



Using CMS data to explain growth in the home noninvasive ventilation market

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Background

In 2017 and 2018, Philips Sleep and Respiratory Care (SRC) procured data from the Centers for Medicare and Medicaid Services (CMS). The team's goal was to correlate diagnosis codes of COPD with the Healthcare Common Procedure Coding System (HCPCS), which identifies devices prescribed by physicians and subsequently reimbursed through CMS. After obtaining the data, the SRC team and its partners conducted analysis. Because of some data anomalies, which included – data from a sub-set of limited sample data provided by CMS and not the entire population, data based on a limited number of years and a switch in HCPCS, the team was unable to definitively answer its research question. However, the data analysis did appear to depict an increase in claims for home NIV, among some codes.

The research question is outlined below:

RQ: What evidence exists in claims data that can either prove or disprove that the growth in the US home non-invasive ventilation (NIV) EO464/EO466 market is due to an increasing level of prescriptions for NIV devices to treat COPD-affected individuals?

The team turned to Insightin Health, a Maryland-based technology company that specializes in using deep analytics, machine learning and artificial intelligence to understand the consumer journey through data visualization, to obtain claims data from the Centers for Medicare and Medicaid Services (CMS). Note: For analysis like this, CMS provides limited sample data only and not the entire population.

Philips SRC is a business unit of Koninklijke Philips, based in Amsterdam. It is a manufacturer of solutions designed to treat sleep disorders (obstructive sleep apnea (OSA), sleep-disordered breathing and others) as well as respiratory conditions (COPD, neuromuscular diseases such as amyotrophic lateral sclerosis (ALS), muscular dystrophy and cystic fibrosis (CF), among others). The home respiratory care (HRC) business is charged with the development and commercialization of devices to treat those respiratory conditions. Those devices primarily include nebulizers, oxygen concentrators and home ventilation devices. Because of the situation identified in the Introduction section of this paper, the remainder of it focuses on the home NIV devices EO464/EO466.

Historical observations

Generally, during the 1980s and 1990s, the number of patients ventilated at home increased substantially, due to a mix of factors including increased longevity as well as technological developments in home NIV devices (EO464/EO466) (Bilevel devices/Similar to RAD devices)¹ Those treated on home NIV from this period forward into the 2010s were being treated for a range of disorders. Many times, according to Simonds, these were predicated by the development of home ventilator therapy programs. Those developed in the “1960s and 1970s have a large cohort of neuromuscular and chest wall (restrictive) patients”.¹ However, those developed later tended to focus more on obstructive disorders and primarily involved older patients. Indeed, even into the early and mid-2010s, researchers and managers at SRC had positioned the home NIV products primarily for these more-restrictive patients.

One industry premise was that the primary use of home NIV was for restrictive rather than obstructive disorders. The projection models had indicated that approximately 35% of neuromuscular patients were using home NIV but only 3-4% of COPD patients were. Indeed, as indicated by Raveling, et al., and² NIV was the standard treatment for patients with chronic hypercapnic respiratory failure (CHRF) due to these restrictive disorders.

Until recently, the use of home NIV for severely hypercapnic COPD-affected individuals had been met with a measured level of controversy,^{1,3,4,5} primarily because of mixed results and positive outcomes only for select patient groups. These long-standing beliefs led to the cautious use of home NIV for COPD-affected individuals. However, that was not the case everywhere. In fact, Crimi et al. had identified, through a survey of physicians involved in the prescription of long-term NIV,

that it was “common practice in some countries”.⁴ Beginning in the mid 2010s, other research was being published that also indicated additional benefits for some patients with the use of home NIV. In 2015, White et al.³ published a study that recommended the use of NIV for COPD patients with a PaCO₂ (Partial Pressure of Carbon Dioxide) of >50 to 52 mmHg, an overnight PaCO₂ of >55mm Hg or both. In results of a Randomized Controlled Trial (RCT) of 150 patients, published in 2016, Ankjærgaard et al.⁵ indicated the long-term use of NIV can reduce both mortality and hospital admissions due to exacerbation among COPD-affected individuals regardless of their previous hypercapnia. Additionally, in 2017, Duiverman et al.⁶ published a study which indicated the use of long-term NIV did not adversely affect cardiac performance among stable COPD-affected individuals, although the authors had cautions for comorbid chronic heart failure (CHF) patients.

