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WHITE PAPER

Estimating the economic impact of a digital therapeutic in type 2 diabetes

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Key points

- Cost of diabetes up 26% since 2012 to $327 billion in 2017[1]
- Digital therapeutics may offer promise, alongside drugs and treatment pathways, to improve patient self-engagement, adherence to therapy and outcomes
- BlueStar, WellDoc's FDA-cleared digital therapeutic for type 2 diabetes,[2] has demonstrated measured reduction in A1C values[3-5]
- Reduction in A1C values, achieved through digital therapeutic engagement, can be associated with claims and cost utilization data to estimate potential cost savings
- This paper reviews our conclusion that savings are greatest for patients with higher initial A1C values and larger drops in A1C values

Executive summary

People in the US with type 2 diabetes comprise nearly a tenth of the total population; diabetes care presents a multi-billion-dollar financial burden and is rapidly growing in size and cost.[6] Despite advances in pharmaceutical therapeutics and glucose-sensing technologies, many patients' glucose levels—both averages and standard deviations or excursions—remain uncontrolled, putting them at a higher risk for complications and higher treatment costs.[7] One pathway to improved clinical and economic outcomes is evidence-based, frequent and informed patient self-management.

BlueStar®, a digital therapeutic developed by WellDoc, has assisted patients and providers in improving glucose control by using real-time data and feedback to support healthy behaviors, such as medication adherence, diet and exercise control and psycho-social wellness.[2] BlueStar has demonstrated the capacity to shift HbA1C (A1C) levels in populations with diabetes.[3-5] But, the current literature lacks established methods for translating reductions in A1C into cost savings. Quantifying these cost savings has historically been difficult due to the chaotic nature of real-world data, and any reduction in A1C level is often regarded as simply a "savings."

This paper introduces a novel method to estimate the economic impact of a reduction in A1C by utilizing a large, administrative claims database for a real-world segment of type 2 diabetes patients. The documented A1C reductions achieved through engagement with BlueStar are fractionalized and correlated with fractional cost differences associated with acute utilization, cost of supplies and pharmacy, and the cost of co-morbid complications. A key finding is that the cost reductions associated with reduction in A1C are a function of both the delta in

Burden of diabetes

- Approximately 1 in 10 Americans has diabetes[6]
  - 90% of these are classified as type 2 (acquired insulin resistance)
  - For every 1 diagnosed, as many as 3 remain undiagnosed
- The CDC predicts 1 out of every 3 people born in the US after the year 2000 will develop diabetes[8]
- Diabetes is the 7th leading cause of death in the US[9]
  - Poorly controlled patients are at increased risk of vascular complications such as heart attack, kidney failure, blindness, amputation and stroke
- The annual cost of diabetes in the US was $327 billion in 2017[1]
- Costs have increased 26% since 2012[1]
  - Reduced workplace productivity and absenteeism account for roughly $30 billion per year
  - Average medical expenditures among diagnosed patients are 2.3x higher than for those without a diabetes diagnosis

A1C achieved as well as the starting A1C value. This analysis supports the assessment that tools such as BlueStar that facilitate A1C reduction have near-term cost savings, and can drive improvement to quality measures such as STARS ratings in Medicare populations and Healthcare Data and Information Set (HEDIS®) scores in commercial populations.

Introduction

Diabetes is a major disease in the US; with over 23 million diagnosed diabetes patients in the country, this population is growing rapidly. Patients often present with not just diabetes, but with significant comorbid conditions such as hypertension and hyperlipidemia.[6] Treatment can involve a costly range of primary care providers, specialists and supporting clinicians such as physician assistants, certified diabetes educators, care coordinators and so on. Notably missing from this equation is the importance of the patient themselves and greater involvement in informed self-care.

