RAD Devices for Chronic Respiratory Failure Consequent to Chronic Obstructive Pulmonary Disorder (COPD)

RAD Without Back Up Rate E0470		RAD With Back Up Rate E0471	
Initial Coverage (First 6 months)	**Continued Coverage**	**Initial Coverage (First 6 months)**	**Continued Coverage**
1. The patient exhibits hypercapnia as demonstrated by PaCO2 ≥ 52 mmHg by arterial blood gas during awake hours while breathing their prescribed FiO2; AND 2. Sleep apnea is not the predominant cause of hypercapnia (Formal sleep testing is not required if, per the treating clinician, the patient does not experience sleep apnea as the predominant cause of hypercapnia.).	Patients must be evaluated at least twice within the first year after initially receiving a RAD. Evaluations must occur by the end of the six-month initial coverage period and again during months 7-12. **First evaluation**: By 6 months after receiving initial coverage of a RAD, the treating clinician must establish that usage criteria and clinical outcomes are being met. Specifically, the patient must be determined by a clinician to use the RAD at least 4 hours per 24-hour period, on at least 70% of days in a 30-day period and achieve at least one the following clinical outcomes: • Normalization (< 46 mmHg) of PaCO2, or • Stabilization of a rising PaCO2, or • 20% reduction in PaCO2 from baseline value, or • Improvement of at least one of the following patient symptoms associated with chronic hypercapnia: – Headache – Fatigue – Shortness of breath – Confusion – Sleep quality **Second evaluation**: Between 7-12 months after initially receiving a RAD, the treating clinician must establish the patient is using the device at least 4 hours per 24-hour period on at least 70% of days in each paid rental month. **Post second evaluation**: The patient must be using the device at least 4 hours per 24-hour period on at least 70% of days in each remaining paid rental month and any month in which accessories/supplies are dispensed.	1. The patient exhibits hypercapnia as demonstrated by PaCO2 ≥ 52 mmHg by arterial blood gas during awake hours while breathing their prescribed FiO2; AND 2. Sleep apnea is not the predominant cause of the hypercapnia (Formal sleep testing is not required if, per the treating clinician, the patient does not experience sleep apnea as the predominant cause of the hypercapnia.); The patient demonstrates **one of the following** characteristics: • Stable COPD, without increase in or new onset of more than one respiratory symptom (cough, sputum production, sputum purulence, wheezing, or dyspnea) lasting 2 or more days and no change of pharmacological treatment during the 2-week period before initiation of NIV, **or** • Hypercapnia present for at least 2 weeks post hospitalization after resolution of an exacerbation of COPD requiring acute NIV. • By the end of the initial 6-month period, a RAD with backup rate feature must be utilized as high intensity therapy, defined as a minimum IPAP ≥15 cm H2O and backup respiratory rate of at least 14 breaths per minute.	Patients must be evaluated at least twice within the first year after initially receiving a RAD. Evaluations must occur by the end of the six-month initial coverage period and again during months 7-12. **First evaluation**: By 6 months after receiving initial coverage of a RAD, the treating clinician must establish that usage criteria and clinical outcomes are being met. Specifically, the patient must be determined by a clinician to use the RAD at least 4 hours per 24-hour period, on at least 70% of days in a 30-day period and achieve at least one the following clinical outcomes: • Stabilization of a rising PaCO2, **or** • 20% reduction in PaCO2 from baseline value, **or** • Improvement of at least one of the following patient symptoms associated with chronic hypercapnia: – Headache – Fatigue – Shortness of breath – Confusion – Sleep quality **Second evaluation**: Between 7-12 months after initially receiving a RAD, the treating clinician must establish the patient is using the device at least 4 hours per 24-hour period on at least 70% of days in each paid rental month. **Post second evaluation**: The patient must be using the device at least 4 hours per 24-hour period on at least 70% of days in each remaining paid rental month and any month in which accessories/supplies are dispensed.