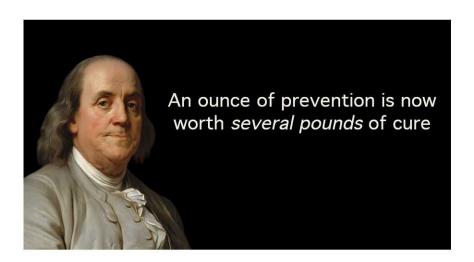
Competitive Bidding for DME - Is It Still Part of Medicare's Future?

The Case for Medicare Investment in DME Continues to Strengthen in 2024

Brian Leitten, Leitten Consulting

In 2011, we opened the first study of Medicare investment in Durable Medical Equipment (DME) with a quote from Ben Franklin – "An ounce of prevention is worth a pound of cure." That quote alluded to the efforts of the Centers for Medicare and Medicaid Services (CMS) to use competitive bidding to slash the cost of providing needed DME to Medicare beneficiaries. Instead, it should have been prudently investing in providing DME.

The logic supporting continued investment in DME was and is that the cost of treating the injuries and illnesses incurred by beneficiaries who lack the critical DME far exceeds the cost of providing needed DME in a timely manner. Thirteen years later, as competitive bidding for DME has ground to a halt and appears to be on its last days, Franklin's quote seems to have been an understatement – "an ounce of prevention is now worth several pounds of cure."



The Cost of Treatment versus Prevention

The initial study (and the updates that followed)¹ calculated the savings available to CMS if it were to manage the costs of treatment for the injuries and illnesses that the DME was designed to mitigate, rather than continue to try and shrink its spending on prevention. CMS chose to squeeze down DME pricing, drive out competitors and reduce availability of DME for

beneficiaries. Those decisions and the implementation of competitive bidding led to a 45% reduction in total spending on all the items that were included in the program over the first four years of program². The share of beneficiaries receiving DME dropped 11% over the same period.³

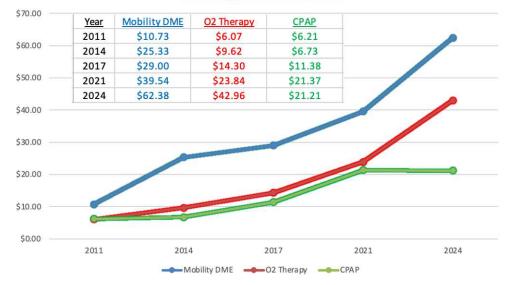
Those decisions also reduced the number of viable DME suppliers. Supplier locations operating during the first decade of competitive bidding dropped by between 29% and 40%, depending on the data source. Reductions were even more drastic in some individual DME categories, where the number of suppliers available to beneficiaries were nearly cut in half.^{4, 5}

After the first two rounds of the program, things changed. Delays and failures in the rounds that followed led to cessation of competitive bidding for DME. CMS calls it a 'temporary gap period' but much of the evidence suggests that competitive bidding may have reached its natural end. For over five years, CMS has been unable to cobble together even a single effective round of competitive bidding.

"Competitive bidding may have reached its natural end"

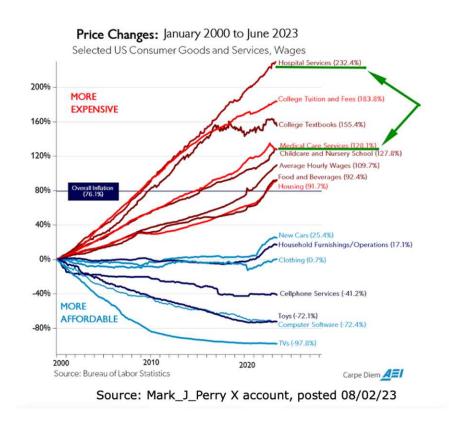
Three DME product categories (mobility DME; supplemental oxygen equipment; and CPAP [Continuous Positive Airway Pressure] machines and supplies) accounting for a significant portion of CMS DME spending were analyzed. In every iteration of the study, the treatment spending losses incurred by CMS in every category were orders of magnitude greater than the cost of providing the needed DME. In each new iteration of the study, the ratio of treatment cost to prevention increased. Simultaneously, the size of the Medicare beneficiary population grew 36% as more and more seniors reached age 65. Total dollars CMS had to spend on treatment soared.





The potential savings from treatment spending grew at an ever-increasing pace. The leverage of \$1 spent on CPAP machines and accessories skyrocketed 3.4X over the period (from \$6.21 to \$21.21); mobility DME equipment 5.8X (from \$10.73 to \$62.48); and O_2 equipment 7.1X (from \$6.07 to \$42.96).

The shear amount of money spent in the U.S on treatment is staggering. Hospital and medical care services that Medicare funds have swelled, growing at some of the highest rates of all consumer goods and services in the economy since 2000 and well above overall inflation numbers.



