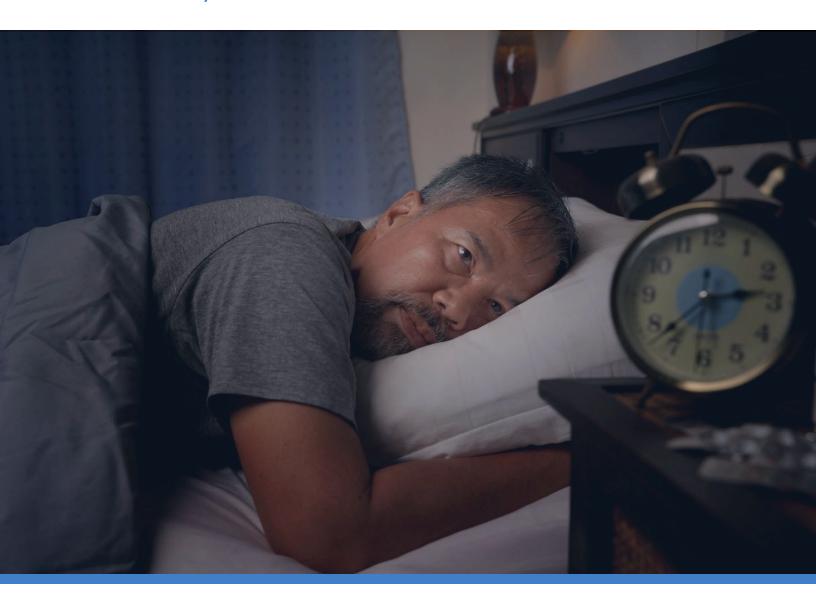


In the Fight Against Chronic Disease, Sleep is the Hidden Gap in Care (Part 1)

Revised February 2025 IMPORTANT UPDATE





In the Fight Against Chronic Disease, Sleep is the Hidden Gap in Care

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In light of the FDA's recent approval of Zepbound, a GLP-1 used in the treatment of Obstructive Sleep Apnea (OSA), revisions to this white paper highlight its impact.

Executive Summary

By appropriately diagnosing individuals with sleep disorders and optimizing their adoption and adherence to sleep therapy, plan sponsors can improve health outcomes, reduce healthcare utilization, and realize significant total healthcare cost savings. Sleep is a major gap in care for the treatment of those suffering from chronic health conditions.

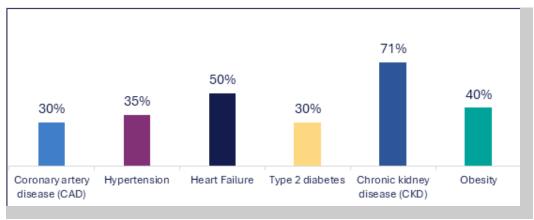
1. Polychronic patients disproportionately drive underlying health risks and account for the majority of total healthcare costs. In a population of 8M+ commercial lives, polychronic patients represent 17% of the population and account for 48% of total health care costs (Table 1).

Table 1: Plan cost of members by number of chronic conditions

	Age Gender Adj� Allowed \$43�4 B	Chronic Conditions	% of Member Months	Age-gender Adjusted	
Member Months 100,830,917				% of Allowed	PMPY
		Exactly 0 Chronic Conditions	68.30%	29.50%	\$2,231.58
		Exactly 1 Chronic Conditions	14.70%	22.60%	\$7,977.98
		Exactly 2 Chronic Conditions	7.70%	15.50%	\$10,386.08
		Exactly 3 Chronic Conditions	4.90%	11.80%	\$12,412.74
		Exactly 4 Chronic Conditions	2.70%	8.80%	\$16,895.22
		5+ Chronic Conditions	1.80%	11.80%	\$34,446.50
		Totals:	100%	100%	\$5,168.27

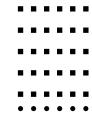
Chronic sleep impairment is highly prevalent in polychronic patients. Sleep disorders are often linked to systemic inflammation that can lead to chronic disease. In fact, OSA prevalence in comorbid chronic diseases ranges from 30% to 71% (Chart 1). Further, 80% of commercial plan members suffering from untreated OSA have two or more chronic conditions.