Finally, a study published in JAMA, and co-sponsored by Philips, indicated that the use of home NIV along with the application of home oxygen therapy could lead to both prolonged time to hospital readmission and death among persistent hypercapnic, COPD-affected individuals.⁷

Because these studies, all of which indicated benefits with home NIV, had been published around the same time (the mid-2010s), there was a belief that this represented a critical mass that captured the attention of physicians who were prescribing the use of home NIV for COPD-affected individuals.

The general notion, supported by numerous research articles, implies that it takes 17 years to diffuse new research through the practice environment.⁸



Methodology

Because, as stated above, Philips SRC is a manufacturer of the home NIV devices and sells them through durable medical equipment (DME) companies, which then distributes the products, it does not have clear line-of-sight concerning the reasons why its devices are being prescribed. The SRC team procured external data. It needed to identify two types of data, one which would indicate the diagnosis of COPD and another that would indicate the use of noninvasive ventilation to treat COPD.

For the first set of data, it identified COPD through various codes, as established by the World Health Organization (WHO) through the International Statistical Classification of Diseases and Related Health Problems (ICD). Research conducted by Ford et al.¹⁰ projected medical costs through 2020, and the authors depicted that costs for COPD were primarily managed through Medicare and Medicaid (51% and 25% respectively). That left only 18% managed through private insurance.

With this knowledge, the SRC team sought claims data to connect a COPD diagnosis with claims payment for NIV through CMS, which manages both Medicare and Medicaid. The team was able to leverage CMS public (PUF) and limited use (LUF) data sets to conduct research in an attempt to answer the specific research question. Partners at Insightin Health, a Maryland-based technology company that specializes in using deep analytics, machine learning and artificial intelligence to understand the consumer journey through data visualization also collaborated on this project. As a provision of use of this data, Philips SRC agreed with CMS, through Insightin Health, that it would publish its findings from the analysis of the data in order to make them publicly available. This paper serves as the published findings of the analysis.

In order to stipulate the types of claims needed from the data that aligned with noninvasive ventilation, the MI and Insightin Health teams identified the HCPCS outlined in Table 1.¹⁰ In order to answer the research question, it was necessary that Insightin Health pull data according to the HCPCS identified in the table over a several-year period. This would assist the analysts in trending the data in order to determine if there was an increase in claims of home NIV for treatment of COPD and, if so, to determine if this increase occurred following the publication of the research that indicated benefits of home NIV treatment for COPD-affected individuals.



As a result, analysts objectively identified data according to the identified HCPCS from 2012 through 2016 as appropriate for this analysis. However, Year-over-Year (YoY) changes by disease state were only identified for 2015 and 2016. Note, too, that 2016 was the last full year for which data were available at the time of the analysis. Due to the volume and existing CMS restrictions, Insightin Health analysts' approach was to use the available 5% representative sample size to build a model that would demonstrate a 100% population view. In order to perform the analysis along with data visualization, they built a digital tool in which they populated the data. From this, the analysis was conducted, which led to the findings that are discussed below.

Code	Definition
E0464	Pressure support ventilator with volume control mode, may include pressure control mode, used with noninvasive interface, (e.g. mask) *Terminated Dec. 31, 2015.
E0466	Home ventilator, any type, used with noninvasive interface, (e.g., mask, chest shell). *Initiated in 2016.
E0470	Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, (e.g., nasal or facial mask) (intermittent assist device with continuous positive airway pressure device).
E0471	Respiratory assist device, bi-level pressure capability, with backup rate feature, used with noninvasive interface, (e.g., nasal or facial mask) (intermittent assist device with continuous positive airway pressure device).

Table 1: HCPCS Used to Pull CMS Claims Data

Findings

This section details the findings relevant to the research question. Analysts and the SRC team uncovered three pertinent findings. Each of these is discussed individually below the restatement of the research question, which was:

RQ: What evidence exists in claims data that can either prove or disprove that the growth in the US home noninvasive ventilation (NIV) market is due to an increasing level of prescriptions for NIV devices to treat COPD-affected individuals?