Hospital and Medical Care Services that Medicare funds have skyrocketed since 2000

In FY2023, Medicare spent \$1 Trillion, the bulk of which was spent on treating illnesses and injuries in hospitals and skilled nursing facilities and through home health, hospice care, physician visits and prescription drugs.^{6, 7} Less than 3% of U.S. healthcare spending is spent on prevention.⁸

A Seismic Shift in Care

Healthcare is in the midst of a seismic shift that will expand the value of timely providing DME to Medicare beneficiaries. One key element is a shift in the location of providing care. In the very near future, up to 25 percent of the total cost of care for Medicare Fee-For-Service and MA

beneficiaries (i.e., more than \$250 Billion worth of annual care costs) will likely shift from traditional facilities (hospitals, outpatient clinics, physicians' offices, skilled nursing facilities, urgent-care centers and emergency departments) to the home. It is projected that this shift will happen without a reduction in quality or access. 10

The COVID-19 pandemic triggered an almost 40-fold growth in the use of telehealth, with patients remaining in their home settings. ¹¹ The emergence of new capabilities, including remote patient monitoring, expanded digital technologies, increased testing by mail and 'acute care at home' programs, is making the home a real possibility as the care location of choice and preference for more beneficiaries. ¹² Most DME is specifically designed for home use and will become an increasingly important element of providing care and maximizing prevention as this shift continues.

Another important shift is the growth of Medicare Advantage, which places the burden of providing overall care to beneficiaries to private insurers who contract with CMS to manage the total care programs. This year, for the first time, the majority of Medicare beneficiaries will be participating in MA programs as opposed to traditional fee-for-service Medicare. This means CMS will have less direct control over DME pricing and utilization, since they are bundled into the overall dollar amount that CMS pays insurers to cover the cost of care. This loss of control may be a factor in CMS deciding to 'pause' competitive bidding going forward, as it will directly impact less and less DME volume.

The Overall Savings Potential

CMS needs to realize that DME is not the culprit but an important part of the solution. It has to acknowledge that relatively small investments in prevention can reduce much larger costs for treatment. Until then, it will not be able to capture the savings from treatment reduction costs and get better control of overall Medicare spending. In all, CMS can achieve a minimum savings of \$130 Billion that could approach \$200 Billion (when undiagnosed COPD and OSA costs are included) by focusing on managing treatment. This equates to 13-20% of its total annual spending and does not include the additional \$32-\$40 Billion in additional savings that will flow to Medicare beneficiaries and their payors. Certainly, all these savings cannot be realized immediately, but nothing will happen until CMS shifts its focus.

"CMS can achieve a minimum savings of \$130 Billion that could approach \$200 Billion"

The current pause in competitive bidding is encouraging. It appears to be an acknowledgement that the initial cost savings realized through competitive bidding has stalled and that savings going forward cannot be achieved. The 2019 round was delayed¹³ when CMS found it was no longer able to extract additional costs and still maintain a viable supplier network. The 2021 round was limited to off-the-shelf braces and effectively failed.¹⁴

For mobility DME, the goal is still to eliminate all senior falls by providing the proper DME in advance of need. Annually, over 9 million seniors require treatment for fall injuries. For supplemental O_2 and CPAP therapies, the goal is to identify and treat Medicare beneficiaries with diagnosed and undiagnosed COPD [Chronic Obstructive Pulmonary Disease] and OSA [Obstructive Sleep Apnea]. 50-60% of Medicare beneficiaries with COPD and up to 95% with OSA remain undiagnosed. $^{15, 16, 17}$

To maximize savings and the reduction of senior falls, CMS not only needs to invest in providing mobility DME but simultaneously invest in fall prevention and fall risk screening, education and training. Similarly, to minimize long-term treatment costs and increase the early diagnosis of COPD and OSA, CMS must also invest in beneficiary screening and educating and training providers and beneficiaries, in addition to providing oxygen and CPAP equipment and supplies. In our 2021 update, we recognized that it is difficult to project how much it would cost CMS to develop an effective set of screening, educational and training tools. We arbitrarily recommended matching current investments in providing the equipment itself. Our logic was that investment at that level was certainly a good starting point for CMS to meaningfully commit to refocusing on prevention versus treatment.

The foundation of our original 2011 study and the updates that followed have encompassed the analysis of three product categories of DME – mobility equipment (wheelchairs; walkers; bathing aids; power chairs; and similar items) designed to help beneficiaries avoid falls; supplemental oxygen therapy equipment and supplies (oxygen concentrators; portable and stationary liquid and gaseous systems; and oxygen refill supplies) needed to help beneficiaries deal with damage to their pulmonary systems, mainly from COPD; and CPAP equipment to treat sleep apnea.

Mobility DME Helps Prevent Falls. Falls are the leading cause of injury and the leading cause of injury-related deaths among U.S. adults aged 65 years and older. As life expectancies and the number of people in the U.S. turning 65 continue to grow, healthcare costs for treating falls also continues to grow. Mobility DME reduces falls if it is provided to Medicare beneficiaries in a timely manner. When falls are avoided, Medicare and its beneficiaries spend less on treatment.

For every dollar that Medicare spends providing mobility DME, CMS can avoid spending \$62.38 on direct fall-related healthcare costs, including ER visits; hospitalizations; doctor visits; rehabilitation care; and other related costs. Medicare beneficiaries and their private insurers, who shoulder copays that Medicare doesn't cover, save an additional \$15.59.

Supplemental O₂ Mitigates the Symptoms of COPD. COPD is the 6th overall leading cause of death, accounting for 4.5% of all U.S. deaths in 2022¹⁹. COPD is also the 5th leading cause of disease-based death in the United States, behind heart disease, cancer, COVID-19 and stroke.²⁰

85% of all COPD deaths occur among those age 65 years or older.²¹ Supplemental oxygen therapy is used to treat individuals who have labored breathing symptoms caused by COPD.

