Digital Diabetes Management Solutions

HEALTH TECHNOLOGY ASSESSMENT | MARCH 2024 | V1.1

About This Report

The Peterson Health Technology Institute (PHTI) provides independent evaluations of innovative healthcare technologies to improve health and lower costs. Through its rigorous, evidence-based research, PHTI analyzes the clinical benefits and economic impact of digital health solutions, as well as their effects on health equity, privacy, and security.

These evaluations inform decisions for providers, patients, health plans, and investors, accelerating the adoption of high-value technology in healthcare. PHTI was founded in 2023 by the Peterson Center on Healthcare. PHTI assessments evaluate evidence on the clinical and economic impact of these technologies using an ICER-PHTI Assessment Framework for Digital Health Technologies that was designed by a team of experts specifically for digital health products and solutions. This is a secondary research review that relies on published literature and information. PHTI did not conduct original testing of the products.

PHTI selects assessment topics based on the:

- Burden of disease to the healthcare system;

- Investment and innovation in the digital health technology;

- Body of evidence about the effectiveness of the technology; and

- Stakeholder interest (purchasers, providers, and patients)

All companies included in this report were notified and given an opportunity to submit clinical, commercial, and/or economic data, which were included when determined to be relevant to the evaluation.

The findings contained within this report are current as of the date of publication. Readers should be aware that new evidence may emerge following the publication of this report that could influence the results. Digital diabetes management solutions are likely to evolve over time, which may impact their performance. PHTI may revisit its analyses in updates to this report in the future.

The economic models used in this report are intended to compare clinical outcomes and expected costs at the population level. Model results represent average findings and should not be presumed to represent cost or outcomes for any specific patient or payer.

The Peterson Health Technology Institute

focuses on health technologies designed to replace or augment traditional care delivery, including digital therapeutics, chronic care management apps, and remote patient monitoring technologies.

The findings and recommendations represent the opinions of PHTI based on the information considered in this assessment.

Version 1.1 was posted on April 19, 2024.
It includes updated 2021-22 company-provided pricing data for Virta.

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Letter From the Executive Director

The Peterson Health Technology Institute (PHTI) was established in July 2023 with a steadfast commitment to advancing innovative technologies that improve health and lower costs. At the heart of our mission lies the recognition that the United States spends too much on healthcare and gets too little in return.

Technology is a critical tool capable of improving healthcare system efficiency and performance. Yet too often, health technology drives added cost and complexity without clear benefits to health outcomes or health equity. PHTI addresses these challenges by providing independent evaluations of digital technologies to help inform decision-making about digital health product development and adoption.

Our first evaluation focuses on some of the earliest digital health solutions: those that support diabetes management. Diabetes is a persistent, growing, and expensive condition that disproportionately affects diverse and underserved populations.[1] Diabetes places a tremendous burden on patients and families to monitor blood glucose and make diet and lifestyle changes to support better outcomes. In this context, the timely innovation in technology solutions aimed to augment diabetes care holds promise — but all new technologies must also be met with scrutiny.

People living with diabetes deserve good medical advice, support, and compassion. They also deserve to know that if they invest time, energy, and money to engage with a digital health solution, that it will improve their health. And the providers of diabetes care should have clarity about the performance of these digital solutions. Payers, including health plans and employers, also deserve to know how these solutions impact the health of their members and employees and be able to determine whether the clinical benefits justify the added cost.

Central to our approach is the recognition that reported estimates of cost savings must be interpreted judiciously and thoroughly. Increasing value lies in tangible improvements in patient outcomes, including glycemic control, reduced prescription use, fewer hospital visits, and improved affordability. Through this report, we aim to help the sector define and evaluate what clinically effective solutions look like, including what additional evidence gaps warrant further research. Ongoing improvement and technological innovation depend on a comprehensive understanding of what works.

As we seek to raise the bar for digital health technologies, I extend my gratitude to our partners and advisors who contributed to this report, and the many stakeholders who support the mission of PHTI. Together, we can and must harness the transformative power of technology to improve the care people across the United States receive today.

Sincerely,

Caroline Pearson, Executive Director
Peterson Health Technology Institute

Report Contributors and Reviewers

PHTI partners with a diverse set of contributors, advisors, and stakeholders throughout the assessment process. See our website for a full list of partners and advisors.

