

## CHEST

#### **Topics in Practice Management**

# The Changing Landscape of Adult Home Noninvasive Ventilation Technology, Use, and Reimbursement in the United States

Bernie Y. Sunwoo, MBBS; Mary Mulholland, MHA, BSN RN, CPC; Ilene M. Rosen, MD, MSCE; and Lisa F. Wolfe, MD, FCCP

There has been an exponential increase in the use of home noninvasive ventilation (NIV). Despite growing use, there is a paucity of evidence-based guidelines and practice standards in the United States to assist clinicians in the initiation and ongoing management of home NIV. Consequently, home NIV practices are being influenced by complicated local reimbursement policies and coding. This article aims to provide a practice management perspective for clinicians providing home NIV, including Local Coverage Determination reimbursement criteria for respiratory assist devices, Durable Medical Equipment coding, and Current Procedural Terminology coding to optimize clinical care and minimize lost revenue. It highlights the need for further research and development of evidence-based clinical practice standards to ensure best practice policies are in place for this rapidly evolving patient population. CHEST 2014; 145(5):1134–1140

Abbreviations: AMA = American Medical Association; BPAP = bilevel positive airway pressure; CCCC = Complex Chronic Care Coordination; CCV = critical care ventilator; CMS = Centers for Medicare and Medicaid Services; CPT = Current Procedural Terminology; DME = Durable Medical Equipment; DMEPOS = Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; E/M = Evaluation and Management; HCPCS = Healthcare Common Procedure Coding System; LCD = Local Coverage Determination; NIV = noninvasive ventilation; OHS = obesity hypoventilation syndrome; PA = positive airway pressure; RAD = respiratory assist device; TCM = Transitional Care Management

There has been an exponential increase in the use of home noninvasive ventilation (NIV). Driven in part by advances in sleep medicine and the demonstrated efficacy in 1981 of CPAP to treat OSA, NIV is progressively replacing tracheostomy and invasive

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Affiliations: From the Department of Medicine (Drs Sunwoo and Rosen), Division of Pulmonary, Allergy and Critical Care Medicine, Division of Sleep Medicine, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA; the Department of Medicine (Ms Mulholland), Hospital of the University of Pennsylvania, Philadelphia, PA; the Division of Pulmonary and Critical Care Medicine (Dr Wolfe), Northwestern University Feinberg School of Medicine, Chicago, IL.

Correspondence to: Bernie Y. Sunwoo, MBBS, Perelman School of Medicine, University of Pennsylvania, Department of Medicine, Division of Pulmonary, Allergy, and Critical Care Medicine, Division of Sleep Medicine, Perelman Center for Advanced Medicine, 1st Floor, W Pavilion, 3400 Civic Center Blvd, Philadelphia PA 19104; e-mail: bernie.sunwoo@uphs.upenn.edu

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mechanical ventilation in the home. CPAP (E0601) refers to application of continuous positive pressure throughout the respiratory cycle in a spontaneously breathing individual. It is used primarily to treat OSA and hypoxemia. CPAP is distinct from NIV, which is intended to increase alveolar ventilation, and is considered separate from NIV in this article.

Prevalence data on home NIV use in the United States are lacking. No national database or registry exists, and most prevalence estimates are extrapolations from insurance claims or hospital surveys. In 2010, based on Centers for Medicare and Medicaid Services (CMS) claims data, approximately 47,981 CMS patients were estimated to be receiving some form of home ventilation in the United States, with approximately 6.6% using invasive ventilation. With ongoing technologic advances in noninvasive ventilators and interfaces, increasing numbers of patients surviving critical illness, evidence supporting a growing list of disorders that can be successfully managed by NIV, and economic pressures, it is anticipated that home NIV use will continue to grow.

Despite the growing use of home NIV, with the exception of certain neuromuscular disorders, such as Duchenne muscular dystrophy and amyotrophic lateral sclerosis, <sup>2,3</sup> there is a paucity of evidence-based guidelines and practice standards in the United States to assist clinicians in the initiation and ongoing management of home NIV. Consequently, home NIV practices are being influenced by complicated local reimbursement policies. This article aims to provide a practice management perspective for clinicians providing home NIV, including coverage, coding, and reimbursement to optimize clinical care and minimize lost revenue.