For every dollar that Medicare invests in providing oxygen therapy equipment and supplies to beneficiaries in need, CMS can avoid spending approximately \$42.96 in COPD-related treatment costs. Beneficiaries and insurers can realize an additional cost savings of \$10.74.

CPAP Treats Obstructive Sleep Apnea. OSA is a condition of recurring complete or partial collapse or obstruction of the upper airway during sleep, resulting in cessation of breathing, snoring, gasping for air and choking. One study found that 56% of people aged 65 and older have a high risk of developing OSA.²² Untreated sleep apnea can lead to heart, kidney, and metabolic health complications.²³ When Medicare pays for CPAP machines and supplies, the cost of treating these medical complications drops dramatically. CPAP therapy reduces OSA severity, reduces daytime sleepiness, improves sleep-related quality of life and reduces blood pressure for people with and without blood pressure medications.

For every dollar that Medicare invests in providing CPAP therapy, CMS can avoid spending \$21.21 for treatment of OSA and OSA-caused medical complications. Medicare beneficiaries and their private insurers receive an additional cost savings of \$5.30.

To summarize, when CMS invests proactively in prevention by providing needed DME to beneficiaries, dramatic reductions in treatment costs can be realized by the Medicare program and by beneficiaries and their payors:



Notes on the Study

- This version of the study takes advantage of new data available from recently published research on Medicare beneficiary hospital readmissions that was not previously available. This data allows the inclusion of readmission costs that were not included in previous versions of the study. As a result of including this data, the overall savings potential for mobility DME and oxygen equipment has increased by 16.9%²⁴ and for CPAP equipment by 19.3%²⁵.
- Since Medicare only pays for a portion of their beneficiaries' costs (generally ~80%), this study
 focuses on those costs borne directly by Medicare but also takes into consideration the costs
 covered directly by beneficiaries or their private insurers, to estimate overall Medicare-related
 spending and savings potential.
- In the past, we have on occasion attempted to account for the extended life of typical DME. Most DME has a useful life of more than one year, supporting an argument that there is residual value to providing DME that extends beyond the initial year of use by a beneficiary. We find this argument compelling, i.e., one could expect that the overall value of providing DME extends beyond one year and the study therefore underestimates to some extent the leverage factor of prevention versus treatment. While readers should keep this in mind, for this update and going forward, we do not plan to try and quantify that incremental value. When considering Medicare data and numerous other factors, including the expected life of the equipment, the projected period of use and the ability to conveniently get repair services, value calculations become unnecessarily complicated. This means that the data presented here is on the low side if the effective utilization period of the equipment DME beneficiaries receive is greater than one year.
- On March 13, 2024, CMS announced its decision to incorporate a competitive application screening and scoring process into its Medicare Advantage Value-Based Insurance Design (VBID) program, beginning with the 2025 benefit year. 26 36% of all MA plans have VBID coverage. 27 CMS cannot directly control DME pricing of MA plans, since CMS uses bundled payments to MA providers that cover all beneficiary care, but deploying competitive bidding would no doubt have an indirect impact on DME pricing to MA providers. While CMS appears to have had the authority to institute this approach under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003²⁸, the same act that served as the basis of the DMEPOS competitive bidding program, the speed with which CMS introduced and began implementation is surprising. The date for submitting 2025 applications under the program has already passed. This rushed process is in sharp contrast to its May 2023 announcement²⁹ implementing a Temporary Gap Period in the DMEPOS competitive bidding program, CMS clearly stated that no new round of competitive bidding would start until it was able to:
 - Complete the formal public notice and comment rulemaking process

- Implement necessary DMEPOS CBP changes to:
 - Establish sustainable prices
 - Save money for Medicare patients and taxpayers
 - Help limit fraud, waste, and abuse in the Medicare Program
 - Ensure patient access to quality items and services

An argument can easily be made that the same procedure must apply to this new effort and that CMS has failed to make any effort to comply beyond issuing an initial notice. Litigation from providers to stop implementation and possible implementation delays can be expected.

"Litigation from providers to stop implementation [of competitive bidding in Medicare Advantage programs] and possible implementation delays can be expected"



FALLS

Since Year 1 of competitive bidding, we have presented a litany of statistics that frame the problems that happen when Medicare beneficiaries sustain costly fall injuries, and that litany has remained reasonably constant. This is the best, most up-to-date set of key points about fall injuries:

- 28% of senior Americans, 14 million, fall each year^{30, 31}
- Those seniors account for 36 million falls each year, averaging 2.5 falls each³²
- Those falls result in over 9 million injuries that require treatment³³
- Falls are the leading cause of injury among senior adults³⁴
- Every 11 seconds, one of those falls is serious enough to require a trip to an emergency room³⁵ and even more lead to a visit to a doctor's office or a clinic³⁶, ³⁷
- In 2021, hospital admissions for senior falls equaled 50% of ER visits for falls³⁸
- After a fall-related hospital stay, most senior patients are discharged to a rehabilitation or skilled nursing facility to recover
- Life expectancies are increasing, and the latter years require more costly care
- More people turn 65 and receive Medicare benefits each year³⁹

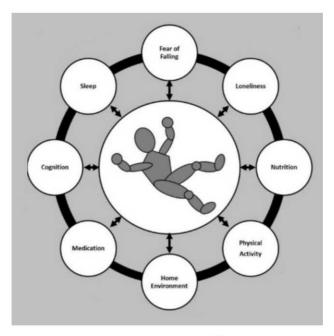
Falls are often viewed as a natural and inevitable part of aging that cannot be prevented or managed. The complex and multi-factor circumstances resulting in a fall require a more holistic

view of the event.⁴⁰ Falls are not inevitable; rather, they are largely preventable.⁴¹ Successful control of fall spending requires the ability to predict, prevent and manage falls among older adults before they require treatment.

