

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**SLEEP MANAGEMENT, LLC:  
AUDIT OF CLAIMS FOR  
MONTHLY RENTAL OF NONINVASIVE  
HOME VENTILATORS**

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A-04-18-04066

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## Report in Brief

Date: May 2021

Report No. A-04-18-04066

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
**OFFICE OF INSPECTOR GENERAL**



### Why OIG Did This Audit

A previous OIG review found that medical equipment suppliers could bill Medicare for a noninvasive home ventilator (NHV) as if it were being used as a ventilator, when use of a lower cost respiratory assist device or basic continuous positive airway pressure device was indicated by the patient's medical condition.

Sleep Management, LLC (Sleep Management), was among the top three suppliers of NHVs in calendar years (CYs) 2016 and 2017. Medicare paid Sleep Management \$36.8 million for NHVs during our audit period.

Our objective was to determine whether Medicare claims submitted by Sleep Management for the monthly rental of NHVs complied with Medicare requirements.

### How OIG Did This Audit

We selected a random sample of 100 claim lines for the monthly rental of NHVs submitted by Sleep Management that Medicare paid in CYs 2016 and 2017 (audit period). An independent medical review contractor reviewed supporting documentation to determine whether the claim lines complied with Medicare coverage and payment requirements.

## Sleep Management, LLC: Audit of Claims for Monthly Rental of Noninvasive Home Ventilators

### What OIG Found

Most Medicare claims submitted by Sleep Management for the monthly rental of NHVs did not comply with Medicare requirements. Of the 100 sampled claim lines with payments totaling \$75,694, 2 complied with Medicare requirements; however, 98 claim lines with payments totaling \$74,288 did not. Based on our sample results, we estimated that Medicare made overpayments to Sleep Management of at least \$29.1 million for the monthly rental of NHVs that did not comply with Medicare requirements.

These overpayments occurred because Sleep Management did not follow its policies and procedures to ensure that it obtained sufficient documentation to support the medical necessity of the NHV or discontinued service for lack of beneficiary usage.

### What OIG Recommends and Sleep Management Comments

We recommend that Sleep Management: (1) refund the portion of the estimated \$29.1 million in Medicare overpayments for claim lines incorrectly billed that are within the 4-year reopening period; (2) exercise reasonable diligence to identify, report, and return any similar overpayments in accordance with the 60-day rule; and (3) follow existing policies and procedures to help ensure that it complies with Medicare requirements.

Sleep Management did not concur with our recommendation to refund the estimated overpayments contending that: (1) its NHV claims were medically necessary, (2) we applied clinical standards not required by CMS and improperly applied clinical guidance, (3) our sampling methodology and extrapolation were improper, (4) our medical reviewer was not independent, and (5) it was not liable for the overpayments. Additionally, Sleep Management stated that it recognized its responsibility under the 60-day rule and had exercised more than reasonable diligence in determining and quantifying any overpayments owed as a result of this audit. Finally, Sleep Management did not concur with our recommendation to follow its existing policies and procedures to ensure compliance with Medicare requirements maintaining that its compliance programs were adequate.

After reviewing Sleep Management's comments, we maintain that our findings and recommendations are valid. However, to avoid potential confusion, we removed a finding related to a beneficiary's continued need for an NHV. Removing this finding did not change our estimated overpayments or recommendations.

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## INTRODUCTION

### WHY WE DID THIS AUDIT

Medicare covers monthly rental payments for noninvasive home ventilators (NHVs) when the device is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.<sup>1</sup> A previous Office of Inspector General (OIG) report<sup>2</sup> found that NHVs had features that created an opportunity for abuse whereby durable medical equipment (DME) suppliers<sup>3</sup> could bill Medicare for an NHV as if it were being used as a ventilator, when use of a lower cost respiratory assist device (RAD) or basic continuous positive airway pressure (CPAP) device was indicated by the beneficiary's medical condition. From 2009 through 2017, Medicare payments for NHVs increased from \$3.1 million to \$268.8 million. Sleep Management, LLC (Sleep Management), and two other suppliers accounted for the majority of growth in billing for NHVs.

### OBJECTIVE

Our objective was to determine whether Medicare claims submitted by Sleep Management for the monthly rental of NHVs complied with Medicare requirements.

### BACKGROUND

#### Medicare Program

Title XVIII of the Social Security Act (the Act) established the Medicare program, which provides health insurance coverage to people aged 65 and over, people with disabilities, and people with end-stage renal disease. The Centers for Medicare & Medicaid Services (CMS) administers the program. Medicare Part B provides supplementary medical insurance for medical and other health services and supplies when they are medically necessary, including the coverage of DME items such as NHVs.

During calendar years (CYs) 2016 and 2017 (audit period), CMS contracted with two Medicare administrative contractors (MACs) to process and pay supplier claims for DME provided to Medicare beneficiaries who resided in one of four geographical jurisdictions. The contractors' responsibilities also included responding to supplier inquiries, educating suppliers about coverage and billing requirements, and reviewing DME claims.

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<sup>1</sup> The Social Security Act (the Act) § 1862(a)(1)(A).

<sup>2</sup> *Escalating Medicare Billing for Ventilators Raises Concerns* (OEI-12-15-00370).

<sup>3</sup> A "DME supplier" is an entity or individual, including a physician or a Part A provider, that sells or rents items covered by Medicare Part B to Medicare beneficiaries.

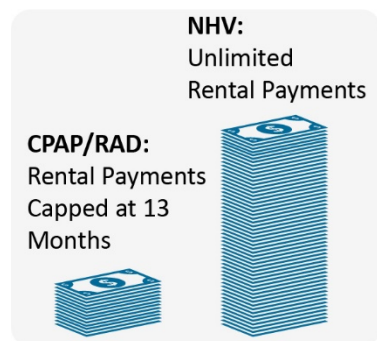
## Noninvasive Home Ventilators

NHVs are medical devices used in the beneficiary's home that provide mechanical ventilation to assist with or replace the beneficiary's spontaneous breathing.<sup>4</sup> NHVs use a noninvasive interface—such as a mask—that is similar to the interfaces used with RAD or CPAP devices. Additionally, NHV products can treat numerous conditions by operating in several modes—i.e., traditional ventilator mode, RAD mode, and CPAP mode.<sup>5</sup>

The combination of the NHVs' features—the noninvasive interface and multimodal capability—creates an opportunity for abuse whereby DME suppliers could bill Medicare for an NHV as if it were being used as a ventilator, when use of a lower cost RAD or CPAP device is indicated by the beneficiary's medical condition. In contrast, invasive ventilators require the beneficiary to be intubated, making the inappropriate use of such a ventilator in place of other devices unlikely.



Medicare pays for home ventilators under the category of DME items that require frequent and substantial servicing to avoid risk to the beneficiary's health.<sup>6</sup> The average monthly rental rate



for NHVs in CY 2017 was \$1,007, which covered the base device, servicing of the device, and replacement of essential supplies (e.g. tubing, masks, and filters). The monthly rental rate for RADs or CPAP devices was substantially less, ranging from approximately \$40 to \$394.<sup>7</sup> Medicare pays suppliers a monthly rental payment for NHVs until the beneficiary dies or the device is removed from the beneficiary's possession;<sup>8</sup> however, rental payments for the RAD and CPAP device are capped at 13 months, after which the beneficiary owns the device.<sup>9</sup> The considerably

<sup>4</sup> The Health Care Common Procedure Coding System (HCPCS) code for NHVs is E0466. HCPCS is a standardized code system necessary for medical providers to submit healthcare claims to Medicare and other health insurers in a consistent and orderly manner.

<sup>5</sup> A CPAP provides a continuous stream of pressurized air to keep airways free of obstruction. A RAD has all the functionality of a CPAP device, delivers two different pressure settings for inspiration and expiration, and can deliver a physician-determined number of mandatory breaths per unit of time. An NHV has all the functions of a CPAP device and RAD and the capacity to automatically adjust inspiratory and expiratory pressures.

<sup>6</sup> 42 CFR § 414.222 and *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 20, section 30.

<sup>7</sup> Monthly rental rates are State specific. The average monthly rental rates that we calculated for NHVs, RADs, and CPAP devices do not include the rates for the United States territories of Puerto Rico and the Virgin Islands.

<sup>8</sup> *Ibid.*

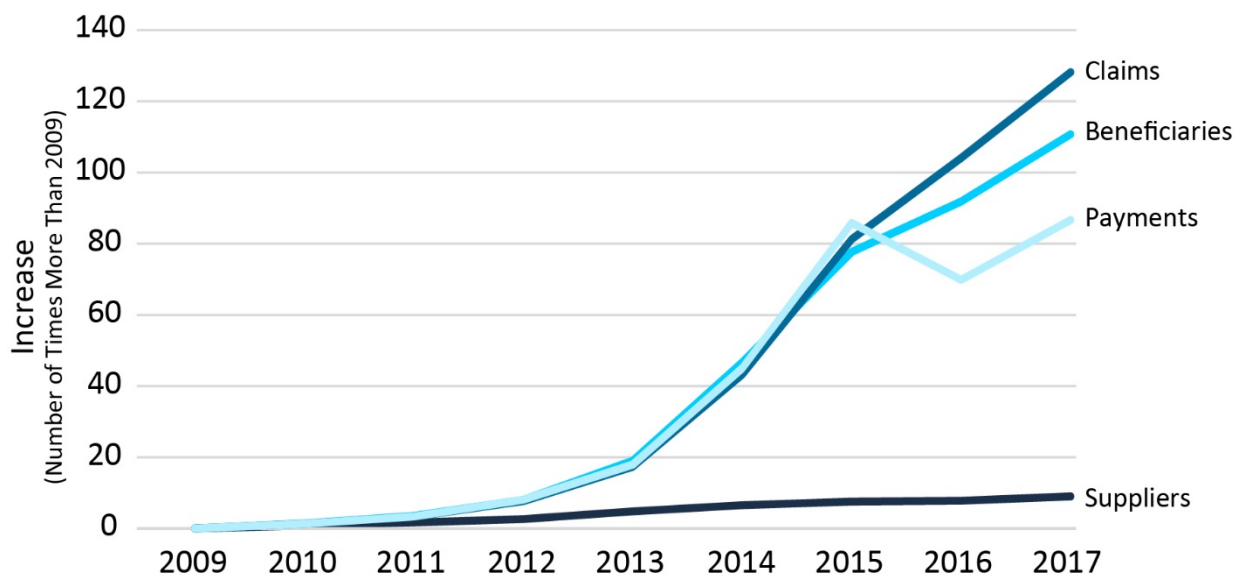
<sup>9</sup> 42 CFR § 414.229 and *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 20, section 30.5.



higher and potentially indefinite monthly payment rates for NHVs could create an incentive for suppliers to provide beneficiaries with an NHV when a RAD or CPAP device is warranted by the beneficiary’s medical condition.

From CYs 2009 to 2017, suppliers’ Medicare billing for NHVs increased substantially. During this period, the number of suppliers that billed NHV claims increased from 74 to 742, beneficiaries with NHV claims increased from 418 to 46,704, the number of NHV claims increased from 2,670 to 344,867, and Medicare payments for NHVs increased from \$3.1 million to \$268.8 million. (See Figure 1 below.<sup>10</sup>)

**Figure 1: Increase in Suppliers, Beneficiaries, Claims, and Medicare Payments From CYs 2009 Through 2017**



<sup>10</sup> While the number of claims and beneficiaries continued to increase in 2016, payments decreased because Medicare decreased the reimbursement rate for NHVs.

The distribution of primary diagnoses on NHV claims also changed dramatically from 2009 to 2017. The most common diagnosis codes in 2009 represented neuromuscular diseases<sup>11</sup> (56 percent), but by 2017 only 6 percent of claims listed a neuromuscular disease diagnosis. For the same period, diagnoses of chronic respiratory failure and chronic obstructive pulmonary disease (COPD) increased substantially. The proportion of NHV claims with such a diagnosis rose from 29 percent to 93 percent.<sup>12</sup> This shift is notable because diagnoses of chronic respiratory failure and COPD were similar to diagnoses for conditions treated using RADs and indicates that suppliers may have provided a ventilator to the beneficiary when the beneficiary could have been appropriately treated with a RAD.

### **Medicare Requirements for Noninvasive Home Ventilators**

NHVs are covered by Medicare when they are reasonable and necessary for the treatment of neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to COPD.<sup>13</sup> In addition, the MACs may issue local coverage determinations (LCDs) that specify what items are reasonable and necessary and define what items or services are covered in their jurisdictions. Although the MACs did not issue an LCD for the NHV, they issued an LCD for the RAD that discusses how a provider should determine whether an NHV or RAD is the appropriate device for treatment.<sup>14</sup> (See Table 1 on the next page.) The MACs also issued supplemental guidance regarding the coverage of ventilators.<sup>15</sup>

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<sup>11</sup> Many progressive neuromuscular diseases involve the muscles of the respiratory system. Ventilatory assistance becomes an important part of disease management for patients with advanced neuromuscular disease.

<sup>12</sup> To describe the change in the distribution of diagnoses for NHVs from 2009 to 2017, we summarized the number of claims associated by primary diagnosis codes and then identified the 10 most common diagnoses for each year.

<sup>13</sup> The Act § 1862(a)(1)(A) and *Medicare National Coverage Determinations Manual*, Pub. No. 100-03 chapter 1, part 4, section 280.1.

<sup>14</sup> Local Coverage Determination (LCD): Respiratory Assist Devices (L33800) for DME MAC Jurisdictions A, B, C, and D.

<sup>15</sup> Noridian Healthcare Solutions, Medicare PDAC (Pricing, Data Analysis, and Coding) contractor. *Correct Coding and Coverage of Ventilators*, Joint DME MAC Publication, April 28, 2014, and *Correct Coding and Coverage of Ventilators*, Joint DME MAC Publication, May 24, 2016.

**Table 1: Noninvasive Home Ventilator, Respiratory Assist Device, and Continuous Positive Airway Pressure Device Medicare Coverage Comparison**

Device	Conditions Treated	Additional Information About Medicare Coverage
NHV	Covered for treatment of neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to COPD.	
RAD*	Covered for restrictive thoracic disorders, <sup>†</sup> severe COPD, central sleep apnea, complex sleep apnea, or hypoventilation syndrome.	Ventilator-related disease groups overlap conditions used to determine coverage for RADs. All of these disease categories are conditions in which the specific presentation of the disease can vary from patient to patient, so the treatment plan will vary accordingly. The physician chooses an appropriate treatment plan, including the determination to use a ventilator versus a RAD, based on the specifics of each beneficiary’s medical condition. <sup>‡</sup>
CPAP	Covered for obstructive sleep apnea.	Beneficiary has been diagnosed with obstructive sleep apnea on the basis of a sleep test.**
<p>* A RAD is synonymous with a Bi-Level Positive Airway Pressure or BiPAP device. CMS often uses these terms interchangeably throughout guidance it issues to suppliers. Sleep Management used the term BiPAP in its comments to our report; as such, when responding to its comments we also used the term BiPAP.</p> <p>† The terms “thoracic restrictive diseases” and “restrictive thoracic disorders” are synonymous. Both terms refer to disorders that increase work of breathing by increasing elastic resistance in the lungs or chest wall. NHVs and RADs both address these diseases but at different levels of severity.</p> <p>‡ Local Coverage Determination (LCD): Respiratory Assist Devices (L33800). The LCD states that, in the event of a claim review, there must be sufficient detailed information in the medical record to justify the treatment selected.</p> <p>** <i>Medicare National Coverage Determinations Manual</i>, Pub. No. 100-03, chapter 1, part 4, section 240.4. Program abuse is occurring when NHVs are billed for the treatment of sleep apnea (CMS, Internal Healthcare Common Procedure Coding System (HCPCS) Decision Regarding Codes for Ventilators).</p>		

## Medicare Requirements To Identify and Return Overpayments

OIG believes that this audit report constitutes credible information of potential overpayments. Upon receiving credible information of potential overpayments, providers must exercise reasonable diligence to identify overpayments (i.e., determine receipt of and quantify any overpayments) during a 6-year lookback period. Providers must report and return any identified overpayments by the later of (1) 60 days after identifying those overpayments or (2) the date that any corresponding cost report is due (if applicable). This is known as the 60-day rule.<sup>16</sup>

The 6-year lookback period is not limited by OIG's audit period or restrictions on the Government's ability to reopen claims or cost reports. To report and return overpayments under the 60-day rule, providers can request the reopening of initial claims determinations, submit amended cost reports, or use any other appropriate reporting process.<sup>17</sup>

## Sleep Management, LLC

Sleep Management, d.b.a. VieMed, is a disease management company headquartered in Lafayette, Louisiana. It provides home-based, noninvasive ventilation therapy services including rental of respiratory equipment, such as NHVs, RADs, and CPAP devices, in 24 States. Sleep Management markets its NHV product by conducting educational events at hospitals and physicians' offices and providing educational information at health care industry trade shows and conferences. Most of its NHV patients are referrals from a hospital setting. After the initial device setup, Sleep Management generally visits its patients every 3 months to monitor the patients' use of the devices, replenish supplies, and re-educate the patients on device use as necessary.

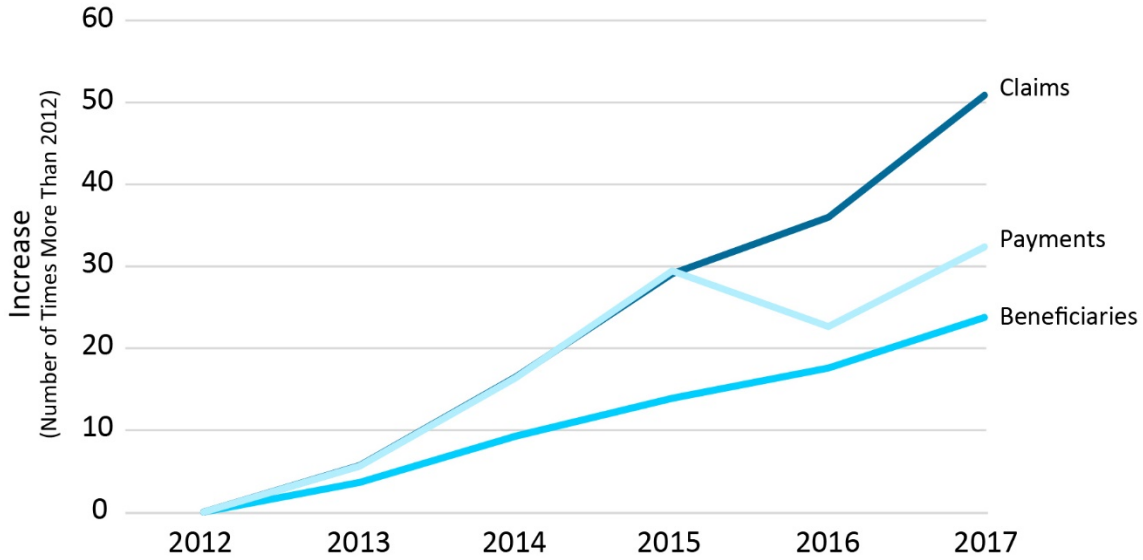
Sleep Management first provided NHVs to Medicare beneficiaries in 2012. From 2012 to 2017, the number of beneficiaries that Sleep Management supplied with NHVs increased from 158 to 3,912, claims increased from 537 to 27,858, and Medicare payments increased from \$645,813 to \$21.6 million. (See Figure 2 on the next page.)

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<sup>16</sup> The Act § 1128J(d); 42 CFR §§ 401.301–401.305; 81 Fed. Reg. 7654 (Feb. 12, 2016).

<sup>17</sup> 42 CFR §§ 401.305(d), 405.980(c)(4), and 413.24(f); CMS, *Provider Reimbursement Manual*—part 1, Pub. No. 15-1, § 2931.2; 81 Fed. Reg. at 7670.

**Figure 2: Sleep Management Increase in Beneficiaries, Claims, and Medicare Payments From 2012 to 2017**



During our 2-year audit period, Sleep Management was among the top three suppliers of NHVs and received \$36.8 million in related Medicare payments. During the audit period, approximately 95 percent of Sleep Management’s claims were for beneficiaries with a primary diagnosis related to respiratory failure or COPD.

**HOW WE CONDUCTED THIS AUDIT**

For Sleep Management, we identified 47,720 Medicare paid claim lines totaling \$36,826,896 for the monthly rental of NHVs during CYs 2016 and 2017 (audit period). From this number of claim lines, we excluded 7,404 that (1) were previously reviewed by Medicare Recovery Audit Contractors (RACs), (2) had dates of service concurrent with beneficiary inpatient stays,<sup>18</sup> or (3) had payments of less than \$500. From the remaining 40,316 claim lines totaling \$30,927,491, we selected a random sample of 100 claim lines with payments totaling \$75,694. Sleep Management provided us with copies of supplier and medical records as support for the

<sup>18</sup> We excluded these claims from our audit to potentially include them in a separate audit. However, we do not have immediate plans to conduct such an audit.

sampled claim lines.<sup>19</sup> In turn, we provided those records to an independent medical review contractor (medical reviewers) to determine whether the sample claim lines complied with Medicare requirements.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains our audit scope and methodology, Appendix B contains our statistical sampling methodology, Appendix C contains our sample results and estimates, and Appendix D contains the results for each sampled claim line.

## FINDINGS

Most Medicare claims submitted by Sleep Management for the monthly rental of NHVs did not comply with Medicare requirements. Of the 100 sampled claim lines with payments totaling \$75,694, 2 complied with Medicare requirements; however, 98 claim lines with payments totaling \$74,288 did not. Based on our sample results, we estimated that Medicare made overpayments to Sleep Management of at least \$29,131,187 for the monthly rental of NHVs that did not comply with Medicare requirements.<sup>20</sup>

These overpayments occurred because Sleep Management did not follow its policies and procedures to ensure that it obtained sufficient documentation to support the medical necessity of the NHV or discontinued service for lack of beneficiary usage.

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<sup>19</sup> Generally, CMS requires that Medicare claims be supported by information contained directly in the contemporaneous medical record. Medical records include the treating physician's office records and records from hospitals, nursing facilities, home health agencies, and other healthcare professionals. Supplier-produced records are not deemed to be medical records for Medicare payment purposes. Records from supplier or healthcare professionals with a financial interest in the claim outcome are not considered sufficient by themselves for determining that an item is reasonable and necessary (Local Coverage Article: Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426)).

<sup>20</sup> See Appendix B for our sample design and methodology and Appendix C for our results and estimates. To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

As of the publication of this report, these overpayments include claim lines outside of the 4-year reopening period.<sup>21, 22</sup>

## **MOST CLAIMS DID NOT COMPLY WITH MEDICARE REQUIREMENTS**

Of the 100 sampled claim lines, 98 did not comply with Medicare requirements. All of the 98 claim lines contained more than 1 error (Table 2). See Appendix D for the results for each sampled claim line.

**Table 2: Errors in Sampled Claim Lines**

Description of Error	Number of Errors*
Noninvasive home ventilator not medically necessary	98
Continued use of device not supported	28
*The total exceeds 98 because all 98 sampled claim lines contained more than 1 error.	

### **Noninvasive Home Ventilators Not Medically Necessary**

The Act prohibits Medicare payment for services that are not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member.<sup>23</sup> The *Medicare National Determinations Manual* states that NHVs are covered for the treatment of neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to COPD.<sup>24</sup>

Each of these disease categories is composed of conditions that can vary from severe and life-threatening to less serious forms. These ventilator-related disease groups overlap conditions described in the LCD used to determine coverage of RAD devices. Each of these disease groups is a condition in which the specific presentation of the disease can vary from patient to patient. For conditions such as these, the specific treatment plan for any individual patient will vary as well. Choice of an appropriate treatment plan, including the determination to use an NHV or RAD, is made based on the specifics of each individual beneficiary’s medical condition. In the event of a claim review, there must be sufficient detailed information in the medical record to justify the treatment selected. Additionally, although NHVs may have the capability to operate

<sup>21</sup> 42 CFR § 405.980(b)(2) (permitting a contractor to reopen an initial determination within 4 years for good cause) and 42 CFR § 405.980(c)(2) (permitting a supplier to request that a contractor reopen within 4 years for good cause).

<sup>22</sup> Notwithstanding, a supplier can request that a contractor reopen an initial determination for the purpose of reporting and returning overpayments under the 60-day rule without being limited by the 4-year reopening period (42 CFR § 405.980(c)(4)).

<sup>23</sup> The Act § 1862(a)(1)(A).

<sup>24</sup> *Medicare National Coverage Determinations Manual*, chapter 1, part 4, section 280.1.

in a RAD or CPAP mode, they are not eligible for reimbursement when used to provide RAD or CPAP therapy.<sup>25</sup>

Suppliers should obtain as much documentation from the beneficiary's medical record as necessary to assure themselves that coverage criteria for an item are met. If the information in the beneficiary's medical record does not adequately support the medical necessity for the item, the supplier is liable for the dollar amount involved.<sup>26</sup>

For 98 claim lines in our sample, the medical records that Sleep Management provided did not contain objective evidence to support a qualifying diagnosis. For most claim lines, the physician's order listed a qualifying diagnosis,<sup>27</sup> and frequently, the supporting medical records contained a statement from the treating physician that the beneficiary had a qualifying diagnosis. However, the medical records did not contain objective evidence to support the diagnosis. Generally, the medical records (1) did not support that the severity of the beneficiary's condition warranted an NHV, (2) contained no medical tests or functional measurements to support a qualifying diagnosis, (3) supported other nonqualifying diagnoses, (4) indicated that the NHV was prescribed while the beneficiary was in a hospital setting during an acute medical episode, or (5) did not rule out co-contributing factors.