Chart 1: Rate of chronic condition comorbidities of OSA





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3. We identified sleep as a hidden but foundational gap in care that needs attention. There are two gaps to be closed: first, the gap in the diagnosis of sleep disorders, specifically OSA, and second, the issue of adherence to treatment among those who are diagnosed with OSA.

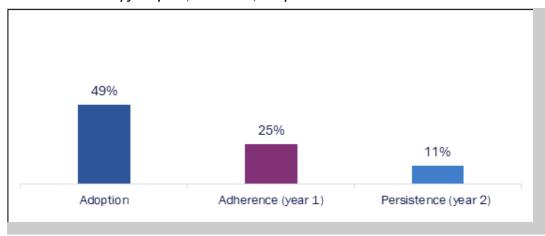
Gap 1: While the claims-based prevalence rate identified in our studies was 5.4% (Table 2), it is estimated that 15% or more of the US population may have OSA.1 This suggests that as many as two-thirds of OSA cases are undiagnosed and therefore untreated.² This creates a significant gap in care and a substantial opportunity for improved health and cost management for plan sponsors.

Table 2: OSA period prevalence

Ara	Ger	Total		
Age	Male	Female	Total	
<35	1.5%	0.9%	1.2%	
35-44	8.4%	3.7%	5.9%	
45-54	12.5%	6.5%	9.4%	
55-64	13.5%	8.3%	10.7%	
Total:	6.9%	4.0%	5≬4%	

Gap 2: Our analysis found that few who are diagnosed with OSA subsequently adopt CPAP therapy, adhere to therapy (defined as compliance at end of year one), and persist on therapy (defined as compliance with CPAP at the end of year two). While CPAP therapy improves health outcomes and is inexpensive, our research demonstrates that adoption and adherence are challenging. Only 49% of those tested for OSA adopt CPAP therapy. By the end of the first year, only 25% are adherent to therapy, and that drops to 11% of those who are persistent with using CPAP therapy (Chart 2).

Chart 2: CPAP therapy adoption, adherence, and persistence rates in traditional care model





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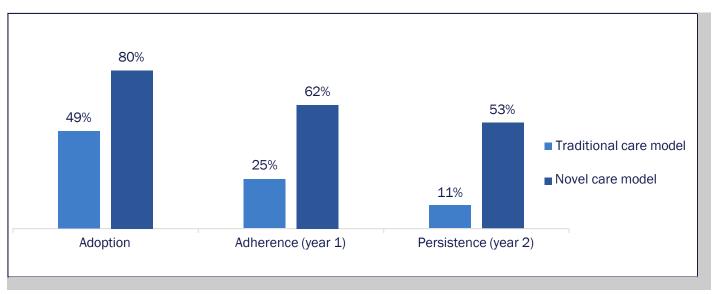
4. When patients adopt, adhere, and persist in CPAP therapy, total healthcare utilization declines, which is reflected in lower healthcare costs. In terms of cost savings, our research shows that on an age-, gender-, and risk-adjusted basis, the difference in total healthcare costs for members with OSA who adhere to therapy compared to those who are non-adherent is significant: \$2,743 per patient per year (PPPY) for each of the first two years of therapy (Table 3). Note that the \$2,700 represents an average member PPPY cost, including those with chronic medical conditions. These savings were determined using a doubly robust, propensity-weighting approach to control confounding related to member age, gender, geography, morbidity, and overall risk.

Table 3: Comparison of adherent vs non-adherent health plan members over a two-year period

ltem	Non- Adherent	Adherent	Savings
Year 1 clinical and sleep costs	\$17,082	\$14,547	\$2,535
Year 2 clinical and sleep costs	\$18,793	\$15,853	\$2,950
Total two-year clinical and sleep costs	\$35,875	\$30,390	\$5,485
Per treated patient per year	\$17,938	\$15,195	\$2,743

5. We sought out alternative approaches to sleep care management in the marketplace. Our research uses data from a commercial population of 8 million lives, managed through traditional sleep benefit approaches and a subset of data from a group of large plan sponsors who have employed a novel and comprehensive patient-centric, clinically integrated sleep care delivery model for more than four years. The care delivery model has been developed and implemented by Nox Health. We found demonstrable evidence that, by adopting a comprehensive sleep management program focused on member outcomes, employers were able to substantially increase the population diagnosed with OSA, as well as improve adoption, adherence, and persistence to CPAP therapy. This approach effectively narrowed the existing care gaps versus the traditional care model (Chart 3). This led to not only improved treatment outcomes, but to meaningful healthcare cost savings.