"Falls are not inevitable; rather, they are largely preventable"

By deploying competitive bidding, CMS has taken a narrow view and targeted mainly the cost of mobility DME. Instead, it needs to adopt a holistic view and recognize that by focusing on prevention, it can change these now rather predictable statistics and use DME, screening, education and training to reduce the number and frequency of falls happening to seniors and avoid accepting that falls are inevitable.

The underlying causes that trigger falls are numerous and can be grouped into several categories, including physical; mental; nutritional; environmental; and medication related. Understanding the nature of these causes helps caregivers and insurers clarify their perspective on falls and the pre- and post-fall strategies they need to consider if they are to improve their prevention efforts and drive treatment cost savings out of the system.



The causes of falls⁴²

In 2023, CMS spent \$701 Million on mobility DME for Medicare beneficiaries.⁴³ To determine the average cost to proactively provide mobility DME to Medicare beneficiaries, we looked at the amount CMS pays for that DME when provided to fee-for-service beneficiaries after a fall injury. We calculated that CMS spends on average \$160.88 on mobility DME equipment for each beneficiary treated for a fall injury. In addition, each fall victim incurs at least two doctor visits,

at a cost we estimated at \$106.19 (for one Level-3 doctor office visit and one facility Level-4 doctor visit in an ER).⁴⁴ This brings the average cost to provide DME after a fall injury to \$267.07, which serves as a reasonable proxy for the proactive cost of providing mobility DME and the denominator for our savings calculation.

We next calculated the cost that Medicare pays to treat each fall injury. We started with a data search of the CMS WISQARS database and calculated the cost to treat fall injuries. ⁴⁵ We deducted the amount actually spent on DME to identify the Medicare fee-for-service spending for treatment of fall injuries and accounted for readmission spending. We then divided that amount by the number of fall injuries to calculate a cost per injury to treat falls, the numerator of our equation. Overall CMS fall treatment spending for in 2023 comes to \$77.1 Billion, at an average cost to treat a Medicare beneficiary fall injury of \$17,525. Estimates were then adjusted for effectiveness of using the proper DME by beneficiaries, based on over a decade of historical effectiveness of providing DME to those in need. ⁴⁶

For every dollar CMS invests in proactively providing DME to Medicare beneficiaries who need it, we calculated that CMS could save \$62.38 by avoiding treatment payments. Medicare beneficiaries and their private insurers could also save an additional \$15.59 in payments, bringing the total savings potential to \$77.97.



© 2024 and earlier* Brian Leitten**



HOME OXYGEN THERAPY

Cohorts of older Americans annually reach age 65, with more joining the ranks of Medicare beneficiaries every year. Large numbers have a history of smoking or continue to smoke, and bring with them diagnoses of chronic pulmonary problems, most notably COPD. It comes as no surprise then that COPD treatment costs are a significant burden on Medicare's healthcare budget. COPD is the fifth leading cause of mortality⁴⁷ and a major cause of disability in the United States. The CDC reported that \$49 Billion was spent in 2020 treating COPD in the U.S. ⁴⁸ Medicare bore \$25 Billion of that cost. ⁴⁹ Several studies show similar levels of treatment spending.

COPD is a group of progressive lung diseases, including emphysema and chronic bronchitis, that typically get worse over time. With emphysema, the walls between many of the air sacs in the lungs are damaged. As a result, the air sacs lose their shape and become floppy. This damage also can destroy the walls of the air sacs, leading to fewer and larger air sacs instead of many tiny ones. When this happens, the amount of gas exchange in the lungs is reduced. In chronic bronchitis, the lining of the airways stays constantly irritated and inflamed, and this causes the lining to swell. Lots of thick mucus forms in the airways, making it hard to breathe. Most people who have COPD have both emphysema and chronic bronchitis. 50

COPD patients also suffer from a broad range of comorbidities that exacerbate the main diagnosis and lead to higher treatment costs. Over 70% of COPD patients will typically have at least one comorbidity. 30-50% have two or more. The most prevalent comorbidities include hypertension, coronary artery disease and diabetes. In all, over a dozen comorbidities with significant prevalence have been cataloged. COPD will continue to burden the healthcare system. Over the next twenty years, COPD is expected to cost the U.S. healthcare system an additional \$800 Billion in direct medical costs, one quarter of those costs for the hospital treatment of COPD exacerbations.

