

Appendix A

Clinical Indications for the Use of Respiratory Assist Device (RAD) Therapy

Indications for use of a RAD is divided into four categories:

- Restrictive thoracic disorders, e.g., neuromuscular disorders such as amyotrophic lateral sclerosis;
- Severe chronic obstructive pulmonary disease (COPD);
 - Use of a RAD in COPD patients requires,
 - A facility-based polysomnogram to rule out obstructive sleep apnea in order to initiate Medicare coverage,
 - A prerequisite trial of noninvasive ventilation without a backup rate, and
 - Treatment with continuous positive airway pressure devices.
- Central sleep apnea, i.e., apnea not due to airway obstruction; and
- Obstructive sleep apnea (OSA).

Initial Coverage (First 3 Months of Therapy)

Medical record must document symptoms characteristic of sleep-associated hypoventilation, e.g.:

- Daytime hypersomnolence;
- Excessive fatigue;
- Morning headache;
- Cognitive dysfunction;
- Dyspnea, etc.; and
- Beneficiary has one (1) of the disorders listed in the Documentation Verification Procedures section below and meets all coverage criteria for that disorder.

Continued Coverage (Beyond First 3 Months of Therapy) - E0470 or E0471

Medical records document the beneficiary was re-evaluated on/after the 61st day of therapy demonstrating:

- Progress of relevant symptoms; and
- Beneficiary usage of the device (average 4 hours per 24 hours)

Documentation in supplier's records includes the following:

- Signed and dated physician statement completed no sooner than 61 days after initiating use of the device declaring:
- Beneficiary is consistently using device an average of 4 hours per 24 hour period; and
- Beneficiary is benefiting from its use.

Replacement of an E0470 or E0471

Following the 5 year reasonable useful lifetime (RUL), there must be an F2F that documents:

- The beneficiary continues to use and benefit from the device; and
- A new prescription is required

Beneficiaries Entering Medicare

There must be documentation of the following:

- A qualifying test confirming that the beneficiary had testing prior to Fee-for-Service (FFS) Medicare enrollment, that meets the current coverage criteria in effect at the time that the beneficiary seeks Medicare coverage of a replacement device and/or accessory; and
- An F2F clinical evaluation following enrollment in FFS Medicare that confirms all of the following:
 - The beneficiary has the qualifying medical condition for the applicable scenario; and
 - Testing performed, date of the testing used for qualification and results; and
 - The beneficiary continues to use the device; and
 - The beneficiary is benefiting from the treatment.

For coverage of RAD (E0470 or E0471), the documentation needs to confirm one or more of the following requirements supporting the use of RAD therapy are met for the patient's diagnosed condition:

Restrictive Thoracic Disorder

Medical record documents:

- Progressive neuromuscular disease (i.e. amyotrophic lateral sclerosis) or a severe abnormality of the thoracic cage (i.e. post-thoracoplasty for TB); **and**
- Arterial blood gas PaCO₂, done while awake and breathing the usual FIO₂, is ≥ 45 mm Hg; **or**
- Sleep oximetry demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing the beneficiary's prescribed recommended FIO₂; **or**
- For a neuromuscular disease only, maximal inspiratory pressure is < 60 cm H₂O or forced vital capacity is < 50% predicted; **and**
- Chronic Obstructive Pulmonary Disease (COPD) does not contribute significantly to the beneficiary's pulmonary limitation.

Severe COPD – E0470

Medical record documents:

- Arterial blood gas PaCO₂ is ≥ 52 mm Hg while beneficiary is awake and breathing the prescribed
- FIO₂; **and**
- 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 LPM or the beneficiary's usual FIO₂ (whichever is higher); **and**
- Prior to initiating therapy, obstructive sleep apnea (OSA) and treatment with a CPAP has been considered and ruled out.

Severe COPD – E0471

Situation one:

- An E0471 started any time after a period of initial use of E0470 is covered if:
 - An arterial blood gas PaCO₂, done while awake and breathing the beneficiary's prescribed FIO₂, shows the beneficiary's PaCO₂ worsens ≥ 7 mm Hg compared to original result above; **and**
 - A facility based polysomnogram (PSG) demonstrates oxygen saturation $\leq 88\%$ 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 (AHI < 5).

Situation two:

- An E0471 will be covered no sooner than 61 days after initial issue of the E0470 if:
 - An arterial blood gas PaCO₂ is done while awake and breathing the beneficiary's prescribed FIO₂, still remains ≥ 52 mm Hg; **and**
 - Sleep oximetry while breathing with the E0470 demonstrates oxygen saturation $\leq 88\%$ for ≥ 5 cumulative minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the beneficiary's prescribed FIO₂ (whichever is higher).

Central Sleep or Complex Sleep Apnea

Central sleep apnea (CSA) is defined by the following:

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

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

- 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 bi-level 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).

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- 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
- After resolution of the obstructive events, a central apnea-central hypopnea index (CAHI) greater than or equal to 5 per hour.
- Prior to initiating therapy, a complete facility-based, attended PSG was performed documenting:
 - Diagnosis of either central (CSA) or complex sleep apnea (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 FIO₂.

