



Escalating Medicare Billing for Ventilators Raises Concerns

AT A GLANCE

Medicare paid 85 times more claims for noninvasive pressure support ventilators in 2015 than it did in 2009, leading to a rapid increase in expenditures.

Growth in claims for these types of ventilators was driven primarily by three suppliers.

Diagnoses on these claims have shifted dramatically from neuromuscular to respiratory conditions.

Medicare paid \$25 million for noninvasive pressure support ventilator claims with indicators of inappropriate billing.

The Centers for Medicare & Medicaid Services (CMS) and its contractors have expressed concerns about the recent substantial increase in Medicare billing for noninvasive pressure support ventilators.^{1,2} In addition to describing the current payment trends, this data brief explores factors possibly contributing to the billing surge. This information provides useful context for CMS as it develops further policy and refines its program integrity efforts in this area.

In recent years, ventilator technology has evolved so that it is possible for a single device to treat numerous conditions by operating in several different modes—i.e., basic continuous positive airway pressure (CPAP) mode, respiratory assist device (RAD) mode, and traditional ventilator mode.³ This creates an opportunity for abuse, whereby suppliers could bill Medicare for the device as if it were being used as a ventilator, when use of a lower cost CPAP device or RAD is indicated based on the patient's medical condition.^{4,5} Because of concerns about possible abuse related to ventilator claims, two Durable Medical Equipment (DME) Medicare Administrative Contractors conducted prepayment reviews that resulted in the denial of more than 90 percent of claims for noninvasive pressure support ventilators, primarily for deficient clinical documentation.^{6,7}

Medicare Coverage of Home Respiratory Devices

The CMS Medicare National Coverage Determinations Manual stipulates that ventilators are covered for the treatment of conditions associated with “neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease.”⁸ In 2014, the Medicare Pricing, Data Analysis, and Coding contractor provided further clarification to a CMS non-binding decision memo from 2001, stating that ventilators are considered “reasonable and necessary” only when the beneficiary has a severe condition in which the interruption of respiratory support would

be life-threatening or lead to serious harm.^{9,10} This guidance was in effect through May 2016 and therefore covers the time period that is the subject of our review. In May 2016, CMS and its contractors updated the guidance, making it less proscriptive about the use of ventilators for non-life-threatening conditions.¹¹ In this new guidance, CMS and its contractors deferred to providers’ clinical judgment about the severity of the patient’s condition and which device—a ventilator or a RAD—would be the appropriate treatment plan.

Even though a ventilator may be capable of operating in CPAP or RAD mode, the device would not be eligible for reimbursement for treatment of any of the less severe conditions that the local coverage determinations (LCDs) for RADs describe, or for the treatment of obstructive sleep apnea as described in the Medicare National Coverage Determinations Manual (see Table 1).¹² Medicare covers ventilators and RADs for similar respiratory diagnoses (e.g., chronic obstructive pulmonary disease), but the selection of the appropriate device is based on the severity of the beneficiary’s condition.¹³ RADs are covered for beneficiaries with less severe conditions that require only relatively short durations of respiratory support, whereas ventilators are covered for more severe conditions.¹⁴ CPAP devices are covered for the treatment of obstructive sleep apnea.¹⁵ CMS’s guidance specifically states that program abuse is occurring when ventilators are billed for the treatment of obstructive sleep apnea.^{16, 17}

We have focused this data brief on one specific type of ventilator that may be particularly vulnerable to inappropriate billing: the noninvasive pressure support ventilator. Certain marketed products in this category are multimodal devices that can function as a ventilator, RAD, or CPAP device. Additionally, this device utilizes a noninvasive interface—such as a mask or chest shell—that is similar to the interfaces used with CPAP devices or RADs. In contrast, an invasive ventilator requires the beneficiary to have a tracheostomy tube, which would likely discourage the inappropriate use of such a ventilator in place of other devices. The combination of these features—the noninvasive interface and the multimodal capability—could make the noninvasive pressure support ventilator susceptible to inappropriate billing.

Table 1: Comparison of Medicare Coverage for Home Respiratory Devices

Device Type	Condition(s) Treated	Circumstances Under Which Device Is Considered Reasonable and Necessary
Ventilator	Neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease ¹⁸	Beneficiary has a severe condition in which the interruption of respiratory support could lead to serious harm
RAD	Restrictive thoracic disorders, severe chronic obstructive pulmonary disease, central sleep apnea, complex sleep apnea, or hypoventilation syndrome ¹⁹	Beneficiary has a less severe, non-life-threatening condition that requires only intermittent and relatively short durations of respiratory support ²⁰
CPAP device	Obstructive sleep apnea ²¹	Beneficiary has been diagnosed with obstructive sleep apnea on the basis of a sleep test

Medicare Payment Policies for Home Respiratory Devices

Medicare pays for home ventilators under the category of durable medical equipment (DME) items that require frequent and substantial servicing to avoid risk to the patient's health.²² Medicare makes monthly rental payments for this category of DME as long as medical necessity and Part B coverage remain.²³ The monthly rental payment covers the base device (i.e., the ventilator); frequent and substantial servicing of the device; and replacement of essential accessories (e.g., tubing, masks, and filters).

Medicare covers CPAP devices and RADs under its category for capped rental for DME items. This category limits the rental period to 13 months of continuous use, after which the Medicare monthly payment for the base equipment ceases and the beneficiary takes ownership of the device.^{24, 25} The monthly rental payment covers only the base device and any necessary maintenance and servicing of the rented device; suppliers bill separately for related accessories (e.g., masks, filters, humidifiers). After the capped rental period ends, Medicare continues to pay for replacement of the accessories.