#### HOME NIV INDICATIONS AND COVERAGE DETERMINATION

Much of the increase in home NIV use has been fueled by technologic advances in noninvasive ventilators and interfaces. Home NIV ventilators are generally positive pressure devices, and although negative pressure devices like the chest cuirass exist, they are rarely used, and for the purposes of this article will not be reviewed. Noninvasive ventilators vary in design characteristics depending on their intended purpose of use. Traditional critical care ventilators designed for invasive mechanical ventilation are characterized by dual-limb circuits with an active exhalation valve and sophisticated modes and alarms. They are typically labeled as "ventilators" by the reimbursement community and will be denoted critical care ventilators (CCVs) in this article. In contrast, respiratory assist devices (RADs) or portable "bilevel devices" are designed for home noninvasive ventilation use1 and are the focus of this article.

RADs use a single-limb circuit with a passive exhalation port incorporated into the circuit and allow for better leak compensation. Bilevel devices can be spontaneous (E0470) or have a backup rate (E0471). Newer autotitrating devices that change pressure support based on feedback from various patient parameters using proprietary algorithms are becoming available. In adaptive servoventilation, the degree of ventilatory support is dynamically adjusted breath to breath to stabilize minute ventilation and is used in patients with central and complex sleep apnea.<sup>4-7</sup> The compact size, lower cost, and portability of RADs have made them more appealing for use at home.

Although traditionally CCVs and RADs varied in the features offered, technologic developments have blurred the distinction between the two. RADs are becoming increasingly sophisticated, whereas newergeneration CCVs allow for better leak compensation and noninvasive use. This has created confusion as to what exactly constitutes a CCV or RAD, challenging coding and reimbursement. Although CCVs were originally designed for patients requiring full invasive

mechanical ventilatory support or "life support" and RADs for patients requiring no or partial ventilatory support, the practice of associating the type of ventilator to the degree of ventilator dependence or type of interface is no longer always applicable with the recent US Food and Drug Administration approval of a RAD for use with a tracheostomy. This RAD device also falls under the category of a CCV and, like other CCVs, has an active exhalation valve, internal battery source, and alarms to address safety. Similarly, the recent US Food and Drug Administration approval of advanced E0471 devices marketed for specific conditions, such as COPD, was based on built-in alarms. Conversely, CCVs can function to provide home NIV. Life support is often presumed to mean ventilator dependence, where cessation can be life threatening, but no uniform definition exists. With this ambiguity in what constitutes ventilator dependence, it is not entirely clear when to prescribe a CCV vs an RAD.

The home NIV population is becoming increasingly heterogeneous, with an expanding list of medical indications for NIV. NIV has been shown to improve survival, palliate symptoms, and improve quality of life in patients with neuromuscular disease, including amyotrophic lateral sclerosis and Duchenne muscular dystrophy.<sup>2,9-11</sup> Similarly, prolonged survival and reduced morbidity have been demonstrated in scoliosis and restrictive chest wall disease. 12,13 The evidence for NIV in stable COPD has been inconsistent, 14-16 but COPD is a frequent cause for home NIV use worldwide. 17 There is growing interest in the role of NIV in the overlap syndrome or coexisting COPD and OSA,18 whereas sleep-related breathing disorders and the obesity hypoventilation syndrome (OHS) have become leading indications for home NIV.19,20 The risk of OSA and OHS increases with obesity, and in the United States it is now estimated that more than one-third of adults are obese.<sup>21</sup> An OHS prevalence of 10% to 20% has been reported in obese patients with OSA.<sup>22</sup> OHS was the leading indication for home NIV, responsible for 31%, in a recent study exploring prevalence and patterns of home mechanical ventilation in Australia and New Zealand.<sup>23</sup>

With escalating NIV use and costs, in 1998 a consensus conference was convened by the National Association for Medical Direction of Respiratory Care to develop practice guidelines for NIV use. Subsequently, a consensus report was published describing clinical indications for NIV in restrictive thoracic disorders, including neuromuscular disorders, COPD, and nocturnal hypoventilation syndromes. The report was adopted by CMS and then secondarily by third-party carriers and serves as the guide for most current home NIV reimbursement coverage policies today. CMS coverage is executed with a trickle-down model by which a central federal plan, known as National

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