Chart 3: CPAP therapy adoption, adherence, and persistence rates in traditional care model vs. plan sponsors implementing novel sleep care model





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The FDA's recent approval of Zepbound, a GLP-1 with an indication for sleep apnea should be a wakeup call for plan sponsors seeking to manage rising costs while improving the health of populations suffering from chronic conditions.

While GLP-1 agonists have demonstrated effectiveness in achieving meaningful weight loss, which in turn improves OSA, one cannot equate significant improvement with curative results, as they are not suitable for monotherapy. In fact, their impact on sleep apnea is modest when compared to the gold standard, Continuous Positive Airway Pressure (CPAP). As our study shows, adoption, adherence and persistence to CPAP leads to near complete remission, and a \$2,700 annual reduction in the total cost of care. Comparatively, Prime Therapeutics found that GLP-1 compliance, is 15% at two years, and individuals without diabetes who newly started glucagonlike peptide-1 (GLP-1) agonist drugs for obesity experienced an average of \$6,994 higher total cost of care in their first year compared to like members not taking a GLP-1 drug for obesity, and a \$4,206 higher total cost of care in their second year. Proper diagnosis, treatment, and ongoing management of OSA are essential to avoid the increased total healthcare costs and utilization linked with untreated OSA.

Our study concluded that plan sponsors who are focused on improving the overall health of those suffering from chronic conditions should explore programs designed to improve adoption and adherence to sleep therapy. Such initiatives have demonstrated member health improvements but also decreased healthcare expenses. Historically, plan sponsors have focused on disease-specific solutions rather than focusing on polychronic patients as a cohort. Nevertheless, because OSA is frequently comorbid with many more costly diseases and conditions, the identification, treatment, and ongoing management of sleep disorders, particularly OSA, is central to a successful program.

Introduction

Our research shows that sleep is a hidden but foundational gap in care. Further, well-managed sleep therapy plays a pivotal role in improving the health of individuals suffering from chronic health conditions.

The duration and consistency of a good night's sleep is fundamental to physical and mental health. Sleep disorders, such as untreated obstructive sleep apnea (OSA), can be a primary contributor to chronic health conditions as they have been linked to inflammation.³ Inflammation, in turn, is linked to a variety of chronic health conditions, including, but not limited to, cardiovascular disease, type 2 diabetes, metabolic syndrome, and depression. 4.5.6 In fact, greater than 80% of people with OSA suffer from two or more chronic conditions.

The current fee-for-service [FFS] care paradigm for the diagnosis and management of OSA is broken. The core of the problem is rooted in the fragmentation of provider responsibility for diagnosing and treating sleep disorders, as well as a payor focus on unit costs rather than clinical outcomes.

When OSA is effectively managed, plan sponsors can:

- 1. Measurably improve the health of those suffering from chronic conditions.
- 2. Reduce patient consumption of healthcare services,
- Realize a significant reduction in total healthcare costs.





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Our study examined alternative care management models and concluded that the impact of an equitable, clinically integrated, and patient-centered sleep care management solution directly addresses the key problems in the current FFS care paradigm. Data from several large plan sponsors showed that there is a meaningful opportunity to not only increase the identification and accurate diagnosis of OSA, but also substantially improve adoption and adherence to sleep therapy, thus leading to measurable financial savings for plan sponsors.

Sleep and Chronic Condition Primer

Sleep Is as or More Important Than Diet and Exercise

Sleep is an essential human function and necessary for the proper functioning of all systems. Adequate and restful sleep is just as crucial to maintaining good health as a balanced diet and regular exercise. According to the National Sleep Foundation, it has been suggested that sleep health includes adequate:

- Sleep duration (seven to nine hours per night for adults).
- Sleep continuity (the ability to easily fall asleep and stay asleep),
- Sleep timing (which leads to feeling alert and refreshed during the day and satisfied with overall sleep quality)7



Those who do not achieve these sleep parameters are at elevated risk for health complications and worsening of co-morbidities.