For example, in one case, the independent medical reviewers determined that the beneficiary was hospitalized with shortness of breath and cough. A hospital progress note indicated a plan to arrange an NHV and cited acute on chronic hypoxemic and hypercapnic respiratory failure<sup>28</sup> due to COPD, pneumonia, and influenza as justification. Even though RAD therapy was provided in the hospital, the provider stated that use of a RAD at home may not be sufficient. According to our medical reviewers, in the presence of lobar pneumonia and influenza, the medical record supported only acute hypercapnic respiratory failure, not chronic hypercapnic respiratory failure. The provider's recommendation to initiate NHV therapy was based on the beneficiary's performance during an episode of acute illness, not under the conditions indicated for use of an NHV. The provider also kept the beneficiary on RAD therapy, even when the

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<sup>25</sup> LCD: Respiratory Assist Devices (L33800).

<sup>26</sup> The Act § 1862(a)(1)(A) and Local Coverage Article: "Standard Documentation Requirements for All Claims Submitted to DME MACs" (A55426).

<sup>27</sup> Generally, the physician-signed order for the NHV was a form produced by the supplier from which the physician could select a listed diagnosis of COPD, chronic respiratory failure, or neuromuscular disease; or write in another diagnosis. The COPD and chronic respiratory failure diagnoses were selected on most physician orders.

<sup>28</sup> Respiratory failure is a problem getting gases in and out of the blood. Acute respiratory failure is sudden and may pass once the cause is treated, but chronic respiratory failure is long term and often needs lifelong support. Both acute and chronic respiratory failure can exist at the same time. The two types of acute and chronic respiratory failure are hypoxemic and hypercapnic, and both conditions can exist at the same time. Hypoxemic means there is not enough oxygen in the blood, and hypercapnic means there is excessive carbon dioxide in the blood.



clinical condition was at its most extreme, further demonstrating that NHV therapy was not medically necessary. If the higher level of support offered by an NHV was unnecessary during an acute illness, its use after resolution of that illness was unlikely to be medically necessary.

In another case, the independent medical reviewers determined that the physician order stated that the beneficiary was prescribed an NHV for COPD and chronic respiratory failure with hypercapnia. However, the beneficiary's COPD was only mentioned in a list of historical diagnoses, and there was no objective evidence, such as arterial blood gas results or electrolyte panel results, documented to substantiate the severity of COPD or chronic respiratory failure with hypercapnia. The combination of morbid obesity and severe sleep apnea documented in the record and the very limited information about COPD made obesity hypoventilation syndrome<sup>29</sup> the only conclusively documented condition that can cause chronic hypercapnia. Obesity hypoventilation syndrome is not a qualifying diagnosis for an NHV.

In a third case, the independent medical reviewers determined that the medical records documented hypoxia and hypercapnia during hospitalizations for acute episodes. However, the records did not document whether the conditions occurred between acute episodes. The records indicated that a RAD was the treatment of choice during hospitalization and would be prescribed for the beneficiary's transition back to home therapy. Between acute episodes, the beneficiary was weaned from the RAD and appeared to be on no ventilatory support at all. In addition, there was no objective evidence (e.g., pulmonary function test results, 6-minute walk test results) provided to support that the beneficiary's COPD was at a severe level. Further, the medical records documented two treatable conditions (obstructive sleep apnea and mucous plugging) that may have contributed to the beneficiary's hypoxia and hypercapnia. Untreated obstructive sleep apnea had not been excluded as a likely contributor to either hypoxia or hypercapnia. In the absence of records that (1) quantified the severity of the beneficiary's disease, (2) documented that a CPAP or RAD was unsuccessful at treating the beneficiary's diseases at home between acute episodes, and (3) described the beneficiary's ability to oxygenate after relief of mucous plugging, the NHV was not medically necessary.

### **Continued Use of Device Not Supported**

The Act requires that services be reasonable and necessary; therefore, suppliers must monitor the beneficiary's utilization of the NHV and discontinue billing Medicare when the beneficiary no longer uses the device. The supplier can use either beneficiary medical records or supplier records to confirm that the beneficiary continues to use the device.<sup>30</sup>

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<sup>29</sup> Obesity hypoventilation syndrome is a condition in some obese people in which poor breathing leads to low oxygen levels and higher carbon dioxide levels in the blood.

<sup>30</sup> The Act § 1862(a)(1)(A); 42 CFR § 414.222(b); Local Coverage Article: "Standard Documentation Requirements for All Claims Submitted to DME MACs" (A55426).

Generally, Sleep Management’s respiratory therapists visited beneficiaries every 3 months to monitor the beneficiary’s usage of the NHV, replenish supplies, and re-educate the beneficiary about device usage as necessary. During the visit, the therapist downloaded statistics from the NHV that detailed the beneficiary’s usage since the previous visit. Sleep Management maintains these usage reports in the beneficiary’s patient file. Sleep Management’s policy stated that if the therapist discovers “zero or minimal usage time” during the visits, the beneficiary should be asked to participate in a “7-day achievement plan.” The policy stated that Sleep Management should discontinue service if the beneficiary’s usage of the device does not improve during the 7 days.

For 28 claim lines in our sample, our medical reviewers determined that continued use was not supported because the beneficiary would not likely receive the intended benefit of NHV therapy with the level of use documented.

Once determined medically necessary, an NHV is likely needed for the remainder of a beneficiary’s life, and, as the severity of the disease progresses, it is likely needed for increasingly longer periods until needed around the clock. For all 28 of these claim lines, the beneficiary used the device 4 hours or less a day, and, for 12 of these 28 claim lines, the beneficiary used the device for less than 1 hour a day. For example, in one case, the beneficiary used the device 4 of the 94 days documented by the usage report that included the date of service. On those 4 days, the beneficiary used the device an average of 10 minutes a day. In another case, the beneficiary used the device an average of 9 minutes a day during a 3-month period that included the date of service. Despite the beneficiaries’ lack of usage of the device, Sleep Management did not discontinue the service.

## **ESTIMATE OF OVERPAYMENTS FOR SAMPLE ITEMS**

Based on our sample results, we estimated that Medicare overpaid Sleep Management at least \$29,131,187 for the monthly rental of NHVs that did not comply with Medicare requirements.

## **SLEEP MANAGEMENT DID NOT FOLLOW ITS POLICIES AND PROCEDURES**

Sleep Management had policies and procedures in place that were intended to ensure Medicare requirements were met prior to submitting NHV claims. Sleep Management policies required that it obtain and review beneficiary medical records (such as a prescription for the device, physician notes from hospital admissions and clinic visits, and medical test results) and other documentation to verify that medical necessity was met and maintain the documentation in its patient files.

According to Sleep Management, it provided all the documentation that it had in its patient files for the sample items and contacted prescribing physicians after the start of our audit to obtain and provide additional documentation. The errors identified in our sample occurred primarily because the beneficiary's medical record documentation that Sleep Management provided was not sufficient to support the medical necessity of the NHV. In most cases, the

records provided: (1) were not sufficient to establish the chronic severity of the beneficiaries' condition at a level necessary to support a qualifying diagnosis, (2) contained no medical tests or functional measurements to support a qualifying diagnosis, (3) supported other nonqualifying diagnoses, (4) indicated that the NHV was prescribed while the beneficiary was in a hospital setting during an acute medical episode, or (5) did not rule out co-contributing factors. Also, Sleep Management did not follow its policy to discontinue services despite clear evidence of some beneficiaries' continued lack of usage of the device.

## RECOMMENDATIONS

We recommend that Sleep Management:

- refund to the Federal Government the portion of the estimated \$29,131,187 in Medicare overpayments for claim lines incorrectly billed that are within the 4-year reopening period;<sup>31</sup>
- based upon the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule<sup>32</sup> and identify any of those returned overpayments as having been made in accordance with this recommendation; and
- follow existing policies and procedures to help ensure that it:
  - obtains medical record documentation that is sufficient to satisfy Medicare medical necessity requirements and
  - discontinues service when beneficiaries do not continually use the device.

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<sup>31</sup> OIG audit recommendations do not represent final determinations by Medicare. CMS, acting through a MAC or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures. Providers have the right to appeal those determinations and should familiarize themselves with the rules pertaining to when overpayments must be returned or are subject to offset while an appeal is pending. The Medicare Part A and Part B appeals process has five levels (42 CFR § 405.904(a)(2)), and if a provider exercises its right to an appeal, the provider does not need to return overpayments until after the second level of appeal. Potential overpayments identified in OIG reports that are based on extrapolation may be re-estimated depending on CMS determinations and the outcome of appeals.

<sup>32</sup> This recommendation does not apply to any overpayments that are both within our sampling frame (i.e., the population from which we selected our statistical sample) and refunded based upon the extrapolated overpayment amount. Those overpayments are already covered in the previous recommendation.

## **SLEEP MANAGEMENT COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, Sleep Management did not concur with our first and third recommendations. Regarding our second recommendation, Sleep Management stated that it had exercised more than reasonable diligence in determining and quantifying any overpayments owed as a result of this audit.

Sleep Management did not concur with our recommendation to refund the estimated \$29,131,187 in Medicare overpayments contending that:

- its NHV claims were medically necessary;
- we applied improper standards, clinical guidance not required by CMS and improperly applied clinical guidance;
- our sampling methodology and extrapolation of the results were improper;
- our medical reviewer was not independent; and
- it was not liable for the overpayments identified by our audit.

Additionally, Sleep Management stated that it recognized its responsibility under the 60-day rule and had exercised more than reasonable diligence in determining and quantifying any overpayments owed as a result of this audit.

Finally, Sleep Management did not concur with our recommendation to follow its existing policies and procedures to ensure compliance with Medicare requirements maintaining that the strength of its current compliance programs was adequate.

After reviewing Sleep Management's comments, we maintain that our findings and recommendations are valid. However, to avoid potential confusion, we removed a finding related to a beneficiary's continued need for an NHV. Removing this finding did not change our estimated overpayments or recommendations.

Below, we have addressed Sleep Management’s specific comments on our findings and recommendations.<sup>33</sup> Sleep Management’s comments are included as Appendix E.<sup>34</sup>

## **MEDICAL NECESSITY**

### **Sleep Management Comments—Medical Opinions**

Sleep Management stated that the beneficiaries’ treating physicians prescribed the claims we disallowed and that our medical reviewers substituted their own medical opinions for the medical opinions of the physicians who examined the beneficiaries. Sleep Management contended that our medical reviewers often: (1) ignored the qualifying diagnoses documented by the treating physicians, (2) disregarded a beneficiaries’ acute exacerbation of COPD<sup>35</sup> and resulting inpatient admission as an indication of disease severity, or (3) attributed a beneficiary’s symptoms and respiratory failure to other causes.

### **Office of Inspector General Response—Medical Opinions**

#### *Medical Reviewers Did Not Ignore Treating Physicians’ Documented Diagnoses*

Our medical reviewers did not ignore the treating physicians’ documented diagnoses. The medical records that Sleep Management provided to support its NHV claims often contained a statement that the beneficiary had a qualifying diagnosis. However, our medical reviewers’ examination of those records determined that there was no objective evidence to support the stated diagnosis. Our medical reviewers had no obligation to defer to the treating physicians’ statements that the beneficiary had a qualifying diagnosis without objective evidence to support those statements.

#### *Acute Exacerbation and Inpatient Hospitalization Alone Is Not an Indication for NHV*

Our medical reviewers recognized and did not dispute the severity of certain beneficiaries’ conditions at the time of hospitalization for an acute exacerbation. However, the occurrence of

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<sup>33</sup> We prepared our responses to Sleep Management’s comments in consultation with our medical reviewers.

<sup>34</sup> Sleep Management included multiple exhibits as part of its comments. These exhibits included the following: correspondence between Sleep Management and CMS regarding Medicare’s payment suspension; CMS’s decision regarding codes for ventilators; a report related to our sampling methodology from a statistical expert and the expert’s curricula vitae; video attestations from certain Sleep Management patients included in our sample; a claim-by-claim rebuttal of the findings in our draft report; an NHV study funded by Sleep Management; and copies of our draft report, sampling plan, and claims review checklist. Although we did not include the exhibits as appendices in this final report, we considered the entirety of these documents in preparing our final report and will provide Sleep Management’s comments in their entirety to CMS.

<sup>35</sup> “Acute exacerbation of COPD” describes the phenomenon of sudden worsening in airway function and respiratory symptoms in patients with COPD.

an acute exacerbation on its own is not an indication for an NHV. In fact, the recommended time for assessing the appropriate choice of long-term, noninvasive ventilation is not while the beneficiary is hospitalized for an acute exacerbation, but, instead, 2 to 4 weeks after such an episode.<sup>36</sup> Additionally, the supporting medical records must include sufficient detailed information to establish severe chronic hypercapnia or chronic respiratory failure with hypercapnia. Our medical reviewers further defined “chronic” as “persistent, unresponsive to most treatment, and reflective of damaged refractory pathology.”

Our medical reviewers noted that, in most cases, the assessment of a beneficiary’s medical need for an NHV was completed during hospitalization for an episode of acute illness rather than at the patient’s baseline.<sup>37</sup> Assessment of a patient’s condition at baseline is necessary to evaluate the severity of the alleged chronic illness. Often, no information was documented about a beneficiary’s treatment history between acute episodes or any objective measures of function obtained at the beneficiary’s baseline to establish the chronicity of a beneficiary’s condition. In most of the claim lines reviewed, the degree of severity and the chronicity of the beneficiary’s condition were absent from the record.

#### *Chronic Respiratory Failure Must Be the Result of COPD To Be a Qualifying Diagnosis for an NHV*

Our medical reviewers did not reject Sleep Management’s claims based on an alternative explanation of the patient’s condition. The physician orders for almost all of the claim lines we reviewed alleged chronic respiratory failure as the qualifying diagnosis.<sup>38</sup> Chronic respiratory failure must be the result of COPD to be a qualifying diagnosis for an NHV. Often, our medical reviewers did not find the objective medical evidence necessary to conclude that a patient’s respiratory failure was the result of COPD. In some cases, the medical record indicated that the patient’s ventilation was compromised by factors other than COPD. In those cases, our medical reviewers could only conclude that the beneficiary’s respiratory failure was due to the factors that were clearly documented in the medical record.

#### **Sleep Management Comments—Hospital BiPAP Functions Like an NHV**

Sleep Management stated that, in several instances, our medical reviewers noted that a beneficiary was on a BiPAP<sup>39</sup> during an acute care inpatient stay and that our medical reviewers referenced the BiPAP treatment as evidence that an NHV was not medically necessary. Sleep

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<sup>36</sup> Macrea M, Oczkowski, S, et. al., “Long-Term Noninvasive Ventilation in Chronic Stable Hypercapnic Chronic Obstructive Pulmonary Disease,” *Am J Respir Crit Care Med.* 2020 Aug 15; 202(4): pp e74-e87, e81.

<sup>37</sup> Patients are at baseline when their disease condition is at a steady state.

<sup>38</sup> Of the 100 claim lines we reviewed, the physician orders for 94 alleged chronic respiratory failure as the qualifying diagnosis.

<sup>39</sup> A Bi-Level Positive Airway Pressure (BiPAP) device is synonymous with a RAD. Sleep Management used the term BiPAP in its comments to our report; as such, when responding to its comments, we also used the term BiPAP.

Management stated that the term BiPAP is widely used colloquially to describe any bi-level positive airway pressure device and that the BiPAP devices referenced by our medical reviewers and used in hospital settings are ventilators. Sleep Management stated that the hospital BiPAPs offer real time volume and pressure adjustment related to changes in pulmonary mechanics, guarantee the delivery of a specific minute volume, and are not equivalent to home BiPAP devices; rather, a hospital BiPAP is comparable to an NHV in functionality.

### **Office of Inspector General Response—Hospital BiPAP Functions Like an NHV**

Our medical reviewers made determinations based on the evidence in the beneficiary’s medical record. In most cases, the medical record indicated that a patient received a BiPAP in the hospital; however, there were no device settings for the BiPAP documented. As such, our medical reviewers could only conclude that the hospital BiPAP was not delivering “volume-controlled ventilation” (i.e., it was not functioning as an NHV). In addition, a patient’s needs for respiratory assistance in the hospital are not necessarily the same as a patient would need after hospitalization. As previously mentioned, the recommended time for assessing the appropriate choice of long-term noninvasive ventilation is not while the beneficiary is hospitalized for an acute exacerbation, but 2 to 4 weeks after such an episode.<sup>40</sup>

### **Sleep Management Comments—Beneficiary’s Continued Use of NHV**

Sleep Management contended that we improperly denied claims for failure to demonstrate a beneficiary’s continued use of the device. Sleep Management argued that we improperly applied a 4-hour use requirement that does not exist in Medicare rules or policy.

### **Office of Inspector General Response—Beneficiary’s Continued Use of NHV**

Medicare requires that justification of medical need for all DME items be established at the time the item was initially ordered. Additionally, for rented DME and ongoing supplies, information in the beneficiary’s medical record or in the supplier’s records must support that the item continues to remain reasonable and necessary.<sup>41</sup> Our medical reviewers applied a standard of meaningful use to evaluate whether continued use of a device was substantiated. In medical terms, meaningful use reflects medical need.

Our reviewers based their determinations of meaningful use on a medical understanding that the changes in respiratory physiology that occur with sleep affect drive, oxygenation, and ventilation. The normal physiological changes that occur with sleep (decreases in the rate and depth of breathing, decreases in oxygen saturations, and increases in partial pressures of carbon dioxide) are magnified in conditions of pathologic hypoventilation. Our medical

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<sup>40</sup> Macrea M, Oczkowski, S, et. al., Long-Term Noninvasive Ventilation in Chronic Stable Hypercapnic Chronic Obstructive Pulmonary Disease, *Am J Respir Crit Care Med.* 2020 Aug 15; 202(4): pp e74-e87, e81.

<sup>41</sup> The Act §§ 1862(a)(1)(A) & 1833(e).

reviewers determined that continued use was not supported because the beneficiary would not likely receive the intended benefit of NHV therapy with the level of use documented.

## **STANDARDS AND CLINICAL GUIDANCE**

### **Sleep Management Comments—Standards and Clinical Guidance**

Sleep Management contended that we applied incorrect standards and improperly applied clinical guidance when we determined that 98 of 100 claims were not in compliance with Medicare requirements. Sleep Management asserted that the only requirement for the prescription of an NHV is listed in the Medicare National Coverage Determinations Manual (NCD) section 280.1, which required that the beneficiary be diagnosed with a neuromuscular disease, thoracic restrictive disease, or chronic respiratory failure consequent to COPD and that the BiPAP LCD was not applicable to NHV claims.

As such, Sleep Management argued that nothing required the medical record to demonstrate that: (1) objective medical tests or functional measurements be performed to substantiate a qualifying diagnosis, (2) other factors that may have contributed to the beneficiary's symptoms or diagnosis be ruled out, including co-morbidities, (3) NHV therapy was ordered outside of an acute episode, or (4) the beneficiary failed to benefit from BiPAP therapy.

### **Office of Inspector General Response—Standards and Clinical Guidance**

Medicare requires that the prescription of an NHV be reasonable and necessary for the treatment of neuromuscular disease, thoracic restrictive disease, or chronic respiratory failure consequent to COPD.<sup>42</sup> We understand that NHV claims do not have to meet the requirements in the BiPAP LCD to be covered by Medicare. However, because the NHV-related disease groups overlap conditions described in the BiPAP LCD, the BiPAP LCD may be considered when determining which device (i.e., a BiPAP or an NHV) is reasonable and necessary for a beneficiary's specific medical condition.

The basic tenet of our evaluation of Sleep Management's claims was to ascertain whether the NHV was reasonable and necessary for the treatment of each individual beneficiary's medical condition. Our medical reviewers made this determination by reviewing the medical record; as with any medical service or item, the medical record must support the beneficiary's diagnosis and treatment, and the service or items prescribed must meet but not exceed the beneficiary's medical need. We maintain that, for the 98 claim lines that we disallowed, the medical records did not contain sufficiently detailed information to support compliance with Medicare requirements for medical necessity. We addressed Sleep Management's specific assertions below.

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<sup>42</sup> The Act § 1862(a)(1)(A); Medicare National Coverage Determinations Manual, Pub. No. 100-03 chapter 1, part 4, section 280.1.



### *Objective Medical Tests and Co-Contributing Factors*

Sleep Management suggested that only a diagnosis, without underlying objective medical documentation to support that diagnosis, is required to prescribe an NHV. Objective medical tests are necessary to diagnose neuromuscular diseases, thoracic restrictive diseases, or chronic respiratory failure consequent to COPD, as well as the severity of any of these conditions.

Additionally, from a medical perspective, it is important to rule out co-contributing factors to make an accurate diagnosis. For example, in one case, the medical records documented a condition of mucous plugging that may have contributed to the beneficiary's respiratory failure. However, the medical record did not describe the patient's ability to oxygenate after relief of mucous plugging. This description could have supported or negated the relationship between the mucous plugging and the patient's respiratory failure. Without the description, the record was inconclusive as to whether the patient's respiratory failure was the result of COPD and left open the possibility that something other than an NHV could have been reasonable and necessary for this patient.

In conclusion, it was appropriate for our medical reviewers to determine whether the medical records contained objective medical evidence that justified the claimed qualifying diagnosis and that ruled out other factors that could have caused or contributed to the beneficiary's condition.

### *NHV Ordered During an Acute Episode Instead of to Treat a Chronic Condition*

NHV therapy is maintenance therapy designed for use by patients at baseline status during stable clinical periods. Evidence of the patient's condition at baseline is necessary to evaluate the severity of the alleged chronic illness. A change in the patient's baseline condition occurs during an acute episode, so a true clinical picture of the patient's needs cannot be achieved with facts representative of only an acute episode. In most cases, the bulk of the documentation that Sleep Management provided to support medical necessity was from an acute or sub-acute medical episode and was insufficient to support that the chronic severity of the beneficiary's condition warranted an NHV.

### *Use of BiPAP Not Ruled Out*

The NHV and BiPAP both address the same disease groups but at different levels of severity. The feature that distinguishes the NHV from a BiPAP is the NHV's ability to deliver variable airway pressures within a preset range to reach a targeted volume of ventilation with each breath. This feature is referred to as average volume-assured pressure support. The use of an NHV is indicated when a patient's residual work of breathing on a BiPAP at optimized settings exceeds the functional reserves available to the patient. BiPAP failures to provide adequate ventilatory support are confirmed by arterial blood gas results that show a partial pressure of

carbon dioxide that is at or above 45 mmHg<sup>43</sup> while patients are at their baseline between episodes of acute illness and functional decompensation. For patients whose needs have been shown to exceed the support that a BiPAP at optimal settings can provide, an NHV is the next reasonable step. None of the medical records for the 98 cases that we disallowed contained evidence that a BiPAP was insufficient to treat the patient's condition or that an NHV was necessary.

### **Sleep Management Comments—Clinical and Diagnostic Standards**

Sleep Management stated that our medical reviewers did not specify or outline the clinical and diagnostic standards applied. It also said our medical reviewers denied claims based on criteria that was neither clinically valid nor nationally recognized for either the treatment of chronic respiratory failure consequent to COPD or the use of an NHV. Sleep Management contended that our medical reviewers often applied standards that were in direct conflict with accepted evidence-based treatment and therapeutic guidelines. Further, Sleep Management argued that there was a lack of clear Medicare coverage guidelines related to NHV therapy and stated that CMS and other ventilator suppliers confirmed the lack of such guidelines.

### **Office of Inspector General Response—Clinical and Diagnostic Standards**

Our medical reviewers applied the relevant Medicare statutory and regulatory requirements, the NCD, and their clinical education and experience (to include referring to a variety of medical literature, journal articles, and studies)<sup>44</sup> to evaluate the medical necessity of the NHV claims in our audit.

Throughout its comments Sleep Management contends that the NHV is inherently better than other devices at providing respiratory assistance, but studies have shown that an NHV is not medically necessary in many circumstances.<sup>45</sup> Medicare requirements obligated our medical reviewer to determine whether the NHV supplied to the beneficiary was reasonable and necessary in each given situation.

We noted that Sleep Management referenced various studies in its comments with findings of mortality reduction, hospitalization reduction, etc., as the result of NHV use. However, the fact that some of these studies were undertaken by vendors, including Sleep Management, should

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<sup>43</sup> Millimeter(s) of mercury. A unit of pressure equal to the pressure that can support a column of mercury one millimeter high.

<sup>44</sup> The medical literature included over 40 pieces on respiratory medicine, noninvasive ventilation, and medicine in general.

<sup>45</sup> Shaughnessy, P, Olson, E, Morgenthaler, T, *Noninvasive Volume-Assured Pressure Support for Chronic Respiratory Failure: a Review*, *Curr Opin Pulm Med*, 2019 November:25. This review cites to more than 30 articles discussing studies and other analyses in support of its conclusions.

factor into an assessment of their value. Sleep Management cited one study for its finding that “clinical evidence demonstrates that the increased mortality risk following hospital discharge can be ameliorated by the early institution of NHV.” This quotation is from an observational study funded by Sleep Management that compared patients treated with NHV to those not treated with NHV, rather than a comparison of treatments (e.g., a study looking at patients on NHV compared to patients properly titrated on BiPAP). The findings in such a study tend to distract from the evaluation of reasonableness and necessity that pertains to individual claims.

### **Sleep Management Comments—Review by Pulmonology Physicians**

Sleep Management stated that, because of the lack of clinical guidelines or coverage criteria for NHVs, they specifically requested that the medical documentation review be conducted by physicians with experience and expertise in pulmonology, especially chronic respiratory failure and COPD.

### **Office of Inspector General Response—Review by Pulmonology Physicians**

Our medical reviewer was an active physician in emergency room medicine, board certified in internal medicine, with a fellowship in pulmonary medicine. The reviewing physician received contribution from a physician board certified in pulmonary disease.

## **SAMPLING METHODOLOGY AND EXTRAPOLATION**

### **Sleep Management Comments—Reduced Sampling Frame**

Sleep Management stated that our audit excluded 7,404 claim lines that were previously reviewed by CMS’s RACs.<sup>46</sup> Sleep Management stated that the exclusion of these claim lines improperly reduced our sampling frame and caused a biased result by not considering the conflicting determinations of the 7,404 claims in the RAC audit.