Hypoventilation Syndrome

- E0470 is covered if the medical records support:
 - An initial arterial blood gas PaCO₂, done while awake and breathing the beneficiary's prescribed FIO₂, is ≥ 45 mm Hg; **and**
 - Spirometry shows an FEV₁/FVC $\geq 70\%$ and an FEV₁ $\geq 50\%$ of predicted; **and**
 - An arterial blood gas PaCO₂, done during sleep or immediately upon awakening, and while breathing the beneficiary's prescribed FIO₂, shows the beneficiary's PaCO₂ worsened ≥ 7 mm Hg compared to the original result; **or**
 - A facility based PSG or home sleep testing (HST) demonstrates oxygen saturation $\leq 88\%$ for ≥ 5 minutes of nocturnal recording (minimum recording time of 2 hours) that is not caused by obstructive upper airway events (AHI < 5).
- E0471 is covered if the medical records support:
 - A covered E0470 is being used; **and**
 - Spirometry shows an FEV₁/FVC $\geq 70\%$ and an FEV₁ $\geq 50\%$ of predicted; **and**
 - An arterial blood gas PaCO₂, done while awake and breathing the beneficiary's prescribed FIO₂, shows the beneficiary's PaCO₂ 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 $\leq 88\%$ 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).

Obstructive Sleep Apnea

An E0470 device is covered for those beneficiaries with OSA who meet the following criteria:

- The beneficiary has a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess the beneficiary for obstructive sleep apnea;
- The beneficiary has a sleep test (as defined below) that meets either of the following criteria (1 or 2);

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- 1. The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events, or,
- 2. The AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of: a.
 - Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia, or
 - Hypertension, ischemic heart disease, or history of stroke.
- The beneficiary and/or their caregiver has received instruction from the supplier of the device in the proper use and care of the equipment;
- An E0601 (PAP) device has been tried and proven ineffective based on a therapeutic trial conducted in either a facility or in a home setting.

NOTE: Ineffective is defined as documented failure to meet therapeutic goals using an E0601 during the titration portion of a facility-based study or during home use despite optimal therapy (i.e., proper mask selection and fitting and appropriate pressure settings).

- A bi-level positive airway pressure device with back-up rate (E0471) is not reasonable and necessary if the primary diagnosis is OSA.
- If an E0471 is billed with a primary diagnosis of OSA, it will be denied as not reasonable and necessary.

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Appendix B

Respiratory Assist Device (RAD) Therapy Accessories

The following accessories do not require an F2F within the six (6) months prior to the detailed written order:

- A4604 TUBING WITH INTEGRATED HEATING ELEMENT FOR USE WITH POSITIVE AIRWAY PRESSURE DEVICE
- A7027 COMBINATION ORAL/NASAL MASK, USED WITH CONTINUOUS POSITIVE AIRWAY PRESSURE DEVICE, EACH
- A7028 ORAL CUSHION FOR COMBINATION ORAL/NASAL MASK, REPLACEMENT ONLY, EACH
- A7029 NASAL PILLOWS FOR COMBINATION ORAL/NASAL MASK, REPLACEMENT ONLY, PAIR
- A7030 FULL FACE MASK USED WITH POSITIVE AIRWAY PRESSURE DEVICE, EACH
- A7031 FACE MASK INTERFACE, REPLACEMENT FOR FULL FACE MASK, EACH
- A7032 CUSHION FOR USE ON NASAL MASK INTERFACE, REPLACEMENT ONLY, EACH
- A7033 PILLOW FOR USE ON NASAL CANNULA TYPE INTERFACE, REPLACEMENT ONLY, PAIR
- A7034 NASAL INTERFACE (MASK OR CANNULA TYPE) USED WITH POSITIVE AIRWAY PRESSURE DEVICE, WITH OR WITHOUT HEAD STRAP
- A7035 HEADGEAR USED WITH POSITIVE AIRWAY PRESSURE DEVICE
- A7036 CHINSTRAP USED WITH POSITIVE AIRWAY PRESSURE DEVICE
- A7037 TUBING USED WITH POSITIVE AIRWAY PRESSURE DEVICE
- A7038 FILTER, DISPOSABLE, USED WITH POSITIVE AIRWAY PRESSURE DEVICE
- A7039 FILTER, NON DISPOSABLE, USED WITH POSITIVE AIRWAY PRESSURE DEVICE
- A7044 ORAL INTERFACE USED WITH POSITIVE AIRWAY PRESSURE DEVICE, EACH
- A7045 EXHALATION PORT WITH OR WITHOUT SWIVEL USED WITH ACCESSORIES FOR POSITIVE AIRWAY DEVICES, REPLACEMENT ONLY
- A7046 WATER CHAMBER FOR HUMIDIFIER, USED WITH POSITIVE AIRWAY PRESSURE DEVICE, REPLACEMENT, EACH
- E0561 HUMIDIFIER, NON-HEATED, USED WITH POSITIVE AIRWAY PRESSURE DEVICE
- E0562 HUMIDIFIER, HEATED, USED WITH POSITIVE AIRWAY PRESSURE DEVICE