While there is currently no cure for COPD (damage to the lungs and airways is not reversible), supplemental oxygen therapy, medication and pulmonary rehabilitation are the main forms of treating the symptoms of COPD. The primary treatment goals are to reduce symptoms and reduce the frequency and severity of exacerbations.⁵⁶ In many severe cases, oxygen therapy can increase survival rates.⁵⁷

With no cure for COPD on the horizon and a burgeoning over 65 population straining Medicare, CMS is faced with another prevention vs. treatment dilemma. Its efforts to drive oxygen equipment and supplies pricing to the bottom reflect its seemingly universal mindset to drive

down costs, regardless of the relative size of the return or the overall wellbeing of its beneficiaries. Treatment costs are orders of magnitude greater than the price of investing in prevention and growing each year.

In 2023, we estimate that CMS spent just under \$700 Million on supplemental oxygen therapy equipment for Medicare beneficiaries.⁵⁸ The bulk of that spending went to beneficiaries suffering from COPD, the prevalent disease requiring supplemental oxygen. To determine the average cost to proactively provide supplemental oxygen therapy equipment to Medicare beneficiaries, we looked at the amount CMS pays for that equipment when provided to Medicare fee-for-service beneficiaries after hospitalization or other diagnosis. Conservatively estimating that beneficiaries receive and use equipment for a full 12 months, we calculated the number of COPD beneficiaries using equipment in 2023.⁵⁹ Using this approach, we calculated the average cost to provide supplemental oxygen equipment, accessories and supplies to COPD beneficiaries to be \$702.78, which serves as a reasonable proxy for the proactive cost of providing the equipment.

To model the cost saving of providing supplemental oxygen therapy to Medicare beneficiaries in need, we determined the annual incremental cost of treating COPD patients with frequent exacerbations. We blended the data for four different sources to calculate an average cost.^{60, 61, 62, 63} Adjusted to 2023 dollars, those incremental costs averaged \$30,191 per patient.⁶⁴

That means that for every dollar CMS invests in providing supplemental oxygen therapy equipment to Medicare COPD beneficiaries who need it, CMS has the potential to save \$42.96 in treatment payments for beneficiaries with COPD. Medicare beneficiaries and their insurers have the potential to save an additional \$10.74 in payments to treat beneficiaries with COPD, bringing the total possible savings per dollar invested to \$53.70.





CPAP Therapy

According to CMS, approximately 40 million Americans suffer from chronic sleep disorders and 95% of these are undiagnosed and untreated.⁶⁵ Sleep apnea is the most significant of these disorders and the medical problems requiring treatment that result from OSA, whether diagnosed or undiagnosed, place a heavy burden on the U.S. healthcare system. Sleep apnea is a medical condition characterized by the repeated stopping and starting of breathing while asleep. By far the most common type of sleep apnea is obstructive sleep apnea. OSA occurs when a person's throat muscles intermittently relax to the point of collapse and block the person's airway during sleep.

CPAP is a critical therapy for treating OSA. It prevents the collapse and blockage of a person's airways during sleep. CPAP is a very effective tool but not universally tolerable by users. A somewhat cumbersome mask and hose connection are required to be worn that can limit movement during sleep and can cause discomfort and distress. This results in decreases in compliance. An implant technology marketed by the U.S.-based Inspire Medical Systems is emerging as a viable alternative to CPAP. First approved by the FDA in 2014, Inspire is a hypoglossal nerve stimulator device. A small implant is placed near the collarbone during an approximately 90-minute outpatient procedure. The implant delivers gentle pulses to airway muscles to keep the airway open, permitting regular breathing during sleep. A handheld remote is used to initiate therapy before sleep and to end the therapy upon waking. No mask or hose required. The current cost for the stimulator and the insertion surgery is \$30,000-\$40,000, which is increasingly covered by Medicare and private insurance for a limited set of beneficiaries.

During the pandemic, fall injuries and COPD continued to require immediate attention. Treatment for broken bones, bruises, cuts and pulmonary exacerbations could not be delayed. Care had to be provided when the medical problems occurred. The story was different for OSA. When the pandemic hit, interpersonal contact was severely restricted. Treatment of sleep apnea starts with a sleep study and sleep clinics where these studies are conducted abruptly shut down across the country. A portion of sleep studies are conducted at home, but the pandemic restrictions also severely constricted the home caregiver visits that were needed to set up the sleep studies. The result was a sharp decline in new machines provided to Medicare beneficiaries, a 22.7% drop from pre-pandemic numbers. Spending on DME and treatment were both delayed.

In 2023, we estimate CMS spent \$1.1 Billion on CPAP equipment and supplies for Medicare beneficiaries.⁶⁸ To calculate the average cost to proactively provide CPAP equipment to Medicare fee-for-service beneficiaries, we looked at the amount CMS pays for that equipment when

provided after an authorized sleep study has been conducted. We determined the number of CPAP beneficiaries using equipment and supplies and the number of sleep studies conducted in 2022. We calculated the average cost to provide CPAP diagnosis and equipment to beneficiaries at \$1475.72, which serves as a reasonable proxy for the proactive cost of diagnosing OSA and providing CPAP equipment.

To model the cost saving of diagnosing OSA and providing CPAP equipment to Medicare beneficiaries in need, we determined the average annual incremental cost of treating OSA patients. A recent publication provided the most accurate breakdown our research uncovered of annual per capita health services payments for beneficiaries with untreated obstructive sleep apnea. ⁶⁹ Adjusted to 2023 dollars and accounting for the cost of readmissions, those incremental costs averaged \$31,306 per patient.