To obtain payment for DME provided to beneficiaries, suppliers submit claims to their Medicare contractors using Healthcare Common Procedure Coding System (HCPCS) codes. HCPCS codes provide a standardized coding system for describing specific items and services provided in the delivery of health care. At the time of our review, there were five HCPCS codes for ventilators. Table 2 lists the specific characteristics for each ventilator type.

As Table 2 shows, the rental rates for noninvasive pressure support ventilators (HCPCS code E0464) were as much as \$660, \$1,470, and \$1,352 more per month, respectively, than the rates for volume ventilators, CPAP devices, and RADs during the period of our review.^{26, 27, 28} Additionally, the monthly rental payments for ventilators continue indefinitely, whereas those for CPAP devices and RADs are capped at 13 months. The reimbursement rates shown in Table 2 include the 20-percent copayment paid by the beneficiary. Because E0464 ventilators have both higher reimbursement rates and uncapped rental periods, beneficiaries not only pay higher monthly copayments for these devices but also pay over a longer rental period.

Table 2: Medicare Reimbursement for Home Respiratory Devices

Device Type	Description of Device	Medicare Reimbursement Floor and Ceiling Monthly Rates as of July 2015*	
Ventilators			
E0450	Volume control ventilator used with invasive interface (i.e., tracheostomy tube)	\$900.55	\$1,059.47
E0460	Negative pressure ventilator, portable or stationary	\$692.09	\$814.22
E0461	Volume control ventilator used with noninvasive interface (i.e., mask)	\$900.55	\$1,059.47
E0463	Pressure support ventilator with volume control mode used with invasive interface (i.e., tracheostomy tube)	\$1,326.87	\$1,561.02
E0464	Pressure support ventilator with volume control mode used with noninvasive interface (i.e., mask)	\$1,326.87	\$1,561.02**
RAD	Respiratory assist device	\$208.66	\$614.34**
CPAP device	Continuous positive airway pressure device	\$90.84	106.87**

Source: CMS, *DMEPOS Fee Schedule*, revised for July 2015.

* The monthly rental rates in this table do not include additional Medicare payments for accessories (e.g., masks, humidifiers) associated with using CPAP devices and RADs. In contrast, the monthly rental rates for ventilators are all-inclusive; they cover both the device and related accessories.

** The monthly rental rates for CPAP devices and RADs in this table do not reflect the payment amounts under the Competitive Bidding Program, which are lower than the DMEPOS Fee Schedule amounts listed above.

Since January 2011, Medicare’s DME Competitive Bidding Program has included CPAP devices and RADs.^{29, 30, 31} In the 109 Competitive Bidding Areas, payment amounts for CPAP devices and RADs are even lower than the regular Medicare fee schedule amounts listed in Table 2.³² Through the Competitive Bidding Program, contract suppliers are paid based on a single payment amount derived from the median of all winning bids for an item.³³ In Round 2 of the Competitive Bidding Program, the 2013 single payment amounts for CPAP devices ranged from \$41 to \$56 per month, depending on the location. For RADs, the single payment amounts ranged from \$107 to \$464 per month.³⁴ With the reduced reimbursement for CPAP devices and RADs in Competitive Bidding Areas, the difference between Medicare payment for those devices and ventilators is even greater. For example, if a Medicare beneficiary diagnosed with obstructive sleep apnea were inappropriately provided with an E0464 ventilator, rather than a traditional CPAP device, the increased costs to Medicare over just 12 months could be as much \$18,000 per beneficiary.

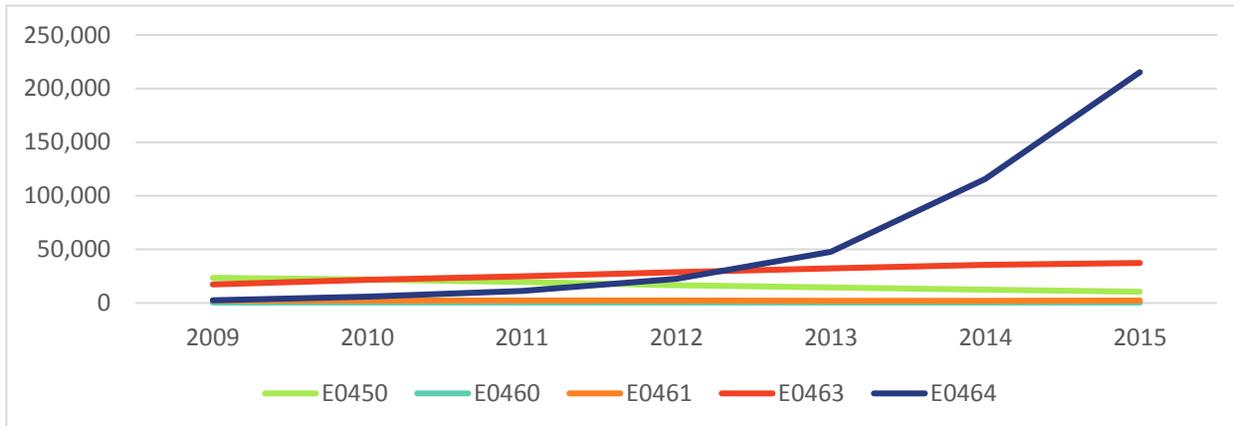
RESULTS

In 2015, Medicare paid 85 times more claims for E0464 ventilators than it did in 2009, leading to rapidly escalating expenditures for this device

Medicare paid for 215,379 E0464 ventilator claims in 2015—85 times more than the 2,528 claims it had paid just 6 years earlier. As depicted in Figure 1, Medicare billing for other types of ventilators either increased at much slower rates or decreased during the same period. Medicare billing for E0464 ventilators also far outpaced the growth in

billing for CPAP devices, RADs, and accessories, which increased 1.4 times since 2009.