Sleep Management also stated that, under the Medicare Program Integrity Manual (MPIM), we were not allowed to exclude previously reviewed claims; and, because we removed claims, our estimate was flawed, and the methods that we used to obtain our estimate departed from accepted statistical practice. As such, they claimed that our estimate and sampling methodology did not comply with Generally Accepted Government Auditing Standards (GAGAS) and did not represent sufficient and appropriate evidence to support our findings and conclusions.

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<sup>46</sup> Not all of the claims that we excluded were previously reviewed by CMS’s RAC. As previously stated in the report, we excluded 7,404 claim lines because they: (1) were previously reviewed by CMS’s RACs, (2) had dates of service concurrent with beneficiary inpatient stays, or (3) had payments of less than \$500.

## **Office of Inspector General Response—Reduced Sampling Frame**

Our overpayment estimate was unbiased and did not extend beyond the 40,316 Medicare paid claim lines in our sampling frame. The purpose of our sample was to estimate any amounts overpaid to Sleep Management for claims within our sampling frame; we intentionally excluded from our frame the 7,404 claims. We made no determination on claims that were not in our sampling frame, and we excluded from our recommended recovery amount any overpayments related to those claims. We are not required, nor would it be advantageous to Sleep Management, to calculate an estimate that covers all potential overpayments made during the audit period.

The MPIM does not apply to OIG; rather, it applies to Medicare contractors. Nevertheless, the MPIM states that claims “discovered to have been subject to a prior review” may be excluded from the sampling frame.<sup>47</sup> The legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology.<sup>48</sup> We properly executed a valid statistical sampling methodology; as such, the results of our sample are sufficient and appropriate, and they support our findings and conclusions.

## **Sleep Management Comments—Sample Results Conflict With CMS Review**

Sleep Management stated that our audit included 6,226 claim lines that were previously reviewed by CMS's Unified Program Integrity Contractor<sup>49</sup> under a payment suspension and pre-payment review initiated in October 2017. According to Sleep Management, CMS denied only 366 of those claim lines for not meeting Medicare coverage requirements. Sleep Management also stated that the beneficiaries represented by the 6,226 claim lines accounted for 29,981 of the 40,316 claim lines in our sampling frame. By extension, they contended that a total of 29,981 claim lines in our sampling frame were previously reviewed and that CMS determined that the vast majority of those claim lines were fully supported by medical record documentation, satisfied all Medicare coverage criteria, and were properly reimbursable by Medicare. Sleep Management stated that CMS terminated the review in January 2018 and in March 2018 CMS informed them that it would not issue any overpayment demands and would return any funds held in escrow.

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<sup>47</sup> MPIM, Chapter 8, §§ 8.4 and 8.4.3.2.

<sup>48</sup> See *John Balko & Assoc. v. Sebelius*, 2012 WL 6738246 at \*12 (W.D. Pa. 2012), *aff'd* 555 F. App'x 188 (3d Cir. 2014); *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at \*13 (S.D. Tex. 2012).

<sup>49</sup> A Unified Program Integrity Contractor is a Medicare contractor whose primary function is to investigate instances of suspected fraud, waste, and abuse in Medicare or Medicaid claims.

Sleep Management also stated that 42 of the 100 beneficiaries in our sample were included in that review and that the claim lines for 41 of the 42 beneficiaries were approved by CMS. It argued that the results of CMS's review directly conflicted with our 98 percent error rate.

### **Office of Inspector General Response—Sample Results Conflict With CMS Review**

Sleep Management's concerns about our sampling frame and sample are predicated on the idea that our sampling frame and sample contained claim lines that CMS previously reviewed and determined were allowable. We worked with CMS to identify the scope of its work. We reviewed correspondence between CMS and Sleep Management and found that CMS made no determinations on the claim lines that Sleep Management stated were in our sample frame and sample.

In CMS's January 30, 2018, letter notifying Sleep Management of its intent to terminate the prepayment suspension, CMS stated, "[p]lease be advised that this action to terminate your payment suspension should not be construed as any positive determination regarding your Medicare billing, nor is it an indication of government approval of or acquiescence regarding the claims submitted. It does not relieve you of any civil or criminal liability, nor does it offer a defense to any further administrative, civil or criminal actions against you."

The statement in CMS's January 30, 2018, letter makes it clear that the prior review made no positive determinations and was not meant to preclude future reviews of Sleep Management's claims or to serve as evidence that Sleep Management's claims were free of substantial errors. Therefore, Sleep Management's comments regarding our sampling frame and sample are unfounded.

### **Sleep Management Comments—Statistical Extrapolation**

Sleep Management stated that the glaring disparity between the clinical determinations of our medical reviewers and CMS for the same claim lines demand that we reconsider both the validity of our findings and whether using extrapolation was appropriate when the only basis for denial of the claims was a matter of clinical dispute. Sleep Management cited court cases to argue that a difference of opinion in clinical judgment was not enough to prove falsity and that a physician's clinical judgment dictates eligibility if it represents a reasonable interpretation. Further Sleep Management argued that the courts' rulings support that statistical sampling was inappropriate because medical necessity, or the lack thereof, requires a claim-by-claim determination of each patient's medical need and that extrapolation was inappropriate because the establishment of medical necessity for each claim requires fact-intensive inquiries.

### **Office of Inspector General Response—Statistical Extrapolation**

As we have previously stated, CMS made no determinations on the allowability of the claim lines we reviewed during our audit. Also, the court cases Sleep Management cited were limited to whether a claim can be deemed "false" under the Federal False Claims Act. Therefore, those

cases do not apply to our recommendations or any resulting CMS recoveries. We also noted that none of the cases Sleep Management cited were from the Federal appellate court jurisdiction that covers Louisiana where Sleep Management is located (i.e., not the U. S. Court of Appeals for the Fifth Circuit).

In a recent case<sup>50</sup> (not a False Claims Act case), the U. S. Court of Appeals for the Fifth Circuit upheld a CMS contractor's use of extrapolation for claims involving medical necessity. In its ruling the court stated: "To the extent that Dominion raises a broader claim that extrapolation is inappropriate where medical necessity is at issue, that claim also fails. As numerous courts have held, extrapolating from a randomly selected sample of paid claims presents a 'fairly low risk of error' in calculating the ultimate overpayment amount. Other courts have concluded that 'statistical sampling is the only feasible method available' for HHS to effectively audit waste and fraud in the Medicare and Medicaid programs. Dominion's proposed alternative—that HHS individually audit over twelve thousand claims—would likely make it impossible for HHS to audit the program in a meaningful way, especially when applied to all Medicare providers nationwide."<sup>51</sup>

## **MEDICAL REVIEWER'S INDEPENDENCE**

### **Sleep Management Comments**

Sleep Management stated that since September 2019 our medical reviewer has also acted as the Qualified Independent Contractor (QIC)<sup>52</sup> for Medicare DME appeals and that we were mandated by GAGAS to evaluate whether our medical reviewers had a self-interest, financial interest, or other interest that would inappropriately influence their judgment or behavior. Sleep Management stated that a reasonably informed third party could conclude that our reviewers existing financial interest with CMS compromised their objectivity and was a threat to our independence that must be eliminated before we could come to a final determination in our audit.

Sleep Management also stated that we directed our reviewers to find a justification to deny the claim. Sleep Management asserted that we instructed our reviewers to explain why the medical records did not justify NHV treatment instead of simply outlining coverage requirements for NHVs.

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<sup>50</sup> Dominion Ambulance, L.L.C. v. Azar, 968 F.3d 429; 2020 U.S. App. LEXIS 24399; 2020 WL 4382779.

<sup>51</sup> Dominion, 968 F.3d at 440.

<sup>52</sup> A QIC is an independent entity with which Medicare contracts to handle the reconsideration level of an Original Medicare (Part A or Part B) appeal.

## **Office of Inspector General Response**

Our medical reviewer addressed potential independence concerns resulting from its serving as the QIC for Medicare DME appeals by applying certain safeguards such as setting up a firewall between the systems and staffs performing medical reviews and potential subsequent QIC appeals.

As part of our review, we identified the requirements applicable to Medicare's coverage of NHVs. Our legal counsel reviewed and approved the requirements as legally valid and relevant to our audit objective. We provided the Medicare requirements to our medical reviewer to apply when evaluating Sleep Managements claims for compliance.

## **SLEEP MANAGEMENT'S LIABILITY**

### **Sleep Management Comments**

Sleep Management stated that, under the without fault provision in section 1870 of the Act and the limitation of liability provision in section 1879 of the Act, it was not liable for overpayments our audit identified. Sleep Management stated that it could not have reasonably known that claims during our audit period would be denied based on the medical necessity standards used by our medical reviewers. It stated that its understanding of the statutes and regulations in effect at the time the services were rendered was reasonable and consistent. Sleep Management went on to say that the standards we applied were not in the Act, in CMS regulations, in any NCD or LCD governing NHVs, or in any other CMS guidelines. Furthermore, it said that the standards we applied were not clinical standards or best practices used by the medical profession.

## **Office of Inspector General Response**

We maintain that the criteria and standards we used during our audit were applicable and support our findings and recommendations. OIG audit recommendations do not represent final determinations by Medicare. Therefore, a decision regarding whether the "without fault" and "limitation of liability" provisions apply would be premature. CMS, acting through a MAC or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures, including determining whether sections 1870 and 1879 of the Act apply.

## **CREDIBLE INFORMATION OF POTENTIAL OVERPAYMENTS**

### **Sleep Management Comments**

Sleep Management stated that it recognized its responsibility under the 60-day rule and had exercised more than reasonable diligence in determining and quantifying any overpayments owed as a result of this audit. It stated that it performed a thorough investigation of the 100

claims in our sample and determined the existence of, at most, a 1 percent error rate, which does not constitute credible information that overpayments might exist outside of the audit period.

### **Office of Inspector General Response**

As previously stated, the criteria and standards we applied to the 100 claims in our sample were applicable and valid, and we properly executed a valid statistical sampling methodology. As such, we maintain that the results of our sample support our findings and conclusions and constitute credible information of potential overpayments.

## **COMPLIANCE PROGRAMS**

### **Sleep Management Comments**

Sleep Management maintained that its compliance programs were adequate. It stated that the strength of its current coding and compliance programs provides adequate controls to ensure compliance with Medicare billing requirements.

### **Office of Inspector General Response**

We maintain that Sleep Management did not follow its policies and procedures that were intended to ensure its NHV claims met Medicare requirements prior to claiming reimbursement.

## **OTHER MATTERS**

As a condition for payment, certain Medicare covered DME items require a physician's detailed written order before the item is delivered to the beneficiary. The detailed written order must include the beneficiary's name, item of DME ordered, signature of the prescribing physician, prescribing physician National Provider Identifier (NPI), and the date of the order. During our audit period, CMS published a list of the specified covered DME items along with the related Healthcare Common Procedure Coding System (HCPCS) codes used to bill Medicare. CMS was required to update the list annually in the Federal Register.<sup>53</sup> Prior to our audit period, CMS

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<sup>53</sup> The Act § 1834(a)(11)(B)(i); 42 CFR § 410.38(g)(1), (2), (4), and (5) (prior to 84 Fed. Reg. 60648, 60802 (Nov. 8, 2019), amending 42 CFR § 410.38 effective Jan. 1, 2020).



consolidated the previous HCPCS codes into a single code<sup>54</sup> but failed to update the list to include the current HCPCS code for NHVs.

For seven claim lines, the detailed written order did not include the prescribing physician's NPI, and for two claim lines, Sleep Management did not obtain the detailed written order prior to delivery of the NHV to the beneficiary.

Because the current HCPCS code for NHVs was not on the list, we did not question the amounts associated with these errors.<sup>55</sup> However, we would have considered these claim lines to be unallowable had CMS updated the list of specified covered DME items to include the current HCPCS code used to bill for NHVs.

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<sup>54</sup> Effective January 1, 2016, products previously assigned to HCPCS codes E0464 – noninvasive pressure support ventilator, E0461 – noninvasive volume control ventilator, and E0460 – negative pressure ventilator must use HCPCS code E0466 – noninvasive home ventilator (Noridian Healthcare Solutions, Medicare PDAC (Pricing, Data Analysis, and Coding) contractor. Correct Coding and Coverage of Ventilators, Joint DME MAC Publication, May 24, 2016).

<sup>55</sup> The claims had other errors for which the amounts were unallowable.

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

We identified 47,720 Medicare paid claim lines totaling \$36,826,896 for the monthly rental of NHVs from Sleep Management during CYs 2016 and 2017 (audit period). From this number of claim lines, we excluded 7,404 that (1) were previously reviewed by Medicare RACs, (2) had dates of service concurrent with a beneficiary inpatient stay,<sup>56</sup> or (3) had payment amounts of less than \$500. From the remaining 40,316 claim lines totaling \$30,927,491, we selected a simple random sample of 100 claim lines totaling \$75,694.

We did not review the overall internal control structure of Sleep Management. Rather, we limited our review of internal controls to those that related to the objective of our audit.

We conducted our audit from June 2018 through June 2020.

### METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal requirements and Medicare contractor guidance;
- held discussions with CMS officials and officials from the MACs to gain an understanding of claim processing, payment procedures, system edits, monitoring, and Federal requirements related to NHVs;
- interviewed Sleep Management officials to obtain an understanding of their procedures for (1) supplying NHVs to beneficiaries, (2) maintaining required documentation, and (3) billing Medicare;
- used the CMS National Claims History (NCH) file to identify Medicare paid claim lines for the monthly rental of NHVs from Sleep Management during CYs 2016 and 2017;
- created a sampling frame of 40,316 paid claim lines from the NCH data and selected a simple random sample of 100 claim lines totaling \$75,694 (see Appendix B and Appendix C);

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<sup>56</sup> We plan to conduct a future audit to determine whether these claims were paid in accordance with Medicare requirements.

- obtained medical and supplier records from Sleep Management for the 100 sampled claim lines and provided the documentation to an independent medical reviewer (medical professionals certified by a recognized American medical specialty board in an area appropriate to the treatment under review), who determined whether each sample item complied with Medicare requirements;
- reviewed and summarized the independent medical reviewer’s results;
- estimated the amount of the unallowable payments for NHVs during our audit period (see Appendix C); and
- shared the results of our audit with Sleep Management officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

## **APPENDIX B: STATISTICAL SAMPLING METHODOLOGY**

### **SAMPLING FRAME**

We identified 47,720 Medicare paid claim lines totaling \$36,826,896 for monthly rental of NHVs during CYs 2016 and 2017. We excluded 7,404 claim lines that (1) were previously reviewed by Medicare RACs, (2) had dates of service concurrent with a beneficiary inpatient stay, or (3) had payment amounts of less than \$500. The resulting sampling frame consisted of 40,316 Medicare paid claim lines totaling \$30,927,491.

### **SAMPLE UNIT**

The sample unit was a claim line.

### **SAMPLE DESIGN AND SAMPLE SIZE**

We used a simple random sample of 100 claim lines.

### **SOURCE OF RANDOM NUMBERS**

We generated the random numbers using the OIG, Office of Audit Services (OIG/OAS), statistical software.

### **METHOD OF SELECTING SAMPLE ITEMS**

We consecutively numbered the claim lines in the sampling frame. After generating the random numbers, we selected the corresponding frame items.

### **ESTIMATION METHODOLOGY**

We used the OIG/OAS statistical software to estimate the total amount of Medicare overpayments. To be conservative, we recommend recovery of unallowable payments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual unallowable payment total 95 percent of the time.

**APPENDIX C: SAMPLE RESULTS AND ESTIMATES**

**Table 3: Sample Results**

<b>Frame Size</b>	<b>Value of Frame</b>	<b>Sample Size</b>	<b>Value of Sample</b>	<b>Number of Overpayments</b>	<b>Value of Overpayments</b>
40,316	\$30,927,491	100	\$75,694	98	\$74,288

**Table 4: Estimated Value of Overpayments  
(Limits Calculated for a 90-Percent Confidence Interval)**

Point estimate	\$29,949,966
Lower limit	29,131,187
Upper limit	30,768,746

**APPENDIX D: RESULTS FOR EACH SAMPLED CLAIM LINE**

**Legend**

A	Noninvasive home ventilator not medically necessary
B	Continued medical need not supported
C	Continued use of device not supported

**OIG Audit Determinations for the 100 Sampled Claim Lines**

Sample Number	A	B	C	Number of Errors
1	X	X		2
2	X	X		2
3	X	X	X	3
4	X	X	X	3
5	X	X	X	3
6	X	X		2
7	X	X		2
8	X	X		2
9	X	X		2
10	X	X		2
11	X	X		2
12	X	X	X	3
13	X	X		2
14	X	X		2
15	X	X		2
16	X	X	X	3
17	X	X		2
18	X	X		2
19	X	X		2
20	X	X		2
21	X	X	X	3
22	X	X		2
23	X	X	X	3
24	X	X		2
25	X	X	X	3
26	X	X		2
27				0
28	X	X		2
29	X	X		2

<b>Sample Number</b>	<b>A</b>	<b>B</b>	<b>C</b>	<b>Number of Errors</b>
30	X	X		2
31	X	X		2
32	X	X		2
33	X	X		2
34	X	X		2
35	X	X		2
36	X	X		2
37	X	X		2
38	X	X		2
39	X	X	X	3
40	X	X		2
41	X	X		2
42	X	X		2
43	X	X		2
44	X	X		2
45	X	X	X	3
46	X	X		2
47	X	X	X	3
48	X	X	X	3
49				0
50	X	X		2
51	X	X		2
52	X	X	X	3
53	X	X		2
54	X	X		2
55	X	X	X	3
56	X	X		2
57	X	X	X	3
58	X	X		2
59	X	X	X	3
60	X	X		2
61	X	X		2
62	X	X	X	3
63	X	X	X	3
64	X	X		2
65	X	X		2
66	X	X	X	3
67	X	X		2
68	X	X		2
69	X	X	X	3

<b>Sample Number</b>	<b>A</b>	<b>B</b>	<b>C</b>	<b>Number of Errors</b>
70	X	X		2
71	X	X		2
72	X	X		2
73	X	X		2
74	X	X		2
75	X	X	X	3
76	X	X		2
77	X	X		2
78	X	X		2
79	X	X		2
80	X	X		2
81	X	X		2
82	X	X		2
83	X	X	X	3
84	X	X		2
85	X	X		2
86	X	X	X	3
87	X	X		2
88	X	X	X	3
89	X	X		2
90	X	X		2
91	X	X	X	3
92	X	X	X	3
93	X	X		2
94	X	X		2
95	X	X	X	3
96	X	X		2
97	X	X		2
98	X	X	X	3
99	X	X		2
100	X	X		2



## APPENDIX E: SLEEP MANAGEMENT COMMENTS



K&L GATES

September 21, 2020

Joshua I. Skora  
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Ms. Lori S. Pilcher  
Regional Inspector General for Audit Services  
US Dept. of Health and Human Services Office of the Inspector General  
Office of Audit Services, Region IV  
61 Forsyth Street, SW  
Suite 3T41  
Atlanta, GA 30303

Re: Sleep Management, LLC; Report # A-04-18-04066

Ms. Pilcher:

The enclosed correspondence is being submitted on behalf of our client, Sleep Management, LLC d/b/a VieMed ("VieMed"), in response to the U.S. Department of Health and Human Services, Office of the Inspector General's ("OIG") draft report entitled Sleep Management, LLC: Audit of Claims for Monthly Rental of Noninvasive Home Ventilators dated June 25, 2020 ("Draft Report"). A copy of the Draft Report is attached as Exhibit A.

The Draft Report states that VieMed did not comply with Medicare billing requirements related to the monthly rental of non-invasive home ventilators ("NHV"). The findings contained in the report appear to be based almost entirely on the claims review commissioned by OIG from Maximus Federal Services ("Maximus"). VieMed is committed to corporate compliance, including compliance with the Centers for Medicare and Medicaid Services ("CMS") billing requirements and appreciates the opportunity to respond to the findings and recommendations outlined in the Draft Report. We respectfully request your careful consideration of the enclosed response.

### **BRIEF STATEMENT OF CONCURRENCE/NON-CONCURRENCE**

***1. OIG recommends that VieMed refund the Federal Government \$29,131,187 in Medicare overpayments for claims incorrectly billed that are within the 4-year reopening period.***

VieMed does not concur with the finding that it received \$29,131,187 in overpayments related to incorrectly billed claims and the recommendation to refund this amount to the Federal Government. OIG Audit findings identified that 98 of 100 claims audited purportedly did not comply with CMS billing requirements. OIG made no adverse finding related to 2 of the 100 audited claims. VieMed disagrees with OIG's Audit findings for numerous reasons, but predominately on the basis that (i) the claims were medically necessary, (ii) OIG and Maximus improperly applied clinical guidance and/or applied clinical guidance that is not required by CMS, (iii) the sampling plan and methodology was improperly applied by excluding claims with conflicting clinical determinations by other CMS reviewers, and (iv) extrapolation was improperly applied when the nature of the claims prohibit the proper use of extrapolation and conflicting clinical determinations within the same sampling frame make use of statistical extrapolation

mathematically improper.

Although OIG applied incorrect and improper standards to all 98 claims in the Audit sample that were determined by OIG to be unsupported by the medical record, based on VieMed's medical review, it agrees that one of the 98 claims was incorrectly coded. The coding error related to the provision of a home *invasive* ventilator, properly indicated by the E0465 HCPCS code. VieMed inadvertently identified the E0466 HCPCS code—related to provision of a home non-invasive ventilator. The OIG did not identify this technical coding error in its review. Even still, the documentation previously submitted for this claim substantiates the propriety of the E0465 HCPCS code. Because the reimbursement rate for the E0465 and E0466 HCPCS codes are identical, the error resulted in no financial impact. VieMed has notified the applicable DME Medicare Administrative Contractor (“MAC”), CGS Administrators, LLC (“CGS”), of this inadvertent technical error, but as no overpayment occurred, VieMed will not refund CGS the reimbursement associated with the claim (the “CGS Notice Letter”). A copy of the CGS Notice Letter is attached as Exhibit B. VieMed believes this approach to be consistent with the underlying goal of administrative efficiency and finality in the processing of claims, for both CGS and VieMed, as discussed in the Medicare Claims Processing Manual.<sup>1</sup> Therefore, VieMed disagrees with the findings related to the 98 claims that OIG determined were improperly billed to Medicare.

**2. OIG recommends that VieMed exercise reasonable diligence to identify and return any overpayments in accordance with the 60-day rule, and identify any of those returned overpayments as having been made in accordance with OIG's recommendation.**

VieMed recognizes that an OIG Audit such as this one may constitute credible information of a potential overpayment which obligates a provider or supplier to proactively investigate whether it has in fact received funds to which it is not entitled over a 6-year lookback period. If an overpayment is identified, we understand that the provider or supplier is obligated to return the overpayment in a timely fashion as set forth in 42 C.F.R. § 401.305 (the “60-day overpayment rule”). VieMed has exercised more than reasonable diligence in determining and quantifying any overpayments owed as a result of this audit.<sup>2</sup>

As more fully described herein, VieMed undertook a thorough investigation of the 100 audited claims and has determined based on the 100 claim sample set selected by OIG that the existence of at most a 1% error rate does not constitute credible information of potential overpayments that might exist outside of the Audit period. VieMed notified CGS of the one claim discovered to have a coding error. However, since the coding error did not result in an overpayment, a refund was not made.

**3. OIG recommends that VieMed strengthen its controls to ensure full compliance with CMS billing requirements.**

VieMed is constantly reviewing its processes to strengthen its controls to ensure full compliance with CMS billing requirements. However, in the context of this audit, VieMed does not concur with this recommendation and maintains that the strength of its current coding and compliance programs provide adequate controls to ensure compliance with Medicare billing

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<sup>1</sup> DEP'T OF HEALTH AND HUMAN SVCS., CTRS. FOR MEDICARE & MEDICAID SRVS., Medicare Claims Processing Manual, ch. 34, § 10.6.2, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c34.pdf>.

<sup>2</sup> 42 C.F.R. § 401.305(a)(2).

requirements.

## **I. BACKGROUND INFORMATION**

### **A. History of VieMed**

VieMed formed in 2006 as a respiratory Durable Medical Equipment (“DME”) supplier in the Lafayette and Opelousas, Louisiana areas. Following the introduction to the market of effective NHV in 2012, VieMed began an outpatient chronic respiratory failure treatment program utilizing this new technology. It quickly became obvious to physicians, patients, hospital case managers, and hospital administrators that this program was a major step forward in the treatment of vulnerable, complex patients with neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease (“COPD”).

With the introduction of NHV, physicians and patients had a new tool to increase life expectancy, decrease hospital admissions, and improve quality of life all while keeping patients safe and comfortable in their homes. Because of its clinical efficacy, NHV became the standard of care for treating neuromuscular disease, and thoracic restrictive disease, and chronic respiratory failure. Stakeholders soon understood that the use of NHV improved clinical outcomes and reduced the cost of care.

Subsequently, VieMed identified a tremendous unmet need and national demand for improving patient’s lives with NHV therapy. From VieMed’s prior history of treating all stages of COPD with respiratory equipment, it knew the best way to care for these patients was with a skilled and licensed respiratory therapist and not a delivery driver or a non-clinical sales representative, like those employed by many of its competitors. Moreover, VieMed recognized the importance of having correct documentation to substantiate the diagnosis rendered by the treating physician. Using these best practices while also continuously evolving new care models, VieMed made a conscious decision to make medically necessary NHV therapy accessible to more patients, resulting in the supplier’s expansion into other states. Today, VieMed furnishes DME and related services in 35 states and currently services approximately 8,000 non-invasive and invasive ventilator patients.

As one of the largest independent suppliers of NHV in the country, VieMed constantly strives to set the standard of care within its industry, across all areas. Eligibility criteria are no exception. VieMed’s internal policies and practices exceed the coverage requirements for ventilators established by third-party payors, which typically only require the existence of a specific diagnosis. In particular, VieMed proactively self-regulates by requiring specific procedures, higher internal coverage criteria, and certain supporting documents to support a patient’s diagnosis.