Independent Evaluation Partners

PHTI worked with the following independent evaluation partners.[a]

- Curta assessed the clinical and economic impact of these technologies using the published Assessment Framework, including the systematic literature review and budget impact assessment.

- Charm Economics developed insight into how different technologies work, what they cost to deliver, and their impact on patients and purchasers.

- The Institute for Clinical and Economic Review (ICER) co-developed the ICER-PHTI Assessment Framework for Digital Health Technologies, and was consulted to review its implementation in this report.

Report contributors and reviewers provided important expertise and insight throughout our process. PHTI is solely responsible for the report and its findings.

Clinical Advisors

The following clinical experts in diabetes management and digital health solutions provided insight on the clinical sections of the report.

- Ami Bhatt, MD
  Chief Innovation Officer of American College of Cardiology

  No relevant conflicts of interest to disclose.

- Richard Milani, MD
  Chief Clinical Innovation Officer, Sutter Health; Former Innovation lead at Oschner

  No relevant conflicts of interest to disclose.

- Karen Rheuban, MD
  Co-founder and Director of the University of Virginia Center for Telehealth

  No relevant conflicts of interest to disclose.

Patient Perspectives

PHTI conducted focus groups and interviews with people living with type 2 diabetes who had experience with digital glucose tracking tools. Feedback from these sessions was incorporated into the report.

Company Submissions

PHTI engaged all companies included in the report, providing an opportunity to meet, share data, and understand our methodology and approach. PHTI did not conduct any primary analysis on patient data. PHTI applied the same standards for minimum evidence requirements and risk of bias reviews to company-submitted information as all other studies included in the report. Companies did not influence the assessment methods or findings.

Other Partners

Manatt Health provided consulting, research, and operational support throughout the development of the report.

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[a] Evaluation partners have no conflicts of interest to disclose.

The Case for Innovation

Type 2 diabetes is a widespread and increasingly common condition. Most people develop type 2 diabetes after the age of 45; however, more and more Americans are developing the condition at younger ages.[2] Over the past decade, diabetes prevalence has risen dramatically — from 10.3% in 2001–2004 to 13.2% in 2017–2020[3] — and is projected to accelerate in the decade to come.[4] The consequences of inadequate diabetes management are so profound that innovation in diabetes care remains a national and global priority.[5,6]

Achieving glycemic control in people with type 2 diabetes is important. People who live with diabetes have a much higher likelihood of suffering from eye, kidney, nerve, immune, vascular, and heart damage caused by excess sugar circulating in their blood.[7,8,9] As blood glucose levels rise, people require more medical care, which reduces their quality and length of life and increases overall healthcare spending.[10,11,12] Conversely, if people with type 2 diabetes are supported in regulating their blood sugar, they suffer fewer health consequences.[13]

Diabetes self-management is complex and demanding on patients. Leading organizations, such as the American Diabetes Association (ADA), have clinical guidelines that define the standard of care ("standard care").[14] However, real-world practice ("usual care") almost always lags behind guidelines and reflects variations in knowledge, resources, and practice patterns across care settings. Current treatment recommendations require significant coordination between physicians and patients, as well as patient self-management, to monitor blood glucose levels, calibrate medication levels, and manage diet and exercise.[15]

Technology has the potential to support patients' self-management. Over the past 10–15 years, a range of digital technologies have come to market that aim to support both patients and providers between doctor's visits. Many are built on a foundation of noncontinuous glucose monitoring integrated with digital applications that can be accessed on patients' mobile devices or desktop computers. These solutions integrate varying levels of clinical, behavioral, and/or diet-related coaching and education via synchronous, asynchronous, and AI-enabled communication.

Purchasers want meaningful results for patients. Purchasers (i.e., health plans, self-insured employers, and providers) have responded by widely adopting these solutions because, if they work well, people live healthier, longer lives and require less costly medical care. However, purchasers would benefit from deeper analysis of clinical and economic impact and clear information on performance expectations.