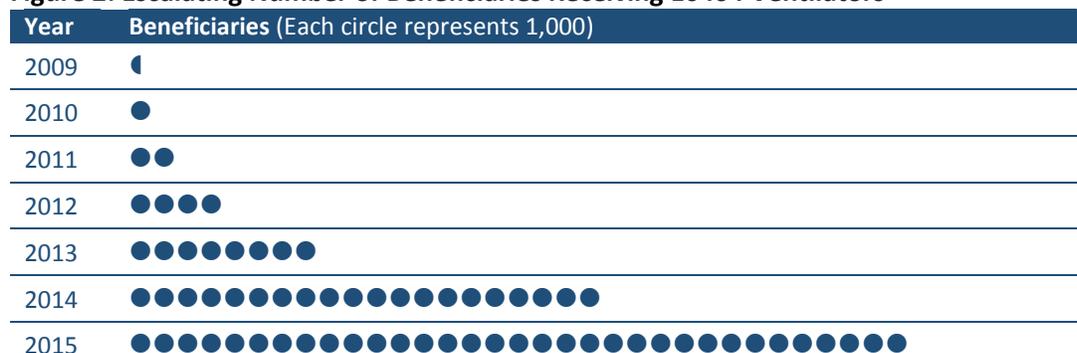
Figure 1: Claims for E0464 Ventilators Grew Faster Than Those for Other Ventilators



Source: Office of Inspector General (OIG) analysis of data from the CMS National Claims History (NCH) File, 2016.

Because of increased billing for E0464 ventilators, combined expenditures for Medicare and its beneficiaries surged from 2009 to 2015, increasing 89-fold (from \$3.8 million to \$340 million). Medicare and beneficiary expenditures for this device have continued to grow rapidly each year. Expenditure increases from 2014 to 2015 alone accounted for 47 percent of the entire \$337 million increase from 2009 to 2015. Consistent with the increase in expenditures, the number of beneficiaries associated with claims for E0464 ventilators also escalated, increasing 79-fold (from 415 to 32,848) between 2009 and 2015. (See Figure 2.)

Figure 2: Escalating Number of Beneficiaries Receiving E0464 Ventilators



Source: OIG analysis of data from the CMS NCH File, 2016.

Increased billing for E0464 ventilators was less prevalent in areas subject to the Competitive Bidding Program. Round 2 of the Competitive Bidding Program started on July 1, 2013, and included CPAP devices, RADs, and related accessories, but not ventilators. Through competitive pricing, Medicare reimbursement for CPAP devices and RADs has decreased in areas covered by the Competitive Bidding Program. Reduced payment for CPAP devices and RADs in these localities might induce suppliers to bill inappropriately for E0464 ventilators instead. To examine this, we compared whether billing for E0464 ventilators increased more sharply in areas where the reimbursement rates for CPAP devices and RADs fell because of competitively bid prices. In areas subject to Round 2 of the Competitive Bidding Program, claims for E0464 ventilators increased by 51 percent after the implementation of competitive bidding for CPAP devices and RADs. However, claims for E0464 ventilators increased by 62 percent in

areas *not* subject to competitive bidding during the same period. Therefore, the reduced prices for CPAP devices and RADs under the Competitive Bidding Program do not appear to be driving increased billing for E0464 ventilators.

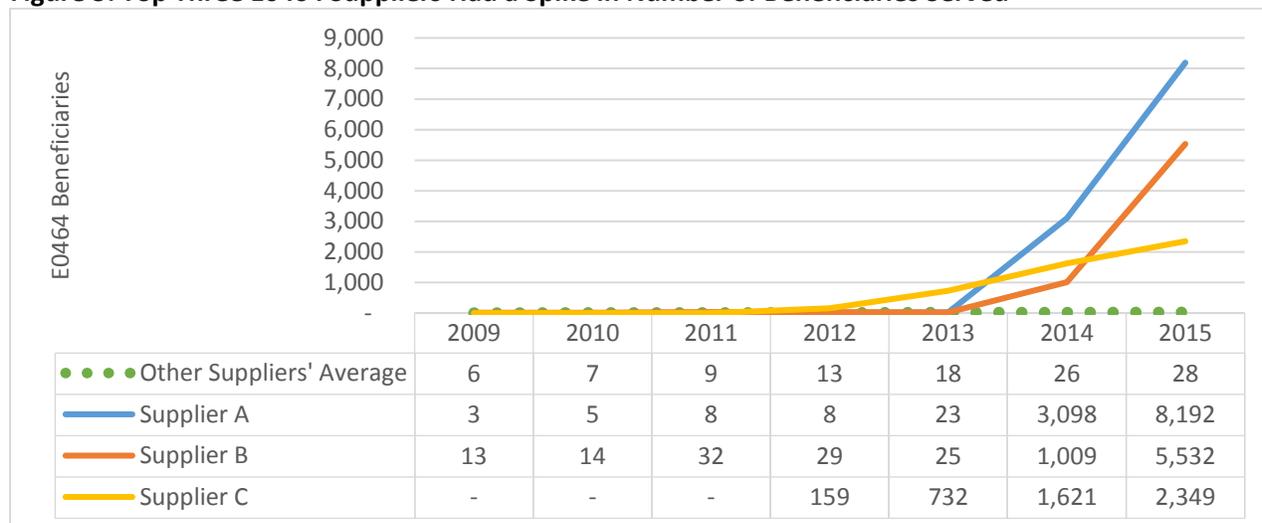
Seven percent of E0464 ventilator beneficiaries had also used lower cost respiratory devices in the preceding year. Increased billing for ventilators could be driven, in part, by suppliers switching beneficiaries from less expensive devices to more expensive devices that would also function in CPAP or RAD mode. However, it does not appear that such switching is a primary driver of the increased billing for E0464 ventilators. Of the 32,644 beneficiaries who had claims in 2015 for E0464 ventilators, only 2,125, or 7 percent, had prior or concurrent claims for CPAP devices or RADs within a year of their first ventilator claim.³⁵

Of these 2,125 beneficiaries, 49 percent had a claim for a CPAP device in the preceding year. Switching from a CPAP device to a ventilator may be appropriate if the beneficiary's diagnosis changed. However, CPAP devices are primarily intended to treat obstructive sleep apnea, a condition that is explicitly excluded from the Medicare coverage policy for ventilators. Therefore, when beneficiaries switch from CPAP devices to ventilators, it could signal program abuse if the ventilator is being used to treat obstructive sleep apnea.