The American Diabetes Association recommends that adults with diabetes achieve control in three key health measures: 1) A1C less than 7%, 2) a blood pressure of less than 130/80 mmHg and 3) LDL cholesterol less than 100 mg/dL, collectively known as "ABC."[10] Yet, achievement of this level of control is at suboptimal levels: 52.3% of patients meet hemoglobin A1C guidelines, but only 18.8% achieve all of the "ABC" guidelines.[11] Healthcare providers can be pressed for time during office visits,[12] and communication on how to optimize diabetes care may be limited. Overcoming these issues can require a paradigm shift in treatment philosophy, where episodic encounters between patients and their healthcare providers are augmented by automated, real-time patient intervention and clinically-validated feedback and adjustments to therapy pathways for type 2 patients.

Not all drops in A1C are economically equivalent

Smartphones and tablets provide a 24x7 platform for delivering real-time education and coaching to guide type 2 patients in the self-management of their disease. The analyzed, patient-generated data and insights that result from these platforms may also be shared with the care team to inform better or more optimal treatment decisions or pathways.

Problem definition

Historically, cost-savings estimates associated with a reduction in A1C have been computed by pooling patients' retrospective financial data and producing per person, per month (PPPM) appraisals for patients with diabetes as a whole.[13] Even those studies that attempted to stratify this population did so by assigning patients to one of two groups: controlled (those with A1C<7%) and uncontrolled (those with A1C≥7%).[14] This practice does not take into consideration the differences in costs incurred between smaller subgroups of patients, and does not present an accurate estimation of savings from all starting levels of A1C. It is well established that decreased A1C levels are correlated with reduced risks of stroke, heart attack and early death.[15] However, the cost savings associated with these reductions are often unspecific and do not apply evenly to all patients. In other words, not all drops in A1C are economically equivalent.

To provide a more accurate estimation of cost-savings associated with A1C reduction, accurate patient-level lab data must first be captured from a diverse and representative segment. In the real world, this collection presents a significant problem. A large portion of patients with diabetes do not utilize testing services on the recommended timetable, with up to 49% of patients not meeting guidelines for A1C testing every 3 - 4 months;[20] patients who are not consistently tested and assessed by healthcare professionals are more likely to have an A1C above recommended levels.[16]

Blood glucose

- Levels vary throughout the day, increasing after ingestion of carbohydrates or decreasing after exercise, and are measured in milligrams per deciliter (mg/dL) using a simple fingerstick test.[17]
- Those without diabetes typically have a blood glucose range of 70 - 130 mg/dL throughout the day without any medications, while that for those with diabetes ranges from 80 - 180 mg/dL with medications.[18] These ranges must be monitored carefully, against recommended secondary target ranges that are based on parameters related to meals, exercise, sleep and medications.

A patient's A1C values are hypothesized to fall into different strata or "bands" over the course of their treatment in the same calendar year.[17,18] These values are often variable and can vary significantly even within the same year of measurement due to a plethora of reasons that relate to genomics, patient medication adherence behavior, activity and diet management, stress levels and so on.

Methodology

Our hypothesis was that the cost savings associated with decreased A1C levels would be a function of both the delta in A1C achieved as well as the starting point in A1C. The higher the starting point and the higher the drop, the larger the economic savings potential. WellDoc contributed starting and ending A1C data from over 3,000 patients in the real world. WellDoc was able to create a fractional delta A1C matrix, which characterized the percentage of patients in 1) each of the four bands: in control (6.0% - 6.99%), elevated (7.0% - 7.99%), high (8.0% - 8.99%), and not controlled (≥9%) and 2) the percentage of patients within each band who experienced no drops in A1C, or a drop in A1C in 0.5 increments (from 0.0% - 0.49%, 0.5% - 0.99%, 1.0% - 1.49%, 1.5% - 1.99%, ≥2.0% and so on).