Digital diabetes management solutions should deliver meaningful benefits to patients. Effective digital diabetes management solutions should demonstrate clear, substantial and durable progress toward glycemic control in people with type 2 diabetes, resulting in a lower prevalence of uncontrolled type 2 diabetes across the population. This would result in important reductions in diabetes-related health risks, fewer prescriptions, fewer healthcare events, and lower healthcare spending. Digital solutions should also target patients with severe disease and diverse groups who would benefit most from improved self- management support. Ideally, these solutions would help achieve diabetes remission.[16]

This report reviews the performance of digital diabetes management solutions as a category, and eight widely-used solutions more specifically. It incorporates scientific evidence, company data, and budget modeling to answer three fundamental questions: **How well do they work? For whom do they work? And are they worth it?**

DIGITAL DIABETES MANAGEMENT SOLUTIONS EXPLORED IN THIS REPORT

DarioHealth   Glooko   Omada   Perry Health   Teladoc (Livongo)   Verily (Onduo)   Vida   Virta

Summary of Findings

Digital diabetes management solutions in the remote patient monitoring and behavior and lifestyle modification categories do not deliver meaningful clinical benefits, and they increase healthcare spending relative to usual care. Nutritional ketosis solutions hold promise for diabetes remission.

Based on PHTI's review of clinical evidence, digital diabetes management solutions consistently demonstrate that they help patients achieve small reductions in HbA1c beyond what they would achieve with usual care, but the evidence rarely reported improvement that exceeded commonly-used thresholds for meaningful clinical benefit. Further, evidence suggests that such small benefit will reduce over time. After accounting for the average price of these products, these solutions increase net healthcare spending for purchasers because the small, estimated savings are less than the cost of the solution.

Exceptions may include:

- People with higher starting HbA1c who are newly starting insulin; and

- People seeking diabetes remission through nutritional ketosis.

These findings are based on the criteria set forth in the Assessment Framework and the currently available evidence.

There are three main ways that digital diabetes management solutions engage patients and providers:[b]

- **Remote patient monitoring** — Enable physicians to support patient monitoring of blood glucose between visits.

- **Behavior and lifestyle modification** — Engage patients with a mix of behavioral, clinical, and lifestyle modification programs in addition to glycemic feedback.

- **Nutritional ketosis** — Induce a state of ketosis in patients through intensive dietary guidance with the goal of diabetes remission.

Results for remote patient monitoring and behavior and lifestyle modification solutions:

- Deliver small incremental benefits (0.23–0.60% point reduction [% pt] in HbA1c) when compared to usual care.

- Have potential for stronger clinical benefits in populations with higher starting HbA1c levels who are newly starting insulin.

- Increase total health spending over 1–3 years because the cost of the solution exceeds the savings from improved clinical outcomes.

- If 25% of eligible users participated, **remote patient monitoring** solutions would increase Year 1 spending by $21.3 million per million commercially-insured lives; **behavior and lifestyle modification** would increase spending by $5.1 million per million enrollees in Year 1.

Results for nutritional ketosis solutions:

- Are more likely than other digital diabetes management solutions to achieve clinically meaningful benefits in glycemic control, including remission in patients who can maintain the rigorous requirements of therapy.

- Produce superior results in secondary health and durability effects among patients who were able to complete the intervention.

In terms of **health equity and access,** the studies reviewed do not show compelling evidence that these solutions are preferentially addressing health disparities. Further, only 29% of studies reporting on HbA1c included participants with levels above 9%, suggesting that solutions are being tested in less complex patient populations, rather than among individuals who are at highest risk for diabetes-related complications. Therefore, published results should be reviewed carefully before generalizing across populations.

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[b] This evaluation is conducted at the category level. Based on the similarity of approaches and the consistency of clinical outcomes, it is likely that individual solutions perform in line with the category.

Exhibit 1

SUMMARY OF PHTI EVALUATION OF DIGITAL DIABETES MANAGEMENT SOLUTIONS

WHAT IS THE GOAL OF THE TECHNOLOGY?

Improved glycemic control for adults with type 2 diabetes, achieved through improved self-management using a noncontinuous glucometer with digital reminders, education, and behavioral coaching.

WHICH CATEGORIES ARE INCLUDED?