The massive growth in E0464 ventilator claims was largely driven by three suppliers that had billing far exceeding the national average. The increased billing from three suppliers accounted for 54 percent of the nationwide growth in beneficiaries with E0464 claims from 2012 to 2015. These 3 suppliers went from serving a combined total of 196 beneficiaries in 2012 (i.e., 5 percent of beneficiaries with E0464 claims) to serving 16,073 beneficiaries in 2015 (i.e., 48 percent of beneficiaries with E0464 claims). This growth far exceeded the growth in the average number of E0464 beneficiaries among other suppliers, which rose from 13 beneficiaries per supplier to 28 during the same period (see Figure 3). OIG is further reviewing information on the 3 suppliers that accounted for 54 percent of the nationwide growth to determine whether to initiate audits or investigations and/or to refer them to CMS for followup, as appropriate.

Growth in billing for E0464 ventilators was driven primarily by three suppliers

Figure 3: Top Three E0464 Suppliers Had a Spike in Number of Beneficiaries Served



Source: OIG analysis of data from the CMS NCH File, 2016.

Diagnoses on E0464 ventilator claims have shifted from neuromuscular to respiratory conditions

The distribution of primary diagnoses on E0464 ventilator claims has changed dramatically since 2009. Ventilators are covered for the treatment of conditions associated with neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease.³⁶ To describe the change in the distribution of diagnoses for

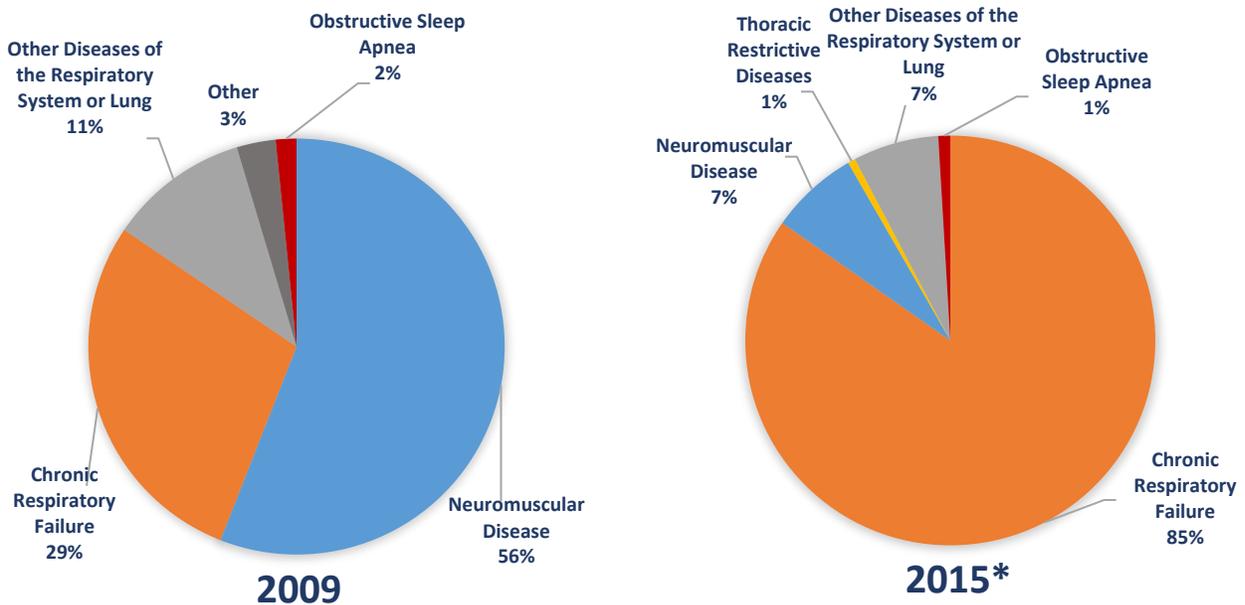
E0464 ventilators from 2009 to 2015, we summarized the number of claims associated by primary diagnosis codes and then identified the top 10 most common diagnoses for each year. Of the E0464 ventilator claims with the most common diagnosis codes in 2009, more than half (56 percent) represented neuromuscular diseases. (See Figure 4.) By 2015, the proportion of these claims listing a neuromuscular disease diagnosis decreased to 7 percent. During the same time period, there was a substantial increase in diagnoses of chronic respiratory failure; the proportion of these ventilator claims with such a diagnosis rose from 29 percent to 85 percent.

The shift in the diagnosis mix on E0464 ventilator claims is notable because diagnoses of chronic respiratory failure are similar to diagnoses for conditions that are treated by using RADs. Medicare covers ventilators and RADs for similar diagnoses, but the selection of the appropriate device is based on the severity of the beneficiary's condition.³⁷ We cannot determine solely on the basis of the diagnosis listed on the claim whether the claim is for a beneficiary with a severe respiratory condition or whether the supplier might have "upgraded" the beneficiary to a ventilator when the beneficiary could have been appropriately treated with a RAD instead. Further review of medical records would be necessary to determine whether these claims met Medicare coverage requirements.