In sum, for every dollar CMS invests in providing CPAP therapy equipment to diagnosed Medicare OSA beneficiaries, CMS can potentially realize \$21.21 in OSA treatment payment reductions. Medicare beneficiaries and their private insurers can potentially save \$5.30 in copayments for treatment of beneficiaries with OSA. This brings the total savings potential per dollar invested to \$26.51.



A Potentially Disruptive Shift in OSA Treatment

While it is too early to reach firm conclusions, it is important to take note of a study⁷⁰ released earlier this year that could have a long-term impact on the CPAP market. Eli Lilly released a Phase 3 study of obese people using CPAP machines that showed that tirzepatide, classed as a glucagon-like peptide-1 (GLP-1) receptor agonist, reduced the average number of hourly sleep apnea events by 63% compared to a placebo. GLP-1 are a class of drugs now used to treat type 2 diabetes and obesity. Lilly, which markets tirzepatide under the Zepbound brand for diabetes treatment and the Mounjaro brand for treating obesity, plans to seek FDA approval later this year for tirzepatide for treating OSA.



The Bottom Line

The American healthcare landscape is in flux. A dramatic shift in care from hospitals and other tradition medical settings to the home has begun. Even services like acute care, which were previously limited only to hospital settings, are being brought into the home. More seniors are reaching age 65 each year and life expectancies are growing. The pandemic has accelerated the development of remote patient monitoring and testing and other digital technologies. Medicare Advantage has become the choice for a majority of seniors receiving Medicare benefits, shifting direct spending control for DME from CMS to insurers. Competitive bidding is broken and no longer delivers significant additional savings for CMS.

This shift to the home makes DME, which is designed primarily for home use more so than in traditional medical settings, even more important to providing optimal care to Medicare beneficiaries going forward. CMS needs a new approach to funding DME that recognizes the tremendous value and reduction in spending that can be achieved by shifting its focus and using DME to control treatment costs. That approach needs to encourage the expanded use of DME to help Medicare beneficiaries proactively avoid the injuries and illnesses that have become a part of fall injuries, COPD, OSA and other medical problems. These injuries and illnesses are not natural and inevitable parts of aging that cannot be prevented or managed. They are avoidable. By not focusing on prevention, CMS has allowed treatment costs to snowball and become significant contributors to overall Medicare spending. Ben Franklin would be appalled!

Investing more in DME will not completely address the situation. CMS needs to concurrently invest more in developing more aggressive and comprehensive screening, diagnosis and treatment tools and programs. It needs to build new and more effective prevention and screening tools and incent insurers to use those tools and to create more on their own. With the growing financial impact of MA plans, insurers need strong reasons to drive down spending on illness and injury.

In this update, the leverage of spending a dollar on preventing fall injuries and COPD-related illnesses has grown significantly. The unexpected COVID-19 pandemic temporarily stalled the growth of OSA diagnosis and treatment and the growth in leverage of DME spending for that category, but the reopening post-pandemic of sleep clinics and the shift to more home-based sleep studies will lead to increased leverage in coming years.

The leverage value of one dollar invested in prevention is powerful. Medicare spending on treatment costs for the injuries and illnesses that could be mitigated by providing DME to Medicare beneficiaries who need it has soared since the imposition of competitive bidding thirteen years ago. Every dollar CMS invests in DME in 2024 creates the potential to eliminate \$62.38 now spent by CMS to treat fall injuries; \$42.96 now spent to treat COPD; and \$21.21 now spent to treat OSA.

Taken together, CMS has the opportunity to cut its overall annual Medicare spending by a minimum of \$130 Billion by focusing on managing treatment. This equates to 13% of the entire \$1 Trillion annual CMS spending budget.



^{*} Earlier copyrights include 2021; 2018; 2017; 2014; and 2011.

FOOTNOTES

^{**} Brian Leitten, CEO of Leitten Consulting and Sidekck Development. Previously Managing Partner at Bluespring Partners (private equity), VP Corporate Development & Technology (Hill-Rom/Hillenbrand, Fortune 500 healthcare company) and CEO/COO of healthcare, technology and consumer goods businesses.

¹ The 2011 original study was completely updated in 2014; 2017; 2021; and in this 2024 update - https://leitten.com/medicare-cost-studies; https://www.vgm.com/webres/File/Gov Docs/Resource Center/Research Studies and Articles/The Case for Medicare Investment in DME (Full Study) - Brian Leitten.pdf;

https://www.fahcs.us/resources/Documents/Leitten%20Study%202021 Medicare%20Investment%20in%20DME.pdf

² Ji, The Impact of Competitive Bidding in Health Care: The Case of Medicare Durable Medical Equipment, https://scholar.harvard.edu/files/yunan/files/dme.pdf, 2023

¹⁰ Id.

¹¹ Id.

¹² Id.

https://www.medtechdive.com/news/medicare-dme-competitive-bidding-in-doubt-after-failed-round-analysts/594675/, MedTechDive 2021

³ Id.