Remote Patient Monitoring	Behavior and Lifestyle Modification		Nutritional Ketosis
Glooko	DarioHealth	Teladoc (Livongo)	Virta
	Omada	Verily (Onduo)	
	Perry Health	Vida	

WHAT ARE THE CLINICAL BENEFITS?

Small improvement in HbA1c compared with usual care — only three out of 10 comparative HbA1c studies achieved a clinically meaningful between-group difference of at least 0.5% pt HbA1c (e.g., 8.0% to 7.5%). People who complete a nutritional ketosis program experience greater benefits.

WHAT IS THE BUDGET IMPACT?

Digital diabetes management solutions increase total health spending because the average price of the solutions exceeds the savings from improved clinical outcomes. Nutritional ketosis programs have greater potential to produce savings over multiple years for patients who can complete them.

WHICH TARGET POPULATIONS COULD BENEFIT MOST?

1 | People with higher starting HbA1c who are newly starting on insulin; or

2 | People who are able to complete nutritional ketosis

HOW CAN PURCHASERS ACHIEVE BETTER VALUE?

| Regularly analyze outcomes and tie contracts to clinical performance | Deploy solutions to more diverse and high-risk populations | Reward evidence generation |

WHERE ARE THERE OPPORTUNITIES FOR FURTHER INNOVATION?

Evolve solutions to achieve clinically meaningful outcomes, which may include GLP-1s, continuous glucose monitors, and nutritional ketosis. Focus R&D efforts on underserved populations.

Technology Context

In the United States, about one in seven adults — more than 38 million Americans — has type 2 diabetes, which is the eighth leading cause of death. At $412.9 billion of total healthcare spending annually (2022), it is the most expensive chronic condition to treat and manage.[17]

Each year, an additional 1.2 million adults are diagnosed with diabetes, with a disproportionate impact on low-income individuals and cer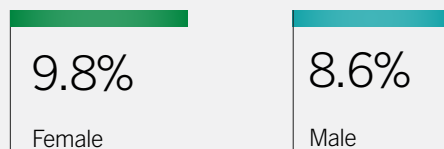tain racial and ethnic groups, including American Indians, Alaskan Natives, and Black and Hispanic people (Exhibit 2).[18,19] As alarming as this sounds, future projections are worse: The number of adults with type 2 diabetes is projected to double by 2030 as the rate of new diagnoses accelerates (Exhibit 3).[20] The current and projected burden of diabetes has been a powerful motivator for digital health technology companies and investors over the past 15 years.

Exhibit 2

RATES OF DIABETES, ADULTS 18+, BY DEMOGRAPHIC GROUP*

GENDER

9.8%	8.6%
Female	Male

RACE AND ETHNICITY

14.5%	9.1%	12.1%	12.7%	6.9%
American Indian or Alaska Native	Asian, non-Hispanic	Black, non-Hispanic	Hispanic, overall	White, non-Hispanic

INCOME

13.1%	10.3%	7.7%	5.1%
<100% FPL**	100–299% FPL	300–499% FPL	≥500% FPL

AGE

2.4%	12.5%	19.5%	20.6%
18–44	45–64	65–74	≥75
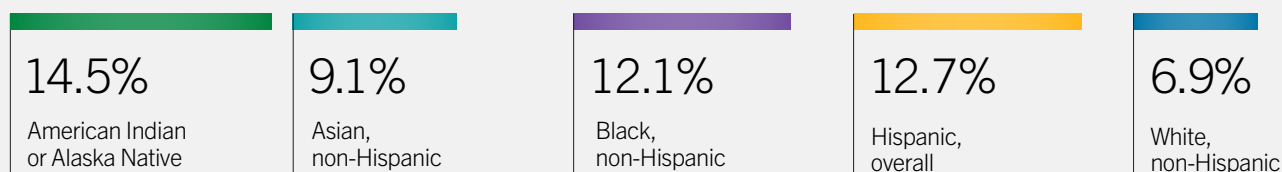
Notes.

* Includes type 1 and type 2 diabetes.

** FPL = Federal poverty level.

Source: Centers for Disease Control and Prevention. "United States Diabetes Surveillance System." Accessed January 30, 2024.
https://gis.cdc.gov/grasp/diabetes/diabetesatlas-surveillance.html.