Similarly, Truven Health Analytics®, now part of IBM® Watson Health™, provided data from its MarketScan® Commercial Claims and Encounters Database and the MarketScan® Medicare Supplemental and Coordination of Benefits. These databases capture administrative inpatient, outpatient, and prescription drug data for more than 80 million individuals. Claims are gathered from approximately 150 large employers and health plans across the United States and provide detailed diagnostic, cost and outcomes information from fully-adjudicated claims.

Hemoglobin A1C test

- The glucose concentration in a red blood cell is the same as the glucose concentration in the bloodstream; the amount of attachment of glucose to hemoglobin in the red blood cell is measured to give an indication of the blood glucose levels over the past 90 days and is reported as a percentage[19]
- The A1C test is used to diagnose and monitor diabetes at regular intervals during a patient's care path and is typically assessed up to four times a year for patients with diabetes[15]
- People without diabetes typically have an A1C value of ≤5.7%, while people whose diabetes is poorly managed can often have values ≥9.0%[18]
- Every percentage point rise in A1C above the target of 7% can lead to an increase in the risk of macro and micro vascular complications[20]

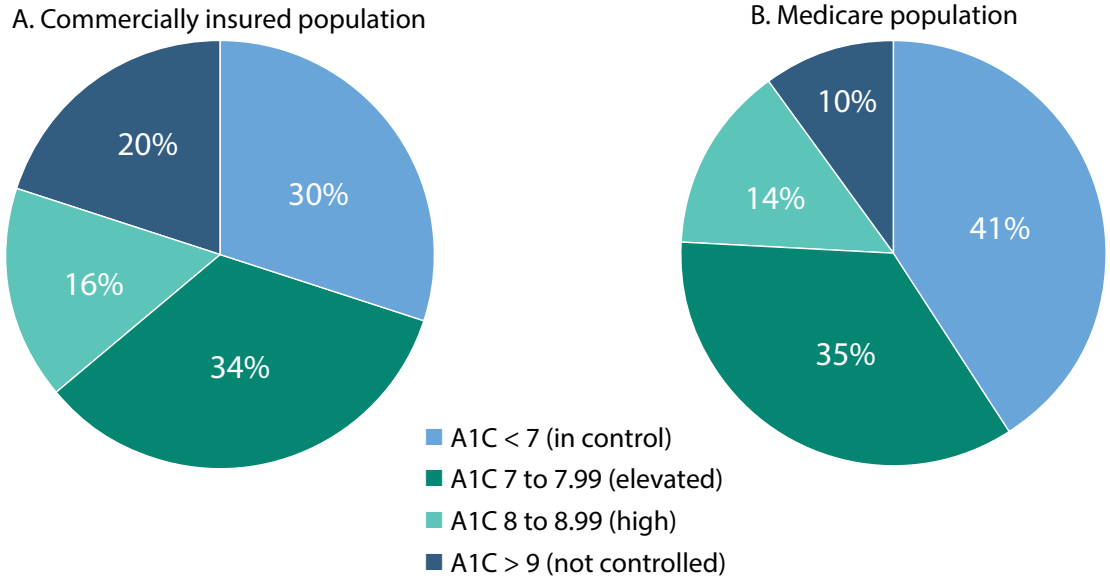
Data from patients aged 40 and older with diabetes was captured from the databases, using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), and Tenth Revision (ICD-10-CM) diagnosis codes. The patient population was narrowed to include only those patients with at least four A1C tests in a one-year period, from January 2014 to December 2015. Results of A1C tests were tabulated, and stratifications for A1C value range were established in the same bands as specified above to match the "fractions" and increments that WellDoc provided in its delta A1C matrix. Patients were then stratified on stable versus variable, and if the patients were enrolled in a commercial versus Medicare insurance plan. Stable is defined as all four readings in the same year falling into the same A1C band, and variable is defined as having at least two, but less than four, readings in the same band. From these segments, total healthcare costs were summarized, and average costs per year by A1C range were analyzed.

