



## COVERAGE CRITERIA FOR NON-INVASIVE VENTILATION

Acceptable documentation for coverage\* of a non-invasive ventilator (NIV), like the **Life2000** Ventilation System, must be submitted that demonstrates disease progression and severity as well as indicates the prescriber's reasoning for medical necessity. Typical candidates for this device are those needing more ventilatory support than can be provided with a Bilevel, and those that need this support while ambulating.

Submit documentation for each category with the prescription to support your patient's coverage.

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### DEMONSTRATE DISEASE SEVERITY AND PROGRESSION

Include at least one test result and all relevant notes to demonstrate COPD or other pulmonary disease severity and Chronic Respiratory Failure:

#### TEST RESULTS

- Pulmonary Function Test (PFT)**  
Indicate COPD stage if applicable (FEV<sub>1</sub> <50%)
- Arterial Blood Gas (ABG)**  
pCO<sub>2</sub> ≥ 48 mmHG

#### DOCUMENTATION (TYPICALLY LAST 3 VISIT NOTES) THAT INCLUDES:

- Confirmation of diagnosis
- Explanation of why non-invasive ventilation is medically necessary
- Need for ventilation and changes in condition since last PFT and/or ABG
- Explanation of why ventilatory support may benefit the patient
- Explanation of why use of NIV for ambulation may benefit the patient Including precise rationale if patient is sedentary or with limited mobility

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### INDICATE BILEVEL HAS BEEN CONSIDERED/RULED OUT OR TRIED/FAILED AS AN OPTION

Include at least one of the following, depending on the patient's situation:

- For patients who do not use Bilevel, explain why this therapy was ruled out
- For patients who currently use Bilevel, explain why NIV therapy is needed instead of or in addition to Bilevel

#### LMN OR MEDICAL RECORDS SHOULD INCLUDE:

- Medical history and respiratory condition justifying the need for a ventilator and why other breathing machines (CPAP or Bilevel) won't suffice.
- Explanation of why Bilevel (with back up rate or volume assured pressure support) is not suitable for the patient, including clinical justification.
- Prescriber's precise rationale for choosing a ventilator over Bilevel for the patient's care

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### PATIENTS THAT ALREADY HAVE A NON-INVASIVE VENTILATOR

Include the reason why the patient needs the **Life2000** Ventilation System in addition to their current NIV therapy.

\*Some payers may have additional requirements including, but not limited to, face-to-face encounter, prior authorization, on-going medical need, and collection on compliance data.

# COMMONLY REIMBURSED DIAGNOSES FOR NIV

National Coverage Determination for Durable Medical Equipment (280.1): Covered for the treatment of Chronic Respiratory Failure (CRF) consequent to Chronic Obstructive Pulmonary Diseases (COPD), Thoracic Restrictive Diseases, and Neuromuscular Diseases.

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## CHRONIC RESPIRATORY FAILURE (CRF) CONSEQUENCE OF COPD/OTHER RESPIRATORY

For patients that have medical documentation to support a diagnosis of CRF, the medical records MUST ALSO include support COPD or other respiratory diagnosis. One cannot stand by itself (CRF + COPD or Other Respiratory).

A diagnosis of Chronic Respiratory Failure is required, Acute Respiratory Failure alone is not sufficient.

### MUST INCLUDE

#### CRF DIAGNOSES

- CRF with Hypoxia
- CRF, unspecified with Hypoxia or Hypercapnia
- Chronic Respiratory Failure with Hypercapnia
- Acute and Chronic Respiratory Failure, unspecified with Hypoxia or Hypercapnia
- Acute and Chronic Respiratory Failure with Hypoxia
- Acute and Chronic Respiratory Failure with Hypercapnia

### AND

#### COPD DIAGNOSIS

- COPD with exacerbation
- COPD unspecified

#### OTHER RESPIRATORY

- Chronic Bronchitis
- Emphysema
- Bronchiectasis

B

## THORACIC RESTRICTIVE DISEASE

Thoracic Restrictive Diseases does not require a CRF diagnosis.

#### THORACIC RESTRICTIVE DISEASE DIAGNOSES

- Obesity Hypoventilation Syndrome
- Idiopathic Pulmonary Fibrosis
- Interstitial Pulmonary Disease, unspecified
- Pulmonary Fibrosis, unspecified
- Sarcoidosis of the lung or unspecified
- Kyphosis
- Scoliosis

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## NEUROMUSCULAR DISEASE

Neuromuscular Diseases do not require a CRF diagnosis.

**NOTE:** Medical record documentation must clearly support the diagnosis, demonstrate disease progression and need for ventilatory support.

The information provided in this document is for educational purposes only and is not intended to serve as reimbursement advice. It is the responsibility of the provider to consult with the Medicare Program or other applicable health plan for appropriate coding and reporting of all items and services. In all cases, items and services billed must be medically necessary, actually furnished as reported and appropriately documented in conformance with applicable standards. Billing codes (e.g., E0290) and coverage criteria are subject to change. Consult the appropriate Medicare contractor with questions related to Medicare coverage, including the Pricing, Data Analysis & Coding (PDAC) contractor for product coding questions and the respective DMEMAC for other coding or criteria questions.

For complete Important Risk Information, please refer to the **Life2000** Ventilation System Instructions for Use.

**Rx Only.** For safe and proper use of product mentioned herein, please refer to the Instructions for Use or Operator Manual.

### Baxter.com

Baxter International Inc.  
One Baxter Parkway / Deerfield, Illinois 60015

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