Introduction   **Technology
Context**   Clinical
Effectiveness   Economic
Impact   Summary
Ratings   Next
Steps

Exhibit 3

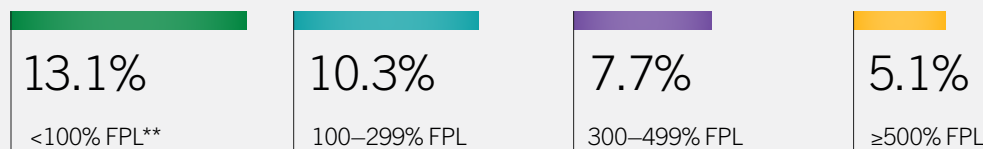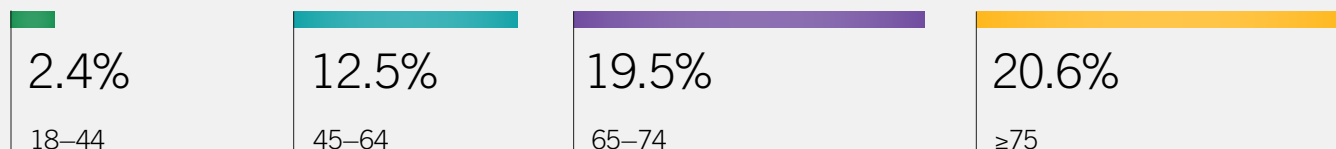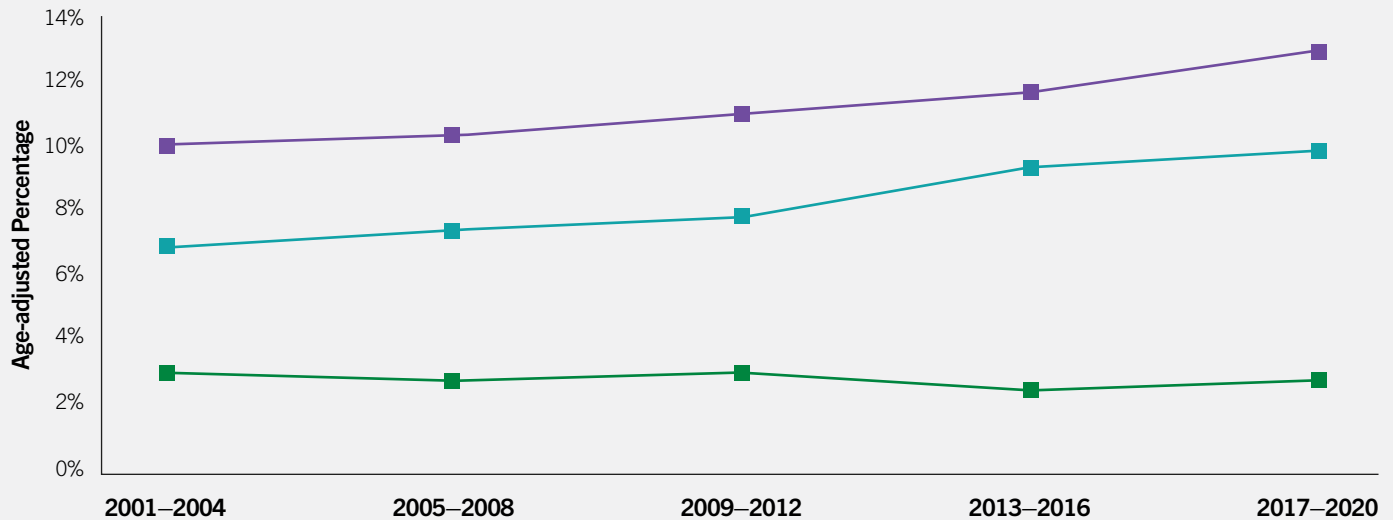## DIABETES PREVALENCE BY DIAGNOSIS STATUS, 2001—2020*

● Undiagnosed Diabetes ● Diagnosed Diabetes ● Total Diabetes

*Includes type 1 and type 2 diabetes.

Source: Centers for Disease Control and Prevention. "National Diabetes Statistics Report." November 29, 2023.
https://www.cdc.gov/diabetes/data/statistics-report/index.html.