Epidemiology of OSA

Obstructive sleep apnea (OSA), the most prevalent form of sleep-disordered breathing, is characterized by a narrowing or closure of the airway at the back of the throat, leading to frequent interruptions in breathing. Such interruptions often result in the patient waking up or undergoing brain arousal, leading to periodic declines in blood oxygen levels. This condition can also prompt the release of cortisol, a stress hormone, potentially causing surges in blood pressure, heart rate, and blood sugar levels while sleeping. In moderate cases, patients may wake up 15-30 times an hour, and in severe cases may wake more than 30 times per hour. The constant awakenings impede restorative sleep, placing chronic stress on the body. This stress can trigger inflammation, potentially leading to various health issues such as diabetes, stroke, depression, hypertension, compromised immune function, and even premature mortality. 8.9 Without proper diagnosis, treatment, and ongoing management, OSA is a serious, potentially life-threatening condition.

Given the inextricable link between untreated OSA and chronic disease, the economic costs associated with untreated OSA are substantial for both the individual and society as a whole.

It is estimated that, in the US, sleep disorder costs are ~\$130 billion per year, comparable to the cost of diabetes. The fact that as many as 70%-80% of those suffering with OSA go undiagnosed suggests the costs are even greater.

BURDEN OF IMPACT: Left unmanaged, OSA can have serious consequences not only for the patient but also for their employer, as the impact on worker performance:



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- Leads to excessive daytime sleepiness, impairing one's ability to focus, stay alert and perform functions that require close attention and memory.
- Affects behavioral health as well, resulting in increased stress and irritability, impacting work performance.

With a claims-based prevalence of 5.4%, OSA is present in workers across all industries. Not surprisingly, there is even higher prevalence amongst commercial transportation, workers who work night shift or do not have regular schedules¹⁰, e.g., construction, safety, healthcare workers, truck drivers¹¹, pilots, railway workers, as well as police¹² and fire fighters. 13 Untreated OSA is estimated to reduce life span by 8.7 years. 14 Treatment with CPAP potentially makes the difference between life and death for patients.

Diagnosis Requires a Comprehensive Sleep Study

While 80% of primary care physicians discuss exercise and healthy diet with patients on a regular basis, only 43% of primary care physicians say they spend time counseling patients about sleep. 15, 16



of adults report that their primary care provider never asks them about sleep, which is why as many as 70-80% of those suffering from OSA go undiagnosed.



The diagnosis of a sleep disorder is made by a board-certified sleep medicine specialist who may need to conduct a sleep study, either through polysomnography (PSG) in a sleep lab or a more limited home sleep apnea test (HSAT).

Polysomnography is the gold standard for diagnosing all forms of sleep-disordered breathing (SDB), including OSA¹⁷ Both studies utilize sensors to measure respiratory activity, airflow, and blood oxygen levels; however, only PSG includes the measurement of electrocardiogram (EKG), electroencephalogram (EEG), and electromyogram (EMG). Only PSG achieves a truly accurate assessment of a patient's brain and breathing activity during sleep.

While home sleep studies are substantially less expensive than in-lab studies, they can only confirm, not exclude, a diagnosis of OSA. When OSA is not confirmed, the test is deemed inconclusive. While best practice requires that an inconclusive home test be followed by an in-lab PSG, unfortunately, that is rarely the case.

Sleep medicine physicians determine the presence and severity of OSA using the Apnea-Hypopnea Index (AHI), which quantifies the number of times the patient stops breathing and/or airflow is blocked. Normal AHI is less than five events per hour, while severe AHI is more than 30 events per hour.

Individuals facing a higher risk for OSA include those with one or more chronic conditions, including obesity, hypertension, hyperlipidemia, congestive heart failure, atrial fibrillation, type 2 diabetes, and metabolic syndrome. Those experiencing symptoms such as loud snoring, gasping for air during sleep, daytime sleepiness, dry mouth, and/ or headaches are often candidates for testing for OSA.