Up to 70% of patients with diabetes represent the “market opportunity” for cost savings

Current patient populations

Thirty percent of commercial sector patients with diabetes who had at least four A1C tests in a year displayed an “in control” result; this highlights the 70% majority of patients who are uncontrolled and who represent the “market opportunity” for cost savings (Figure 1A). In contrast, 41% of Medicare patients tested were labeled as in control, surpassing control levels in the commercial sector (Figure 1b). Elevated and high-range patients were present at similar levels in both Medicare and commercial sectors (34% versus 35%, and 14% versus 16%), however the proportion of patients with diabetes in the highest result band (≥9, “not controlled”) is doubled in the commercial sector when compared with that in the Medicare segment. This finding implies that commercially insured patients with diabetes have poorer control than their Medicare counterparts.

Figure 1: Starting A1C readings



Patients with diabetes were shown to have average annual healthcare costs ranging from $10,601 to $19,980

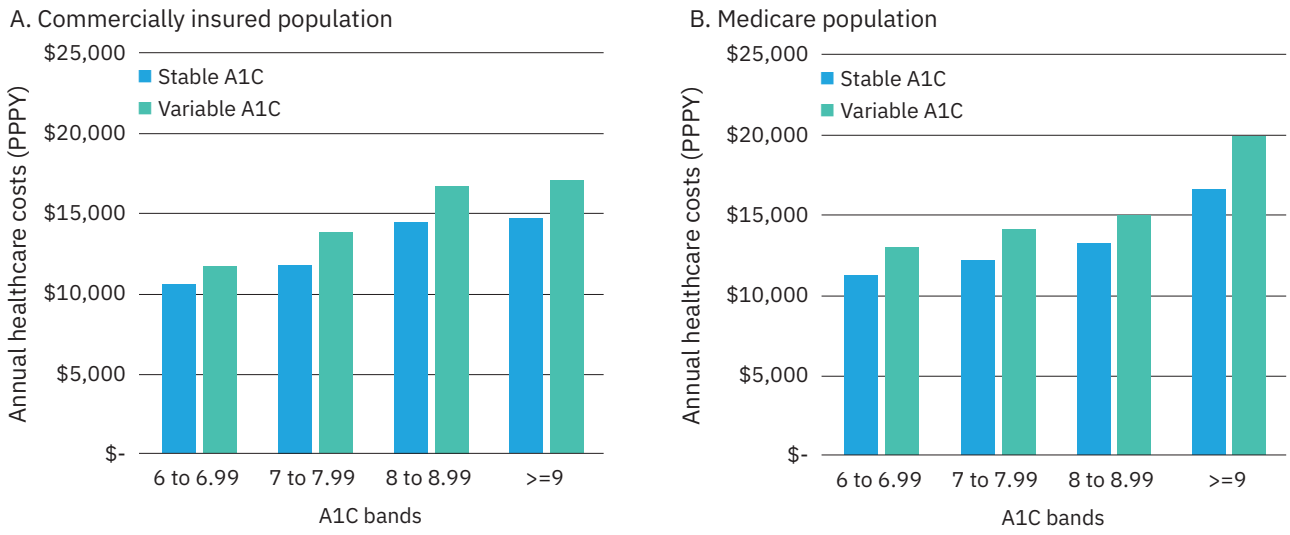
Current annual costs

Patients with diabetes captured in our analysis had average annual healthcare costs ranging from $10,601 to $19,980, per patient (Figure 2A and 2B). Total healthcare costs were lowest for the elevated A1C patients (A1C 7% - 7.99%) and progressively rose as A1C ranges increased. The trends for Medicare segment costs were similar to those in the commercial segment in the majority of A1C bands, though slightly lower in the band with high A1C values (A1C 8% - 8.99%).

