VER. 8.25

Frontier Home Medical

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RESPIRATORY ASSIST DEVICE (RAD) COVERAGE GUIDELINES

INITIAL COVERAGE (FIRST 3 MONTHS OF THERAPY):

Medical Records Document *(including physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports):*

- 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 (i.e. amyotrophic lateral sclerosis) or a severe thoracic cage abnormality (i.e. post-thoracoplasty for tuberculosis [TB]).	**One of the following:** • **Arterial blood gas (ABG**) PaC02, done while awake and breathing the usual 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 FiO2. • **For neuromuscular disease only**, maximal inspiratory pressure is < 60 cm H2O, **or** forced vital capacity (FVC) is < 50% predicted.	Chronic obstructive pulmonary disease (COPD) does not contribute significantly to patient's pulmonary limitation.	**E0470 or E0471** *Based on the treating physician's judgment*

II. Severe COPD

Medicare NCD changes for the severe COPD pathway are currently being reviewed. **Please reach out to our clinical team to discuss qualifying criteria.**

E0470 or E0471

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 the physician prescribed for initial use at home while breathing the usual FiO_2.

E0470 or E0471 *Based on the treating physician's judgment*

IV. Hypoventilation

An initial ABG $PaCO_2$, done while awake and breathing the patient's prescribed FIO_2, is ≥45 mm Hg	**Spirometry** shows an FEV1/ FVC ≥ 70%	• An ABGs PaCO2, done during sleep or immediately upon awakening, and while breathing the patient's prescribed FiO2, shows the patient's PaCO2 worsened ≥7mm Hg compared to the original result, or • A facility-based PSG or home sleep testing (HST)* demonstrates oxygen saturation ≤88% for ≥5 minutes of nocturnal recording (minimum recording time of 2 hours) that is not caused by obstructive upper airway events (AHI < 5)	**E0470**
Covered E0470 isbeing used	**Spirometry** shows an FEV1/ FVC ≥ 70%	• **An ABG**s PaCO2, done while awake and breathing the patient's prescribed FiO2, shows the patient's PaCO2 worsens ≥7 mmHg compared to the ABG result per formed 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 (AHI <5 while using an E0470).	**E0471**

ResMed E0470 and E0471 Devices

E0470-Bilevel without a backup rate:

•AirCurve 10 VAuto •AirCurve 10 S •S9 VPAP COPD

E0410-Bilevel with a backup rate:

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

CONTINUED COVERAGE (BEYOND THE FIRST 3 MONTHS OF THERAPY):

Medical Records Document:

- Patient was re-evaluated by the treating physician on/after the 61st day of therapy
- Progress of relevant symptoms
- Patient usage of the device (average 4 hours per 24 hours)

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 consistently using device an average of 4 hours per 24 hour period, **and**
  - Patient is benefiting from its use.

GLOSSARY:

FiO2: *The fractional concentration of oxygen delivered to the beneficiary for inspiration. The beneficiary's prescribed FiO2 refers to the oxygen concentration the beneficiary normally breathes when not undergoing testing to qualify for coverage of a respiratory assist device (RAD). That is, if the beneficiary does not normally use supplemental oxygen, their prescribed FiO2 is that found in room air.*

FEV1: *Forced expired volume in 1 second.*

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.*

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) device 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.*

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

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.*

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

CAHI. *Central apnea-central hypopnea index and 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).*

OSA: *Obstructive sleep apnea*

TB: *Tuberculosis*

FAX PRESCRIPTION & FACE-TO-FACE NOTES TO THE LOCAL FRONTIER BRANCH.

If you have any questions or concerns, please contact Frontier Home Medical. Thank you for your cooperation!

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