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Treatment is Effective and Efficient, but May be Challenging Without Support

When OSA is moderate to severe, continuous positive airway pressure (CPAP) therapy is considered the first-line treatment and is the recommended evidence-based treatment by the American Academy of Sleep Medicine (AASM)¹⁸. Further, CPAP therapy is relatively inexpensive, with health outcomes that can be life-changing, including improvements not only in sleep but also mood, cognition, glycemic control, and blood pressure.

A CPAP machine uses an air tube connected to a full face or nasal mask to deliver constant and steady positive airway pressure, assisting patients in maintaining unobstructed breathing during sleep. As a result, the frequency and duration of respiratory-related sleep arousals are effectively managed down to zero.

However, CPAP therapy can be challenging for patients to adopt without proper instruction, training, and support. Adherence to CPAP therapy requires:

- The Correct Mask: A well-fitting mask is crucial, as ill-fitting masks can lead to leaks.
- Appropriate Air Pressure: The air pressure setting must be specific to each user.
- Patience: Adjusting to sleeping with a CPAP machine, for both the patient and their partner, may take time.
- Diligence: Regular cleaning of the mask, tube, and humidifier is essential.



OSA is one of very few chronic diseases for which it is possible to objectively measure treatment compliance, given that daily CPAP device use can be tracked via remote monitoring. When remote monitoring is employed, CPAP data can be reviewed daily on a secured platform, and clinicians can intervene to support patients whose duration or frequency of use is low, whose mask leak levels are high, or who do not see a reduction in OSA events.

OSA lends itself to a clinically integrated approach given the ability to employ telemedicine, remotely monitor patient compliance, and provide just-in-time support until members are adherent to treatment.

The Current Fee-for-Service Care Paradigm is Fragmented

The current fee-for-service [FFS] care paradigm unintentionally influences against the effectiveness of both OSA diagnosis and treatment and contributes to the significant gaps in care for those suffering from chronic conditions.



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The patient experience is fragmented, time-consuming, and unsupported.

Patients who suspect they may have OSA typically:

- 1. See their primary care physician or specialist for a referral to a sleep medicine specialist.
- 2. Get a comprehensive evaluation from the sleep specialist.
- 3. Take an in-lab or home sleep test.
- 4. Return to the specialist for a diagnosis of OSA (if appropriate) and receive a prescription for a CPAP machine.
- 5. Select a durable medical equipment (DME) vendor to acquire the CPAP machine.
- 6. Receive limited training on how to use the CPAP machine from the DME vendor.
- 7. Patients are then left on their own to navigate from this point, as neither the primary care provider nor the sleep medicine specialist are responsible for overseeing the ongoing management of their sleep therapy.

The patient experience is often further complicated, as most payors require that the patient get prior approval for BOTH the sleep test and the CPAP machine, while frequently mandating prior approvals for masks and supplies.

Overall, the lack of care coordination between the primary care provider, sleep medicine specialist, and the DME provider means that today, no single person is responsible for the patient's outcome. Specifically, the current care paradigm does not provide the support required to optimize patient adoption, adherence, and persistence to CPAP therapy. Without appropriate and continuous support throughout their sleep care journey, most patients will not adopt or become adherent to treatment, particularly over time.



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Sleep is a Foundational Hidden Gap in Care

The current care paradigm leads to two critical gaps in care:

1. Underdiagnosis of OSA

Approximately 80% of individuals with OSA remain undiagnosed. Closing this gap necessitates an emphasis on sleep testing and care management that abandons the current disjointed approach to care. This focus should be comparable to the emphasis placed on diet, exercise, and weight management.

2. Lack of adoption, adherence, and persistence to therapy

There is a low rate of therapy adoption among patients diagnosed with OSA and few patients who persist on therapy after the second year. Our research found that while about 5% of a commercially insured population is diagnosed with OSA, only 49% of diagnosed members adopted therapy, only 25% of those diagnosed remain on therapy at the end of Year 1, and only 11% are persistent with treatment at the end of year two.