Estimated cost savings

Stratifying the aforementioned costs by A1C band allow us to create a cost delta matrix, where we summarize the cost savings associated with shifts in A1C for different A1C starting points. This matrix was designed to match the groups of the delta A1C matrix provided by WellDoc and generated from internally collected, aggregated data from real patient experiences with BlueStar. Combining the two matrices allows us to estimate the savings associated with utilizing BlueStar. Table 1 summarizes the annual estimated savings for three A1C bands. The highest cost savings are correlated with both the highest starting A1C as well as the largest drops in A1C achieved. Therefore, there is a disproportionate cost savings value proposition for patients whose diabetes is more out-of-control.

Figure 2: Estimated per person per year (PPPY) healthcare costs



The highest potential cost savings are correlated with both the highest starting A1C as well as the largest drops in A1C achieved

Adding BlueStar to patients' care

The savings impact model below uses a representative population of commercially and Medicare insured patients who could utilize the BlueStar application to estimate the potential cost savings projected over one year of use of BlueStar, stratified by starting A1C level.

In this model, all patients, regardless of starting disease severity or blood glucose stability, demonstrate a reduction of total healthcare costs after the inclusion of BlueStar therapy in their care pathway. We project that patients with elevated blood glucose levels (A1C 7% - 7.99%) may incur fewer savings than those whose blood glucose levels are not controlled (A1C ≥9%); however, there were projected cost benefits to all groups.

Table 1: Estimated annual cost savings by starting A1C bands

Segment by starting A1C bands	Commercial sector estimated cost savings	Medicare sector estimated cost savings
	(Per patient, annually)	(Per patient, annually)
For all bands with A1C ≥ 7% 7% to 7.99%; 8% to 8.99%; ≥9%	$1,824	$1,392
For all bands with A1C ≥8% 8% to 8.99%; ≥ 9%	$3,252	$3,048
For A1C ≥ 9%	$5,244	$3,672

Summary

The market opportunity to reduce the total cost of diabetes in the US is significant, particularly to help those patients whose diabetes remains uncontrolled (A1C >7%) and costly, even while under physician care. Our model shows that the opportunity yielding the highest cost savings is to deploy BlueStar among those patients whose A1C is above 8%. A secondary opportunity exists to deploy BlueStar among patients whose A1C levels are between 7% and 8%. The former is an opportunity to realize near-term cost savings while the latter is an opportunity to avoid longer-term cost increases associated with rising A1C over time.

Future analysis and work

In this paper, we addressed an important question related to the integration of digital therapeutics into mainstream healthcare delivery: How can we quantify and estimate the economic value that digital therapeutics create? As we've seen, cost savings are a part of that economic value. But, in addition to addressing decreases in the number of patients with uncontrolled diabetes, digital therapeutics also can increase the payment equation for health payers. Programs such as STARS in Medicare or quality measures such as HEDIS can enable payers and providers to boost revenues by incentivizing more effective diabetes care.

While economics will change on a plan-by-plan or payer-by-payer basis, the ability of digital therapeutics to increase revenue sources should be further investigated. These topics will be the subjects of future analysis and work with BlueStar and other digital therapeutics.

About BlueStar, Powered by WellDoc

BlueStar provides individualized guidance for people with diabetes using technology that is founded on evidence-based guidelines in clinical diabetes management, behavioral science, and user experience. As an in-app digital diabetes coach, BlueStar allows patients to enter different kinds of data – including glucose levels, blood pressure, weight, medications, food, activity and symptoms – and receive educational, behavioral, and motivational messages specific to the entered data[3].

Digital therapeutics leverage the breakthroughs and progression in technology to supplement traditional medical therapy for chronic diseases, particularly, those that benefit from more continuous patient engagement[21]. Several modalities for interaction between the digital therapeutic and the patient exist, with most focused on behavior modification that include the ability to self-report disease symptoms. Digital therapeutics are distinct from wellness technologies; the former are grounded in clinical evidence and regulatory by the health and regulatory authorities, the latter need only pass download requirements for a mobile application[22].