Finding 1 – Use of HCPCS for various disease states

The analysis indicated that the HCPCS identified as part of the research had been prescribed for various disease states; however, some of them were overwhelmingly prescribed for a specific disease state. This was particularly true of E0464, which was primarily used for chronic respiratory failure (in approximately 55% of the cases in 2015) and COPD (in approximately 13% of the cases in 2015). However, as noted in Table 1, this code was terminated in Dec. 2015. As a result, no comparison to 2016 is available.

E0470 was consistently used from 2012 through 2016; however, it was prescribed primarily for obstructive sleep apnea (in 88% of all cases in 2015 and 91% in 2016). Some of the cases for which it was prescribed did involve COPD and, as such, it remained part of the analysis; however, in more detailed analysis below, growth rates for its use in COPD should be tempered by the fact that it represented a small portion of overall claims based on a CMS subset of data in E0470. Similarly, E0471 was primarily utilized for central sleep apnea (representing 77% of the cases in 2015 and 81% of the cases in 2016).

When including all apnea conditions, this HCPCS code was prescribed in 89% and 92% of the cases in 2015 and 2016 respectively. Here again, as in the case of E0470, this HCPCS code was used for COPD, but the total numbers represent a very small portion of overall claims.

Finding 2 – Use of HCPCS for COPD

While the research question put forth in this paper specifically involves COPD, Finding 1, which comprised mostly findings about apnea, was described in order to set the stage for this finding. Analysts discovered that HCPCS E0464, E0470 and E0471 had all been used for COPD, although at a much lower rate than other disorders, such as apnea or chronic respiratory failure. Data were not available to analyze the volume of devices categorized under E0466 for the use in COPD. In addition, since this HCPCS code was newly established in 2016, no comparative data to prior years exists. With this said, analysts ran a comparative analysis on the available data and determined that there was increased use of ventilation between 2015 and 2016, see Table 2. This table indicates that, while the overall numbers are small, there was an increase in the absolute number of claims for home noninvasive ventilation devices coded under E0470 and E0471 between 2015 and 2016. That represented a 78% increase between 2015 and 2016 when considering the total of both HCPCS. Investigating the individual codes, both had increases in the absolute number of cases (with E0470 increasing nearly 81% and E0471 increasing 62.5%) and in the percent of the codes attributed to COPD in comparison to all other disease states. For E0470, the percentage of use for these devices for COPD, in comparison to all uses, increased nearly 74% between 2015 and 2016, and for E0471, this increase was nearly 68%. While these increases could be due to the added attention given to home NIV because of the research released in 2015 and 2016,

the number of cases involved in the analysis is still quite small; therefore, the percentage increases.

Cases included are based on the limited sample data provided by CMS and not the entire population

Code	2015	2016	Change
E0470 cases	108	195	80.6%
E0471 cases	16	26	62.5%
Total	124	221	78.2%
E0470 % of total	1.90%	3.30%	73.7%
E0471 % of total	0.90%	1.50%	66.7%

Table 2: Use of E0470 and E0471 for COPD

Finding 3 – Data inconsistencies and unavailability of data

The goal of this analysis, to answer the stated research question, was hampered by two factors which are linked with one another. First, there were data inconsistencies and, second, because of those inconsistencies, there was unavailability of complete data. Each of these factors will be discussed in this section. To address the first issue, it should be noted that CMS changed the HCPCS between 2015 and 2016, the two years on which this analysis focused. As outlined in Table 1, HCPCS E0464 was eliminated at the end of 2015 and HCPCS E0466 was initiated in 2016. This made comparisons using these two HCPCS impossible.

To address the second issue, because of the change in codes, and because the data sample represented only 5% of the overall claims data, analysts were uncertain how the claims for COPD were accounted for in the revised coding. In 2015, there were a total of 352 claims in the sample attributed to COPD under HCPCS E0464. However, as was mentioned previously, this code was eliminated at the end of 2015. While E0466 was initiated the following year, its definition differed from that of E0464; see Table 1.

In addition, analysts did not have the available data for E0466 attributable by disease state; therefore, they could not determine how many of the claims for this code were attributed to the treatment of COPD. Furthermore, the 352 cases ascribed to E0464 in 2015 could not be accounted for in the two codes where analysts could make comparisons (E0470 and E0471). In total, these codes only accounted for 124 claims in 2015 and 221 claims in 2016. That is substantially lower than the COPD-related claims in the one code that was eliminated in 2015, E0464. It is possible that many of these were then attributed to E0466, but without complete data, it is impossible to tell.