The top three suppliers cited above were more likely than all other suppliers to cite chronic respiratory failure as the primary diagnoses on their E0464 claims. Ninety-seven percent of these suppliers' E0464 claims listed diagnoses of chronic respiratory failure, and only 2 percent of their E0464 claims listed diagnoses of neuromuscular disease. In contrast, other suppliers' E0464 claims listed diagnoses of

chronic respiratory failure in 75 percent of cases and diagnoses of neuromuscular diseases in 12 percent.

Figure 4: Distribution of Top Diagnoses for E0464 – All Suppliers



Source: OIG analysis of data from the CMS NCH File, 2016.

* The total equals 101 percent due to rounding.

Medicare paid \$25 million for E0464 ventilator claims with indicators of inappropriate billing, such as billing for multiple devices, billing for separate accessories, or billing to treat obstructive sleep apnea

Some beneficiaries had claims for multiple devices concurrently, which suggests inappropriate billing. Among the 32,848 beneficiaries who used E0464 ventilators in 2015, 932 also had 1 or more months with concurrent claims for CPAP devices or RADs.³⁸ CMS staff stated that it is unlikely that beneficiaries would need to use both a ventilator and a CPAP device or RAD during the same period. Therefore, this pattern might suggest inappropriate billing for multiple devices for the same beneficiary.

Medicare and its beneficiaries paid more than

\$21.7 million for these claims (close to \$19.9 million for E0464 ventilators and close to \$1.9 million for CPAP devices, RADs, and accessories). We will refer these claims to CMS for appropriate followup.

Some beneficiaries had claims for accessories that were paid for separately (rather than “bundled” with claims for the ventilator), which violates Medicare payment policies for ventilators. Seven hundred and four beneficiaries who used E0464 ventilators in 2015 had one or more claims for accessories during the year without a history of claims for base CPAP devices or base RADs. Ventilators are covered under the DME “frequent and substantial servicing” category, which covers the base device

(i.e., the ventilator); frequent and substantial servicing of the device; and accessories (e.g., tubing, masks, and filters) through a single monthly rental payment. Therefore, suppliers should not bill Medicare separately for accessories used with ventilators. Medicare and its beneficiaries paid a total of \$262,050 for these claims for accessories. We will refer these claims to the CMS for appropriate followup.

In 2015, 1 percent of paid E0464 claims listed a primary diagnosis of obstructive sleep apnea, which is not an eligible diagnosis for Medicare coverage for this device. CMS and its contractors have stipulated that ventilators are not eligible for reimbursement for the treatment of obstructive sleep apnea.³⁹ However as indicated in Figure 4 above, Medicare and its beneficiaries inappropriately paid close to \$2.9 million in 2015 for 1,892 E0464 claims with a primary diagnosis of obstructive sleep apnea. We will refer these claims to CMS for appropriate followup.

CONCLUSION

The evolution in ventilator technology has resulted in products that are capable of operating in multiple modes—as CPAP devices, as RADs, or as ventilators. The emergence of this multimodal device, when combined with Medicare coverage and payment policies that favor reimbursement for ventilators, may create incentives for suppliers to provide and bill for a ventilator when the device is actually being used as a RAD or CPAP device. At the same time, the number of Medicare claims for E0464 ventilators has grown 85-fold since 2009, raising serious concerns about inappropriate billing and abuse. Inappropriate use of ventilators in place of CPAP devices or RADs drives up costs for Medicare as well as for beneficiaries, who pay increased copayments for ventilators.

In this data brief, we examined factors that might—but ultimately do not—explain the substantial increase in E0464 ventilator billing in relation to billing for other respiratory devices. For example, the reduced prices for CPAP devices and RADs in Competitive Bidding Areas do not appear to be driving increased billing for E0464 ventilators. Additionally, it did not appear that a large proportion of the beneficiaries with E0464 ventilators had recently switched to these devices from using a CPAP device or RAD.

Instead, the E0464 ventilator billing trend is being driven primarily by 3 national suppliers that have rapidly expanded their market share and who accounted for 54 percent of the nationwide growth in beneficiaries with E0464 ventilator claims from 2012 to 2015. Additionally, there was a dramatic shift in the use of ventilators to treat respiratory conditions (i.e., the same category of conditions treated by CPAP devices and RADs) rather than neuromuscular conditions. This pattern of having a majority of claims with respiratory diagnoses was even more pronounced for the top three suppliers.

CMS has taken recent actions to address concerns with E0464 ventilator billing. In January 2016, CMS consolidated billing codes for ventilators and reduced the reimbursement amount for noninvasive pressure support ventilators. This action may somewhat reduce the incentive to bill for such ventilators, but even with the decreased payments, ventilators will continue to be reimbursed at significantly higher rates than CPAP devices and RADs. Further, suppliers will continue to receive the higher monthly rental payments for as long as the beneficiary needs the device, rather than having their payments end after 13 months as is the case with the less expensive devices. Therefore, the growth trends highlighted in this data brief could continue despite CMS's changes to billing codes and reimbursement amounts.

The information presented in this data brief provides useful contextual information for CMS as it develops further policy and refines its program integrity efforts in this area. For example, CMS could consider focusing its efforts on monitoring the providers with the largest market shares of ventilator beneficiaries or exploring the causes and implications of the shift in diagnoses on ventilator claims. This 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.^{40, 41}

Finally, we also identified some E0464 claims with indicators of inappropriate billing, including claims with diagnoses of obstructive sleep apnea, claims for multiple devices for the same beneficiary, and claims for accessories that were paid for separately. We will refer these potentially inappropriately paid claims to CMS for further review. In addition, OIG is further reviewing information on the three suppliers driving the increase in ventilator claims to determine whether to initiate audits or investigations of any of them and/or to refer them to CMS for followup, as appropriate.

