



Pioneering Innovative Solutions in Respiratory Care

Presented by Carlos M. Nunez, MD to the Medicare Evidence Development &
Coverage Advisory Committee (MEDCAC)

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DISCLAIMER

Disclosures

Dr. Carlos Nunez is the full-time Chief Medical Officer (CMO) of ResMed. He receives compensation in the form of salary and equity. (Major)

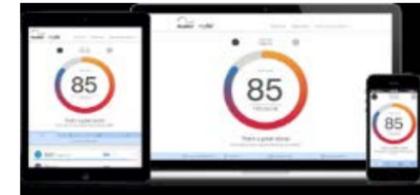
ResMed is a manufacturer of technologies that are the subject of this MEDCAC meeting and has a financial interest in the topics discussed herein.

Culture of Innovation

- ResMed invests in innovation, building intelligent solutions enabled by sensor technology, data analytics, artificial intelligence and machine learning
- Committed to scientific research to enable better patient experiences and improved clinical outcomes
- Clinical indications differ between device types
 - Home mechanical ventilators (HMV) are indicated for life support devices for patients with respiratory failure
 - Bi-level positive airway pressure ventilation devices are indicated for respiratory insufficiency
 - Continuous positive airway pressure devices are indicated for obstructive sleep apnea



AirView™
Cloud-based patient management system



myAir™
Patient engagement program



Restrictive Requirements May Limit Access for Patients

- **Standards of care for patients**

- **Neuromuscular disease.** For example, Duchenne muscular dystrophy (DMD) and spinal muscular atrophy are two diseases that are marked by progressive respiratory insufficiency. [1]
- **Chronic respiratory failure, with chronic hypercapnia, due to chronic obstructive pulmonary disorder:** Long-term NIV can be considered [5] with further evidence that bi-level with back-up rate is an effective ventilation strategy (HOT-HMV ref).

- **Not a one size fits all option**

- Approved clinical indications also differ between these device types, with home mechanical ventilators (HMs) indicated for patients with respiratory failure, bi-level positive airway pressure (BPAP) indicated for respiratory insufficiency and continuous positive airway pressure (CPAP) indicated for OSA
- The relationship between these bi-level devices for treatment of respiratory insufficiency and home mechanical ventilators for treatment of chronic respiratory failure are inextricably linked

- **Clinicians need flexibility**

- HMV devices have the unique advantage of having additional modes of ventilation and settings – in particular, additional alarms that can alert care providers in the home – allowing the care provider to apply safe and targeted care for the patient
- Pilot studies in neuromuscular clinics in Europe have suggested that remote monitoring of non-invasive ventilation in patients with ALS improves at least some aspects of quality of care (such as improved patient satisfaction) and value (reduced costs and hospitalizations) [2-4]

[1] <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5656914/> Paganoni S. et al, Developing multidisciplinary clinics for neuromuscular care and research, Muscle Nerve, 2017 Nov; 56(5): 848–858.

[2] Pinto A, Almeida JP, Pinto S, Pereira J, Oliveira AG, de Carvalho M. Home telemonitoring of non-invasive ventilation decreases healthcare utilisation in a prospective controlled trial of patients with amyotrophic lateral sclerosis. J Neurol Neurosurg Psychiatry 2010;81:1238–1242

[3] Vitacca M, Assoni G, Pizzocaro P. A pilot study of nurse-led, home monitoring for patients with chronic respiratory failure and with mechanical ventilation assistance. J Telemed Telecare 2006;12:337–342

[4] Vitacca M, Bianchi L, Guerra A. Tele-assistance in chronic respiratory failure patients: a randomised clinical trial. Eur Respir J 2009;33:411–418

[5] <https://goldcopd.org/wp-content/uploads/2018/11/GOLD-2019-POCKET-GUIDE-DRAFT-v1.7-14Nov2018-WMS.pdf>

Current Evidence Suggests Increased QoL with NIPPV

Patient outcomes of home NIPPV

- HOT-HMV study compared home NIPPV plus oxygen to oxygen alone in 64 patients over a 12-month study period. Bi-level with back-up rate devices were used with a high pressure strategy, as this therapeutic approach to titrate home NIPPV to lower PaCO₂ has been shown to be the most effective in this patient population.
- This study built upon the earlier evidence from Murphy, Struik, Kohnlein, and others further refining the appropriate patient population (chronic hypercapnic severe COPD patients) and NIV strategy (high pressure with back-up rate) to provide clarity on home NIPPV use.
- Results show a 51% reduction in the risk of hospital readmission or death in the HOT-HMV arm compared to the HOT arm.
- Median admission-free survival time was 4.3 months in the HOT-HMV arm compared to 1.4 months for those in the control group.
- Significant effects in quality of life were seen at 6 weeks and 3 months follow-up, non-significant trends at 12 months. The modest effect on QoL is not surprising, considering the severity of the patient population enrolled and the high levels of physical impairment at baseline. Overall, the results of the trials suggest that HOT-HMV therapy improved the overall clinical outcome without adding to the health burden of the patient.

Results of this pivotal study lead to an update to the GOLD guidelines, which incorporated home NIPPV therapy for chronic hypercapnic COPD patients after an exacerbation requiring NIV therapy.

Cost-Effectiveness of NIPPV

- Secondary objective of the HOT-HMV trial [1]
 - Determine if adding home NIV (HMV) to home O2 therapy (HOT) for hypercapnic COPD patients following a life-threatening exacerbation is cost-effective in the US
- Cost-effectiveness was determined by calculating an incremental cost-effectiveness ratio (ICER)
 - Compared the addition of HMV to HOT versus HOT alone
 - ICER = ratio of the total cost of each intervention relative to the respective quality adjusted life year (QALY)
- The economic analysis demonstrated that adding NIV to HOT is more effective and less costly than HOT alone
 - The ICER = -\$50,856 per QALY gained
 - HOT-HMV is a dominant therapy strategy

[1] https://www.atsjournals.org/doi/pdf/10.1164/ajrccm-conference.2018.197.1_MeetingAbstracts.A2518 Criner GJ. et al, Cost-Effectiveness of Home Oxygen Therapy-Home Mechanical Ventilation (HOT-HMV) for Treatment of Chronic Obstructive Pulmonary Disease (COPD) with Chronic Hypercapnic Respiratory Failure Following an Acute Exacerbation of COPD in the United States (US), Am J Respir Crit Care Med 2018;197:A2518.

ResMed Recommendations to MEDCAC

- MEDCAC should consider the spectrum of technology and broad range of clinical scenarios
- MEDCAC should consider in totality the technological innovations, including remote monitoring, combined with physician oversight and clinical support services as critical components for quality care
- MEDCAC should consider and prioritize recent evidence and clinical guidelines, specifically the 2020 Global Initiative for Chronic Obstructive Lung Disease (GOLD) report and 2019 European Respiratory Standards (ERS) guidelines
- MEDCAC should not include patient usage criteria in coverage recommendations as there is insufficient clinical evidence and this criteria would interfere with clinical decision making