AAHOMECARE
American Association for Homecare

Costs and Value of Non-Invasive Ventilation in the Home

Background

Ventilators are a type of Durable Medical Equipment (DME) that provide life support to medically fragile patients. Non-invasive ventilation (NIV) uses a ventilator attached to a mask and/or mouthpiece to assist individuals who cannot breathe sufficiently on their own; in contrast, invasive ventilation requires an addition of an artificial airway, such as a tracheostomy or endotracheal tube. Medical and technological advancements have vastly improved NIV since the iron lung of the 1920s, allowing end users to have a much higher quality of life with better survival rates, fewer respiratory infections, and fewer hospital admissions.

Individuals who require ventilation either have progressive (deteriorating) diseases such as neuromuscular diseases like Amyotrophic Lateral Sclerosis (ALS), restrictive thoracic disease such as Kyphoscoliosis, or chronic respiratory failure from serious medical conditions such as Chronic Obstructive Pulmonary Diseases (COPD) and spinal cord injuries.

Ventilators provide critical life support for those who require them and require careful assessment, ongoing monitoring, extensive education, training, support, titration, and servicing by qualified personnel. The Food and Drug Administration (FDA) classifies ventilators (NIV and invasive) as Class II devices and indicates that they provide continuous or intermittent ventilation via mask, mouthpiece, tracheostomy tube, or endotracheal tube. The National Association for Medical Direction of Respiratory Care (NAMDRC) explains that "[ventilators] are intended to provide life support, and interruption of the device can reasonably be expected to lead to eventual or rapid clinical deterioration, leading to medical harm or even death".[1] Ventilators are also classified as requiring "frequent and substantial servicing" by the Centers for Medicare and Medicaid Services (CMS), a classification reserved for items for which there "must be frequent and substantial servicing in order to avoid risk to the patient's health".[2] To date, CMS has never included a "frequent and substantial servicing" category item in Competitive Bidding.

The high touch nature of ventilators, coupled with the numerous supplies and accessories required for the device to work properly for the end user, contribute a significant portion of the overall cost of providing NIV to end users beyond the cost of the device itself. Currently, Medicare and many other payors bundle all the services, supplies, and support along with the device into one recurring monthly payment. As such, it is imperative that all of these costs are factored in when determining reimbursement in order to ensure continued access to this life sustaining technology.

NIV Initiation and Management

NIV therapy requires a highly trained, credentialed, licensed Respiratory Therapist (RT) or other appropriately licensed clinician that delivers, initiates, manages, services, and educates patients and family on a critical life support device.

The doctor sends the DME supplier an order for a patient who has a diagnosis that requires a ventilator. Before treatment is initiated, all documentation must be reviewed by the supplier, including the prescription, face-to-face clinical notes, and insurance benefit verification. When an RT initiates home NIV, they spend an extended amount of time at the home. Based upon the physician's prescription, they may be required to adjust the settings on the ventilator in accordance with the therapy goals and the patient's comfort. Additionally, they fit the mask on the patient, show the patient and caregiver how to use the mouthpiece, and provide education on ventilator settings, alarms and general troubleshooting, supplies, and emergency preparedness. The RT also discusses disease management, maintenance and cleaning, attaching accessories, and infection control. It is the job of the RT to ensure the patient and caregiver(s) are comfortable and confident with operating the ventilator.

Patients supported with ventilators must have regular and frequent evaluations. According to the American Association for Respiratory Care (AARC) Clinical Practice Guidelines, "Health care professionals should

perform a thorough, comprehensive assessment of the patient and the patient-ventilator system on a regular basis as prescribed by the plan of care… Health care professionals are also responsible for maintaining interdisciplinary communications concerning the plan of care."[3] A regular RT home visit consists of an evaluation of the patient's current health status, the caregiver's need for continuing education, the home environment, and a function check of the ventilator. Physicians rely on the RT to report any change in patient health status noted during the visit. Regulations also require that an RT is available 24/7 for patient and caregiver support.

The time, equipment, supplies, clinical services, maintenance, and 24/7 support required to properly care for an NIV patient comes with a cost. As an example, below are some of the potential acquisition costs a supplier may incur that are associated with caring for an NIV patient; all these costs must be covered by the average monthly reimbursement rate.

