Noninvasive Ventilator (NIV) Coverage Checklist (Per CMS NCD 240.2)

Applies to: **E0466** (Respiratory Assist Device with backup rate)

1. Patient Diagnosis

☐ Chronic respiratory failure consequent to one of the following:

- Severe **chronic obstructive pulmonary disease (COPD)**
- **Restrictive thoracic disorders** (e.g., neuromuscular disease, thoracic cage abnormalities)
- **Hypoventilation syndrome** (including obesity-related hypoventilation)

2. Arterial Blood Gas (ABG) Findings

For COPD:

☐ Awake arterial **$PaCO_2$ ≥ 52 mm Hg**, measured while breathing prescribed FiO_2

-FiO2 is the concentration of oxygen in the air a person breathes. Normally, room air is 21%. This can be increased by medical oxygen from 24% to 100%.
-PaCO2 is the amount of carbon dioxide dissolved in the blood. On room air the normal range is 35 to 45 mmHg). Anything greater than or equal to 52 mmHg indicates hypercapnia.

☐ Sleep oximetry shows oxygen saturation **≤ 88% for ≥ 5 cumulative minutes** while using prescribed FiO_2

☐ Sleep oximetry performed **after oxygen and/or CPAP optimization** (if applicable)

For Restrictive Thoracic Disorders:

☐ Awake **$PaCO_2$ ≥ 45 mm Hg**, measured while breathing prescribed FiO_2

☐ Sleep oximetry shows oxygen saturation **≤ 88% for ≥ 5 cumulative minutes** while using prescribed FiO_2

☐ Spirometry shows **max inspiratory pressure < 60 cm H_2O** or **FVC < 50% predicted**

For Hypoventilation Syndrome:

☐ Awake **$PaCO_2$ ≥ 45 mm Hg** while on prescribed FiO_2

☐ Sleep oximetry shows oxygen saturation **≤ 88% for ≥ 5 cumulative minutes** while using prescribed FiO_2

☐ Exclusion of **COPD** and **restrictive thoracic disorders** as primary cause

Timing of Testing

☐ ABG and sleep oximetry performed **within 30 days prior to initiation**
☐ If CPAP was tried, documentation must show **continued hypercapnia despite CPAP**
☐ **Sleep oximetry** must be performed **while breathing prescribed FiO_2**; pulse-ox alone on room air doesn't meet criteria
☐ If testing performed in a facility, MACs expect the **physician to acknowledge and interpret** the test results in their note

4. Physician Documentation Requirements

The treating practitioner's medical record must include:
☐ Diagnosis of chronic respiratory failure due to one of the covered conditions
☐ ABG report showing qualifying $PaCO_2$ level (hypercapnia)
☐ Sleep oximetry report meeting saturation criteria
☐ Clinical evidence of symptoms related to chronic respiratory failure (e.g., fatigue, dyspnea, morning headaches, or hypersomnolence)
☐ Confirmation that sleep apnea and CPAP therapy were considered and ruled out as the primary cause
☐ If patient has OSA, documentation must explain **why CPAP alone is insufficient**
☐ Statement of medical necessity for NPPV based on failure of other treatment (oxygen, CPAP, etc.)
☐ Plan for follow-up to assess ongoing use and benefit
☐ Documentation at 61–90 days showing patient continues to use and benefit from therapy (stabilization or improvement in $PaCO_2$ or symptoms)

5. Continued Use / Re-Certification

☐ Continued use and benefit documented at **61–90 days -** — a statement like "patient uses NIV nightly with symptomatic improvement" is required

☐ Treating practitioner notes show **symptom improvement or $PaCO_2$ stabilization**

☐ Supplier must keep documentation supporting **compliance and benefit**

6. Replacement after 5-Year RUL

☐ **In-person evaluation** documenting continued use and benefit before new device is ordered

7. Required Supporting Documentation

Initial Issue

☐ Face-to-face evaluation by treating practitioner

☐ Arterial blood gas (ABG) report showing qualifying $PaCO_2$

☐ Sleep oximetry report showing qualifying desaturation

☐ Documentation that CPAP/oxygen therapy was considered and ruled out

☐ Physician progress note supporting diagnosis and medical necessity

☐ Signed order / Standard Written Order (SWO)

☐ Proof of delivery and setup record

☐ 61–90-day follow-up note showing continued use and benefit

Replacement After 5-Year Reasonable Useful Lifetime (RUL)

☐ In-person evaluation by treating practitioner prior to order

☐ Documentation of continued use and benefit

☐ New signed order / SWO

☐ Supplier record showing replacement date (≥ 5 years from original issue)

☐ Prior documentation retained in file

☐ (If replaced < 5 years) Evidence explaining loss, damage, or irreparable failure