As an FDA 510K-cleared digital therapeutic, BlueStar is designed to coach adults with type 2 diabetes to self-manage their condition and enhances patient-provider-payer communication[2]. The therapeutic is comprised of three elements: (1) an app available to patients on their mobile internet device or browser; (2) clinical decision support for providers through a detailed report that summarizes patient progress, key areas in need of attention, and recommended clinical actions that are backed by evidence-based guidelines; and (3) a population management portal that allows for the administration and management of a population program.

BlueStar has been the subject of several randomized control clinical trials and real-world studies and has published peer-reviewed data to validate its ability to materially lower A1C3-5. One of these, the Mobile Diabetes Intervention Study was a cluster-randomized control trial to establish the effects of a mobile diabetes management system for type 2 diabetes patients over a one-year period[4]. This study was novel; few previous related studies included a control group and others had shorter follow up periods of intervention and observation. The intervention was a patient coaching system and provider data. The findings showed a 1.9-point reduction in the intervention group, compared with a 0.7 point drop in A1C in the non-intervention group ($p<0.001$), emphasizing the benefit of using the digital therapeutic.

The outcomes achieved by BlueStar are driven by its proprietary, patented algorithms and uniquely provide real-time as well as longitudinal, individualized coaching to assist patients manage the full spectrum of their key diabetes parameters[23]. BlueStar also provides insights from correlations between glucose and activity, medication, and food; these A1C-driven correlative insight functions are not available in many, if not all, digital health solutions in diabetes. Few other industry solutions offer peer-reviewed, published outcomes and evidence that their solutions deliver value across different patient populations. This observation was noted independently by both JAMA and Nature Magazine in 2015, where BlueStar was specifically highlighted as the leading, differentiated solution in a “sorting the wheat from the chaff” analysis[24,25].

Research cited on this page provided by WellDoc

BlueStar is the **only one of two products for type 2 diabetes** in the United States that meets the newly formed Digital Therapeutics Alliance[26] definition of a digital therapeutic:

"Clinically validated, regulatory-cleared, cyber-secure and clinically-integrable software as a medical device (SaMD) applications which demonstrate safety and efficacy in multiple randomized clinical trials conducted by independent third parties. DTx solutions may be used as standalone interventions or in association with other treatments to engage patients and improve the overall quality, cohesion, outcomes, and value of healthcare delivery."

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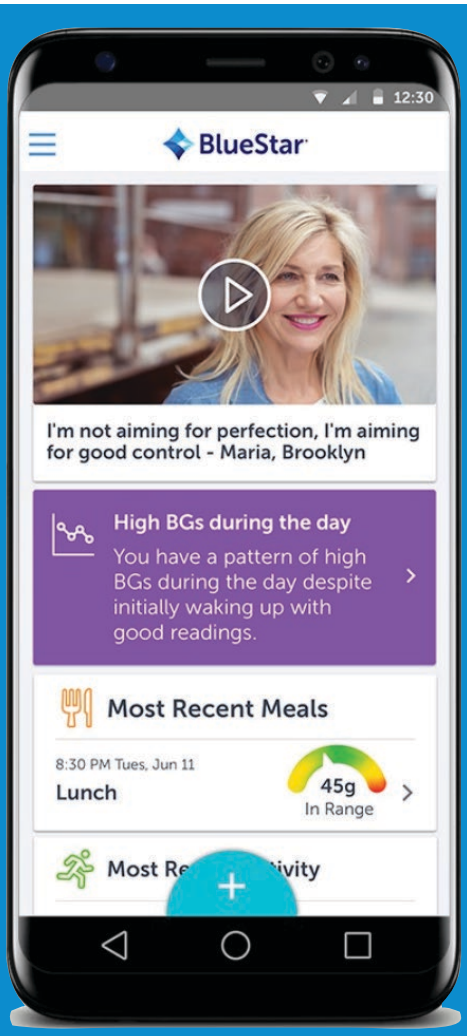

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