METHODOLOGY

We used CMS's National Claims History (NCH) file to identify all DME claims for ventilators (HCPCS codes E0450, E0460, E0461, E0463, and E0464), RADs (HCPCS codes E0470, E0471, and E0472), CPAP devices (HCPCS code E0601), and related supplies with dates of service from 2006 through 2015.

Billing Trends for Ventilators, RADs, and CPAP devices

To describe billing trends for ventilators, RADs, and CPAP devices, we identified the total number of claims for each year. We also calculated the allowed charges for E0464 ventilators and the number of unique beneficiaries associated with claims for ventilators, RADs, and CPAP devices.

Ventilator Beneficiaries with a History of Claims for CPAP Devices or RADs

To examine whether beneficiaries had switched from a CPAP device or RAD to a ventilator, we first used the NCH DME file to identify all beneficiaries with E0464 ventilator claims in 2015. For this group of beneficiaries, we then reviewed NCH DME files from 2014 through 2015 to identify whether they had any claims for CPAP devices, RADs, or related accessories in the previous 365 days. We calculated the number of days between each beneficiary's most recent claim for a CPAP device, RAD, or accessory and the beneficiary's first E0464 ventilator claim to determine how many had switched devices within a year or had multiple devices concurrently. For beneficiaries with simultaneous claims for multiple devices, we also calculated the allowed dollars that Medicare and its beneficiaries paid for ventilators, CPAP devices, RADs, and accessories during the overlap period.

Effect of the Competitive Bidding Program on Ventilator Claims

To assess the effect of the Competitive Bidding Program on ventilator billing trends, we examined whether billing for ventilators increased in areas where the reimbursement rates for CPAP devices and RADs decreased due to competitively bid prices. We used the 2013 NCH DME file along with the Competitive Bidding Implementation Contractor's ZIP Code files for Competitive Bidding Areas in the Round 1 Rebid and Round 2. For the periods before and after the July 2013 implementation of Round 2 of the Competitive Bidding Program, we identified the total number of claims and allowed charges for ventilators in areas that were Round 2 Competitive Bidding Areas versus areas that were not. We excluded all claims in Round 1 Competitive Bidding Areas to target the change in claims after the implementation of Round 2. Starting in January 2011, CPAP devices and RADs were subject to competitive bidding prices in the nine areas included in the Round 1 Rebid. In July 2013, competitively bid prices for CPAP devices and RADs were expanded to 100 new areas under Round 2 of the Competitive Bidding Program.

Suppliers of E0464 Ventilators

We identified the number of E0464 ventilator beneficiaries each supplier served annually between 2009 and 2015. To identify suppliers, we used Tax Identification Numbers (TINs) so that DME supply companies with multiple locations and participating providers were included as single entities. We calculated the annual average number of E0464 ventilator beneficiaries served per supplier and compared the suppliers with the highest number of E0464 beneficiaries to the national average.

Distribution of Diagnoses

To describe the change in the distribution of diagnoses for E0464 ventilators, we summarized the number of claims associated by primary diagnosis codes in 2009 and 2015. We then selected the 10 diagnosis codes in 2015 that had over 1,000 associated claims. We subsequently selected the top 10 primary diagnosis codes in 2009.

In consultation with our Chief Medical Officer, we classified the top 10 diagnosis codes in 2009 into the following 5 categories: neuromuscular diseases, chronic respiratory failure, obstructive sleep apnea, other diseases of the respiratory system or lung, and other diseases (nonrespiratory). Similarly, we grouped the top 10 diagnoses in 2015 into the categories of neuromuscular diseases, chronic respiratory failure, thoracic restrictive diseases, obstructive sleep apnea, and other diseases of the respiratory system or lung. We compared the top diagnosis groups in 2015 to the top diagnosis groups in 2009. We also compared the top diagnosis groups in 2015 between the top three suppliers and the rest of the supplier population.

A ventilator is not eligible for reimbursement for the treatment of obstructive sleep apnea. To determine the amount that Medicare and its beneficiaries inappropriately paid for noninvasive pressure support ventilators to treat obstructive sleep apnea, we calculated the allowed dollars and the number of DME claims in 2015.

Limitations

Our review relied on Medicare claims and administrative data. We did not conduct a medical record review to determine if devices billed were medically necessary or coded correctly.

Standards

This 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.

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ENDNOTES

¹ NHIC, Corp. *Results of Widespread Prepayment Probe Review of Claims for E0464 (Pressure support ventilator with volume control mode, may include pressure control mode, used with non-invasive interface (e.g. mask))*, April 30, 2015. Accessed on June 10, 2015, at a URL that no longer works; see archived version at <http://web.archive.org/web/20150731020947/http://www.medicarenhic.com/viewdoc.aspx?id=3020>.

² CMS, *Internal Healthcare Common Procedure Coding System (HCPCS) Decision Regarding Codes for Ventilators*. Accessed on June 5, 2015, at a URL whose content has subsequently changed; see archived version at <https://web.archive.org/web/20150610042556/http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/Internal-Coding-Decisions.pdf>.

³ Ibid.

⁴ Noridian Healthcare Solutions, Medicare PDAC (Pricing, Data Analysis, and Coding) contractor. *Correct Coding and Coverage of Ventilators, Joint DME MAC Publication*, April 28, 2014. Accessed on June 10, 2015, at https://www.dmepdac.com/resources/articles/2014/04_10_14.html.

⁵ CMS, *Internal Healthcare Common Procedure Coding System (HCPCS) Decision Regarding Codes for Ventilators*. See Endnote 2 for URL information.