### **B. Procedural Errors with OIG Review**

In a letter dated May 31, 2018, OIG notified VieMed of its intent to audit 100 claims (“sample set”) submitted by VieMed related to NHVs during the period beginning January 1, 2016 through December 31, 2017 (all claims submitted within CY2016-CY2017 is the true “sampling frame”), and requested that VieMed send the corresponding medical records for the sample set to OIG for review (the “Audit”).

On June 25, 2020, VieMed received the Draft Report,<sup>3</sup> which outlined OIG's recommendations related to the Audit. The Audit findings outlined in the Draft Report allege that VieMed did not comply with CMS billing requirements for 98 of the 100 claims reviewed in the sample set. OIG alleged an overpayment of \$74,288 for 98 claims, and the Office of Audit Services ("OAS") extrapolated its calculated error rate of 98% across 40,316 claims filed during the sampling frame to determine an estimated overpayment of \$29,131,187 ("Extrapolated Amount"). The specific history of the claims within the sampling frame and OIG's procedure in conducting the Audit must be addressed before a final determination is made by OIG regarding VieMed's submission of claims during the sampling frame.

The Draft Report excluded 7,404 claims that were previously reviewed by Medicare Recovery Audit Contractors ("RACs"),<sup>4</sup> which improperly reduced the sampling frame from 47,720 to 40,316 claims and caused a biased result by not taking into account the conflicting determinations of the 7,404 claims within the RAC audit. OIG provided no explanation for why it was procedurally or statistically appropriate to exclude the claims from the RAC audit. OIG also failed to recognize, after being informed by VieMed during OIG's field work, that 42 of the 100 patients within the sample set were previously reviewed by another CMS auditor.

On October 10, 2017, AdvanceMed, a CMS Zone Program Integrity Contractor ("ZPIC") and Unified Program Integrity Contractor ("UPIC"), notified VieMed of CMS' decision to place the supplier on payment suspension until an overpayment determination was finalized (the "Notice of Payment Suspension"). A copy of the Notice of Payment Suspension is attached as Exhibit C. Under the payment suspension, AdvanceMed initiated prepayment reviews and sent Additional Document Requests ("ADRs") for each submitted claim. Claims deemed payable via the ADR process were paid by the DME MACs into escrow accounts. During this process, VieMed responded to 6,226 ADRs. On January 30, 2018, AdvanceMed notified VieMed that its payment suspension was terminated, but that monies held in escrow would remain in escrow until final overpayment determinations were issued (the "Suspension Termination Notice"). A copy of the Suspension Termination Notice is attached as Exhibit D. On March 23, 2018, CMS Center for Program Integrity ("CMS-CPI") informed VieMed that no overpayment demands would be issued, the audit would be closed, and monies held in escrow would be returned (the "CPI Correspondence"). A copy of the CPI Correspondence is attached as Exhibit E. The entire prepayment review period of October 2017 through December 2017 ("prepayment review period") is within OIG's sampling frame and overlaps with OIG's sampling set.

Specifically, 6,226 claims for NHV were reviewed by AdvanceMed during the prepayment review period. A complete list of the 6,226 claims for NHV reviewed as part of the ADR process is attached as Exhibit F. These 6,226 claims that were part of the prepayment review represent 29,981 total claims in CY2016-CY2017 for patients that were part of the AdvanceMed review. Of these 6,226 claims reviewed by AdvanceMed, 5,680 of those claims were approved, and only 366 of those claims (or 5.9%) were denied for not meeting Medicare coverage criteria.<sup>5</sup> This means that 29,981 of the 40,316 (74.4%) claims in the OIG sampling frame represent claims previously reviewed by another CMS contractor, the vast majority of which AdvanceMed determined were fully supported by medical record documentation, satisfied all Medicare

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<sup>3</sup> There were no adverse findings for 2 of the 100 claims reviewed, and VieMed agrees with the OIG's conclusion that those 2 claims were properly billed.

<sup>4</sup> See Exhibit A, Draft Report at p. 15.

<sup>5</sup> A total of 546 of the 6,226 claims were denied. Of those 546 claims, 180 claims were denials related to Common Working File edit errors, which are commonly corrected post-claim submission.

coverage criteria, and were properly reimbursable by Medicare.

On May 29, 2018, VieMed provided written notice to OIG of AdvanceMed's review and direct contact information for personnel at CMS-CPI that directly oversaw AdvanceMed's review. A copy of the May 29, 2018 correspondence is attached as Exhibit G. OIG provides no explanation as to why 74.4% of the sampling frame remains within the Extrapolated Amount.

More significantly, 42 of the 100 patients within OIG's sampling set were part of AdvanceMed's prepayment review. A complete list of the 42 claims for NHV reviewed as part of the ADR process *and* the OIG's sampling set is attached as Exhibit H. Of that subset of patients, 41 of the 42 (97.6%) prepayment review claims related to those patients were approved by AdvanceMed, which directly conflicts with OIG's 98% error rate determination. The Draft Report does not address these contradictory findings for the same claims by two government auditors or why it would be professionally or statistically appropriate to use extrapolation with such a low confidence of accuracy.

The Inspector General Act of 1978, as amended in Title 5 of the U.S. Code, requires that all federal inspectors general appointed under that act comply with generally accepted government auditing standards ("GAGAS") for audit of federal establishments, organizations, programs, activities, and functions.<sup>6</sup> The act further states that inspectors general shall take appropriate steps to assure that any work performed by nonfederal auditors complies with GAGAS.<sup>7</sup> The United States Government Accountability Office ("GAO") Government Auditing Standards (Rev. 07-2018) set forth the standards that OIG and Maximus should have followed in conducting the Audit.<sup>8</sup>

In July of 2018, OIG prepared the Sampling Plan for the Audit ("Sampling Plan"), which contained improper parameters that skewed the results of the Audit before it began by excluding claims from the sampling frame without justification and by improperly instructing Maximus on CMS coverage of NHV. A copy of the Sampling Plan is attached as Exhibit I. OIG also drafted and prepared the Coverage Elements template (the "OIG Checklist") used by Maximus for completion of the review, which provides instruction to Maximus in making medical necessity determinations:

All NHVs must meet the following criteria: Social Security Act, Section 1862(a)(1)(A): Medicare National Coverage Determination Manual, Chapter 1, Part 4, Section 2801[.] In addition to the criteria above, use the LCD for RADs when the NHV is used for conditions described in the RAD LCD below. (***If the condition described in the RAD LCD overlaps conditions in the ventilator NCD, explain why the medical records does not justify treatment with a NHV.***) Local Coverage Determinations for Respiratory Assist Devices (L33800) [.] Local Coverage Determination for Respiratory Assist Devices (L33800) - Revised 1/1/2017.

A copy of the OIG Checklist is attached as Exhibit J. OIG's instruction to Maximus to explain why the medical records do not justify treatment if any condition overlaps with the RAD LCD is biased and subjective. OIG knows that COPD overlaps the RAD and ventilator NCDs, and the vast

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<sup>6</sup> 5a U.S.C. *et seq.*; GAGAS 1.09a (Rev. 07-2018).

<sup>7</sup> *Id.*

<sup>8</sup> Unless otherwise notes, all references to GAGAS refer to the 2018 revisions applicable to the OIG Audit period.

majority of VieMed's NHV patients are afflicted with chronic respiratory failure consequent to COPD. OIG's instructions to its medical review contractors should outline coverage requirements, not preordain denials. VieMed addresses OIG's improper CMS coverage guidance to Maximus more specifically below, but exclusion of the determinations of the RAC and ADR claims as OIG's biased review instructions were sufficient from the beginning to bias the result at the outset of the Audit.

GAGAS imposes unconditional requirements and presumptively mandatory requirements on OIG and Maximus.<sup>9</sup> Among the mandatory requirements, are that OIG and Maximus maintain integrity, objectivity, and proper use of government information, resources, and positions.<sup>10</sup> GAGAS defines auditing integrity as performing work that is "objective, fact-based, nonpartisan, and nonideological."<sup>11</sup> Objectivity in auditing is defined to include "independence of mind and appearance when conducting engagements, maintain an attitude of impartiality, having intellectual honesty, and being free of conflict of interest."<sup>12</sup> GAGAS also mandates that auditors "should avoid situations that could lead reasonable and informed third parties to conclude that the auditors and audit organizations are not independent and thus are not capable of exercising objective and impartial judgment on all issues."<sup>13</sup>

GAGAS also provides a conceptual framework approach to ensure auditing independence that includes how to identify threats to independence, how to evaluate those threats, and how to apply safeguards to eliminate or reduce threats to independence.<sup>14</sup> Since September 2019 and therefore during part of the time period related to this Audit, Maximus served and continues to serve as the Qualified Independent Contractor ("QIC") for Medicare DME Appeals,<sup>15</sup> and OIG is mandated by GAGAS to evaluate whether Maximus has a self-interest, financial or other interest that would inappropriately influence an auditor's judgment or behavior,<sup>16</sup> particularly in light of the glaring conflict between Maximus' and AdvanceMed's determinations on the same claims. GAGAS determines that a threat to independence is not acceptable if it either: (a) could affect the auditors' ability to conduct an engagement without being affected by influences that compromise professional judgment; or (b) could expose the auditors or audit organization to circumstances that would cause a reasonable and informed third party to conclude that the integrity, objectivity, or professional skepticism of the auditor organization, or an auditor, had been compromised.<sup>17</sup>

When OIG completed an on-site visit at the beginning of the Audit, VieMed provided OIG access to VieMed's executive leadership, Chief Medical Officer, and all other personnel involved in provision of services. At the on-site meeting, OIG auditors stated that it was not conducting audits of NHV claims nationwide, but rather VieMed was specifically targeted in light of its position as a leader in NHV therapy. OIG auditors also stated that CMS and other ventilator suppliers had confirmed the lack of CMS coverage guidelines related to NHV therapy and that CMS indicated that the lack of guidelines had prompted a recent technology assessment. As further explained

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<sup>9</sup> GAGAS 2.02a-b.

<sup>10</sup> *Id.* 3.06c-d.

<sup>11</sup> *Id.* 3.09.

<sup>12</sup> *Id.* 3.11.

<sup>13</sup> *Id.* 3.19.

<sup>14</sup> *Id.* 3.27a-c.

<sup>15</sup> Noridian Healthcare Solutions, Supplier Information on the Upcoming DME QIC Transition, <https://med.noridianmedicare.com/web/jddme/article-detail/-/view/2230715/supplier-information-on-the-upcoming-dme-qic-transition> (last updated Aug. 27, 2019).

<sup>16</sup> GAGAS 3.30a.

<sup>17</sup> *Id.* 3.47a-b.

below, coverage guidelines are still lacking since completion of the technology assessment.

Given the lack of clinical guidelines or coverage criteria, VieMed specifically requested that the medical documentation review be conducted by physicians with experience and expertise in pulmonology, and more specifically chronic respiratory failure and COPD. OIG auditors indicated that they would attempt to honor this request, but explained that it may not have latitude in the selection of physician reviewers' qualifications since OIG does not engage in medical documentation review on a regular basis. VieMed made multiple requests to OIG and *via* Freedom of Information Act ("FOIA") requests to obtain the credentials of Maximus' reviewers to no avail.

Given these procedural issues and conflicting clinical determinations between Maximus and AdvanceMed, OIG must determine whether a reasonable and informed third party might conclude that the Audit results are improper and whether extrapolation is professionally and statistically appropriate under these circumstances.<sup>18</sup>

### **C. VieMed as a Leader in the NHV Industry**

The NHV industry lacks clear Medicare coverage guidelines regarding the appropriate use of the device. For example, while CMS developed a brief national coverage determination ("NCD") for ventilators, a detailed NCD or local coverage determination ("LCD") has yet to be issued for NHV. As a result, well-intentioned suppliers, like VieMed, are forced to make educated guesses as to the applicable coverage standards.

As noted in the Draft Report, OIG began to note an increased utilization of NHV, versus CPAP or RAD, in 2015 and examined the causes. While it is certainly OIG's duty to evaluate increased usage of a service to determine whether value services are being provided, OIG appears to not take into account the significant changes in the industry that are legitimate causes for the increased utilization. Specifically, in late 2015, the CMS Internal HCPCS Workgroup made the decision to eliminate prior codes that could more easily be abused and created new HCPCS E0466 specifically for NHV to delineate the service from CPAP and RAD. A copy of Internal HCPCS Decision Regarding Codes for Ventilators is attached as Exhibit K. The Medicare Contractor for Pricing, Data Analysis and Coding of HCPCS Level II DMEPOS Codes ("PDAC") published the reclassification of NHV to E0466, which code billed for the multifunction Trilogy device used in all claims under review in the Audit.<sup>19</sup> As the evidence establishes, VieMed immediately complied with this coding change and both Maximus' and VieMed's reviews establish that the Trilogy devices in the claims under review were used in NHV mode and compliant upon the effective date of this coding change on January 1, 2016.<sup>20</sup>

VieMed has been a proactive leader in working with government stakeholders to establish uniform and objective standards for ventilator therapy. VieMed, along with K&L Gates' government relations team, organized and participated in multiple meetings with the CMS Coverage Analysis Group ("CAG") to address the lack of ventilator coverage guidelines. These efforts culminated in a meeting between VieMed and CMS on February 2, 2016, as well as

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<sup>18</sup> *Id.*

<sup>19</sup> See PALMETTO GBA, Durable Medical Equipment Coding System (DMECS), Product Classification List, E0466, [https://www4.palmettogba.com/pdac\\_dmeecs/searchProductClassificationResults.do?codeDecision=E0466](https://www4.palmettogba.com/pdac_dmeecs/searchProductClassificationResults.do?codeDecision=E0466) (last visited Sept. 17, 2020).

<sup>20</sup> *Id.*

subsequent meetings throughout 2017 and 2018.

After the first 2016 meeting, VieMed provided to CMS requested studies, related literature, and a comparison of competing standards relating to the usage of NHV. This included a recommendation to use chronic pCO<sub>2</sub> elevation as a bright line metric to qualify COPD patients for NHV. This recommendation was analogous to the chronic low pO<sub>2</sub> metric used successfully for years to qualify patients for home oxygen use. CMS agreed that an elevated pCO<sub>2</sub> would be a useful qualifying standard for NHV provision, but suggested that formally promulgating the pCO<sub>2</sub> standard would not be a CMS priority given the agency's current workload and the relatively small number of Medicare beneficiaries on ventilators as compared to other services. However, CMS also noted that Congress could change CMS priorities *via* legislation.

Following CMS's recommendation, VieMed supported legislation to clarify CMS coverage criteria for NHV through legislation introduced in the U.S. Senate and House of Representatives in both 2016 and 2017. Education about this issue included a presentation on NHV to the Physicians Caucus of the U.S. Congress in June of 2016. Additionally, VieMed met with the CMS CAG in June of 2019 to present results of a study done on Medicare beneficiaries by VieMed and Precision Health Economics. This study proved an association between NHV use and robust, statistically significant reductions in the risk of death and healthcare utilization in COPD/chronic respiratory failure patients treated with NHV. It was later presented at CHEST, the world's largest meeting about lung diseases and has been submitted for publication.

Clearly, Congress recognizes the inefficiency and frustration among health care providers, suppliers, and patients with the lack of bright line coverage criteria for the provision of NHV. Ironically and frustratingly (given OIG's current Audit), VieMed is doing everything in its power to educate anyone who will listen on the importance of clear medical guidelines for NHV and remains committed to adding to the body of knowledge surrounding NHV through its ongoing research program.

#### **D. NHV Differentiated from RADs**

Physicians prescribe continuous positive airway pressure ("CPAP") for patients diagnosed with obstructive sleep apnea ("OSA"). CPAPs generate only a single, static level of air pressure and do not increase tidal volume, minute ventilation, or directly provide respiratory support. Bi-level devices ("BPAP") have two alternating levels of airway pressure that are independently set by the provider. When the machine senses that a patient is initiating a breath, inspiratory flow increases to a predetermined maximum level (inspiratory positive airway pressure, or IPAP) so that air flow increases and the patient's tidal volume is augmented. When the machine senses that the flow is slowing, it reduces the applied airway pressure to a predetermined level maintained throughout expiration (expiratory positive airway pressure, or EPAP) so that the patient has less resistance to exhalation. This allows the patient to receive higher inspiratory pressures without having to work as hard to exhale against higher expiratory pressures. In addition, advanced generation bi-level devices, the so-called respiratory assist devices ("RADs"), can be set to deliver a fixed respiratory rate.

However, while the number of breaths per minute is predetermined, the size of these breaths is inconsistent and depends on a multitude of factors such as airway resistance, lung and chest wall compliance, patient synchrony with the machine, and the amount of air leak around the mask. These factors can change rapidly and the end result is that the tidal volume delivered by a bi-level device or RAD is neither consistent nor predictable. Even sophisticated bi-level devices



and RADs cannot adjust air flow quickly enough to compensate for the above-described factors. These shortcomings render home bi-level devices and RADs inappropriate therapy for respiratory failure and explain why they do not benefit this group.

NHV are manufactured with more powerful turbines to provide the high airflow that is at the heart of mechanical ventilation and more sophisticated software and algorithms to manage this high airflow than those found in bi-level devices and RADs. For example, BPAPs and RADs can deliver a maximum IPAP of 25-30 cm/H<sub>2</sub>O pressure with a peak airflow of < 90 Liters/minute while a typical NHV can deliver an IPAP of 50 cm/H<sub>2</sub>O pressure and a peak airflow of at least 180 Liters/minute. Also, unlike BPAPs and RADs, the Food and Drug Administration (“FDA”) classifies ventilators as life-sustaining devices, which require backup batteries and alarms necessary for continued therapy during a power outage or natural disaster. Accordingly, unlike BPAPs and RADs, ventilators can always quickly provide the flow rates necessary to keep up with the rapidly changing conditions of a COPD patient’s lung mechanics and mask leaks. These rapid changes in delivered airflow assure the correct tidal volume is delivered the appropriate number of times per minute to optimize ventilation while minimizing lung injury. These are the overall goals of mechanical ventilator support in respiratory failure.

Maximus reviewers note in several instances that the beneficiary was on a “BiPAP” during his or her acute care inpatient stay and references that treatment as evidence that an NHV was not medically necessary. However, while the term BiPAP® is a registered trademark held by Respironics, Inc., the term “BiPAP” is widely used colloquially to describe any bi-level positive airway pressure device. Adding to the confusion, Respironics manufactures two devices called BiPAP but which have very different performance characteristics depending on the setting of their intended use. A home BiPAP is a bi-level device and has the performance limitations described above. A hospital BiPAP, also known as the Respironics V60, is a true mechanical ventilator with its attendant performance capabilities that can be used invasively or non-invasively. Anecdotally, VieMed has had conversations with Respironics where they recognize the confusion this has caused and express regret at having labeled these two different products with the same name. Accordingly, the “BiPAP” devices referenced by Maximus reviewers and utilized in the hospital setting are actually ventilators that offer real time volume/pressure adjustment related to changes in pulmonary mechanics and guarantee the delivery of a specific minute volume and are not equivalent to home BiPAP devices. Rather, hospital “BiPAPs” are comparable to NHV in functionality.

It is notable that OIG indicates in the Draft Report that this Audit was prompted by a September 2016 HHS OIG Data Brief: Escalating Medicare Billing for Ventilators Raises Concerns (“Data Brief”) that found that NHVs have features that “created an opportunity for abuse whereby durable medical (DME) suppliers could bill Medicare for an NHV as if it were being used as a ventilator” when use of the device in RAD or CPAP mode was appropriate for the beneficiary’s medical condition.<sup>21</sup> In the Data Brief, OIG noted substantial increased billing for NHVs over the previous seven years. Similarly, OIG described in the Draft Report that from 2009 through 2017, Medicare payments for NHVs increased from \$3.1 million to \$268.8 million and specifically noted that VieMed and two other DME suppliers accounted for the majority of growth in billing for NHVs.<sup>22</sup>

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<sup>21</sup> Exhibit A, Draft Report, at 1; see also OFF. OF INSPECTOR GEN., *Escalating Medicare Billing for Ventilators Raises Concerns* (OEI-12-15-00370) (Sept. 22, 2016) [hereinafter, OIG, 2016 Report].

<sup>22</sup> Exhibit A, Draft Report, at 1.

Notwithstanding the rationale prompting this Audit, the medical record documentation for every audited claim contained an order from the treating physician for an NHV, not a CPAP or RAD, and demonstrated that the equipment was set up for ventilator mode for NHV therapy, the NHV therapy was medically necessary in each case, and each patient used the device in ventilator mode in a manner consistent with the patient's ventilatory needs and the treating physician's order. In other words, OIG found no evidence in any medical records related to the 100 audited claims that VieMed was using the ventilators in CPAP or RAD mode or billing the Medicare program inappropriately, as reflected in OIG's concerns in the Data Brief.

Finally, as further explained below, manufacturers have not claimed, nor has the FDA cleared or approved any CPAPs or RADs as safe or effective for patients diagnosed with chronic respiratory failure consequent to COPD. In contrast, manufacturers specifically list the treatment of respiratory failure in the home environment as the intended use for NHV such as Respironics' Trilogy.<sup>23</sup> In addition, there is no evidence that the use of a CPAP or RAD benefits Medicare beneficiaries diagnosed with chronic respiratory failure. Accordingly, prescription of a CPAP or RAD for this particular patient population would be considered an "off-label" use.

#### **E. CMS Technology Assessment of Home Mechanical Ventilators**

As evidence of the lack of clinical coverage guidelines for NHV, and as a result of VieMed's meetings with CMS officials over the years, in early 2018 CMS's Center for Clinical Standards and Quality ordered the Department of Health and Human Services' Agency for Healthcare Research and Quality ("AHRQ") to conduct a Technology Assessment of Noninvasive Positive Pressure Ventilation in the Home. The final Technology Assessment report was released on February 4, 2020 (the "Report").<sup>24</sup> The Report acknowledges that there is "substantial variability" regarding usage, prescribing patterns, policies, and guidelines for NHV, BPAPs, and CPAPs and "marked variability" in the conclusions, recommendations and evidence for the clinical guidelines that do exist with regard to NHV and BPAPs. AHRQ specifically states "[w]ith current practice and guideline variability, there is a clear need to synthesize the best available evidence to guide prescribing."<sup>25</sup> CMS's request for this assessment, and the Report itself, demonstrate a current lack of information necessary to enact NHV coverage standards, and an acknowledgment that such standards are vital moving forward. In fact, during the Audit process, OIG auditors acknowledged to VieMed both the lack of NHV guidelines and the need for CMS's requested Technology Assessment.

AHRQ concludes in the Report that additional work is needed, but there is clear evidence that NHV reduces mortality and hospital readmissions for patients with chronic respiratory failure. The benefits of treating chronic respiratory failure patients with NHV are well documented and supported by the Report. This treatment keeps patients safe, comfortable, and out of the hospital in the late stages of their disease.

The VieMed/Precision Health Economics study "NHV Reduces Mortality and Healthcare Utilization in Medicare Beneficiaries with COPD/CRF" referenced above shows a 26% reduction in mortality, an 11% reduction in hospitalizations, and an 18% reduction in Emergency

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<sup>23</sup> See U.S. FOOD & DRUG ADMIN., *510(k) Summary for the Respironics Trilogy Evo Ventilator: K181166* (July 18, 2019, available at [https://www.accessdata.fda.gov/cdrh\\_docs/pdf18/K181166.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181166.pdf)).

<sup>24</sup> U.S. DEP'T OF HEALTH AND HUMAN SVCS., Ag. For Healthcare Res. and Quality, *Technology Assessment Program: Noninvasive Positive Pressure Ventilation in the Home* (Feb. 4, 2020).

<sup>25</sup> *Id.* at ES-1.

Department (“ED”) visits after one year of NHV use. The study concludes that if CMS provided NHV for all eligible patients with COPD/CRF, 96,000 lives could be saved annually while eliminating 62,000 hospitalizations and 130,000 ED visits. Additionally, an economic analysis of this data shows that the use of NHV in this population would come at no increased expense to Medicare as the costs of providing NHV are offset by the decreased healthcare utilization.

#### **F. Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) Review of NHV in COPD Patients**

As further evidence of the lack of clear Medicare coverage guidelines related to appropriate use of NHV, on July 22, 2020, CMS conducted a Medicare Evidence Development & Coverage Advisory Committee (“MEDCAC”) panel to examine the scientific evidence pertaining to the home use of noninvasive positive-pressure ventilation (“NIPPV”) in patients with chronic respiratory failure consequent to COPD. In convening the MEDCAC panel, CMS acknowledged that despite the “substantial variability regarding the prescribing patterns, guidelines and policies” related to NIPPV devices, inappropriate prescription of such devices for patients who need such support can lead to **“clinical deterioration, poor quality of life and ultimately death.”**<sup>26</sup>

Accordingly, CMS is seeking the MEDCAC panel’s recommendations and assessment related to patient selection criteria, usage parameters, concomitant services, and equipment parameters necessary in order to achieve the best possible patient health outcomes in Medicare beneficiaries with chronic respiratory failure consequent to COPD. The specific outcomes of interest included decreased mortality, decreased frequency of exacerbations requiring ED or hospital inpatient admission, increased time to hospital readmission for respiratory related disease, and improved function and quality of life. It is worth noting that Dr. William Frazier, VieMed’s Chief Medical Officer, was one of only eight invited speakers who presented to the MEDCAC panel.

This growing body of scientific data under review by CMS highlights several important conclusions that color the Draft Report. First, the technological development of NHV to treat CRF/COPD beginning around 2012 and the subsequent, growing body of medical evidence that NHV provides superior outcomes than RADs for such patients provides a sensible and contrary explanation to the growth of claims, beneficiaries, and payments for NHV used for COPD since 2012. This growth in use does not demonstrate overutilization; rather, it demonstrates evolution of best practices for chronically ill patient populations seeking necessary improvement to their quality of life. Even more importantly, it demonstrates there is danger and harm in relying merely on BiPAPs and RADs for this patient population. As discussed below, waiting for a sick patient to fail use of a RAD when such devices are less effective than NHV is harmful, risking “clinical deterioration, poor quality of life and ultimately death.”