⁴ Higley, HME - Past, Present & Future: State of the Industry/Benchmarking Update, https://www.vgm.com/communities/hme--past-present--future--state-of-theindustrybenchmarking-update/, 2019

⁵ Pigg, Competitive bidding is here to stay for medical suppliers, https://thehill.com/blogs/congress-blog/healthcare/413837-competitive-bidding-is-here-to-stay-for-medical-suppliers, The Hill 2018

⁶ CMS Financial Report FY 2023, https://www.cms.gov/files/document/cms-financial-report-fiscal-year-2023.pdf-0, CMS 2023

⁷ Levine et al., Health Care Industry Insights: Why the Use of Preventive Services Is Still Low, CDC PCD Collection: Health Care Systems, Public Health, and Communities: Population Health Improvements, https://www.cdc.gov/pcd/issues/2019/18 0625.htm, 2022

⁸ The Impact of Chronic Underfunding on America's Public Health System: Trends, Risks, and Recommendations, 2020, Trust for America's Health, https://www.tfah.org/report-details/publichealthfunding2020/#:~:text=While%20the%20United%20States%20spends,toward%20public%20health%20and%20prevention, 2023

⁹ From facility to home: How healthcare could shift by 2025, https://www.mckinsey.com/industries/healthcare/our-insights/from-facility-to-home-how-healthcare-could-shift-by-2025, McKinsey & Company Healthcare 2022

¹³ Kopf, CMS DELAYS COMPETITIVE BIDDING ROUND 2019, https://hmebusiness.com/articles/2017/02/08/2019delay.aspx, HME Business 2017

¹⁴ Taylor, Medicare DME competitive bidding in doubt after failed round: analysts,

¹⁵ Han et al, Detection of Undiagnosed Disease in Medicare Beneficiaries After a Clinical Home Visit, https://pubmed.ncbi.nlm.nih.gov/27123662/, POPULATION HEALTH MANAGEMENT, Volume 10, Number 1, 2017

¹⁶ https://uscopdcoalition.org/, U.S. COPD Coalition 2023

¹⁷ Local Coverage Determination (LCD), Outpatient Sleep Studies, https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35050, Medicare Coverage Database 2024

¹⁸ Older Adult Fall Prevention, Older Adult Falls Data, https://www.cdc.gov/falls/data/index.html#:~:text=Falls%20are%20the%20leading%20cause,ages%2065%20years %20and%20older, CDC 2024

¹⁹ Top 10 Causes of Death in America, 6. Chronic Lower Respiratory Diseases, https://www.usnews.com/news/healthiest-communities/slideshows/top-10-causes-of-death-in-america?slide=6, U.S. News & World Report 2024

²⁰ Xu et al., NCHS Data Brief No. 456, Mortality in the United States, 2021, https://www.cdc.gov/nchs/data/databriefs/db456.pdf, CDC 2022

²¹ COPD Trends Brief: Mortality, https://www.lung.org/research/trends-in-lung-disease/copd-trends-brief/copd-mortality, American Lung Association 2024

²² Study Finds High Rate of Undiagnosed Sleep Apnea in Older Adults, https://foundation.aasm.org/aasm-foundation-study-published-jags/, AASM Foundation 2018

²³ Ling et al., Sleep Apnea Statistics and Facts You Should Know, https://www.ncoa.org/adviser/sleep/sleep-apnea-statistics/#:~:text=Approximately%2039%20million%20U.S.%20adults,kidney%2C%20and%20metabolic%20health%20complications., National Council on Aging Advisor 2023

²⁴ Weiss et al., Overview of Clinical Conditions With Frequent and Costly Hospital Readmissions by Payer, 2018, https://hcup-us.ahrq.gov/reports/statbriefs/sb278-Conditions-Frequent-Readmissions-By-Payer-2018.jsp#:~:text=The%20overall%20readmission%20rate%20was,readmission%20rate%20(8.7%20percent)., AHRQ Healthcare Cost & Utilization Project 2021

²⁵ Medicare data for unplanned hospital visits, specific condition, COPD, https://www.medicare.gov/care-compare/details/hospital/670082/view-all?state=TN, Medicare.gov 2024

²⁶ https://www.cms.gov/files/document/vbid-cy225-application-screening-scoring.pdf, CMS 2024

²⁷ 2024 VBID benefit MA market landscape and 2025 VBID Model application considerations, https://www.milliman.com/-/media/milliman/pdfs/2024-articles/3-26-24 2024-vbid-benefit-ma-market-landscape.ashx#:~:text=Growth%20in%20VBID%20participation%20is,(December%2013%2C%202023)., Milliman 2024

²⁸ https://www.govinfo.gov/content/pkg/PLAW-108publ173/html/PLAW-108publ173.htm, 2003

²⁹ Fact Sheet - DMEPOS Competitive Bidding Program: Temporary Gap Period, https://www.cms.gov/files/document/mln764994-dmepos-competitive-bidding-program-temporary-gap-period.pdf, CMS 2023

³⁰ Stephanacci et al., Falls in Older Adults, <a href="https://www.merckmanuals.com/professional/geriatrics/falls-in-older-adults/

³¹ ld.

³² Id.