Health Equity: OSA Disproportionately Affects Black, Minority, and Rural Americans

Considering that OSA frequently occurs with other chronic conditions, it disproportionately affects black, minority, and rural Americans who are more likely to suffer from them than their urban counterparts, largely as a result of social determinants of health, especially income, education, job security, food insecurity, housing, and access to affordable healthcare. 19, 20, 21, 22



Moreover, long travel times for individuals in rural areas or for those not having access to transportation in urban areas can negatively affect health outcomes. Not surprisingly, an analysis of the location of the nation's sleep study centers and sleep medicine providers relative to the location of the US population confirms that many Americans lack convenient access to a sleep medicine physician or testing facility within an hour of their location. In fact, the ratio of people to sleep specialists in the US is more than 43,000:1.23

Plan sponsors aiming to improve the overall health of individuals suffering from chronic conditions should explore programs aimed at improving identification, adoption, adherence, and persistence to sleep therapy. This approach addresses health inequities by broadly delivering treatment and supporting adherence and thus leads to better overall health outcomes and lower overall healthcare costs.



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Innovative Care Paradigm Overcomes Traditional Barriers

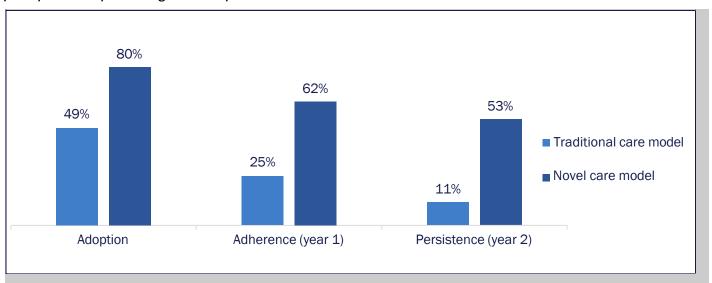
Given the gaps in OSA diagnosis, treatment adoption, adherence, and persistence, there is a clear opportunity to adopt a care delivery model that is more patient-centric, clinically integrated, and digitally innovative than the traditional FFS model.

We sought out alternative approaches to sleep care management in the marketplace. Our research uses data from a commercial population of 8 million lives, managed through traditional sleep benefit approaches and a subset of data from a group of large plan sponsors who have employed a novel and comprehensive patient-centric, clinically integrated sleep care delivery model for more than four years. The care delivery model has been developed and implemented by Nox Health. We found demonstrable evidence that, by adopting a comprehensive sleep management program focused on member outcomes, employers were able to substantially increase the population diagnosed with OSA, as well as improve adoption, adherence, and persistence to CPAP therapy. This led to not only improved treatment outcomes, but to meaningful healthcare cost savings.

In reviewing longitudinal data from the group of large plan sponsors (including but not limited to a large energy company, a large transportation company, a large fuel and travel centers company, and a mid-size municipal government), who employed the novel delivery model, we were able to confirm that:

- All experienced a significant increase in the percent of the population diagnosed with OSA, effectively closing the first gap in care.
- Experienced average levels of CPAP adoption of 80%, average adherence levels of 62%, and average persistence levels of 53% for those newly tested. This far exceeds the levels of adoption, adherence, and persistence in comparison to the data from more than 8mm lives using the current FFS care paradigm.

CPAP therapy adoption, adherence, and persistence rates in traditional care model vs. plan sponsors implementing novel sleep care model



All of these companies were able to overcome the barriers to diagnosis and successful treatment experienced in the current care paradigm via a patient-centric, clinically integrated paradigm. These employers pay only for members successfully managed to an outcome. There is no cost for a comprehensive sleep exam, sleep testing, or diagnosis.



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In this novel model, sleep medicine physicians, respiratory therapists, and behavioral specialists work as one clinically integrated team focused on driving patient outcomes. This model offers patients the ability to:

- Schedule appointments with sleep medicine specialists directly and receive a comprehensive sleep evaluation via telemedicine within 48 hours, anywhere in the US.
- Complete a comprehensive home sleep testing with EEG within 48 hours of their sleep medicine appointment, and have their results interpreted within 48 hours.
- Receive a CPAP machine and start training with their respiratory therapist via telemedicine within 48 hours.
- Receive support through the ability to call a behavioral specialist for assistance until midnight every evening. Member adherence is monitored nightly, and proactive support ensures members get the right mask, the right pressure, and the right start.

FDA APPROVAL OF GLP-1 WITH INDICATION FOR SLEEP APNEA PROVIDES WAKE UP CALL!