Characterized by poor glycemic control, diabetes can lead to substantial clinical complications, such as cardiovascular and kidney damage. Uncontrolled diabetes can also result in severe [21] and high-cost interventions, such as amputation, dialysis, or heart surgery.[22] The most commonly used indicator of glycemic control is HbA1c, a test that measures sugar that is chemically linked to hemoglobin in red blood cells and reflects a three-month average (the average lifespan of a red blood cell). People with HbA1c greater than 6.5%

are considered to have diabetes, and those with HbA1c greater than 9.0% have the highest risk of diabetes-related complications. The likelihood of severe complications [23] increases as HbA1c increases.[24, 25]

Fortunately, diabetes can be managed, and some people with diabetes can achieve remission. Effective management of diabetes is associated with better patient health outcomes and fewer clinical complications [29,30] which in turn reduce overall healthcare utilization and costs.[31]

What is HbA1C?

HbA1c measures the percentage of hemoglobin proteins in the blood that are coated with sugar (glycated).[26] HbA1c represents an average glycated hemoglobin level from the previous three months.[27] Patients with diabetes may also experience acute blood sugar-related events, such as hyperglycemia (high blood sugar) and hypoglycemia (low blood sugar).[28]

Recommended Care for Diabetes

The American Diabetes Association (ADA) recommends that patients and primary care providers work together to manage type 2 diabetes through routine in-person visits.[32] People with type 2 diabetes may take oral medications alone or in combination with insulin (administered by injection) to control their blood glucose, as well as other medications to manage cardiovascular and renal system risks. Clinical guidelines also recommend behavior changes focused on diet and weight loss.

Effectively managing diabetes takes a diverse healthcare team, including primary care providers, certified diabetes educators, and, increasingly, health coaches and community health workers.

Together, they help support clinical diagnosis and treatment management, educating patients on self-management skills, and addressing barriers to care that range from socioeconomic to cultural.[33] Digital diabetes management solutions are designed to augment the coordination, performance, and results of existing team-based care and self-management goals, rather than serve as replacements for them.

Patients with type 2 diabetes typically see their doctor every three months (the time recommended for a new HbA1c measurement). During visits, patients and providers review blood glucose levels to monitor progress; adjust their care plan, including medication changes;

and discuss lifestyle changes that may improve glycemic control (Exhibit 4). Between visits, patients with diabetes are advised to use a blood glucose meter and self-monitor their blood glucose[34] through a combination of diet, exercise, and medication regimens.

Most people living with type 2 diabetes use noncontinuous glucose meters to check their blood glucose levels daily or several times a day.[35] These devices rely on patients sticking their finger with a disposable lancet and apply a drop of blood onto a test strip that is inserted into the meter to be read. These point-in-time glycemic levels help patients associate their diet, medication use, or other dimensions of their lifestyle with their blood glucose levels.

Diabetes management places a significant burden on patients.[36] Patients report that daily finger sticks are painful and that managing multiple medications with different dosing schedules is complex and potentially confusing.[37] The recommended lifestyle changes, which often include significant dietary modifications, can be hard to adopt and follow long-term. These challenges are particularly pronounced for patients with low health literacy, limited social supports, and low incomes. The United States has invested in diabetes education and prevention programs to improve patient education and build stronger self-management skills.[38,39,40]

