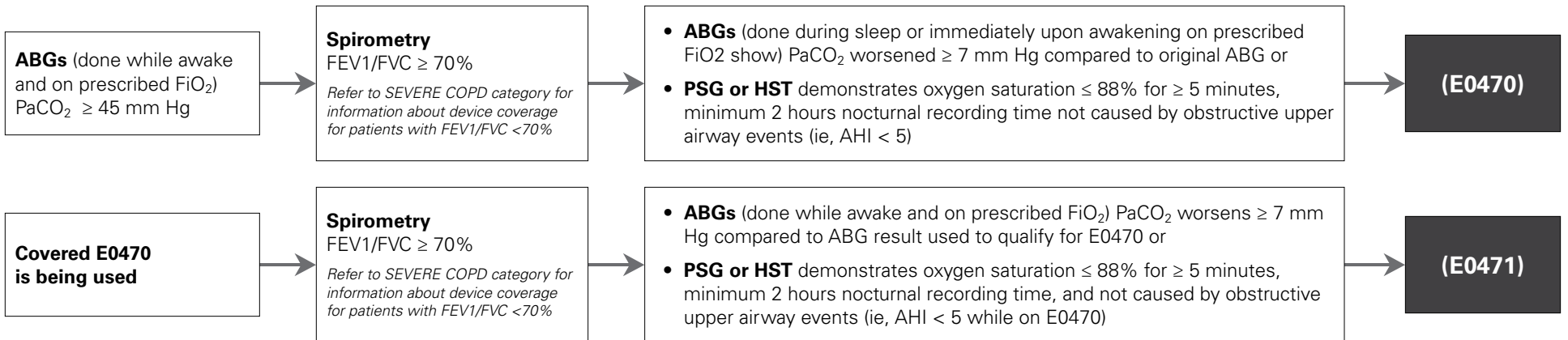
- AirCurve 10 ST
- AirCurve 10 ASV
- VPAP ST-A
- Stellar™*

* For invasive use, code E0472

III. Central Sleep Apnea or Complex Sleep Apnea



IV. Hypoventilation



A diagnosis of **central sleep apnea (CSA)** requires all of the following:

1. An apnea-hypopnea index ≥ 5; and
2. Sum total of central apneas plus central hypopneas > 50% of the total apneas and hypopneas; and
3. CAHI* ≥ 5 per hour; and
4. Presence of either sleepiness, difficulty initiating or maintaining sleep, frequent awakenings, or non restorative sleep, awakening short of breath, snoring, or witnessed apneas; and
5. No evidence of daytime or nocturnal hypoventilation

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

*For CSA diagnosis, central apnea-central hypopnea index (CAHI) is defined as the average number of episodes of central apnea and central hypopnea per hour of sleep without the use of a PAP device.

**For CompSA, the CAHI is determined during the use of a PAP device after obstructive events have disappeared.

Complex sleep apnea (CompSA) is a form of central apnea identified by all of the following:

1. PSG demonstrates the persistence or emergence of central apneas or central hypopneas upon exposure to CPAP or an E0470 device when titrated to the point where obstructive events have been effectively treated (AHI < 5 per hour); and
2. After resolution of the obstructive events, the sum total of central apneas plus central hypopneas is > 50% of the total apneas plus hypopneas; and
3. After resolution of the obstructive events, CAHI** ≥ 5 per hour

Ventilator with Non-Invasive Interfaces: Please reference ResMed's Ventilator Reimbursement Fast Facts: PN 1017230.

This information is provided as of the date listed, and all coding and reimbursement information is subject to change without notice. It is the provider's responsibility to verify coding and coverage with payors directly. For a full description of the policy go to www.cms.hhs.gov.

ResMed reimbursement hotline, dial **1-800-424-0737** and select **option 4**.