## **II. NON-CONCURRENCE WITH OVERPAYMENT AND ANALYSIS OF CLAIMS**

OIG provided its clinical review summary for each of the 98 claims and concluded that 98 claims were improperly billed to Medicare because: (i) each beneficiary’s medical record does not

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<sup>26</sup> DEP’T OF HEALTH AND HUMAN SVCS., CTRS. FOR MEDICARE & MEDICAID SRVS., MEDCAC Meeting Index: MEDCAC Meeting 7/22/2020 - Noninvasive Positive Pressure Ventilation in the Home for Chronic Respiratory Failure Consequent to Chronic Obstructive Pulmonary Disease, Panel Voting Questions, <https://www.cms.gov/medicare-coverage-database/details/medcac-meeting-details.aspx?MEDCACId=77&bc=AAAEAAAAAAAA&> (emphasis added) (last visited Sept. 19, 2020).

adequately support the medical necessity for the NHV or invasive ventilator; (ii) each beneficiary's medical record does not support continued medical need of the NHV or invasive ventilator; and (iii) for 28 claims, the medical record documentation does not adequately support continued use of the NHV. Herein, VieMed provides a detailed analysis of OIG's flawed review and conclusions related to the claims using case-specific examples. In addition, VieMed has also provided a case-specific summary and analysis for each of the 98 claims, which are attached hereto as Exhibit L.

As noted above, 100% of the claims are supported by proper medical record documentation required to demonstrate medical necessity under applicable Medicare coverage criteria. The documentation further met VieMed's enhanced NHV coverage criteria that goes above and beyond what CMS requires. Accordingly, the NHV in all 99 cases, and an invasive ventilator in one (1) case, were appropriately ordered by the treating physicians and the claims were fully justified and properly paid by Medicare.

#### **A. Applicable Medicare Coverage Criteria Related to Ventilators**

As an initial matter, the Draft Report applied improper and unpromulgated coverage criteria to the claims at issue. Coverage of NHV is addressed in a National Coverage Determinations ("NCD") Manual published by CMS. This NCD Manual states that ventilators are "[c]overed for treatment of neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease. Includes both positive/negative pressure types."<sup>27</sup> CMS publishes NCDs in order to establish uniform coverage criteria for an item or service across the Medicare fee-for-service program. NCDs published by CMS are binding on its contractors, regardless of jurisdiction, as well as administrative law judges during the claim appeal process.<sup>28</sup>

In contrast to NCDs, private company MACs hired by CMS can also issue local coverage determinations ("LCDs") for certain services. LCDs are guidance documents issued by a particular MAC to establish reasonable and necessary indications and limitations for items and services within the issuing MAC's jurisdiction. There is no LCD applicable to ventilators, including NHV. As there is no LCD applicable to ventilators, the ventilator provision in the NCD Manual is the only ventilator-specific coverage requirement. In other words, "[t]he contractor [should] apply NCDs when reviewing claims for items or services addressed by NCDs."<sup>29</sup>

CMS clearly draws a distinction between ventilators and RADs, with different reimbursement categories and rates assigned to each. The DME MACs have issued LCD L33800, which by its title and substance is only applicable to RADs ("RAD LCD"). Notwithstanding OIG's acknowledgement in the Draft Report that no MAC has issued an LCD for NHV, OIG and Maximus reviewers have clearly attempted to apply the RAD LCD to NHV and the claims at issue here. **The RAD LCD does not apply to claims for ventilators.** Therefore, OIG cannot apply the RAD LCD to make coverage determinations for ventilators because LCD L33800 only includes the

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<sup>27</sup> DEP'T OF HEALTH AND HUMAN SVCS., CTRS. FOR MEDICARE & MEDICAID SRVS., Medicare National Coverage Determinations Manual, CMS Pub. 100-03, ch. 1, pt. 4, § 280.1 (Rev. 173, 9-4-14); <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd> [hereinafter, CMS, NCD 280.1].

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<sup>28</sup> DEP'T OF HEALTH AND HUMAN SVCS., CTRS. FOR MEDICARE & MEDICAID SRVS., Pub 100-8, Medicare Program Integrity Manual, ch. 13, § 13.1.1 (Rev. 796, 05-11-18); <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c03.pdf> [hereinafter, CMS, MPIM].

<sup>29</sup> *Id.*

HCPCS codes for bi-level RADs, and not the code for NHV at issue in this Audit. The “Coding Information” section of the LCD does not include ventilators in its “list[] of HCPCS codes that spell out which items or services the LCD applies to,” therefore, the LCD for RADs cannot be used to deny a claim for a ventilator.<sup>30</sup>

Because there is no existing LCD for ventilators to apply to VieMed's claims, OIG may only rely solely on the applicable NCD. The medical records and other documentation provided by VieMed demonstrate that each of 97 NHV claims, and 1 invasive ventilator claim, reviewed by OIG are for respiratory care provided to Medicare beneficiaries previously diagnosed with one of the three qualifying diagnoses. Therefore, each of the 98 claims meets the NCD standard, and the claims were fully justified and properly paid by Medicare.

### **B. Maximus Reviewers’ Flawed Review and Analysis**

VieMed undertook a thorough review of all claims audited by OIG using VieMed's rigorous, evidence-based clinical criteria developed to evaluate NHV use. VieMed reasonably believes that 98 of the 98 claims in dispute were properly submitted and paid in accordance with Medicare coverage criteria. Consequently, there is no legal basis to support a refund of the Medicare reimbursement associated with these claims, and clearly no grounds for repayment for a fundamentally flawed Extrapolated Amount.

Proper, efficient, and effective audit tools were used by VieMed as a part of this process for the evaluation of the claims. As outlined below, Maximus reviewers’ analyses and conclusions related to the claims demonstrate that they failed to use any nationally recognized clinical guidelines related to the assessment and treatment of chronic respiratory failure consequent to COPD or the appropriate use of NHV. For example, individual Maximus reviewers used different clinical and diagnostic standards, none of which were specified or outlined, and often-proffered denial reasons that were neither based on criteria in any nationally recognized guidelines for the treatment of chronic respiratory failure consequent to COPD or the use of NHV, nor clinically valid. In addition, Maximus reviewers often applied standards that are in direct conflict with such accepted evidence-based treatment and therapeutic guidelines.

Perhaps most notably, Maximus reviewers utilized the OIG Checklist during the Audit that not only references the inapplicable RAD LCD, but specifically directs Maximus reviewers to locate a justification to deny the claim in the medical record. OIG confirmed that the Checklist was created by OIG and provided to Maximus reviewers and again, is attached hereto as Exhibit J. Specifically, the first criteria in the Checklist states:

***Does the medical record support the medical necessity for a noninvasive home ventilator (E0466)?***

After citing the NCD, the Checklist directs Maximus reviewers as follows:

In addition to the criteria above, use the LCD for RADs when the NHV is used for conditions described in the RAD LCD below. ***(If the condition described in the RAD LCD overlaps conditions in the ventilator NCD, explain why the medical record does not justify treatment with a NHV.)*** Local Coverage Determination for Respiratory Assist Devices (L33800).

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<sup>30</sup> CMS, MPIM, ch. 13, § 13.5.2.

Under this inappropriate, subjective and biased directive, OIG explicitly instructed Maximus reviewers to utilize the medical record to justify denial of the claim, which is completely and utterly contrary to the manner in which Medicare claims review is to be conducted. As government auditors must use generally-accepted auditing standards as well as clinical standards in order to properly conduct a Medicare claims audit and in turn arrive at valid conclusions, each of the issues described above calls into question the validity, accuracy and fairness of OIG's review and the ultimate findings set forth in the Draft Report.

**C. Maximus Reviewers Improperly Denied Claims for NHV as Not Medically Necessary Based on Multiple Invalid Reasons**

Maximus reviewers denied each of the 98 claims based on the allegation that each beneficiary's medical record does not adequately support the medical necessity for NHV therapy. To support this allegation, Maximus reviewers rely on a variety of reasons that are neither supported by current CMS coverage criteria, CMS guidance, nor any valid evidenced-based clinical guidelines related to the treatment of the qualifying diagnoses or the appropriate use of NHV therapy. Rather, Maximus reviewers used unspecified clinical and diagnostic standards that appear to have varied among the different reviewers.

It is noteworthy that the ultimate basis for denial of nearly all claims is the Maximus reviewer's disagreement with the applicable treating physician's independent medical judgment that NHV was medically necessary and an appropriate therapy for each beneficiary (and not whether the qualifying diagnosis was present in the applicable medical record). In fact, the Draft Report specifically acknowledges: "[f]or most claim lines, the physician's order listed a qualifying diagnosis, and frequently, the supporting medical records contained a statement from the treating physician that the beneficiary had a qualifying diagnosis."

In this regard, the Medicare program only provides reimbursement for DME and supplies that have been ordered or prescribed by a treating physician. The treating physician must personally sign and date the prescription order, and DME suppliers are required to maintain the original order in their files.<sup>31</sup> By signing the order, the treating physician attests that the information on the prescription order is true, accurate and complete to the best of the treating physician's knowledge and that he or she understands that any falsification, omission, or concealment of material fact may result in administrative, civil, or criminal liability.<sup>32</sup>

OIG itself has acknowledged the critical importance of the judgment of the treating physician in clinical decisions and determinations of medical necessity:

The Medicare program only pays for health care services that are medically necessary. In determining what services are medically necessary, **Medicare primarily relies on the professional judgment of the beneficiary's treating physician, since he or she knows the patient's history and makes critical decisions**, such as admitting the patient to the hospital; ordering tests, drugs, and treatments; and determining the length of treatment. In other words, **the physician has a key role in determining both the medical need for, and utilization of,**

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<sup>31</sup> 42 C.F.R. § 410.38.

<sup>32</sup> See, e.g., CMS, MPIM, ch. 3, § 3.3.2.4(c) (providing signature attestation model language related to missing, illegible, or otherwise non-compliant treating practitioner signatures).

**many health care services, including those furnished and billed by other providers and suppliers.**<sup>33</sup>

Similarly, in the Compliance Program Guidance for Durable Medical Equipment, Prosthetics, Orthotics, and Supply Industry (“DMEPOS Compliance Guidance”), which outlines OIG’s recommendations to DMEPOS suppliers to assist and promote compliance with applicable health care laws and regulations, OIG acknowledges the treating physicians’ need for discretion in treating patients.<sup>34</sup> Specifically, OIG states “As a preliminary matter, the OIG recognizes that physicians and other authorized persons must be able to order any items or services that they believe are appropriate for the treatment of their patients,” subject to appropriate medical necessity standards.<sup>35</sup> The OIG further acknowledges “DMEPOS suppliers do not and cannot treat patients or make medical necessity determinations,” and specifically identifies as a special area of concern DMEPOS suppliers “[m]anipulating the patient’s diagnosis in an attempt to receive improper payment.”<sup>36</sup> Therefore, it is appropriate to give deference to the expertise of each physician that examined the beneficiaries and determined in good faith that NHV therapy was appropriate. This is especially true when the treating physicians, as is the case here, are independent, disinterested and lack financial relationships with the supplier.

The 98 claims at issue denied by Maximus reviewers reflect the independent medical judgment of **89** different treating physicians from health care facilities across the country. Each and every one of these 89 different treating physicians determined NHV, or home invasive ventilation, therapy was medically necessary and appropriate for their patient. Indeed, the majority of these 89 treating physicians were pulmonologists or other specialists without any ties to VieMed. Yet, Maximus reviewers dispute the independent medical expertise of **all** of these 89 independent treating physicians.

In doing so, Maximus reviewers are substituting their own medical judgment based solely on the paper record for the expert medical judgment of these physicians whom actually examined and treated these patients. In doing so, Maximus reviewers are simply ignoring the professional judgment of each physician. Even more problematic, OIG is determining that in 98 of 100 cases, the pulmonologists and other specialist physicians responsible for prescribing NHV therapy for their patients either did not know or did not follow CMS guidelines. Such a conclusion defies belief. Instead, the reasonable explanation, which is fully supported by VieMed’s separate review of these claims, is that Maximus reviewers failed to apply the correct standards for medical necessity of NHV therapy.

In any event, the determination of medical necessity and what therapy is most appropriate is not within the purview of a DME supplier. To place on a DME supplier the expectation and responsibility of reviewing and scrutinizing each treating physician’s determination with respect to interpretation of diagnostic tests, clinical diagnoses, current and past medical treatments, and choice of NHV as a medically necessary and appropriate therapy is equivalent to expecting a DME supplier to engage in the unauthorized practice of medicine. This is contrary to CMS rules

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<sup>33</sup> DEP’T OF HEALTH AND HUMAN SVCS., OFF. OF INSPECTOR GEN., Special Fraud Alert: Physician Liability for Certifications in the Provision of Medical Equipment and Supplies and Home Health Services, 64 Fed. Reg. 1814 (Jan. 12, 1999).

<sup>34</sup> DEP’T OF HEALTH AND HUMAN SVCS., OFF. OF INSPECTOR GEN., Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics, and Supply Industry, 64 Fed. Reg. 36,368 (July 6, 1999).

<sup>35</sup> *Id.* at 36,375.

<sup>36</sup> *Id.* at 36,374-75.

and guidelines and at best inappropriate, and at worst, unlawful.

*i. Maximus Reviewers Improperly Denied Claims Due to an Alleged Lack of Sufficient Documentation to Establish the Severity of the Beneficiaries' Condition at a Level Necessary to Support a Qualifying Diagnosis*

In many of the 98 claims, Maximus reviewers use as a basis for denial the alleged lack of sufficient documentation in the medical record to establish the severity of the beneficiaries' condition at a level necessary to support a qualifying diagnosis. On the contrary, the medical record documentation clearly demonstrates the severity of each beneficiary's condition and the medical necessity of the NHV therapy.

While **CMS has not adopted any specific standards or guidelines regarding Medicare coverage of NHV**, there are clinical assessment tools and therapeutic guidelines related to COPD that are accepted by the international community. Specifically, the Global Initiative for Chronic Obstructive Lung Disease ("GOLD") was established in 2001 in order to improve diagnostic and treatment outcomes for patients suffering from COPD. GOLD publishes an annual report that analyzes clinical studies related to COPD and provides clinical guidelines and reference tools to assist practitioners in caring for COPD patients.<sup>37</sup> Importantly, use of the evidence-based reference tools outlined in the GOLD reports are widely considered best practices for diagnosing, classifying, and developing treatment plans for patients with COPD.

In this regard, GOLD has developed two complementary staging criteria for COPD severity, one based on pulmonary function test ("PFT") results and the other based on the clinical characteristics of respiratory symptoms and risk of COPD exacerbations. The GOLD guidelines using PFTs grade severity based on FEV1 values and assigns patients to stage 1, 2, 3 or 4. These numerical stages correspond to mild, moderate, severe, and very severe airflow obstruction respectively. The GOLD guidelines using the ABCD assessment tool, grade severity based on COPD symptoms and the risk for exacerbations with A representing the mildest form of the disease, B and C representing intermediate severity disease, and D representing the most severe form. The GOLD 2020 Report specifically notes the limitations of relying solely on spirometry and highlights the critical importance of patient symptoms and exacerbation risks in treatment decisions.<sup>38</sup> In accordance with the GOLD guidelines, a hospitalization for COPD exacerbation places a patient in Group D, the most severe clinical category representing the sickest 10% of all COPD patients, and identifies patients who are at high risk for repeat hospitalizations and death.<sup>39</sup>

Likewise, a multitude of clinical studies have demonstrated that hospitalization for COPD exacerbation is associated with poor prognosis and increased risk of death.<sup>40</sup> For example, patients that require non-invasive ventilation while hospitalized for an acute exacerbation of COPD have a >42% risk of death and a >66% risk of hospitalizations during the next year.<sup>41</sup> This

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<sup>37</sup> See generally Global Initiative for Chronic Obstructive Lung Disease, Inc., Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease: 2020 Report (Dec. 2019) [hereinafter, GOLD Report].

<sup>38</sup> *Id.*, ch. 2.

<sup>39</sup> *Id.*

<sup>40</sup> See, e.g., Soler-Cataluna, JJ, Martinez-Garcia, MA, Roman Sanchez P, Salcedo, E, Navarro M, Ochando, R. Severe acute exacerbations and mortality in patients with chronic obstructive pulmonary disease. *Thorax* 2005; (60(11): 925-31.

<sup>41</sup> Lindenauer PK, Dharmarajan K, Qin L, Lin Z, Gershon AS, Krumholz HM. Risk Trajectories of Readmission and Death in the First Year after Hospitalization for Chronic Obstructive Pulmonary



risk of death and hospitalizations is significantly lowered if NHV therapy is prescribed as treatment.<sup>42</sup>

Notwithstanding the above, Maximus reviewers oftentimes completely disregard the beneficiaries' acute exacerbation of COPD and resulting inpatient admission as an indication of severity to support the medical necessity of the NHV therapy. Even more troubling is that Maximus reviewers in many cases specifically acknowledge objective evidence of severe illness, only to deny the claim for an alleged lack of that objective evidence.

In addition to the case-specific analysis and supporting medical record documentation provided by VieMed for each claim, below are several examples of such erroneous analyses and conclusions:

- **Sample #10.** The patient was prescribed NHV as treatment for chronic hypercapnic and hypoxic respiratory failure consequent to COPD. NHV was started immediately following a 2014 hospitalization for a severe COPD exacerbation complicated by acute on chronic respiratory failure. Notably, this was his fifth hospitalization within six months for the same underlying condition. During the 2014 hospitalization, the patient's ABG results demonstrated severely elevated pCO<sub>2</sub> of 62 mm Hg. The patient was again hospitalized in 2017 for the same condition, and arterial blood gas ("ABG") results obtained during this hospitalization demonstrated a persistence of hypercapnic chronic respiratory failure with a pCO<sub>2</sub> now of 70 mm Hg. The Maximus reviewer alleges that the documentation does not support a level of chronic severity necessary to support the qualifying diagnosis, specifically stating "In this case, severe disease was alleged but not supported by objective measures of function obtained when the patient was at his baseline (e.g., the results of PFT results – FEV1/FVC and MVV, a 6-minute walk test result consistent with severe disease, etc.). Disease severity at baseline was not confirmed by standard measures." This patient had been in and out of the hospital many times for treatment of respiratory failure and COPD exacerbation, and ABG results demonstrated chronic and severe disease. Nonetheless, the Maximus reviewer fails to acknowledge the clear evidence of severity in the medical record. Importantly, the patient's medical records for the date of service audited were separately reviewed by AdvanceMed as part of the ADR process and was approved and paid by CMS.
- **Sample #17.** In November 2015, the patient was prescribed NHV as treatment for hypercapnic chronic respiratory failure consequent to COPD. NHV was started immediately following a hospitalization for an acute exacerbation of severe COPD. This hospitalization and ABG tests revealing a pCO<sub>2</sub> of 79 with compensated pH, prove both the severity of the patient's COPD and the presence of chronic respiratory failure. The Maximus reviewer acknowledged this hospitalization as well as a subsequent hospitalization in September 2016, secondary to yet another COPD exacerbation. According to the GOLD criteria, a hospitalization for a COPD exacerbation places the patient in Group D, the most severe clinical category representing the sickest 10% of all COPD patients. Nonetheless, the Maximus reviewer alleges that the lack of a PFT means there is no proof of severe COPD, which was actually clearly demonstrated by both the ABG results and the repeated COPD hospitalizations. The severity of the patient's condition is most poignantly substantiated by the fact that the patient died in May 2018.

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Disease. *Am J Respir Crit Care Med.* 2018;197(8):1009-17.

<sup>42</sup> *Id.*

Patients with chronic respiratory failure consequent to COPD are severely sick individuals and, like the patient, will suffer from their deteriorating respiratory condition until death.

- **Sample #48.** The patient was prescribed NHV treatment for chronic respiratory failure consequent to COPD during an outpatient visit following a stem cell transplant for very severe COPD. The Maximus reviewer acknowledged that the treating physician obtained a PFT, the results of which objectively proved the diagnosis of very severe COPD. The Maximus reviewer expressly acknowledges the severity of this patient's condition, stating that "[t]he results of PFTs done in 3/2014 provided objective evidence that the patient's obstructive lung disease was very severe by GOLD Classification. COPD this severe would almost certainly be associated with chronic hypercapnia." However, the Maximus reviewer then denies the claim since "no objective evidence of chronic hypercapnia was provided" and therefore alleges that proof of disease severity was missing. As no requirement for hypercapnia as proof of disease severity exists in the NCD for NHV, this rationale for denying the claim is erroneous and is also in complete conflict with the Maximus reviewer's specific acknowledgement of objective evidence supporting the severity of the patient's illness using the PFT criteria from the GOLD guidelines.
- **Sample #94.** The patient was prescribed NHV therapy as treatment for pulmonary fibrosis with associated chronic hypoxemic respiratory failure after being hospitalized complaining of shortness of breath. The Maximus reviewer challenged the severity of the patient's condition, stating, "Even in the setting of acute illness, however, the patient's work of breathing did not appear to the treating physician to be increased, and lab work revealed a respiratory alkalosis rather than a respiratory acidosis that would have signaled impending respiratory muscle exhaustion." This statement shows the reviewer's lack of knowledge and experience judging disease severity in patients with pulmonary fibrosis. Such patients generally exhibit respiratory acidosis only as a terminal event, which is why respiratory acidosis is not a qualifying metric for NHV use in thoracic restrictive disease. The severity of the patient's condition is most poignantly substantiated by the fact that the patient died less than one month after the audited date of service. The patient received NHV services for less than one month before dying. Patients with chronic respiratory failure consequent to COPD are severely sick individuals and, like the patient, will suffer from their deteriorating respiratory condition until death.

In the above claims, and others, Maximus reviewers improperly denied payment based on an alleged lack of sufficient documentation to establish the severity of the beneficiaries' condition at a level necessary to support a qualifying diagnosis which is not a CMS coverage requirement and an improper basis for denial of the claims. Furthermore, the medical record documentation clearly demonstrates the severity of the beneficiaries' conditions, which is oftentimes specifically acknowledged by the Maximus reviewer in the analysis of the claim.

*ii. Maximus Reviewers Improperly Denied Claims Due to an Alleged Lack of Medical Tests or Functional Measurements to Support Qualifying Diagnosis*

In many of the 98 claims, Maximus reviewers use as a basis for denial the lack of documentation in the medical record of specific medical tests results or functional measurements to support a qualifying diagnosis outlined in the NCD Manual. There are no objective or functional tests required to be included in the medical record documentation for CMS coverage of NHV therapy. The NCD Manual only requires a diagnosis of neuromuscular diseases, thoracic restrictive diseases, or chronic respiratory failure consequent to chronic obstructive pulmonary

disease for CMS coverage of NHV.<sup>43</sup>

Nonetheless, Maximus reviewers deny many claims, in part, due to a lack of this documentation in the record, oftentimes without reference to which specific medical tests or functional measurements are purportedly required for diagnosis. In nearly all of these cases, the Maximus reviewers deny the presence of diagnoses based on medical tests and measurements, but fail to reference any nationally-recognized clinical standards. In other cases, Maximus reviewers acknowledge the presence of certain medical test results or functional measurements that indicate severe disease, only to criticize VieMed for not having *other* medical tests or functional measurements. Maximus reviewers will also sometimes acknowledge a test was performed and demonstrated the presence of the disease state in question, and then deny the test's accuracy based on unfounded and unsubstantiated criticisms.

In a few instances, Maximus reviewers actually acknowledge the presence of severe COPD in accordance with the GOLD guidelines (which are internationally-accepted clinical standards), only to deny the appropriateness of NHV for other reasons. Maximus reviewers also often utilize different clinical or diagnostic standards. For example, Maximus reviewers in multiple cases state a  $pCO_2 \geq 45$  mm Hg indicates chronic hypercapnic respiratory failure, but in some cases, Maximus reviewers fail to acknowledge evidence of chronic hypercapnic respiratory failure when the  $pCO_2$  is well above 45 mm Hg (See, e.g., Sample #24,  $pCO_2 \geq 54.7$  mm Hg).

In Sample #5, the Maximus reviewer denies the claim, in part, because the beneficiary's maximum voluntary ventilation ("MVV") measurements were "significantly above the less than 20 percent threshold at which ventilator support is indicated." MVV has never been utilized in any evidence-based clinical guideline to diagnose or treat respiratory failure or determine whether NHV is appropriate therapy, a fact apparently lost on this particular Maximus reviewer.