⁶ Noridian Healthcare Solutions, *Ventilators (HCPCS E0464) Quarterly Results of Service Specific Prepayment Review*, January 27, 2016. Accessed on May 17, 2016, at <https://med.noridianmedicare.com/web/jddme/cert-review/mr/complex-notifications-results/ventilators-hcpcs-e0464-quarterly-results-of-service-specific-prepayment-review>.

⁷ NHIC, Corp. *Results of Widespread Prepayment Probe Review of Claims for E0464 (Pressure support ventilator with volume control mode, may include pressure control mode, use with non-invasive interface (e.g., mask))*, April 30, 2015. See Endnote 1 for URL information.

⁸ CMS, *Medicare National Coverage Determinations Manual*, Pub. No. 100-03, ch. 1, pt. 4, § 280.1, p. 129.

⁹ Noridian Healthcare Solutions, Medicare PDAC contractor. *Correct Coding and Coverage of Ventilators, Joint DME MAC Publication*, April 28, 2014. See Endnote 4 for URL information.

¹⁰ CMS, *Decision Memo for Noninvasive Positive Pressure RADS for COPD (CAG-00052N)*. Accessed on November 16, 2015, at <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=56&ver=&viewAMA=Y&bc=AAAAAAAAIAAA&>.

¹¹ In May 2016, the Medicare PDAC contractor issued a Joint DME MAC publication with updated guidance on the correct coding and coverage of ventilators. This new guidance removed language stipulating that (1) ventilators and RADs are covered for different disease groups and (2) ventilators are not eligible for reimbursement for any of the non-life-threatening conditions described in the LCDs for RADs. The guidance clarified that although the disease categories described in the respective Medicare coverage determinations for ventilators and RADs may overlap, the “choice of an appropriate treatment plan, including the determination to use a ventilator vs. a [RAD], is made based upon the specifics of each individual beneficiary’s medical condition.” The guidance also stated that “in the event of a claim review, there must be sufficient detailed information in the medical record to justify the treatment selected.” Noridian Healthcare Solutions, Medicare PDAC contractor. *Correct Coding and Coverage of Ventilators, Joint DME MAC Publication*, May 24, 2016. Accessed on August 30, 2016, at https://www.dmepdac.com/resources/articles/2016/05_24_16b.html.

¹² Noridian Healthcare Solutions, Medicare PDAC contractor. *Correct Coding and Coverage of Ventilators, Joint DME MAC Publication*, April 28, 2014. See Endnote 4 for URL information.

¹³ Ibid.

¹⁴ Ibid.

¹⁵ CMS, *Medicare National Coverage Determinations Manual*, Pub. No. 100-03, ch. 1, pt. 4, § 240.4, p. 92.

¹⁶ CMS, *Internal Healthcare Common Procedure Coding System (HCPCS) Decision Regarding Codes for Ventilators*. See Endnote 2 for URL information.

¹⁷ CMS and its contractors have clarified that the use of a ventilator to treat any of the conditions contained in the LCDs for RADs is considered “more than is medically necessary.” Ventilators and CPAP devices/RADs are covered under different DME payment categories—ventilators are covered under the Frequent and Substantial Servicing category, and CPAP devices and RADs are covered under the Capped Rental category. Medicare prohibits “upgrade billing” across different payment categories—i.e., when a device covered under one payment category (e.g., a ventilator covered under the Frequent and Substantial Servicing category) is provided to treat conditions covered in LCDs for devices in other payment categories (e.g., conditions described in the LCDs for CPAP devices and RADs covered under the Capped Rental category). Noridian Healthcare Solutions, Medicare PDAC contractor. *Correct Coding and Coverage of Ventilators, Joint DME MAC Publication*, April 28, 2014, p. 2. See Endnote 4 for URL information.

¹⁸ CMS, *Medicare National Coverage Determinations Manual*, Pub. No. 100-03, ch. 1, pt. 4, § 280.1, p. 129.

¹⁹ Local Coverage Determination (LCD): Respiratory Assist Devices (L33800) for DME MAC Jurisdictions A, B, C, and D, available at <https://www.cms.gov/medicare-coverage-database/>. Prior to October 1, 2015, the DME MACs had separate but identical LCDs for RADs (i.e., LCDs L11504, L27228, L5023, and L11493 for DME MAC Jurisdictions A, B, C, and D, respectively), available at http://localcoverage.cms.gov/mcd_archive/.

²⁰ Noridian Healthcare Solutions, Medicare PDAC contractor. *Correct Coding and Coverage of Ventilators, Joint DME MAC Publication*, April 28, 2014. See Endnote 4 for URL information.

²¹ CMS, *Medicare National Coverage Determinations Manual*, Pub. No. 100-03, ch. 1, pt. 4, § 240.4, p. 92.

²² 42 CFR § 414.222; 71 Fed. Reg. 4518, 4525 (Jan. 27, 2006).

²³ Ibid.

²⁴ 42 CFR § 414.229; 71 Fed. Reg. 4518 (Jan. 27, 2006); CMS, *Medicare Claims Processing Manual*, Pub. No. 100-4, ch. 20—Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, § 30.5. Accessed on June 15, 2015, at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf>.

