CLINICIAN CHECKLIST FOR RESPIRATORY ASSIST DEVICE (RAD) - SEVERE COPD

Policy References:

- Local Coverage Determination (LCD) (L33800)
- Policy Article (A52517)

Documentation References: Standard Documentation Requirements Policy Article (A55426)

Severe Chronic Obstructive Pulmonary Disorder (COPD)

For a Respiratory Assist Device (RAD) with or without a backup rate feature to be covered for severe COPD, the treating clinician must fully document in the beneficiary's medical record symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc.

The treating clinician must complete the following items:

- ☐ Standard Written Order
- ☐ Medical record documentation as noted below

RAD Without Backup Rate Feature (E0470)

- ☐ A. Arterial blood gas $PaCO_2$, done while awake and breathing the beneficiary's prescribed FIO_2, is greater than or equal to 52 mm Hg.
- ☐ B. Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to accumulative five minutes of nocturnal recording time (minimum recording time of two hours), done while breathing oxygen at 2 LPM or the beneficiary's prescribed FIO_2 (whichever is higher).
- ☐ C. Prior to initiating therapy, sleep apnea and treatment with a continuous positive airway pressure device (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 beneficiary does not suffer from some form of sleep apnea (Obstructive Sleep Apnea (OSA), CSA and/or CompSA) as the predominant cause of awake hypercapnia or nocturnal arterial oxygen desaturation).

RAD With Backup Rate Feature (E0471)

Covered for a beneficiary with COPD in either of the two situations below, depending on the testing performed to demonstrate the need:

Situation 1 - For Group II beneficiaries (COPD) who qualified for a RAD without a backup rate feature, a RAD with a backup rate feature started any time after a period of initial use of a RAD without a backup feature is covered if both criteria A and B are met:

- ☐ A. Arterial blood gas PaCO2, done while awake and breathing the beneficiary's prescribed FIO2, shows that the beneficiary's PaCO2 worsens greater than or equal to 7 mm HG compared to the original result from criterion A from the LCD: An arterial blood gas PaCO2, done while awake and breathing the beneficiary's prescribed FIO2, is greater than or equal to 52 mm Hg; **and**
- ☐ B. A facility-based PSG demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative five minutes of nocturnal recording time (minimum recording time of two hours) while using a RAD without a backup rate feature that is not caused by obstructive upper airway events – i.e., AHI less than 5. (Refer to the Positive Airway Pressure Devices LCD for information about RAD without a backup rate feature coverage for obstructive sleep apnea).

Situation 2 – For Group II beneficiaries (COPD) who qualified for a RAD without a backup rate feature, a RAD with a backup rate feature will be covered if, at a time no sooner than 61 days after initial issue of the RAD without a backup rate feature, both of the following criteria A and B are met:

- ☐ A. Arterial blood gas PaCO2 is done while awake and breathing the beneficiary's prescribed FIO2, still remains greater than or equal to 52 mm Hg; **and**
- ☐ B. Sleep oximetry while breathing with the RAD without a backup rate feature, demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative five minutes of nocturnal recording time (minimum recording time of two hours), done while breathing oxygen at 2 LPM or the beneficiary's prescribed FIO2 [whichever is higher].

Coverage After 90 Days

The treating clinician must document:

- ☐ Beneficiary was re-evaluated on or after the 61st day of therapy; **and**
- ☐ Progress of relevant symptoms, **and**
- ☐ Beneficiary usage of the device; **and**
- ☐ A signed and dated statement declaring that the beneficiary is compliantly using the device (an average of four hours per 24-hour period) and benefiting from its use.