In addition to the case-specific analysis and supporting medical record documentation provided by VieMed for each claim, below are several examples of such erroneous analyses and conclusions:

- **Sample #9.** The patient was prescribed NHV treatment for acute on chronic respiratory failure with hypercapnia consequent to COPD. NHV was prescribed immediately following a hospitalization for a severe COPD exacerbation, which was the patient's third hospitalization within six months for the same underlying condition. While hospitalized, ABG tests indicated a  $pCO_2$  level of 56.1 mm Hg with pH compensation. Notwithstanding the foregoing, the Maximus reviewer denied the claim due to an alleged lack of objective testing to confirm the diagnosis, specifically stating "objective evidence (e.g., PFT results, 6-minute walk test results) supporting that this patient's COPD was at a severe level that would have made noninvasive mechanical ventilation reasonable was not provided." While there are no specified testing requirements for provision of an NHV, the medical record contains results of ABG testing which clearly meet CMS's standard for chronic respiratory failure as well as multiple references to the treating physician's diagnosis of severe COPD. Most poignantly, the severity of the patient's condition was demonstrated by her death from COPD just over one month after NHV therapy was started.
- **Sample #14.** In December 2016, the patient was prescribed NHV as treatment for acute on chronic hypoxic respiratory failure consequent to COPD immediately following a

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<sup>43</sup> CMS, NCD 280.1.

prolonged hospitalization for an exacerbation of severe COPD. This hospitalization, the PFT results showing a FEV1 of 44% of predicted, and ABG results showing a pCO<sub>2</sub> level of 56.6, pO<sub>2</sub> level of 86.1, HCO<sub>3</sub> level of 39.1, and pH of 7.457, prove both the severity of the patient's COPD and the presence of chronic hypercapnic respiratory failure. The exacerbation of the patient's COPD and hospitalization also demonstrates the severity of patient's respiratory condition. The diagnosis of COPD with chronic respiratory failure was documented in the medical records created by patient's treating physician. Nonetheless, the Maximus reviewer denied the claim for NHV, in part, based on an allegation that "documentation offered no evidence that the patient was in either acute or chronic respiratory failure." However, as acknowledged by the Maximus reviewer, the patient's ABG tests showing a pCO<sub>2</sub> level of 56.6 with pH compensation, amongst other objective evidence, clearly prove the severity and presence of the patient's chronic respiratory failure. Importantly, the patient's medical records for the date of service audited were separately reviewed by AdvanceMed as part of the ADR process and was approved and paid by CMS.

- **Sample #53.** The patient was a 72-year-old male with a medical history including COPD, black lung disease, and chronic respiratory failure. The patient began NHV therapy immediately following a hospitalization for acute exacerbation of chronic respiratory failure consequent to COPD. During this hospital admission, the patient required invasive mechanical ventilation. The Maximus reviewer alleges that VieMed "did not submit additional documentation to establish a qualifying diagnosis," and that medical necessity was "not supported." The patient's medical records specifically list diagnoses of COPD and chronic respiratory failure and progress notes from the hospitalization state that he has chronic hypoxic and hypercapnic respiratory failure. An ABG report demonstrated a pH of 7.07, pCO<sub>2</sub> of 147 mm Hg, PO<sub>2</sub> of 71 mm Hg, and serum bicarbonate level of 43 mEq/L while he was using a hospital-supplied non-invasive ventilator. These ABG results showed elevated pCO<sub>2</sub> and appropriate pH compensation diagnostic of chronic hypercapnic respiratory failure. The NHV claim related to this patient was reviewed, approved, and paid by CMS based on the same documentation used by the Maximus reviewer to reject NHV coverage. Most poignantly, the severity of the patient's condition was demonstrated by his death, in April 2020.
- **Sample #73.** The patient was prescribed NHV treatment for chronic respiratory failure consequent to COPD immediately after multiple acute exacerbations of COPD between March and July 2017. The Maximus reviewer acknowledged the treating physician obtained PFTs, the results of which substantiate the COPD diagnosis. Although the Maximus reviewer acknowledges objective evidence of the patient's COPD, the Maximus reviewer goes on to attack the validity of the test by complaining the testing procedure was insufficient: "Based on the dynamic volumes in both the March and July studies, [the patient's] results would meet GOLD Classification criteria for severe or very severe obstructive disease. However, only one flow-volume loop was shown rather than the flow volume loops from at least three attempts during each session. The purpose of multiple patient attempts and showing multiple flow-volume loops is to assure and confirm test validity. The single flow-volume loop that was shown was confounded by artifact." This tortured critique of the PFT procedures based on a retrospective medical record review demonstrates the lengths to which this particular Maximus reviewer was willing to go in order to deny the patient's NHV claim. This type of review creates standards with which no NHV provider could possibly satisfy. The NHV claim related to this patient was

reviewed, approved, and paid by CMS based on the same documentation used by the Maximus reviewer to reject NHV coverage.

- **Sample #89.** The patient was a 70-year-old male with a medical history including chronic respiratory failure, COPD, atrial fibrillation, hypertension, and diabetes. The patient began NHV therapy immediately following an Intensive Care Unit admission for an exacerbation of COPD complicated by chronic respiratory failure. The Maximus reviewer denied the patient's claim on the rationale that the documentation submitted by VieMed contained "inadequate factual information to support diagnoses of severe COPD and chronic hypercapnia." However, the patient's medical records specifically list diagnoses of COPD and chronic respiratory failure and progress notes from patient's hospitalization state that the patient was suffering from acute on chronic respiratory failure and that the patient was hypercapnic. Contrary to the Maximus reviewer's allegation, the patient's medical records contain ABG results showing a pH 7.323, pCO<sub>2</sub> of 53.3 mm Hg, and PO<sub>2</sub> of 52.6 mm Hg, which demonstrate elevated pCO<sub>2</sub>, low pO<sub>2</sub>, and appropriate pH compensation diagnostic of chronic hypercapnic and hypoxic respiratory failure. The patient's treating physician ordered NHV and specifically stated that BiPAP was "insufficient due to severity of [patient's] condition," and that "COPD/emphysema [was the] primary cause" of patient's chronic respiratory failure. Accordingly, the Maximus reviewer failed to acknowledge the treating physician's diagnoses and medical record documentation which clearly supported the treating physician's diagnoses of COPD and chronic respiratory failure.

In the above claims, and others, Maximus reviewers improperly denied payment based on a lack of objective tests or functional measurements, which is not a CMS coverage requirement and an improper basis for denial of the claims. Furthermore, the medical record documentation clearly contains objective evidence of each patient's disease, which is oftentimes specifically acknowledged by the Maximus reviewer in the analysis of the claim.

*iii. Maximus Reviewers Improperly Denied Claims Because Medical Record Documentation Indicated NHV was Prescribed While the Patient was Hospitalized for an Acute Medical Episode*

In many instances, Maximus reviewers denied claims because the medical record documentation indicated that NHV therapy was prescribed during a hospitalization for an acute clinical episode. In other words, Maximus reviewers allege in these cases that because the beneficiary did not require NHV therapy prior to the acute inpatient admission, the NHV therapy was not medically necessary.

First, there is no requirement that NHV therapy be ordered outside of an acute episode under CMS coverage criteria, and therefore this is a wholly improper basis for denial. Next, this rationale is both irrational and nonsensical. Under this logic, no Medicare beneficiary would ever qualify for NHV therapy, as there would always be an instance in which the beneficiary begins NHV therapy, before which the beneficiary was not on NHV therapy.

Maximus reviewers' reliance on this rationale also demonstrates a complete lack of understanding of the progressive nature of chronic respiratory failure consequent to COPD. As mentioned above, hospitalization for a COPD exacerbation is associated with poor outcomes and an increased risk of death and these risks are highest in the weeks immediately following

discharge.<sup>44</sup> Clinical evidence demonstrates that the increased mortality risk following hospital discharge can be ameliorated by the early institution of NHV.<sup>45</sup> Moreover, as the GOLD guidelines note, NHV is the standard of care for decreasing morbidity and mortality in patients hospitalized with a COPD exacerbation and acute and/or chronic respiratory failure.<sup>46</sup> An inpatient admission due to an exacerbation of COPD with respiratory failure is perhaps the best justification for NHV therapy, which has been shown to reduce hospital readmissions and mortality in this patient population. It is also the only way to limit coverage to the sickest patients, as evidenced GOLD severity level D, the most severe category due to hospitalization from acute exacerbation.

In addition to the case-specific analysis and supporting medical record documentation provided by VieMed for each claim, below are several examples of such erroneous analyses and conclusions:

- **Sample #1.** The patient was prescribed NHV as treatment for hypercapnic chronic respiratory failure consequent to COPD immediately following a prolonged hospitalization for an exacerbation of the patient's severe COPD. This admission included stays at both an acute care facility and at a long-term acute care facility. The patient's diagnosis was confirmed by ABG results both on and off BiPAP therapy. The Maximus reviewer, in part, denied the claim because "[n]othing in the documentation suggested that [the patient] was reliant on home ventilator support before the acute episode," which is an illogical justification that would result in NHV therapy never qualifying for reimbursement.
- **Sample #40.** The patient was prescribed NHV to treat obesity hypoventilation syndrome in May 2016, a diagnosis that necessarily includes chronic hypercapnic respiratory failure and morbid obesity. This patient was over 450 pounds, and began NHV treatment immediately following a series of hospitalizations in 2016, which included an admission to a long-term acute care hospital. An ABG report in the medical record proves severe hypercapnic chronic respiratory failure (pH of 7.30, PCO<sub>2</sub> of 103 mm Hg, and PO<sub>2</sub> of 234 mm Hg on FiO<sub>2</sub> of 60 percent). In this case, the Maximus reviewer alleges that the evidence contained in the patient's medical record supporting the use of NHV therapy "was developed during the subacute phase of a serious disruption in this patient's usual state of health. No information was provided to describe his status while [the patient] was at his baseline and living in the conditions of intended use." However, the Maximus reviewer's denial of medical necessity on this basis is unfounded. The patient's medical record expressly states that clinical instability secondary to his severe medical condition was his baseline state and that the patient would not improve without long term access to mechanical ventilation. Further, a notation in the patient's medical record expressly rules out home BiPAP therapy for treatment, citing the patient's severe and unstable medical condition. The severity and instability of this patient's condition was clearly documented throughout the medical record and, therefore, was representative of the patient's baseline, contrary to the Maximus reviewer's assertion. This patient represents a very sick individual who ultimately passed away not long after the date of service reviewed by Maximus.

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<sup>44</sup> Lindenauer PK, Dharmarajan K, Qin L, Lin Z, Gershon AS, Krumholz HM. Risk Trajectories of Readmission and Death in the First Year after Hospitalization for Chronic Obstructive Pulmonary Disease. *Am J Respir Crit Care Med.* 2018;197(8):1009-17.

<sup>45</sup> William Frazier, M.D. et al., *The Impact of Non-invasive Ventilation on Health Cost and Outcomes* (submitted for publication at The American Journal of Managed Care and CHEST) (A summary of the findings is attached as [Exhibit M](#)).

<sup>46</sup> GOLD Report, at 61.

Finally, the NHV claim related to this patient was reviewed, approved, and paid by AdvanceMed as part of the ADR process, based on the same documentation considered by the Maximus reviewer.

- **Sample #58.** The patient was a 75-year-old female with a medical history of significant cardiovascular issues including cardiac arrest three years earlier, ischemic cardiomyopathy with an ejection fraction under 50 percent, atrial fibrillation and carotid artery disease. The patient also had severe (GOLD Class 3) COPD and a history of chronic respiratory failure. The patient began NHV therapy immediately following a hospitalization for a COPD exacerbation complicated by acute on chronic hypercapnic respiratory failure. The Maximus reviewer acknowledges that patient's spirometry results graded the patient's obstructive disease as severe. However, the Maximus reviewer denied this claim on the rationale that VieMed failed to submit documentation supporting a qualifying diagnosis because the documentation provided "was created during an acute illness without providing a definition of the patient's condition or her needs at baseline." The patient's medical records at the time of hospital admission indicate the patient was suffering from acute COPD exacerbation, acute bronchitis, and acute on chronic respiratory failure with associated acute on chronic hypercapnia and respiratory acidosis. An initial ABG report at time of admission showed a pH of 7.26, pCO<sub>2</sub> of 111, and pO<sub>2</sub> of 158. Contrary to the Maximus reviewer's allegation, medical records show that a second ABG report, taken after intensive treatment, revealed abnormal baseline results of a pH 7.38, pCO<sub>2</sub> of 75, pO<sub>2</sub> of 60, and serum bicarbonate level of 45 mEq/L on hospital NHV and 30% oxygen. The ABG results showed the elevated pCO<sub>2</sub> and appropriate pH compensation diagnostic of chronic hypercapnic respiratory failure. PFTs conducted a year prior to hospital admission showed FVC of 1.51 L (65% of predicted), FEV1 0.67 L (39% of predicted), and a flow ratio of 44%, which are diagnostic of severe obstructive lung disease. Because of the patient's documented hypercapnic respiratory failure and COPD, patient's treating physician ordered NHV and specifically documented that a home BiPAP would be insufficient. The Maximus reviewer completely disregards the substantial evidence in the medical record of objective test results conducted outside of an acute episode. In any case, NHV therapy is not required to be ordered outside of an acute episode of care.
- **Sample #90.** In January 2017, the patient was prescribed NHV as treatment for hypercapnic chronic respiratory failure consequent to COPD. NHV was started immediately following the last in a series of hospitalizations for COPD exacerbations. This hospitalization, and the ABG results from January 2017 demonstrating a pH of 7.43, a PCO<sub>2</sub> of 66 mm Hg, and a PO<sub>2</sub> of 81 mm Hg, showing pCO<sub>2</sub> retention and pH compensation that prove both the severity of the patient's COPD and the presence of hypercapnic chronic respiratory failure. Further, in the hospital progress notes, the patient's treating physician refers to PFT results showing a very low FEV1 and DLCO, which are objective evidence of very severe COPD. The Maximus reviewer alleges the patient's medical records do not support a qualifying diagnoses to support NHV therapy and fail to demonstrate continued medical necessity for NHV therapy, specifically stating "[T]he ABG did not provide a basis for determining the chronicity of hypercapnia. It did not reflect the patient's baseline condition between acute episodes." However, this justification and rationale is counterintuitive. The patient was admitted to the hospital on multiple occasions due to the severity and chronicity of this illness. The NHV was prescribed to prevent future episodes and to improve the health of the patient, as opposed to waiting for additional episodes to occur.

In the above claims, and others, Maximus reviewers improperly denied payment because the medical record documentation indicates that NHV therapy was prescribed during a hospitalization for an acute clinical episode, which is not a CMS coverage requirement and an improper basis for denial of the claims.

iv. Maximus Reviewers Improperly Denied Claims Due to an Alleged Lack of Documentation Demonstrating That the Treating Physicians Ruled Out Co-Contributing Factors Prior to Ordering NHV Therapy

In many of the 98 claims, Maximus reviewers used as a basis for denial the lack of documentation in the medical record that the treating physicians ruled out comorbidities or other factors that may have contributed to the beneficiaries' symptoms or presentation prior to ordering NHV therapy. Similar to the other rationales relied on by Maximus reviewers to deny the claims as medically unnecessary, there is no Medicare coverage requirement that requires a treating physician to rule out other factors, including co-morbidities, which may be contributing to a beneficiary's symptoms or diagnosis. The NCD only requires that the beneficiary suffer from a neuromuscular disease, thoracic restrictive disease, or chronic respiratory failure consequent to COPD. With respect to the last qualifying diagnosis, note that the description is not "chronic respiratory failure solely" consequent to COPD.

Nevertheless, in many instances, Maximus reviewers improperly deny claims by requiring that the medical record documentation contain evidence that the treating physician determined that the qualifying diagnosis was the sole or primary contributing diagnoses necessitating the NHV. Multiple claims are denied for this reason even when the Maximus reviewer specifically acknowledges and agrees that the beneficiary suffers from severe COPD and has chronic respiratory failure. In the medically complex, chronically ill patient population that is the subject of the claims, parsing out whether a certain diagnosis is the sole or primary contributor to chronic respiratory failure is simply not possible.

In many cases, Maximus reviewers specifically note the presence of both severe COPD and Obesity Hyperventilation Syndrome ("OHS") and attributes the hypercapnic respiratory failure to OHS with untreated OSA as a more "plausible explanation." Again, Maximus reviewers come to this conclusion by disregarding the treating physicians' expert medical opinion and rely instead on a limited medical record review and without the benefit of ever having examined the beneficiary. Contrary to Maximus reviewers' conclusion that when OHS is present, BIPAP or RAD therapy is more appropriate, a recent study demonstrates that the co-existence of OHS and COPD in patients (OHS/COPD overlap syndrome) significantly increases the risk of mortality and recurrent hospitalizations, and therefore, NHV therapy is of critical importance in this patient population.<sup>47</sup>

In some instances, Maximus reviewers completely disregard the treating physicians' diagnosis and attempt to re-diagnose the beneficiary based only on a review of a small portion of the medical record. Second-guessing the treating physician and diagnosing patients based on a retrospective review of the medical record sets a troubling and dangerous precedent.

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<sup>47</sup> Milne, S, Obeidat A, Hernandez A, *et. al.*, The Causal Effect of Body Effect of Body Mass Index on Mortality in COPD: Investigation the "Obesity Paradox" Using Non-Linear Medelian Randomization, *Am J Respir Crit Care Med.* 2020; 201: A4580.



In addition to the case-specific analysis and supporting medical record documentation provided by VieMed for each claim, below are several examples of such erroneous analyses and conclusions:

- **Sample #9.** The patient was prescribed NHV treatment for acute on chronic respiratory failure with hypercapnia and COPD immediately following hospitalization for severe COPD exacerbation. This was the patient's third hospitalization within six months for the same underlying condition. While hospitalized, ABG tests indicated a pCO<sub>2</sub> level of 56.1 mm Hg with pH compensation indicating chronic hypercapnic respiratory failure. Notwithstanding the foregoing, the Maximus reviewer minimized the documented COPD and chronic respiratory failure diagnoses, and pointed to additional health conditions which the reviewer argued "may have played a role" in the patient's outcomes, stating "Untreated obstructive sleep apnea had not been excluded as a likely contributor to either finding.... Likewise, mucous plugging – a potential contributor to hypoxia during acute episodes and possibly between them – was not addressed." It is impossible to determine just how much each comorbidity contributes to a patient's chronic respiratory failure. To require that every possible comorbidity be identified and optimally treated creates an impossible-to-satisfy standard. The fact that the patient was diagnosed with mucous plugging and might have had OSA does not mean that the patient does not have chronic respiratory failure consequent to COPD. In fact, sleep apnea without associated OHS very rarely, if ever, leads to chronic hypercapnic respiratory failure. Here, the patient was clearly diagnosed with chronic respiratory failure consequent to COPD, which is sufficient for a valid NHV order. Again, as further evidence of the critical need for NHV, the patient died just over one month following the initial date of service.
- **Sample #13.** The patient was a 71-year-old female with a medical history including COPD, hypertension, anxiety, and depression. The patient began NHV therapy immediately following a second hospitalization for acute-on-chronic hypoxic hypercapnic respiratory failure secondary to COPD. She had been discharged from the hospital only one week earlier after a hospitalization for the same diagnosis. During the second hospital admission, a CT angiogram indicated emphysematous and fibrotic changes in the right upper lobe and infiltrate in the left upper lobe and right lower lobe. The Maximus reviewer denied the claim on the rationale that the documentation submitted by VieMed "did not permit separating the contribution that more than two weeks of pulmonary illness and right upper lobe fibrotic change made to chronic respiratory failure from what could be attributed to COPD." On the contrary, the patient's medical records at the time of the second hospital admission indicated the patient was suffering from acute-on-chronic hypoxic hypercapnic respiratory failure secondary to COPD. The patient's treating physician based this diagnosis on ABG tests conducted during the hospitalization, which indicated a pH of 7.30, a PCO<sub>2</sub> of 77.5 mm Hg, and a PO<sub>2</sub> of 112 mm Hg. Notably, the patient died in January 2018. The Maximus reviewer chose to disregard the conclusions of the physician who was actually treating the patient, and the reviewer is simply grasping at straws in an attempt to deny the claim. The Maximus reviewer's position that a DME supplier must second guess a treating physician's opinion as to the cause of respiratory failure imposes a nonsensical and inappropriate standard.
- **Sample #21.** The patient was prescribed NHV as treatment for hypercapnic chronic respiratory failure consequent to COPD, which was confirmed by diagnostic testing. NHV was started immediately following a hospitalization for an acute exacerbation of the patient's severe COPD. This hospitalization and the patient's ABG results showing

elevated pCO<sub>2</sub> levels of 54 and 66 mm Hg, with pH compensation, prove both the severity of the patient's COPD and the presence of chronic respiratory failure. The Maximus reviewer denied the claim, in part, by complaining, "Noninvasive ventilation was ordered in the wake of temazepam use," and "Noninvasive bilevel positive pressure ventilation was initiated in the hospital when the patient's respiratory drive appeared to have been depressed by a medication administered to [the patient] . . . ." VieMed would make clear that temazepam may cause *acute* hypercapnic respiratory failure, but does not cause *chronic* respiratory failure as the Maximus reviewer asserts, again, demonstrating the reviewer's ignorance as to treatment of patients with chronic respiratory conditions. Regardless, the patient was clearly diagnosed with chronic respiratory failure consequent to COPD, which was fully supported by the medical record documentation and is sufficient to meet CMS coverage criteria. Note that the patient died in September 2019.

In the above claims, and others, Maximus reviewers improperly denied payment based on an alleged lack of documentation demonstrating that the treating physicians ruled out co-contributing factors prior to ordering NHV therapy, which is not a CMS coverage requirement and an improper basis for denial of the claims.

v. *Maximus Reviewers Improperly Denied Claims Due to Alleged Support in Medical Record Documentation for a Non-Qualifying Diagnosis*

Maximus Reviewers often denied claims, in part, because the medical record documentation allegedly supports a non-qualifying diagnosis. Similar to the discussion above related to improper denials based on a failure to rule out co-morbidities as contributing factors, Maximus reviewers in these cases completely ignored the qualifying diagnoses documented by the treating physicians in the medical record. Rather than deferring to the treating physicians, who examined and treated the beneficiaries, Maximus reviewers substituted their own judgment and attribute the beneficiary's symptoms and respiratory failure to other causes.

In several instances, for example, Maximus reviewers acknowledge the treating physicians' diagnoses of COPD and chronic respiratory failure but deny the claims because the phenotype of chronic respiratory failure is hypoxic, alleging that "chronic respiratory failure with hypoxia is not a qualifying diagnosis according to NCD 280.1." Again, the qualifying diagnosis in the NCD is "chronic respiratory failure consequent to chronic obstructive pulmonary disease," and no specific phenotype, such as hypoxic, hypercapnic, or clinically defined chronic respiratory failure, is specified as necessary for coverage.

Multiple claims were denied because the beneficiary was suffering from only OHS (as opposed to COPD and OHS), which Maximus reviewers allege is not a "thoracic restrictive disease" and accordingly is not a qualifying diagnosis. VieMed strongly disagrees with Maximus reviewers' analysis of these particular claims. First, the term "thoracic restrictive disease" is not a term commonly used in the practice of medicine. Rather, the correct medical terminology for this category of disease is "restrictive pulmonary disease," which is distinguished from "obstructive pulmonary disease" such as COPD. Next, CMS does not further specify in the NCD outlining ventilator coverage what diagnoses qualify as a "thoracic restrictive disease"—and CMS certainly could have done so, as it has in many other NCDs—instead leaving that determination to the treating physician. VieMed's policy with regard to diagnoses under the thoracic restrictive disease category for purposes of CMS coverage of NHV, which policy was approved by VieMed's CMO, Dr. William Frazier, includes OHS since almost all patients with OHS have restrictive pulmonary disease as measured by PFTs. Additionally, the most recently published clinical guideline for OHS

in 2019 recommends NHV be started at the time of discharge in all OHS patients requiring hospitalization for respiratory failure because of the high mortality and re-admission rate in this patient population.<sup>48</sup>

In each case, the presence of a qualifying diagnosis required for CMS coverage is fully documented and supported in the medical record. In addition to the case-specific analysis and supporting medical record documentation provided by VieMed for each claim, below are several examples of such erroneous analyses and conclusions:

- **Patient #73.** The patient was prescribed NHV treatment for chronic respiratory failure consequent to COPD immediately after repeated acute exacerbations of COPD documented between March and July 2017. The treating physician's COPD diagnosis was based on two PFTs both showing severe to very severe obstructive lung disease (FEV1/FVC ratio of 61% , FEV1 of 35% of predicted, and FVC of 44% of predicted in March 2017; and FEV1/FVC of 59%, FEV1 of 29% of predicted, and FVC of 38% of predicted in July 2017). Additionally, the patient's serum bicarbonate level was markedly elevated at 37 mEq/L which is consistent with chronic hypercapnic respiratory failure and the treating physician diagnosed the patient with chronic respiratory failure consequent to COPD. The Maximus reviewer alleges the diagnosis of chronic respiratory failure cannot be supported because of the treating physician's failure to eliminate or control the patient's other health conditions and comorbidities, such as OHS. The Maximus reviewer states: "With regard to COPD, the spirometry results that defined the patient's obstructive ventilatory defect as severe may not have been fully accurate, and a second process documented by the clinician - OHS - provided a plausible explanation for chronic hypercapnia with no evidence of respiratory muscle fatigue. OHS was listed in the notes and well supported with clinical documentation of morbid obesity, obstructive sleep apnea, and hypercapnia during waking hours." The Maximus reviewer further suggests OHS as a "plausible explanation." VieMed can find no reference to an OHS diagnosis by the patient's treating physician as asserted by Maximus. The Maximus reviewer appears to diagnose the patient with OHS based only on a limited review of patient's records—a diagnosis never made by the treating physician, and not supported by the patient's medical records. Rejection of patient's claim based on an alternative explanation cannot be the standard by which the OIG reviews claims. In any case, the fact that a patient could possibly have been diagnosed with OHS does not mean that they do not have chronic respiratory failure consequent to COPD, as diagnosed by the treating physician. Additionally, current medical literature suggests that patients with the overlap syndrome of COPD and OHS have a much higher risk of death following a hospitalization than patients with either disease alone; so even assuming the Maximus reviewer is correct about an OHS diagnosis, this only provides further support for NHV therapy for the patient. Here, the patient's medical records for the date of service audited were separately reviewed by AdvanceMed as part of the ADR process and were approved and paid by CMS.
- **Sample #74.** The patient was diagnosed with chronic hypercapnic respiratory failure consequent to COPD. NHV was begun immediately following a hospitalization for a COPD exacerbation during which an ABG showed an elevated pCO<sub>2</sub> of 49 with pH compensation

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<sup>48</sup> Mokhlesi B, Masa JF, Brozek JL, Gurubhagavatula I, Murphy PB Piper AJ, *et al.* Evaluation and management of obesity hypoventilation syndrome. an official American Thoracic Society clinical practice guideline. *Am J Respir Crit Care Med* 2019; 200(3):e6–e24.

proving the chronic respiratory failure diagnosis. Inexplicably, the Maximus reviewer states, “Chronic respiratory failure with hypoxia is not a qualifying diagnosis according to NCD 280.1.” The reviewer also admits that “the diagnosis of COPD is listed in various entries in chart,” though argues that because such documentation lacked “functional testing” the diagnosis could not be confirmed. Given the patient’s well-documented COPD diagnosis, pCO<sub>2</sub> levels, and recommendation for NHV from treating physicians, it is difficult to understand what other evidence may be desired from the Maximus reviewer to demonstrate a “qualifying” diagnosis. Importantly, the patient’s medical records for the date of service audited were separately reviewed by AdvanceMed as part of the ADR process and were approved and paid by CMS.