²⁵ Since January 2011, CPAP devices, RADs, and related accessories have been included in the Medicare DME Competitive Bidding Program. Under the Competitive Bidding Program, payment amounts for CPAP devices and RADs in Competitive Bidding Areas are lower than the regular Medicare fee schedule amounts for these devices. (See CMS Competitive Bidding Implementation Contractor, *DMEPOS Competitive Bidding Program Product Categories*. Accessed on November 16, 2015, at <http://dmecompetitivebid.com/palmetto/cbicrd1rebid.nsf/DocsCat/Product%20Categories>. CMS Competitive Bidding Implementation Contractor, *DMEPOS Competitive Bidding Program Round 1 Rebid*. Accessed on August 8, 2016, at <http://dmecompetitivebid.com/palmetto/cbicrd1rebid.nsf/DocsCat/Home>. CMS, *Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program Round 2: Weighted Average Savings*. Accessed on June 23, 2015, at [http://www.dmecompetitivebid.com/Palmetto/Cbicrd2.Nsf/files/R2_Weighted_Average_Savings.pdf/\\$File/R2_Weighted_Average_Savings.pdf](http://www.dmecompetitivebid.com/Palmetto/Cbicrd2.Nsf/files/R2_Weighted_Average_Savings.pdf/$File/R2_Weighted_Average_Savings.pdf).)

²⁶ CMS, *DMEPOS Fee Schedule, Revised for July 2015*. Accessed on March 21, 2016, at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule-Items/DME15-C.html?DLPAGE=1&DLEntries=10&DLSort=2&DLSortDir=descending>.

²⁷ When pressure support ventilators were added to Medicare coverage in 2005, the fee schedule amounts were established using manufacturer suggested retail prices for specific products, rather than basing these amounts on average reasonable charges for the monthly rental of the items (which was the method used to establish payment for many other DME items). Consequently, the monthly rental fees for pressure support ventilators were higher than for volume ventilators. (See CMS, *Internal Healthcare Common Procedure Coding System (HCPCS) Decision Regarding Codes for Ventilators*. Accessed on June 5, 2015. See Endnote 2 for URL information.)

²⁸ CMS had planned to add noninvasive pressure support ventilators to the DME Competitive Bidding Program beginning in 2017, but reversed this decision and instead discontinued the existing codes and created two new codes for ventilators. CMS established payment amounts for the new codes that restored payment to the levels mandated by the statute for ventilators. These coding and payment changes took effect beginning on January 1, 2016. (See CMS, *Internal Healthcare Common Procedure Coding System (HCPCS) Decision Regarding Codes for Ventilators*. Accessed on June 5, 2015. See Endnote 2 for URL information.)

²⁹ Ibid.

³⁰ CMS Competitive Bidding Implementation Contractor, *DMEPOS Competitive Bidding Program Round 1 Rebid*. Accessed on August 8, 2016, at <http://dmecompetitivebid.com/palmetto/cbicrd1rebid.nsf/DocsCat/Home>.

³¹ CMS Competitive Bidding Implementation Contractor, *DMEPOS Competitive Bidding Program Product Categories*. Accessed on November 16, 2015, at <http://dmecompetitivebid.com/palmetto/cbicrd1rebid.nsf/DocsCat/Product%20Categories>.

³² CMS, *Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program Round 2: Weighted Average Savings*. Accessed on June 23, 2015, at [http://www.dmecompetitivebid.com/Palmetto/Cbicrd2.Nsf/files/R2_Weighted_Average_Savings.pdf/\\$File/R2_Weighted_Average_Savings.pdf](http://www.dmecompetitivebid.com/Palmetto/Cbicrd2.Nsf/files/R2_Weighted_Average_Savings.pdf/$File/R2_Weighted_Average_Savings.pdf).

³³ CMS, *DMEPOS Competitive Bidding Program Overview*. Accessed on August 4, 2015, at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/index.html?redirect=/dmeuposcompetitivebid/>.

³⁴ CMS Competitive Bidding Implementation Contractor, *Round 2 Single Payment Amounts*. Accessed on November 17, 2015, at <http://www.dmecompetitivebid.com/palmetto/cbicrd2.nsf/DocsCat/Single%20Payment%20Amounts>.

³⁵ In this analysis, we included 32,644 beneficiaries that either (1) had a claim for an E0464 ventilator without prior claims for CPAPs or RADs or (2) switched from a CPAP or RAD to E0464. We excluded 204 beneficiaries that originally switched from a CPAP or RAD to another type of ventilator, but then later in the year switched again to the E0464 ventilator. These 204 beneficiaries were included in the analyses for Finding 1 that 32,848 beneficiaries had claims for E0464 ventilators at some point during 2015.

³⁶ CMS, *Medicare National Coverage Determinations Manual*, Pub. No. 100-03, ch. 1, pt. 4, § 280.1, p. 129.

³⁷ Noridian Healthcare Solutions, Medicare PDAC contractor. *Correct Coding and Coverage of Ventilators, Joint DME MAC Publication*, April 28, 2014. See Endnote 4 for URL information.

³⁸ In this analysis, we included 32,644 beneficiaries who either (1) had a claim for an E0464 ventilator without prior claims for CPAP devices or RADs or (2) switched from a CPAP device or RAD to an E0464 ventilator. We excluded 204 beneficiaries who originally switched from a CPAP device or RAD to another type of ventilator, but then later in the year switched again to an E0464 ventilator. These 204 beneficiaries were included in the analyses for Finding 1 that 32,848 beneficiaries had claims for E0464 ventilators at some point during 2015.

³⁹ Noridian Healthcare Solutions, Medicare PDAC contractor. *Correct Coding and Coverage of Ventilators, Joint DME MAC Publication*, April 28, 2014. See Endnote 4 for URL information.

⁴⁰ Noridian Healthcare Solutions, *Ventilators (HCPCS E0464) Quarterly Results of Service Specific Prepayment Review*, January 27, 2016. Accessed on May 17, 2016, at <https://med.noridianmedicare.com/web/jddme/cert-review/mr/complex-notifications-results/ventilators-targeted>.

⁴¹ NHIC, Corp. *Results of Widespread Prepayment Probe Review of Claims for E0464 (Pressure support ventilator with volume control mode, may include pressure control mode, use with non-invasive interface (e.g., mask))*, April 30, 2015. See Endnote 1 for URL information.