Conclusion and recommendations

The objective of this analysis was to answer the following research question:

RQ: What evidence exists in claims data that can either prove or disprove that the growth in the US home noninvasive ventilation (NIV) market is due to an increasing level of prescriptions for NIV devices to treat COPD-affected individuals?

The analysis conducted for this paper did indeed find that there was an increase in Medicare and Medicaid claims between 2015 and 2016 for noninvasive ventilation, to treat COPD-affected individuals. This increase, however, was only in two of the identified HCPCS (EO470 and EO471). While the growth in these two appears impressive (81% and 63% respectively), these are from a small base in 2015 (108 and 16 respectively).

Because of the change made by CMS in the HCPCS, eliminating E0464 at the end of 2015 and initiating E0466 in 2016, it was impossible to make YoY comparisons. In addition, there were no data that allowed analysts to attribute E0466 to specific disease states. With these factors in mind, and with the data available for the analysis, it can be concluded that there appeared to be an increase in claims between 2015 and 2016 for home NIV; however, analysts could not conclude that there indeed was one.

References

1. Simonds, A. K. (2003). Home ventilation. *European respiratory journal*, 22(47 suppl), 38s-46s. doi: 10.1183/09031936.03.00029803
2. Raveling, T., Bladder, G., Vonk, J. M., Nieuwenhuis, J. A., Verdonk-Struik, F. M., Wijkstra, P. J., & Duiverman, M. L. (2018). Improvement in hypercapnia does not predict survival in COPD patients on chronic noninvasive ventilation. *International journal of chronic obstructive pulmonary disease*, 13, 3625. doi: 10.1186/s12931-017-0542-9
3. White, D. P., Criner, G. J., Dreher, M., Hart, N., Peyerl, F. W., Wolfe, L. F., ... & Chin, S. A. (2015). The role of noninvasive ventilation in the management and mitigation of exacerbations and hospital admissions/readmissions for the patient with moderate to severe COPD (multimedia activity). *Chest*, 147(6), 1704-1705. doi: 10.1378/chest.15-0394
4. Crimi, C., Noto, A., Princi, P., Cuvelier, A., Masa, J. F., Simonds, A., ... & Nava, S. (2016). Domiciliary noninvasive ventilation in COPD: an international survey of indications and practices. *COPD: Journal of chronic obstructive pulmonary disease*, 13(4), 483-490
5. Ankjærgaard, K. L., Tønnesen, P., Laursen, L. C., Hansen, E. F., Andreassen, H. F., & Wilcke, J. T. (2016). Home noninvasive ventilation (NIV) treatment for COPD patients with a history of NIV-treated exacerbation; a randomized, controlled, multi-center study. *BMC pulmonary medicine*, 16(1), 32. doi: 10.1186/s12890-016-0184-6
6. Duiverman, M. L., Maagh, P., Magnet, F. S., Schmoor, C., Arellano-Maric, M. P., Meissner, A., ... & Callegari, J. (2017). Impact of High-Intensity-NIV on the heart in stable COPD: a randomised cross-over pilot study. *Respiratory research*, 18(1), 76. doi: 10.1186/s12931-017-0542-9
7. Murphy, P. B., Rehal, S., Arbane, G., Bourke, S., Calverley, P. M., Crook, A. M., ... & Hurst, J. R. (2017). Effect of home noninvasive ventilation with oxygen therapy vs oxygen therapy alone on hospital readmission or death after an acute COPD exacerbation: a randomized clinical trial. *JAMA*, 317(21), 2177-2186. doi: 10.1001/jama.2017.4451
8. Morris, Z. S., Wooding, S., & Grant, J. (2011). The answer is 17 years, what is the question: Understanding time lags in translational research. *Journal of the Royal Society of Medicine*, 104(12), 510-520. doi: 10.1258/jrsm.2011.110180
9. Ford, E. S., Murphy, L. B., Khavjou, O., Giles, W. H., Holt, J. B., & Croft, J. B. (2015). Total and state-specific medical and absenteeism costs of COPD among adults aged 18 years in the United States for 2010 and projections through 2020. *Chest*, 147(1), 31-45. doi: <https://doi.org/10.1378/chest.14-0972>
10. *HCPCSData.com*. (2019). Retrieved from: <https://www.hcpcsddata.com/Codes/E>.