The FDA's recent approval of Zepbound, a GLP-1 medication indicated for the treatment of moderate to severe Obstructive Sleep Apnea (OSA) for adults with obesity, highlights an important consideration for plan sponsors striving to balance cost management with improved health outcomes for individuals with chronic conditions.

While GLP-1 agonists have been shown to support significant weight loss, which can contribute to improvements in OSA, they should not be viewed as a cure and should not be utilized as monotherapy in the treatment of OSA. Their effectiveness in addressing OSA remains limited compared to CPAP, the gold standard treatment. As discussed previously, our analysis indicates that consistent CPAP use results in near-total remission of OSA and an annual total healthcare cost reduction in the first two years of \$2,700 per patient per year. By comparison, research from Prime Therapeutics found that adherence to GLP-1 therapy drops to just 15% after two years. Additionally, individuals without diabetes who started GLP-1 medications for obesity faced an average increase of \$6,994 in total healthcare costs in the first year and \$4,206 in the second year compared to similar individuals not using these medications. Ensuring accurate diagnosis, effective treatment, and long-term management of OSA is crucial to preventing the increased healthcare costs and resource utilization associated with untreated OSA.

Conclusion

While polychronic patients account for a relatively small portion of an employer's population, they account for a disproportionate share of total plan cost. Successfully influencing both the short-term and long-term clinical and financial outcomes of a covered population requires correctly identifying and engaging polychronic members who comprise "rising risk." Central to this success is the identification and treatment of sleep disorders, particularly OSA. Sleep disorders represent a hidden but foundational gap in care essential to the treatment of polychronic patients. Good quality sleep is a key driver of better health, a safer and more productive workforce, and substantial total healthcare cost savings for both individuals and employers. We must manage these chronic conditions by ensuring that evidence-based sleep care is a highly accessible and well-managed treatment. Nonetheless, the current FFS model exhibits notable deficiencies in diagnosing and managing patients with OSA.

The best solution to addressing the current care gaps is a program with a patient-centric and clinically integrated approach that has been demonstrated to be successful in improving health outcomes and reducing cost over time. By improving the way sleep disorders are diagnosed and managed, we can improve quality of life and increase life expectancy for the many people who suffer from these disorders.



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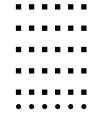
ADDITIONAL REFERENCES RELATED TO UPDATE:

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In the Fight Against Chronic Disease, Sleep is the Hidden Gap in Care



About this study.

This white paper is focused solely on the issue of sleep, and specifically on sleep apnea, one of the most prevalent and dangerous sleep disorders.

We performed a detailed analysis of OSA and specifically sought to understand the connection between sleep and chronic disease, focusing on the polychronic population. The study examines the prevalence of OSA within the claims data examined, the rates of member adoption, adherence, and persistence to sleep therapy, the impact of adherence to therapy on member utilization of healthcare resources, and the cost savings associated with adherence to treatment.

Unless otherwise noted, results pertain to representative employer data comprising members with continuous eligibility over a three-year study period. The health plan cohort used in this study included over 8M members.

At the heart of the analysis is a set of doubly robust, propensity-weighted causal studies measuring the clinical cost savings (sleep-specific as well as total cost of care) associated with adherence to treatment. Indeed, all numbers are presented, at a minimum, on an age and gender-adjusted basis.

Get to know us.

Risk Strategies Consulting is focused on assessing, managing, and abating clinical and financial risks for our clients. We continuously mine our large claims database to expose unseen key issues and extract actionable insights.

Risk Strategies Consulting is comprised of experienced consultants, actuaries, data scientists, auditors, pharmacists, accountants, and other experts able to help payers, providers, and plan sponsors clearly understand the risks of their business and ways to minimize and manage them. As a national consulting and actuarial services business, Risk Strategies Consulting provides high-touch consulting and state-of-the-art analytics services including strategy and consulting (encompassing health and welfare with deep pharmacy expertise, as well as mergers and acquisitions); actuarial services for plan sponsors, providers, and insurers; and benefit and claim audit services. Services are provided for a wide variety of industry segments including government entities, manufacturing and distribution, and self-funded organizations including corporations and trusts, healthcare organizations, national and regional insurance companies, and private equity firms, among others.

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