NCD FOR NIV HIGHLIGHTS

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When providing feedback on the NCD, it's important to express how the proposed overly restrictive coverage criteria and administrative burdens will negatively impact chronically ill patients who rely on non-invasive ventilation. Below are key messages to guide your comments.

These comments represent what we are hearing from the industry as the biggest concerns...

No Grandfathering for Current RAD/HMV Users

There is ***serious*** concern that the proposed NCD does not "grandfather" patients who are already using RAD or HMV devices. Many of these patients will not have the historical documentation required under the new guidelines, despite clearly benefiting from their current therapy. Forcing them to stop therapy because of missing paperwork—rather than clinical need—could lead to hospitalization, deterioration of health, or even death. Physicians should be trusted to determine ongoing medical necessity without risking the removal of life-sustaining equipment.

Six-Month Re-Evaluation Burden

The proposed requirement for re-evaluation every six months creates an unnecessary and unrealistic burden —particularly for patients in rural or underserved areas. These individuals often struggle to access annual care, and increasing the frequency of required visits will introduce further barriers. Additionally, the financial strain of multiple appointments and potential cost-sharing may prevent patients from staying on necessary treatment, which could result in harmful disruptions to care and worse health outcomes.

ABG Testing Requirement

The draft policy's requirement for repeat Arterial Blood Gas (ABG) testing every six months is unnecessarily burdensome for patients and providers alike. ABGs are invasive, painful, and often unavailable in many outpatient or community-based settings—particularly in rural areas. Many providers have moved away from routine ABG testing for chronic management and instead rely on less invasive and clinically valid alternatives, such as transcutaneous $PtcCO_2$ monitoring or end-tidal CO_2 ($ETCO_2$) measurements. Excluding these methods from the qualifying criteria creates a significant access barrier for patients who depend on long-term ventilation therapy.

Furthermore, the proposed CO_2 threshold of $PaCO_2 \geqslant 52$ mmHg has raised concerns among clinicians. Research and clinical experience indicate that hypercapnia can become clinically significant at levels as low as 46-51 mmHg. By setting the threshold too high, the policy risks excluding patients who clearly need therapy but may not meet the arbitrary cutoff. This approach could result in delayed or denied care for individuals who are already struggling with serious chronic respiratory conditions.

Therapy Use Threshold (5-Hour Average Per Day)

The proposed requirement that patients average 5 hours of daily device use is inconsistent with established standards. Current adherence definitions—such as 4 hours per night on 70% of nights over a 30-day period—are widely accepted and clinically supported. Raising the threshold could disqualify patients who are still benefiting from therapy, and will likely create confusion and disruption across the continuum of care, from patients to suppliers to manufacturers.

Challenges with Hospital-to-Home Transitions

The proposed requirement for patients to be on the "same or similar" device within 24 hours of hospital discharge poses significant challenges. In many acute care settings, the ventilators used differ from those prescribed for home use. Enforcing this requirement could delay or even prevent timely access to the appropriate home-based device, jeopardizing patient safety and continuity of care.

Additionally, discharge readiness and planning rarely align perfectly with strict coverage timelines. Requiring precise coordination between hospital protocols and payer policies creates unnecessary friction and confusion for providers and families alike, increasing the risk of gaps in coverage and delaying essential therapy at a critical time in the patient's recovery.