- **Patient #75.** The patient was a 78-year-old female with a medical history of COPD, chronic respiratory failure requiring home oxygen, severe pulmonary hypertension, congestive heart failure, asthma, lung cancer and morbid obesity. The patient began NHV therapy immediately following a hospitalization for an exacerbation of COPD and acute on chronic hypoxemic and hypercapnic respiratory failure, during which the patient was admitted to the Intensive Care Unit. ABGs obtained during the hospitalization showed a pH of 7.40, a PCO<sub>2</sub> of 56.6 mm Hg, and a PO<sub>2</sub> of 95.3 mm Hg, demonstrating the elevated PCO<sub>2</sub> and appropriate pH compensation diagnostic of chronic hypercapnic and hypoxic respiratory failure. Inexplicably, the Maximus reviewer denied the claim on the rationale that “chronic respiratory failure with hypoxia is not a qualifying diagnosis.” Despite the patient’s diagnosis of COPD, the reviewer alleges that the patient’s “severe pulmonary hypertension related to surgical loss of lung tissue and untreated sleep apnea would lead to hypoxia with or without a diagnosis of COPD.” Thus, according to the Maximus reviewer “attributing hypercapnia to COPD is not supportable,” given patient’s sleep apnea and “probable Obesity Hypoventilation Syndrome.” This assertion is simply wrong. Pulmonary hypertension is very rarely caused by lung resection while COPD is the most common cause of it. Also, even if OHS was present, the patient still has severe COPD and patients with this combination of diseases (COPD/OHS overlap syndrome) benefit greatly from NHV. The reviewer again completely disregards both the treating physician’s diagnosis and the objective evidence in the medical record supporting that diagnosis in favor of their own, clinically unreasonable, armchair diagnoses. Importantly, the patient’s medical records for the date of service audited were separately reviewed by AdvanceMed as part of the ADR process and was approved and paid by CMS. Lastly, the severity of the patient’s condition was demonstrated by her death, in April 2019.
- **Sample #100.** The patient was prescribed NHV as treatment for chronic respiratory failure after presenting to the treating physician for follow up after coronary bypass grafting. During that admission, he was diagnosed with chronic respiratory failure secondary to a “restrictive ventilator defect felt to be due to body habitus.” The Maximus reviewer rejected the claim, in part, for lack of a qualifying diagnosis, and appears to diagnose the patient with OHS based only on its review of the patient’s records—a diagnosis never made by the patient’s treating physician, and not supported by the patient’s medical records. Specifically, the Maximus reviewer states: “The provider did not elaborate on what features of body habitus were likely to have been associated with the patient’s restrictive ventilatory defect. . . . If [the physician’s] reference were to morbid obesity, a diagnosis of obesity hypoventilation syndrome (OHS) was implied. . . . Treatment of sleep disordered breathing and weight loss are the recommended treatments for OHS.” Again, VieMed can find no reference to OHS or morbid obesity in medical records created by the patient’s treating physician. Rejection of the claim based on an “implied” alternative explanation

cannot be the standard by which the OIG reviews claims and to suggest the patient forgo NHV treatment, and instead undergo “sleep disordered [sic] breathing and weight loss” to resolve the *implied* OHS diagnosis is absurd. Even if the patient had OHS, this would not exclude a diagnosis of chronic respiratory failure and thoracic restrictive disease. Regardless, the Maximus reviewer once again disregarded the treating physician’s diagnosis and substituted his or her own judgment to attribute the beneficiary’s symptoms and respiratory failure to conditions not diagnosed by the treating physician or supported in the medical record. Importantly, the patient’s medical records for the date of service audited were separately reviewed by AdvanceMed as part of the ADR process and approved and paid by CMS.

In the above claims, and others, Maximus reviewers improperly denied payment based on alleged documentation for a non-qualifying diagnosis. However, contrary to Maximus reviewers’ allegations, the medical records in these cases fully support a qualifying diagnosis in accordance with CMS coverage requirements and therefore this is an improper basis for denial of the claims.

*vi. Maximus Reviewers Improperly Denied Claims Due to an Alleged Lack of Documentation Demonstrating the Beneficiaries Tried and Failed to Benefit from a CPAP or RAD Prior to NHV Therapy*

In many of the 98 claims, Maximus reviewers use as a basis for denial the lack of documentation that patients tried and failed to benefit from a RAD such as a CPAP or BIPAP prior to using a ventilator. Prior failure of CPAP, BIPAP, or RAD therapy is not a CMS coverage requirement. Furthermore, prescribing a CPAP, BIPAP or RAD to such patients is contrary to applicable federal and state law and may place these patients at significant risk.

As the CMS Internal HCPCS Workgroup specifically delineated in the 2015 decision to eliminate prior codes and create E0466 for NHV, use of a multifunction device like the Trilogy with documentation to establish that it was used in NHV mode expressly excludes the use of the device in CPAP or BIPAP mode.<sup>49</sup> Indeed, VieMed followed the express guidance of PDAC and provided evidence to establish that all Trilogy devices used in the Audit were operated in NHV mode.<sup>50</sup> In addition to the clinical guidance on selecting the correct code provided and enforced by CMS, the FDA guidance provides even further direction.

The Draft Report cites to a previous OIG review finding that NHV creates an opportunity for abuse in instances where a DME supplier provides a patient with an NHV in lieu of a CPAP or RAD, but the beneficiary’s medical condition indicates that a CPAP or RAD would suffice. However, many of the claims at issue are for NHV furnished by VieMed to beneficiaries suffering from chronic respiratory failure consequent to COPD, which is not an FDA cleared or approved indication for CPAPs or RADs. Moreover, chronic respiratory failure consequent to COPD is not among the list of conditions treated by RADs or CPAPs in the summary chart of CMS coverage requirements on page five of the Draft Report. Accordingly, suggesting that VieMed should have provided patients suffering from chronic respiratory failure consequent to COPD with a CPAP or RAD instead of an NHV runs contrary to CMS parameters regarding the use of off label devices, and CMS coverage policies for NHV.

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<sup>49</sup> See Exhibit K, Internal HCPCS Decision Regarding Codes for Ventilators.

<sup>50</sup> See PALMETTO GBA, Durable Medical Equipment Coding System (DMECS), Product Classification List, E0466, [https://www4.palmettogba.com/pdac\\_dmecs/searchProductClassificationResults.do?codeDecision=E0466](https://www4.palmettogba.com/pdac_dmecs/searchProductClassificationResults.do?codeDecision=E0466).

Manufacturers have not claimed, nor has FDA cleared or approved any CPAPs or RADs as safe or effective for patients diagnosed with chronic respiratory failure consequent to COPD. In contrast, manufacturers specifically list the treatment of respiratory failure in the home environment as the intended use for NHV such as Respironics' Trilogy.<sup>51</sup> Accordingly, prescription of a CPAP or RAD for this patient population is an “off-label” use. Medical device manufacturers are not permitted to market devices for any indications for use that are not cleared or approved by FDA. In order to market an existing 510(k) cleared medical device like an NHV for a new indication, the manufacturer is required to submit a new 510(k) to FDA for review, as the change would constitute a “major change or modification in the intended use of the device.”<sup>52</sup> If a medical device manufacturer fails to submit a new 510(k) before marketing an existing cleared device for a new indication, FDA may consider the device to be misbranded under the meaning of Section 502(o) of the Federal Food, Drug, and Cosmetic Act, and the manufacturer may be subject to enforcement actions including seizure of the relevant device and criminal liability.<sup>53</sup>

The Medicare program has established parameters outlining the conditions that must be satisfied before the program will provide payment for the “off-label” use of a medical device. However, since the inception of the program, Medicare has never required a provider or supplier to use a drug or device “off-label,” where an FDA cleared or approved alternative that has been proven to be safe and effective is available. Indeed, the applicable CMS guidance and LCD summarized in the table on page 5 of the Draft Report specifically states that the NHV is the only device that should be used to treat chronic respiratory failure consequent to COPD. Accordingly, Maximus reviewers’ suggestion that VieMed should have provided a RAD or CPAP to patients suffering from chronic respiratory failure consequent to COPD instead of an NHV runs directly contrary to CMS policy and coverage guidance.

Furthermore, imposing this requirement in the manner contemplated by Maximus reviewers’ responses would be tantamount to requiring terminally ill Medicare beneficiaries to enroll in a clinical trial—without the patient’s consent and without the possibility of advancing medical science.

Lastly, many states require explicit informed consent before a provider/supplier may prescribe and supply an unapproved drug or device in lieu of an approved device. Imposing this requirement in the manner contemplated by Maximus reviewers’ responses would be tantamount to requiring terminally ill Medicare beneficiaries to enroll in a clinical trial and places providers and suppliers at odds with state law.

In addition to the case-specific analysis and supporting medical record documentation provided by VieMed for each claim, below are several examples of such erroneous analyses and conclusions:

- **Sample #3.** The patient was prescribed NHV therapy to treat chronic respiratory failure consequent to COPD after the patient was hospitalized due to an exacerbation. The

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<sup>51</sup> See U.S. FOOD & DRUG ADMIN., *510(k) Summary for the Respironics Trilogy Evo Ventilator: K181166* (July 18, 2019, available at [https://www.accessdata.fda.gov/cdrh\\_docs/pdf18/K181166.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181166.pdf)).

<sup>52</sup> 21 C.F.R. § 807.81 (a)(3).

<sup>53</sup> See, e.g., U.S. FOOD & DRUG ADMIN., *Warning Letter to RADLogics, Inc.* (April 5, 2018, available at <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/radlogics-inc-515599-04052018>).

patient reported that the previously supplied BiPAP was not sufficiently treating his respiratory condition. The patient's treating physician noted PCO<sub>2</sub> levels continued to remain critically high despite home BiPAP use. The Maximus reviewer specifically alleged, "No specific documentation was provided regarding what prevented [the patient's] effective, regular usage of the [BiPAP] or what efforts had been made to remove impediments to use." The patient's treating physician specifically ruled out treatment via BiPAP because it failed to improve the patient's respiratory conditions. In other words, treatment via BiPAP was ruled out by a lack of clinical response. The patient's treating physician specifically noted: "[The patient] is retaining CO<sub>2</sub> as [the patient] can not use [his] bipap . . . Bipap is not sufficient for the patient due to the severity of [his] COPD . . . ." VieMed cannot imagine a clearer example of a patient who tried and failed a BiPAP than this patient. In fact, the patient was treating his respiratory condition via BiPAP, and because BiPAP treatment failed, the patient was readmitted to the hospital. Regardless, documentation of previous failed treatment with a BiPAP is not a requirement for Medicare coverage and therefore this rationale is an improper basis of denial. The severity of the patient's condition is most poignantly substantiated by the fact that the patient died in May 2019. Patients with chronic respiratory failure consequent to COPD are severely sick individuals and, like the patient, will suffer from their deteriorating respiratory condition until death.

- **Sample #11.** The patient was an 81-year-old male with a medical history including chronic respiratory failure with COPD requiring home oxygen, hypertension, and a history of pneumonia, congestive heart failure, and paroxysmal atrial fibrillation. He had been a heavy smoker for over 50 years. The patient began NHV therapy immediately following a hospitalization for an exacerbation of his chronic respiratory failure consequent to COPD. He was hospitalized with acute on chronic respiratory failure and required intubation and invasive ventilation. The Maximus reviewer denied the claim on the rationale that documentation submitted by VieMed "failed to define this patient's needs at his clinical baseline and to substantiate that BiPAP was not able to meet them." According to the reviewer, "Without a qualifying diagnosis and without substantiation that reasonable treatment alternatives failed to meet the patient's needs, NHV cannot be defined as reasonable and medically necessary." On the contrary, the patient's medical records are replete with notations of COPD and chronic respiratory failure, and records confirm multiple hospital admissions for COPD and respiratory failure. An ABG report during the hospital admission demonstrated a pH of 7.44 and an elevated pCO<sub>2</sub> at 69 mm Hg. These ABG results showed the elevated pCO<sub>2</sub> and appropriate pH compensation diagnostic of chronic hypercapnic respiratory failure. Furthermore, spirometry results indicated that the patient's FEV<sub>1</sub> was 37 percent of predicted at 0.77L, and his FVC was 60 percent of predicted at 1.65 L resulting in a flow ratio of 47% indicating severe COPD. Due to his respiratory condition, the patient's treating physician ordered NHV and specifically noted that a home BiPAP would be insufficient. Once again, the Maximus reviewer ignores the substantial evidence in the medical record supporting both the qualifying diagnoses and the determinations and conclusions made by the treating physician based on independent medical judgment and actually treating the patient. Furthermore, "substantiation that reasonable treatment alternatives failed to meet the patient's needs" is not a Medicare coverage requirement and therefore this is an improper basis of denial of this claim.
- **Sample #18.** The patient was prescribed NHV as treatment for chronic respiratory failure and COPD immediately after a hospital admission in January 2015 due to an exacerbation of COPD. ABG results obtained during this hospitalization show severely elevated pCO<sub>2</sub>

levels with pH compensation, which proves both the severity of the patient's COPD and the presence of chronic hypercapnic respiratory failure. The patient's treating physician expressly ruled out the use of a BiPAP and prescribed NHV to treat chronic respiratory failure consequent to COPD. The Maximus reviewer states that the patient used BiPAP at home prior to the January 2015 admission. The reviewer alleges that the "material presented for review did not provide objective evidence that this patient's obstructive pulmonary disease imposed demands that exceeded his respiratory muscle capacity, or provide evidence confirming that BiPAP was unable to meet his needs." This reasoning is flawed and factually incorrect, as the patient was hospitalized while he was using home BiPAP and the treating physician expressly ruled out continuing the use of home BiPAP following this hospitalization. Therefore, the patient did try BiPAP before engaging in NHV therapy, and BiPAP was deemed insufficient. The Maximus reviewer ignores and the conclusions made by the treating physician based on his independent medical judgment developed from actually treating the patient and then subsequently utilizes the Maximus reviewer's own limited review of the record as an improper basis of denial of this claim.

- **Sample #87.** In March 2016, the patient was prescribed NHV as treatment for hypercapnic chronic respiratory failure consequent to COPD immediately following a prolonged hospitalization for an exacerbation of COPD. An ABG drawn during the hospitalization and while on non-invasive ventilation, showed a pH of 7.428, a PCO<sub>2</sub> of 68.8 mm Hg, and a PO<sub>2</sub> of 83.8 mm Hg, confirming a diagnosis of hypercapnic chronic respiratory failure. A PFT performed in February 2017 demonstrated an FEV<sub>1</sub> of 0.71 L, an FVC of 1.3 L, and an FEV<sub>1</sub>/FVC of 56% confirming severe COPD. The Maximus reviewer alleges that because the medical record indicates that BiPAP was somewhat helpful during patient's hospitalization, the treating physician should have tried and failed a lessor respiratory assist device before beginning NHV therapy. First, as discussed above, hospital grade BiPAPs are in fact non-invasive ventilators and are very different than home BiPAP devices. A home BiPAP cannot provide the same level of ventilator support as can a hospital "BiPAP," and the only way to provide this level of support at home is with NHV. Accordingly, the Maximus reviewer's reliance on the argument that a hospital BiPAP is the same as a home BiPAP is erroneous and demonstrates the reviewer's lack of familiarity with these devices. Further, the Maximus reviewer acknowledges that the treating physician specifically ruled out the use of a home BiPAP because of the severity of the patient's medical condition. Specifically, the treating physician notes: "Ordering Nocturnal/daytime volume ventilator. BiPAP insufficient due to the severity of condition. COPD is the primary cause of hypercapnia/[chronic respiratory failure], ventilation required, absence of respiratory support may lead to death." Accordingly, the Maximus reviewer's rationale is contrary to an acknowledgement that BiPAP was indeed ruled out as a treatment option and in any case, is an improper basis of denial of this claim.
- **Sample #96.** The patient was prescribed NHV because of chronic respiratory failure consequent to COPD. NHV was begun immediately following a hospitalization for a COPD exacerbation. During hospitalization, ABG test results demonstrated an elevated pCO<sub>2</sub> of 85 mm Hg with pH compensation after several days on a hospital BiPAP. According to the Maximus reviewer, "Choice of an appropriate device i.e. a ventilator versus a bi-level positive airway pressure (BiPAP) device is made based upon the severity of the condition," and further, "[w]ithout a qualifying diagnosis and a controlled trial that demonstrates NHV to be superior to BiPAP with the same variables in place, NHV cannot be defined as reasonable and medically necessary." This objective ABG data clearly demonstrates that the patient had chronic respiratory failure, and the patient's COPD was clearly identified



in the record by several treating physicians. Most notably is the following observation from the patient's treating provider: "BIPAP was insufficient (pCO<sub>2</sub> 85). After BIPAP use, patient requires noninvasive ventilation to correct this chronic condition. This will reduce hospital admission, hypercapnic episodes and improve patient work of breathing without such treatment, patient will have further decline in her respiratory status and could ultimately be fatal." Unfortunately, the treating physician's prognosis proved correct, as the patient died two years following the NHV order, in May 2019. Importantly, the patient's medical records for the date of service audited were separately reviewed by AdvanceMed as part of the ADR process and was approved and paid by CMS.

In the above claims, and others, Maximus reviewers improperly denied payment based on an alleged lack of documentation demonstrating the beneficiaries did not benefit from a CPAP or RAD prior to NHV therapy, which is not a Medicare coverage requirement, likely violated federal and state law, and is an improper basis for denial of the claims.

#### **D. Maximus Reviewers Improperly Denied Claims for Failure to Demonstrate Continued Medical Need**

VieMed acknowledges the need for CMS, its contractors, and OIG to ensure that Medicare trust funds are not inappropriately spent on items or services that are not reasonable and necessary. Furthermore, VieMed understands that, in other circumstances, the imposition of the continued medical need requirement serves as an important barrier to prevent the overutilization of accessories, supplies and services. However, such a requirement fails to account for the differences between NHV and other items of DME with respect to both utilization and reimbursement.

In the Draft Report, OIG bases the requirement for demonstrating the beneficiaries' continued medical need for NHV primarily on CMS's Local Coverage Article ("LCA"): Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426). With respect to continued medical need, LCA A55426<sup>54</sup> states, in relevant part, the following:

For ongoing supplies and rented DME items, in addition to information described above that justifies the initial provision of the item(s) and/or supplies, there must be information in the beneficiary's medical record to support that the item continues to remain reasonable and necessary. Information used to justify continued medical need must be timely for the DOS under review. Any of the following may serve as documentation justifying continued medical need:

- A recent order by the treating physician/practitioner for refills
- A recent change in prescription
- A properly completed CMN or DIF with an appropriate length of need specified

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<sup>54</sup> Following its Request Email, OIG provided VieMed a version of LCA A55426 previously retired on April 20, 2017. However, prior and subsequent revisions to LCA A55426 did not affect the continued medical need language for purposes of this letter.

- Timely documentation in the beneficiary's medical record showing usage of the item

Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in the policy.<sup>55</sup>

Beneficiaries receiving NHV from VieMed have been diagnosed by their physicians with a qualifying diagnosis and will likely succumb to their disease state. Of the beneficiaries audited by OIG, 42 are now deceased. Specifically, the claims identified by OIG are for patients with either severe neuromuscular diseases, such as amyotrophic lateral sclerosis ("ALS"), or chronic respiratory failure consequent to COPD. These are terminal disease states. For example, ALS results in the *progressive* deterioration or degeneration of an individual's nerve cells, meaning that the individual's symptoms worsen over time. Chronic respiratory failure consequent to COPD or ALS does not resolve spontaneously or with treatment. Therapy is palliative and can lead to improvements in the clinical condition, but not to a cure. As such, once a patient is placed on a ventilator, such utilization is medically necessary until the patient succumbs to his or her disease state. The intrinsic continued medical necessity of ventilators for patients with neuromuscular diseases or chronic respiratory failure consequent to COPD distinguishes the device from other DME covered by Medicare. Specifically, the use of other DME items, such as CPAPs and RADs, can be temporary, which necessitates evidence of continued medical need.

This distinction is clear when reviewing the applicable coverage criteria for other DME items. For example, the RAD LCD states:

There must be documentation in the beneficiary's medical record about the **progress of relevant symptoms** and beneficiary usage of the device up to that time. Failure of the beneficiary to be consistently using the E0470 or E0471 device for an average of 4 hours per 24-hour period by the time of the reevaluation (on or after 61 days after initiation of therapy) would represent non-compliant utilization for the **intended purposes and expectations** of benefit of this therapy. This would constitute reason for Medicare to deny continued coverage as not reasonable and necessary.<sup>56</sup>

The RAD LCD clearly evidences that RADs, unlike NHV, are not life-sustaining devices. Monitoring of a beneficiary's ongoing symptoms is appropriate in determinations related to continued medical necessity of RADs because there is an opportunity for the patient to improve to a state where the assistance of the equipment is no longer necessary. The utilization of a standard that incorporates the "progress of relevant symptoms" into the documentation requirements for NHV is counterintuitive when the disease state of patients will only worsen and lead to death. Patients treated by NHV only decline in health; they do not progress back to a point where they will no longer require the use of the NHV, unlike as contemplated by the use of a RAD in treatment. Patients treated by NHV will always need a ventilator. Notably, the NCD for ventilators is silent as to the continued documentation of a beneficiary's disease or symptom progression.

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<sup>55</sup> Local Coverage Article: Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426), effective date 1/1/2017 [hereinafter, LCA A55426].

<sup>56</sup> See Local Coverage Determination (LCD): Respiratory Assist Devices (L33800), revision effective date 1/1/2017 (emphasis added) [hereinafter, LCD L33800].

In addition, unlike other categories of DME, CMS's reimbursement methodology for ventilators reduces overutilization incentives for suppliers. The continued medical need requirement acts as a check on overutilization of accessories, supplies, and services when those items or services are reimbursed separately from the base equipment. Specifically, CMS classifies ventilators as a "Frequent and Substantial Service" item. As such, NHV suppliers receive monthly rental payments for the item so long as medical necessity continues.<sup>57</sup> CMS's bundled monthly rental payment covers all services and items rendered by the supplier for the month, including the base device, accessories and supplies, the servicing of the device, professional services provided to the patient, as well as any replacement of the device's accessories (e.g., tubing, masks, etc.).<sup>58</sup> By contrast, DME items prone to higher instances of fraud or abuse, such as CPAPs, are categorized as "Capped Rental" items. For capped rental items, CMS makes monthly rental payments to the supplier but restricts the rental period for the base device to only a predetermined number of months.<sup>59</sup> Following the exhaustion of the rental period, the monthly rental payments to the supplier cease and title to the device is transferred to the beneficiary. Unlike NHV and other items in the frequent and substantial service category, suppliers continue to bill the Medicare program for related accessories after the beneficiary accepts title to the equipment.<sup>60</sup>

The reimbursement methodology and payment classification for items not classified as Frequent and Substantial Service creates opportunities for suppliers to maximize Medicare reimbursements through the overutilization of related supplies and accessories, even when the underlying device no longer remains reasonable and necessary. A recent OIG report exemplifies the overutilization concerns associated with Medicare claims for replacement supplies. In the report, OIG discusses replacement supplies for positive airway pressure ("PAP") devices and the requirement that suppliers document that the supplies *remain* reasonable and necessary.<sup>61</sup> This Report references the requirement of continued medical need in the PAP LCDs specifically in the context of replacement supplies.<sup>62</sup> In such circumstances, the continued medical need requirement functions as a deterrent to suppliers engaging in fraudulent, wasteful or abusive billing practices.<sup>63</sup>

By contrast, bundled monthly payments for ventilators, **and** all related supplies, accessories and services, encourage suppliers to provide only medically necessary items or services, thereby reducing the risk for fraud and abuse. Provided NHV was medically necessary when initially furnished, and given that patients are placed on NHV to treat terminal diseases, the concern for fraud, waste or abuse is low, thereby rendering the continued medical need requirement illogical and superfluous.

Finally, in any event, VieMed previously submitted to OIG usage documentation obtained directly from software embedded in the beneficiary's ventilators. Such logs provide detailed information about the beneficiary's usage patterns, including average daily usage. Accordingly,

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<sup>57</sup> 42 C.F.R. § 414.222(b).

<sup>58</sup> See CGS Administrators, LLC, DME MAC Jurisdiction C Supplier Manual, ch. 5, § 2 (Summer 2018); <https://www.cgsmedicare.com/jc/pubs/pdf/chpt5.pdf>.

<sup>59</sup> 42 C.F.R. § 414.229(f).

<sup>60</sup> *Id.*

<sup>61</sup> DEP'T OF HEALTH AND HUMAN SVCS., OFF. OF INSPECTOR GEN., Most Medicare Claims for Replacement Positive Airway Pressure Device Supplies Did Not Comply With Medicare Requirements, Report No. A-04-17-04056 (June 2018).

<sup>62</sup> *Id.* at 5.