Device/Supply Item	Initial/Set-Up	Monthly
Ventilator	$7,000-$8,000	
Humidifier Unit	$895	
Humidifier Temp Probe & Heater Wire Adapter	$150	$25
Ventilator Stand	$350	
Backup Battery (1-2)	$350-$700	
Heated Circuit (2)	$50	$50
Bacteria Filters (4)	$7.40	$7.40
Oxygen Connectors (2)	$5.75	
Reusable Filter (2)	$6.00	
Mask Interface	$120	$20
Water Chamber (1)	$10	$3.34
Mouthpiece Circuit	$20	$6.67
Mask Cushion		$29
Chin Strap	$10	$3.34
Ventilator Swing Arm	$300	
DC Power Cable for Auto	$150	
Remote Monitoring Technology & Subscription	$33	$33
TOTAL	**$9,457-$10,807**	**$177.75**

Costs and Supply Quantities Vary Depending on Supplier
Table Excludes Shipping Costs, Which is an Added Expense

Labor Costs Associated with Caring for an NIV Patient

While actual salaries of RTs can vary by company and geographic area, below are labor costs based on the national homecare RT salary average and time RTs often spend caring for the patient.[4]

	Duration	Frequency	Labor Cost	Travel Cost	Minimum Cost
Initial Training	4 Hours	One-Time	$100	$50-120	**$150**
Routine Visit	1 Hour	Monthly	$25	$50-120	**$75**
After Hours Phone Call	30 minutes	As Needed	$15		**$15**
After Hours Visit	1 -2 Hours	As Needed	$75	$50-120	**$125**
New Caregiver Training	4 Hours	As Needed	$100	$50-120	**$150**
Follow-Up Training	4 Hours	As Needed	$100	$50-120	**$150**
Physician Interaction	30 minutes	As Needed	$13		**$13**

To ensure the ventilator is in proper working condition, preventative maintenance must be performed every one to two years, at which time certain components must be replaced. A trained and qualified biomedical technician must perform the preventative maintenance. Below are the average costs from biomed companies that perform preventative maintenance on ventilators; these charges are not reimbursed by Medicare.

	Frequency	Cost
10K/2-Year Preventative Maintenance	Every 10,000 use hours or every 2 years, whichever occurs first	$250
Blower/Motor Assembly Replacement	Every 17,500 hours	$1000
Insect Infestation Remediation	As Needed	$1500
Smoke Remediation	As Needed	$1500

NIV Patient Perspective

For many who require NIV, the extensive services and hands on clinical support provided by their supplier and RT are instrumental in successfully managing one's health care needs, increasing quality of life, and avoiding unintended health consequences. Below are two NIV patient stories.

As a caregiver and mother of 49-year old Mark, Diane J. from Colorado shares her experience caring for Mark 24/7 over the past 29 years. Mark has MS with quadriplegic-like symptoms. He uses a noninvasive ventilator, power chair, cough assist machine, suction machine, as well as necessary medical supplies. Diane explains, "we require a [supplier] that can provide us with a Respiratory Therapist (RT) to help manage his care. Our current supplier came to the hospital, trained me as a caregiver and provided all the necessary medical tools I needed to take him home. [My supplier's] RT made this very traumatic experience so easy and gave me the confidence to perform these tasks at home. They deliver the correct supplies in a timely manner, and a knowledgeable RT responds to my calls." She also relayed that the ability to change suppliers to ensure Mark receives the service and care he needs is paramount. "We absolutely need to have the right and ability as a patient to choose a [supplier] of choice for our medical needs. Without that ability, I will not be able to care

for Mark as he needs, causing him to experience a lack of good care which could harm his life and require us to make unnecessary visits to doctors and hospitals."

Steven H., a Texas NIV user with ALS, explains, "I have an excellent relationship with [my supplier]. [They come] to my residence once a month at the very least to check my equipment and answer any questions or concerns I may have. If needed, he will come any time. He understands my needs and goes out of his way to accommodate me." Steven fears for the diminished access and service under the Medicare Competitive Bidding Program. "Medicare and other insurance companies will force good companies to either cut back their services to be able to compete or get out of the business altogether. I'm concerned that will result in more hospital admissions or emergency room visits. Please don't let NIVs be added to Competitive Bidding."

Conclusion

NIV provides life support and enhances quality of life for medically complex individuals. People who would otherwise be forced into institutions to meet their medical needs are able to live at home thanks to the device and extensive services, supplies, and support offered by their supplier and RT. While not recognized as a separate billable expense under Medicare and many other payors, these are essential components of NIV therapy and must be accounted for when evaluating the total cost of providing NIV, which can cost suppliers thousands of dollars as illustrated in the charts above. Medicare and other payors have a responsibility to their beneficiaries to ensure that NIV policies and reimbursement protect end users' ability to receive the care, supplies, and equipment needed to manage their health care needs. Ventilators are inappropriate for the Medicare Competitive Bidding Program, which would cause significant harm to this vulnerable patient population.

Current NIV user Paul C. at an ALS event in Texas

Sources

1. *https://www.namdrc.org/sites/default/files/files/Multi%20Society%20NCD%20Submission%20to%20CMS%203-25-2016.pdf)*
2. *https://med.noridianmedicare.com/web/jddme/policies/dmd-articles/2019/correct-coding-and-coverage-of-ventilators-revised-april-2019*
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