³³ Author's calculation based on earlier CDC data, https://www.cdc.gov/falls/index.html (chart at bottom of page), CDC 2023

³⁴ See Note 17

³⁵ Data Points: Falls by seniors could cost Medicare \$52 billion in 2020, https://www.modernhealthcare.com/safety/data-points-falls-seniors-could-cost-medicare-52-billion-2020, Modern Healthcare 2019

³⁶ Burns et al, The direct costs of fatal and non-fatal falls among older adults — United States, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6823838/, J Safety Res., Sep; 58: 99–103, 2016

³⁷ Bergen et al, Falls and Fall Injuries Among Adults Aged ≥65 Years — United States, 2014, https://www.cdc.gov/mmwr/volumes/65/wr/mm6537a2.htm, 2016

³⁸ CMS WISQARS database, https://www.cdc.gov/injury/wisqars/index.html

³⁹ Promoting Health for Older Adults, https://www.cdc.gov/chronicdisease/resources/publications/factsheets/promoting-health-for-older-adults.htm, CDC National Center for Chronic Disease Prevention and Health Promotion 2024

⁴⁰ Smith et al., Multi-directional nature of falls among older adults: A rationale for prevention and management, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9989446/, NIH National Library of Medicine 2023

41 Id.

⁴² Id. Adapted from Figure 1

- ⁴³ Author's estimate based on compilation of mobility-related HCPCS E and K code 2022 spending, adjusted to 2023 dollars
- ⁴⁴ CMS, Search the Physician Fee Schedule, data for 2020 National Payment Amount for CPT Codes 99203 and 99214, Level 3 visit Non-Facility Price and Level 4 office visit, both involving a moderate level of medical decision-making, Facility Price, https://www.cms.gov/medicare/physician-fee-schedule/search 2021
- ⁴⁵ See Note 38
- ⁴⁶ Effectiveness was calculated using data from the FREE Foundation, Roanoke Virginia. The Foundation has been tracking effectiveness of providing proper DME to those in need for over a decade. Its data shows that having the proper DME results in an ~95.2% reduction in fall injuries, ER visits and hospitalizations (5-year average, 2018-2022), https://www.free-foundation.org/about (data extracted from Annual Reports 2018-2022)
- ⁴⁷ About Provisional Mortality Statistics, 2018 through Last Week, https://wonder.cdc.gov/controller/saved/D176/D374F608, CDC 2024
- ⁴⁸ Chronic Obstructive Pulmonary Disease (COPD) COPD Costs, https://www.cdc.gov/copd/infographics/copd-costs.html, CDC 2020
- ⁴⁹ Id.
- ⁵⁰ National Heart, Lung and Blood Institute, What is COPD?, https://www.nhlbi.nih.gov/health-topics/copd, NIH 2024
- ⁵¹ Raherison et al., Comorbidities and COPD severity in a clinic-based cohort, https://bmcpulmmed.biomedcentral.com/articles/10.1186/s12890-018-0684-7, BMC Pulmonary Medicine 2018
- ⁵³ Dos Santos et al., Prevalence and Impact of Comorbidities in Individuals with Chronic Obstructive Pulmonary Disease: A Systematic Review, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9263346/, NIH National Library of Medicine 2022
- ⁵⁴ 2024 Report, https://goldcopd.org/2024-gold-report/, Global Initiative for Chronic Obstructive Lung Disease 2024
- ⁵⁵Mosher et al., NIH National Library of Medicine, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10559142/, NIH 2023
- 56 See Note 50
- ⁵⁷ Id.
- ⁵⁸ Author's estimate based on compilation of oxygen therapy equipment, accessories and supplies-related HCPCS E and K code 2022 spending, adjusted for 2023 dollars
- ⁵⁹ Author's estimate of approximately 962,000 based on compilation of oxygen therapy equipment, accessories and supplies-related HCPCS E and K code 2022 spending.
- 60 See Note 24
- ⁶¹ ur Rehman et al., The economic burden of chronic obstructive pulmonary disease (COPD) in the USA, Europe, and Asia: results from a systematic review of the literature, https://www.tandfonline.com/doi/full/10.1080/14737167.2020.1678385, Expert Review of Pharmacoeconomics &
- Outcomes Research, Volume 20 Issue 6, 2020
- 62 COPD Costs, https://www.cdc.gov/copd/infographics/copd-costs.html, CDC Centers for Disease Control and Prevention 2018

 © 2024 and earlier* Brian Leitten**

⁶³ Shah et al., Direct Medical Costs of COPD in the USA: An Analysis of the Medical Expenditure Panel Survey 2017-2018, https://pubmed.ncbi.nlm.nih.gov/37270431/, Applied Health Economics and Health Policy 2023

⁶⁴ Author's calculations based on data from the four sources

⁶⁵ Outpatient Sleep Studies, https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35050, CMS Medicare Coverage Database 2021

⁶⁶ Patel et al., The COVID-19 Pandemic Presents an Opportunity to Reassess the Value of Polysomnography, https://www.atsjournals.org/doi/10.1164/rccm.202005-1546ED, American Journal of Respiratory and Critical Care Medicine 2020

⁶⁷ Calculated by the author based on CMS spending for machines pre-and post-pandemic

⁶⁸ Author's estimate based on compilation of CPAP and sleep study-related HCPCS A, E and G code 2022 spending, adjusted for 2023 dollars

⁶⁹ Wickwire et al, Older adult US Medicare beneficiaries with untreated obstructive sleep apnea are heavier users of health care than matched control patients, https://jcsm.aasm.org/doi/full/10.5664/jcsm.8128, Journal of Clinical Sleep Medicine, Volume 16, Issue 1, 2020

⁷⁰ Eli Lilly news release, Tirzepatide reduced sleep apnea severity by up to nearly two-thirds in adults with obstructive sleep apnea (OSA) and obesity, <a href="https://investor.lilly.com/news-releases/news-re