<sup>63</sup> *Id.* at 5-6.

this information constitutes “[t]imely documentation in the beneficiary’s medical record showing usage of the item” and, therefore, further evidences the beneficiary’s continued medical need for the device.<sup>64</sup>

#### **E. Maximus Reviewers Improperly Denied Claims for Failure to Demonstrate Continued Use of the Device**

OIG also cites VieMed as not demonstrating medical necessity for 28 of the sampled claims by not demonstrating continued use of the NHV devices. In doing so, Maximus reviewers adopted a use standard applicable to CPAP devices that has no bearing on the use of NHV. Specifically, OIG stated that for the 28 claim lines denied on this basis, “the beneficiary used the device 4 hours or less a day.” However, the Draft Report provides no citation to any requirement or CMS policy that NHV must be used by a beneficiary 4 hours per day in order for the device to be covered by Medicare. Instead, the Draft Report appears to be erroneously adopting the LCD standard that applies to RADs used in the treatment of sleep apnea—a disease state completely dissimilar to chronic respiratory disease consequent to COPD, thoracic restrictive disease, or neuromuscular disease. There is a continued coverage criteria that applies to BiPAP RADs that requires the beneficiary “to be consistently using the [BiPAP] device for an average of 4 hours per 25 day period by the time of re-valuation” in order to meet established standards for compliant utilization.<sup>65</sup>

However, no such CMS standard for compliant utilization of NHV exists. In short, there is no 4-hour continued use requirement for NHV. Indeed, there is no clear line for the number of hours a patient with chronic respiratory failure consequent to COPD should use an NHV each day to obtain a positive clinical outcome. The published studies contain many examples of patients who use their device much less than 4 hours per day on average and yet still show marked improvements in clinical outcomes.<sup>66</sup> There is no study that purports to show an hours of use of NHV below which no clinical benefit is seen. Anecdotally, VieMed has many patients who report dramatic improvement in quality of life and a reduction in hospitalizations by using NHV on an as needed basis. Patients often use the device as much as necessary to alleviate their symptoms.

The position of the Draft Report is that a NHV should be removed from a patient’s home if they are not using it at least four hours per day. This proposal only serves to remove the device

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<sup>64</sup> LCA A55426 and the Medicare Program Integrity Manual (“MPIM”) confirm that a patient’s medical records may comprise of documents other than a physician’s progress or office notes. In particular, Chapter 5, Section 5.7 of the MPIM states, in relevant part, “The patient’s medical record is not limited to the physician’s office records. It may include hospital, nursing home, or HHA records and records from other health care professionals.” LCA A55426 further states that “[s]upplier-produced records . . . are deemed not to be part of a medical record for Medicare payment purposes.” The usage reports, and data on which the usage logs are based, are compiled and prepared by third-party software built into the furnished ventilators. VieMed merely exports the reports from the ventilator and has no control over, or ability to alter, the underlying data. Accordingly, the usage logs or reports previously submitted to OIG are created or produced by Phillips Respironics, the manufacturer of the ventilators, not VieMed.

<sup>65</sup> See LCD L33800 (emphasis added).

<sup>66</sup> See, e.g., Murphy PB, Rehal S, Arbane G, et al. Effect of noninvasive ventilation with oxygen therapy vs oxygen therapy alone on hospital readmission of death after and acute COPD exacerbation: a randomized clinical trial. *JAMA* 2017; 317(21): 2177-86; Kohnlein T, Windisch W, Kohler D, et. al. Non-invasive positive pressure ventilation for the treatment of severe stable chronic obstructive pulmonary disease: a prospective, multicenter, randomized, controlled clinical trial. *Lancet Respir Med* 2014; 2(9): 698-705.

from a patient's home by which they can relieve their respiratory symptoms, and will only result in additional hospitalizations and increased mortality. Also, VieMed cannot remove a life sustaining device from a beneficiary's home unless ordered by the treating physician. Treating physicians will not write such orders for a variety of reasons, but mainly because removal of NHV from the home puts the patient at greater risk of harm and death, and would expose the treating physician to malpractice liability.

### III. Inappropriate Use of Extrapolation

Math only results in accuracy when the underlying premise and determinates are correct. Prior to the Audit, OIG's discussion of NHV overutilization was set forth in the Data Brief discussed above.<sup>67</sup> The Data Brief confesses OIG's concentration on three main suppliers, one of whom is VieMed.<sup>68</sup> While VieMed has examined some of the clinical misunderstandings in the Draft Report, a few key items from the Data Brief must be noted for an examination of the flawed extrapolation process.

First, OIG noted that the "data brief also reinforces the importance of CMS's and its contractors' reviews (both prepayment and postpayment) of ventilator claims; these reviews have found high rates of improper payments."<sup>69</sup> Most important to the credibility of this assertion is that it shows OIG's awareness of multiple NHV reviews. OIG provides no explanation for why the AdvanceMed prepayment review claims remained within the sampling frame of the Extrapolated Amount in the Draft Report,<sup>70</sup> despite evidence that OIG was notified of AdvanceMed's review by VieMed on May 29, 2018.<sup>71</sup> In addition to the statistical flaws with excluding claims from a sampling frame as set forth below, the practical reality is that OIG excluded 7,404 RAC-revised claims from the true sampling frame of 47,720 (15.5% of the true sampling frame) that had conflicting determinations that would have mathematically changed the Extrapolated Amount and wholly ignored 29,981 AdvanceMed-reviewed claims (62.8% of true sampling frame and 74.4% of OIG reduced sampling frame of 40,316).<sup>72</sup>

The second key acknowledgement by OIG in the Data Brief was that the "study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency."<sup>73</sup> The Council of the Inspectors General on Integrity and Efficiency have expressly adopted GAO's Government Auditing Standards (Rev. 07-2018) that govern how OIG and Maximus were to conduct this Audit.<sup>74</sup> As set forth in Section I.B above, GAGAS mandates that OIG has unconditional duties to ensure that sampling plan, sampling process, and extrapolation was performed with objectivity<sup>75</sup> and independence.<sup>76</sup> OIG has a continuing duty to ensure that any threat to maintaining objectivity

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<sup>67</sup> DEP'T OF HEALTH AND HUMAN SVCS., OFF. OF INSPECTOR GEN., Escalating Medicare Billing for Ventilators Raises Concerns, OEI-12-15-00370 (Sept. 2016), <https://oig.hhs.gov/oei/reports/oei-12-15-00370.pdf>.

<sup>68</sup> *Id.* at 6.

<sup>69</sup> *Id.* at 10.

<sup>70</sup> See Exhibit A, Draft Report.

<sup>71</sup> See Exhibit G, May 29, 2018 Correspondence.

<sup>72</sup> See Exhibit A, Draft Report; Exhibit F, All ADR Claims; Exhibit H, ADR Claims in OIG Sample Set.

<sup>73</sup> U.S. DEPT. OF HEALTH & HUMAN SERVICES, Office of Inspector General, Escalating Medicare Billing for Ventilators Raises Concerns, OEI-12-15-00370 (Sept. 2016), <https://oig.hhs.gov/oei/reports/oei-12-15-00370.pdf> (emphasis original).

<sup>74</sup> 5a U.S.C. *et seq.* (need revision date); GAGAS 1.09a (Rev. 07-2018).

<sup>75</sup> GAGAS 3.09.

<sup>76</sup> *Id.* 3.27a-c.

and independence is eliminated prior to reaching a final determination in the Audit.<sup>77</sup> Improper manipulation of a sampling frame by exclusion of conflicting data/determinates undermines the duty of objectivity in assessing the validity of OIG's purported findings in the Draft Report. Engaging a contract auditor that maintains an existing financial interest with CMS that a reasonably informed third party could conclude compromised Maximus' objectivity is a threat to independence that must be eliminated before OIG can come to a final determination in the Audit.<sup>78</sup>

In the interest of objectivity and integrity, VieMed engaged Ian McKeague, Ph.D., Professor of Biostatistics at Columbia University, to evaluate OIG's process in developing the sampling plan, determining the sampling frame and sample set, and OAS's use of RAT-STATS to extrapolate Maximus' findings. A copy of Prof. McKeague's Report and Curriculum Vitae is attached as Exhibit N. Prof. McKeague notes that exclusion of claims from a sampling frame causes selection bias, confirmation bias, and cherry-picking.<sup>79</sup> He explains that cherry-picking, in the statistical definition, denotes an "act of intentionally ignoring relevant data" that causes "fallacies and threats to the validity of statistical arguments."<sup>80</sup> Confirmation bias in statistics is defined as "ignoring possible bias in the selection of a sampling frame (or of variables that are used to restrict the scope of a sampling frame), leading to 'the tendency to credit sources of confirming evidence over sources of disconfirmation.'"<sup>81</sup> Prof. McKeague highlights that statisticians must consider that "a selected sample may not be representative of the universe of which it is a part," because it is "more appropriate to assess the design of a study in terms of its potential selection bias than to assess characteristics of the resultant sample."<sup>82</sup>

Prof. McKeague found that in the Sample Plan "OIG omitted any assessment of whether using a selected (or biased) sample is justified,"<sup>83</sup> which is counter to statistical authorities. He explains that "without an understanding of the effect of the selection bias on the results of the OIG extrapolation, those results are not generalizable to the sampling frame that is the objective of the audit in the first place."<sup>84</sup> Prof. McKeague explains that cherry-picking includes the "selective culling of evidence to support a claim."<sup>85</sup>

Prof. McKeague draws a number of conclusions from his analysis of the OIG Audit process and extrapolation, finding that "exclusion of data concerning previously-reviewed claims from the OIG sampling frame [reference omitted] is an instance of all the problems mentioned above selection bias, cherry-picking and confirmation bias."<sup>86</sup> In explanation, he concludes that "[c]herry-picking is involved because the OIG sampling frame of 40,316 claims [citation omitted] is picked in a way that misleadingly supports the conclusion of widespread overpayment while ignoring conflicting information (creating confirmation bias)" and that "restricting the sampling frame by excluding 6,976 [RAC-reviewed] claims creates a biased (or selected) sampling frame that leads

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<sup>77</sup> *Id.*

<sup>78</sup> *Id.* 3.47a-b.

<sup>79</sup> See McKeague Report at 5-8.

<sup>80</sup> *Id.* at 6, citing Klass G.M. (2012), *Just Plain Data Analysis*. Rowan & Littlefield Publishers, 2nd Ed., p37.

<sup>81</sup> *Id.*, quoting Klayman, J. (1995). "Varieties of confirmation bias," *Psychology of Learning and Motivation*, 32, p385-418.

<sup>82</sup> *Id.* at 6-7, quoting Ellenberg, J.H. (1994), Selection bias in observational and experimental studies," *Statistics in Medicine*, 13, p557-67.

<sup>83</sup> *Id.* at 7.

<sup>84</sup> *Id.*

<sup>85</sup> *Id.* at 8, quoting Kass (2012).

<sup>86</sup> *Id.*

to a spurious overpayment extrapolation.”<sup>87</sup>

Prof. McKeague also concludes that “[c]herry-picking is further involved because the OIG auditing procedure has been manipulated to provide a misleading result by using the misinterpretation of the 12-month period.”<sup>88</sup> He explains that “‘cherry-pick often involves comparisons with arbitrary beginning and ending time points’ that may be selected to support a particular position,” and that the “selection of individual claims from a sequence within the audit time period 2016-2017 is yet another instance of such cherry-picking or biased sampling (for which no justification is provided in the Sampling Plan).”<sup>89</sup>

The final major flaw that Prof. McKeague found in the OIG procedure was the exclusion of the AdvanceMed prepayment review claims.<sup>90</sup> VieMed provided him with all of the AdvanceMed prepayment review results, and Prof. McKeague determined that exclusion of these claims was “[f]urther indication that cherry-picking and confirmation bias have compromised the audit.”<sup>91</sup> After examining the prepayment review data, he concluded that the “5.9% error rate [in the AdvanceMed review] is in stark contrast to the 98% error rate reported by OIG based on their audit, further calling into question the integrity of the OIG auditing process” because “[i]t is not appropriate to base any extrapolation calculation exclusively on the OIG audit data while ignoring grossly conflicting data.”<sup>92</sup>

Prof. McKeague concluded that under the Medicare Program Integrity Manual (“MPIM”), OIG was not allowed to exclude the previously reviewed claims, that “the estimate of the extrapolated error amount provided by OIG is deeply flawed,” that “the methods used to obtain it depart from accepted statistical practice,” and that “[t]here is no justification for the resulting overpayment assessment.”<sup>93</sup> He supports his conclusion with reference to GAGAS:

When assessing the overall sufficiency and appropriateness of evidence, auditors should evaluate the expected significance of evidence to the audit objectives, findings, and conclusions; available corroborating evidence; and the level of audit risk. ***If auditors conclude that evidence is not sufficient or appropriate, they should not use such evidence as support for findings and conclusions.***<sup>94</sup>

(emphasis added). Prof. McKeague explains that “[t]his makes it clear that OIG had an obligation to broaden their investigation to consider corroborating evidence beyond their own audit in reaching an overall conclusion” and that considering the “conflicting evidence \*\*\* would then have functioned as a corrective \*\*\* [that] would have placed the OIG conclusions in a wholly different light.”<sup>95</sup> Statisticians such as Prof. McKeague are not alone in the conclusion that extrapolation is inappropriate when the basis for the validity of the claim rests solely on disputed clinical determinations.

The glaring disparity between the clinical determinations of Maximus and AdvanceMed for

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<sup>87</sup> *Id.*

<sup>88</sup> *Id.*

<sup>89</sup> *Id.* at 8-9, quoting Kass (2012).

<sup>90</sup> *Id.* at 9-10.

<sup>91</sup> *Id.* at 9.

<sup>92</sup> *Id.*

<sup>93</sup> *Id.*

<sup>94</sup> *Id.* at 10, citing CAO-18-56G Government Auditing Standards, p185.

<sup>95</sup> *Id.* at 10-11.

the same claims militate a genuine reconsideration by OIG as to the validity of Maximus' findings and the appropriateness of using the extrapolation process where the only basis for denial of the claims is a matter of clinical dispute. In *United States v. AseraCare, Inc.*, the 11th Circuit Court of Appeals affirmed the district court's ruling that a mere difference of opinion in clinical judgment was not sufficient to prove falsity.<sup>96</sup> In *AseraCare*, the court went on to state that a physician's clinical judgment dictates eligibility as long as it represents a reasonable interpretation.<sup>97</sup> In *United States ex rel. Conroy v. Select Medical Corporation*, the Indiana District Court ruled that statistical sampling was inappropriate when the government attempted to prove "upcoding" because medical necessity, or the lack thereof, requires a claim-by-claim determination of each patient's medical need.<sup>98</sup> In *United States ex rel. Michaels v. Agape Senior Community, Inc.*, the South Carolina District Court ruled that extrapolation was inappropriate because the establishment of medical necessity for each claim requires fact-intensive inquiries.<sup>99</sup> Admittedly, all these cases applied civil fraud evidentiary standards. However, the same fundamental principle that a disputable determinate (i.e. validity of a claim within the sample set) is inappropriate for extrapolation is also solidly embedded within Chapter 8 of the MPIM:

The General Purpose of the Use of Statistical Sampling for Overpayment Estimation from the MPIM clearly states:

\*\*\*The intent of these instructions is to ensure that a probability sample drawn from the sampling frame of the target population yields a valid estimate of an overpayment in the target population. This means that **every element in the sampling frame has a non-zero probability of being selected.** It is important to note that this is consistent with methodologies such as stratification and cluster sampling as needed to warrant statistically sound inferences from the sample. Reviews conducted by the contractors to assist law enforcement with the identification, case development, and/or investigation of suspected fraud or other unlawful activities may use sampling methodologies that differ from those prescribed herein. However, in those cases, the **methodologies used shall be well-accepted methodologies amongst statisticians, and complete explanation shall be provided for why the methodology used was the appropriate methodology in the situation.**<sup>100</sup>

OIG admitted to removing the RAC claims from the sampling frame and ignored that the majority of the sampling frame was reviewed by AdvanceMed, which violates the fundamental principle set forth in the MPIM that "every element in the sampling frame [must have] a non-zero probability of being selected."<sup>101</sup> OIG has failed to provide an explanation of what methodology allows them to exclude the RAC claims from the sampling frame or why the AdvanceMed claims were not considered at all.

Ironically, as VieMed was preparing this response to the Draft Report, OIG released Report No. A-05-18-00024, titled "Medicare Contractors Were Not Consistent in How They

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<sup>96</sup> *U.S. v. AseraCare, Inc.* 938 F.3d 1278, 1281 (11th Cr. 2019).

<sup>97</sup> *Id.* at 1294.

<sup>98</sup> *U.S. ex rel. Conroy v. Select Med. Corp.*, 307 F. Supp. 3d 896 (S.D. Ind. 2018).

<sup>99</sup> *U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, 848 F.3d 330 (4th Cir. 2017); see also *U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, 2016 U.S. Dist. LEXIS 80160, 2016 WL 3449833 (holding that extrapolation based on after-the-fact examinations of medical charts was inappropriate because eligibility should be looked at on an individual basis).

<sup>100</sup> MPIM, ch. 8, § 8.4.1.1 (Rev. 10184, 06-19-20) (emphasis added).

<sup>101</sup> *Id.*



Reviewed Extrapolation Overpayments in the Provider Appeals Process,”<sup>102</sup> that critiqued MACs and Qualified Independent Contractors (“QICs”) for failing to properly evaluate extrapolated overpayments under MPIM Chapter 8. Specifically, OIG emphasized that MACs and QICs have a legal duty under 42 C.F.R. § 424.5(a)(6) to ensure that contractor extrapolations have properly selected the provider or supplier, the period of review, the sample set and sample frame, among other key tasks set forth in MPIM Chapter 8, section 8.4.1.3.<sup>103</sup> Here, OIG has failed to follow the rules that they assert are mandated on MACs and QICs for the same process.

The determination of whether individualized care is medically necessary for a particular patient requires an in-depth assessment of that patient’s physical condition and other patient-specific consideration. OIG bases the failure of 98 of the 100 claims within the sampling set almost exclusively on Maximus’ determinations that the services were not medically necessary. As mentioned above, 41 of the 98 patients denied by Maximus have conflicting determinations by AdvanceMed. That evidence alone is sufficient to invalidate the Extrapolation Amount and raise genuine concern for OIG of Maximus’ objectivity and independence.

In addition, 29,981 of the 40,316 claims (74.4%) of the OIG sampling frame represent claims for patients subjected to AdvanceMed review, which resulted in a 5.9% technical error rate, meaning the vast majority of the claims reviewed by the OIG and AdvanceMed have conflicting medical determinations based on AdvanceMed’s review. This is also sufficient to invalidate the Extrapolation Amount. The evidence of procedural flaws and OIG’s mandates in GAGAS and MPIM require invalidation of the Extrapolation Amount and reevaluation of how this Audit should be conducted.

#### IV. LIMITATION OF LIABILITY

Even if CMS chooses to adopt the novel medical necessity standards applied by Maximus reviewers in the Draft Report, VieMed is not liable for any overpayments on claims dating back to January 1, 2016 on the basis of such OIG medical necessity standards. Congress issued a clear statutory mandate that health care providers are entitled to Medicare payment when a provider did not know, and reasonably could not have been expected to know, that the items or services it provided would not be covered. Specifically, the limitation of liability in Section 1879 of the Social Security Act states, in relevant part: Where—

(1) a determination is made that, by reason of Section 1862(a) (1) or (9) payment may not be made under Part A or Part B of this title for any expenses incurred for items or services furnished an individual by a provider of services or by another person pursuant to an assignment under section 1842 (b) (3) (B) (ii); and

(2) both such individual and such provider of services or such other person, as the case may be, **did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services under Part A or B**, then to the extent permitted by this title, payment shall, notwithstanding

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<sup>102</sup> U.S. DEPT. OF HEALTH & HUMAN SERVICES, OFF. OF INSPECTOR GEN., Medicare Contractors Were Not Consistent in How They Reviewed Extrapolated Overpayments in the Provider Appeals Process, A-05-18-00024 (Aug. 2016), <https://oig.hhs.gov/oas/reports/region5/51800024.pdf>.

<sup>103</sup> *Id.* at 2.

such determination, be made for such items or services . . . as though section 1862(a)(1) and section 1862 (a) (9).

In assessing whether a provider had actual or constructive knowledge about whether a service was covered, contractors are directed to consider CMS notices, manuals, bulletins and other written guidance, and well as the acceptable standards of practice by the local medical community.<sup>104</sup>

As discussed above, the medical necessity standards used by Maximus reviewers are not found in the Social Security Act, CMS regulations, any NCD or LCD governing NHV, or any other CMS guidelines, nor are they based on the clinical standards or best practices utilized by the medical profession. Furthermore, many of these claims had already explicitly been approved as reimbursable by Medicare contractors under pre-payment review. Accordingly, VieMed could not have reasonably known that claims from 2016 and 2017 would be denied on the basis of these novel standards. Therefore, it was reasonable for VieMed to conclude that the claims billed were appropriate and covered.

## V. WITHOUT FAULT

On a similar basis, VieMed does not owe any overpayment related to claims, even if Maximus reviewers' medical necessity standards are adopted, on the basis the VieMed is without fault. Section 1870 of the Social Security Act limits recovery of an incorrect payment against an individual who is without fault. The MFMM states:

A provider, physician, or other supplier is liable for overpayments it received unless it is found to be without fault. The contractor, as applicable, makes this determination.

The contractor considers a provider, physician, or other supplier without fault, if it exercised reasonable care in billing for, and accepting, the payment; i.e.,

- It made full disclosure of all material facts; and
- On the basis of the information available to it, including, but not limited to, the Medicare instructions and regulations, it had a reasonable basis for assuming that the payment was correct, or, if it had reason to question the payment; it promptly brought the question to the contractor's attention.

Normally, it will be clear from the circumstances whether the provider, physician, or other supplier was without fault in causing the overpayment.<sup>105</sup>

A provider is considered without fault in Section 1870 of the Social Security Act, and recoupment for overpayment is thus not authorized, when a provider did not know or should not have known that the service provided was medically unnecessary.<sup>106</sup> Here, the services provided by VieMed conformed with all governing CMS rules and guidance in place at the time, and were consistent with industry best practices for patients with COPD. Without any guidance from CMS to the

<sup>104</sup> 42 C.F.R. §411.406(e); see also CMS Ruling 95-1, December 1995.

<sup>105</sup> See DEP'T OF HEALTH AND HUMAN SVCS., CTRS. FOR MEDICARE & MEDICAID SRVS., Pub. No. 100-06, Medicare Financial Management Manual, Chapter 3, § 90.

<sup>106</sup> *Cypress Home Care, Inc. v. Azar*, 326 F.Supp.3d 307, 317 (E.D. Tex. 2018).

contrary, VieMed could not have known that the services would be found medically unnecessary as part of OIG's review. VieMed's understanding of the applicable law at the time services were rendered was entirely reasonable, and were entirely consistent with the statute and the regulations in effect at the time.<sup>107</sup> VieMed is thus without fault as to these claims at issue.

## VI. ENCLOSED MATERIALS

In connection with this response to the Draft Report, please find enclosed the following:

- OIG Draft Report, *Sleep Management, LLC: Audit of Claims for Monthly Rental of Noninvasive Home Ventilators*, dated June 25, 2020 (**Exhibit A**);
- CGS Notice Letter, from VieMed to CGS, dated September 9, 2020 (**Exhibit B**);
- Notice of Payment Suspension, from AdvanceMed to VieMed, dated October 10, 2020 (**Exhibit C**);
- Suspension Termination Notice, from AdvanceMed to VieMed, dated January 30, 2018 (**Exhibit D**);
- CPI Correspondence, from CMS-CPI to VieMed, dated March 23, 2018 (**Exhibit E**);
- Spreadsheet of All Claims Reviewed in ADR Process (**Exhibit F**);
- VieMed Correspondence, from VieMed to OIG/OAS, dated May 29, 2018 (**Exhibit G**);
- Spreadsheet of Claims Reviewed in ADR Process Included in OIG Sample, with Corresponding ADR Request Letters (**Exhibit H**);
- HHS – OIG – Office of Audit Services, Sampling Plan for CID: A-04-18-04066, *Sleep Management's Claims for Medicare Noninvasive Home Ventilators*, dated June 8, 2018 (**Exhibit I**);
- OIG Checklist (**Exhibit J**);
- Internal Health Care Common Procedure Coding System (HCPCS) Decision Regarding Codes for Ventilators (**Exhibit K**);
- Case-Specific Summary and Analysis for Disputed Claims (**Exhibit L**);
- Summary of Findings from *The Impact of Non-invasive Ventilation on Health Cost and Outcomes* (**Exhibit M**);
- Prof. McKeague's Report and Curriculum Vitae (**Exhibit N**); and
- Video Patient Attestations (**Exhibit O**).

As OIG is aware, the enclosed materials contains protected health information and is submitted only for purposes of VieMed's response to the Draft Report in relation to this Audit. Due to the confidential nature of this material under state and federal law, VieMed hereby requests confidential treatment under the Freedom of Information Act ("FOIA") of the materials and asks

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<sup>107</sup> See *Caring Hearts Personal Home Services, Inc. v. Burwell*, 825 F.3d 968 (10th Cir. 2016) ("In seeming recognition of the complexity of the Medicare maze, Congress ... indicated that providers who didn't know and couldn't have reasonably been expected to know that their services weren't permissible when rendered generally don't have to repay the amounts they received from CMS").

Ms. Lori S. Pilcher  
September 21, 2020  
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that, before any disclosure pursuant to FOIA, OIG provide notice and adequate time for VieMed to seek protection from disclosure of the record to third parties.

## **VII. SUMMARY**

In summary, VieMed respectfully disagrees with OIG's recommendations, audit methodology, process and clinical review and assessment of VieMed's NHV claims reviewed in the Audit and cited in the Draft Report related to the Audit and the recommendations outlined in the Draft Report.

Based on the reasoning above, VieMed maintains that the claims were properly supported by the documentation, appropriately coded, fully justified, and were properly paid by Medicare.

Respectfully,

Handwritten signature in blue ink, appearing to read "J. Skora".

Joshua I. Skora, Esq.

CC: Casey Hoyt, Chief Executive Officer, VieMed, Inc.  
Todd Zehnder, Chief Operating Officer, VieMed, Inc.