Exhibit 4

CORE COMPONENTS OF TYPE 2 DIABETES STANDARD OF CARE APPROACH

Glycemic Management

Weight Management

MEDICATION MANAGEMENT

Cardiovascular Risk and Renal Management
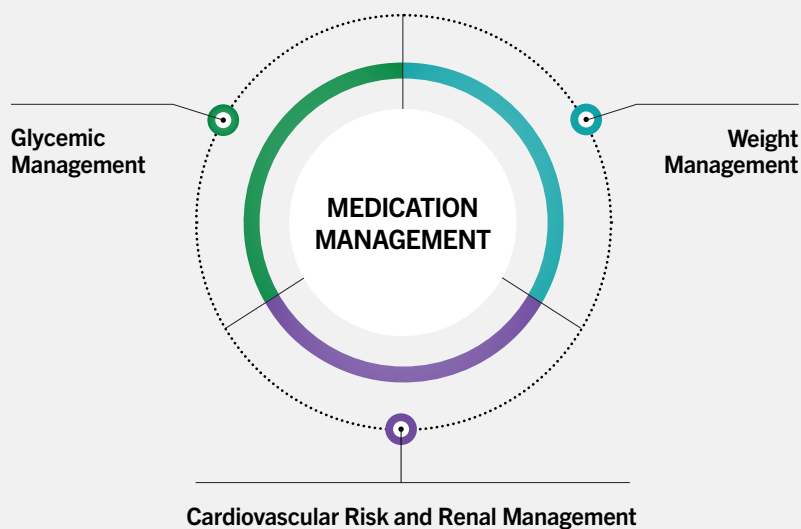
Source: Davies, Melanie, Vanita Aroda, Billy Collins. "Management of Hyperglycemia in Type 2 Diabetes, 2022. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD)." *Diabetes Care.* 45,11 (November 2022): 2753–2786. https://doi.org/10.2337/dci22-0034.

Patient Perspective

Patient Role in Managing Diabetes

Managing diabetes is a complex and demanding task for patients. Beyond frequent doctor visits, patients are asked to take an active role in their own disease management. These demands — which can range from modifications in diet and exercise to interpreting blood glucose levels and self-titrating multiple medications — can be both physically and mentally taxing. Focus group participants reported that having an app that serves as a data repository and provides information on glucose trends can be useful. For this reason, some may regard digital diabetes tools as valuable, independent of their clinical performance.

" When I was first diagnosed with diabetes…

I was overwhelmed by all the new numbers and measurements I had to keep track of. Using the digital solution helped me keep track of my blood sugar levels, what I eat, and organize my meds. It was helpful to have everything in one place. If I was only keeping track using pen and paper, I wouldn't record data points nearly as much as I do now."

— Patient Focus Group Participant

Patient Experience With Digital Solutions

Digital diabetes solutions aim to help make self-management easier through a combination of education, support, reminders, planning, and personalized information. Critical to this is the overall user experience. To be effective, these solutions often require that patients add additional tasks to their self-management routines: recording activities and meals, inputting health data, or answering health status questions produced by a coach or an algorithm. Patients reported varying degrees of engagement with the tools, particularly with inputting self-reported outcomes, such as diet and exercise. These data are critical, as most solutions build recommendations and actions based on a mix of automatically uploaded data and manually inputted patient infor- mation. Minimizing manually entered data requirements is critical to create value for the patient and to ensure they continue to use these solutions over time.

" It senses automatically when I need supplies or any lancets.

All I have to do is just refer to the system and place the order on it and then they put the order in for anything that I need. So, that's good."

— Patient Focus Group Participant

Ongoing Support

Effective use of digital diabetes management solutions often requires multiple types of support. Patients reported needing help at eligibility verification, set-up, and at subsequent regular intervals because of ongoing technical challenges. Most often, patients turned to their provider for support, although they reported receiving varying levels of support.

Digital diabetes management solutions primarily aim to augment traditional care. As such, data sharing with the patient's primary physician is important. Patients reported substantial variation in how they shared their data — from showing their provider their phone during a visit to having their data uploaded/transferred automatically.

" My physician suggested that I use a digital health tool.

I feel that it has helped me significantly, especially to keep track of my glucose every day. It has helped me in learning what my trends are throughout the day and it has helped me manage my medications as well."

— Patient Focus Group Participant

Digital Diabetes Management Solutions

Given the important role of patient self-management in diabetes, over the past 15 years, there has been considerable investment in creating digital diabetes management solutions to support patients' disease management through virtual and technology-enabled platforms. With patients as the primary users, **these solutions aim to improve glycemic control by reminding patients to track their blood glucose and by supplementing glucometer readings with additional information, including timely digital and human intervention.** Interventions may include digital reminders, trend analysis, goal-setting,

Investment in digital diabetes management solutions has been significant. Since 2010, $5.7 billion of venture capital[41] has been invested in companies providing these solutions, and transactions (including mergers and acquisitions and other investments) have totaled $58 billion.[42]

Exhibit 5
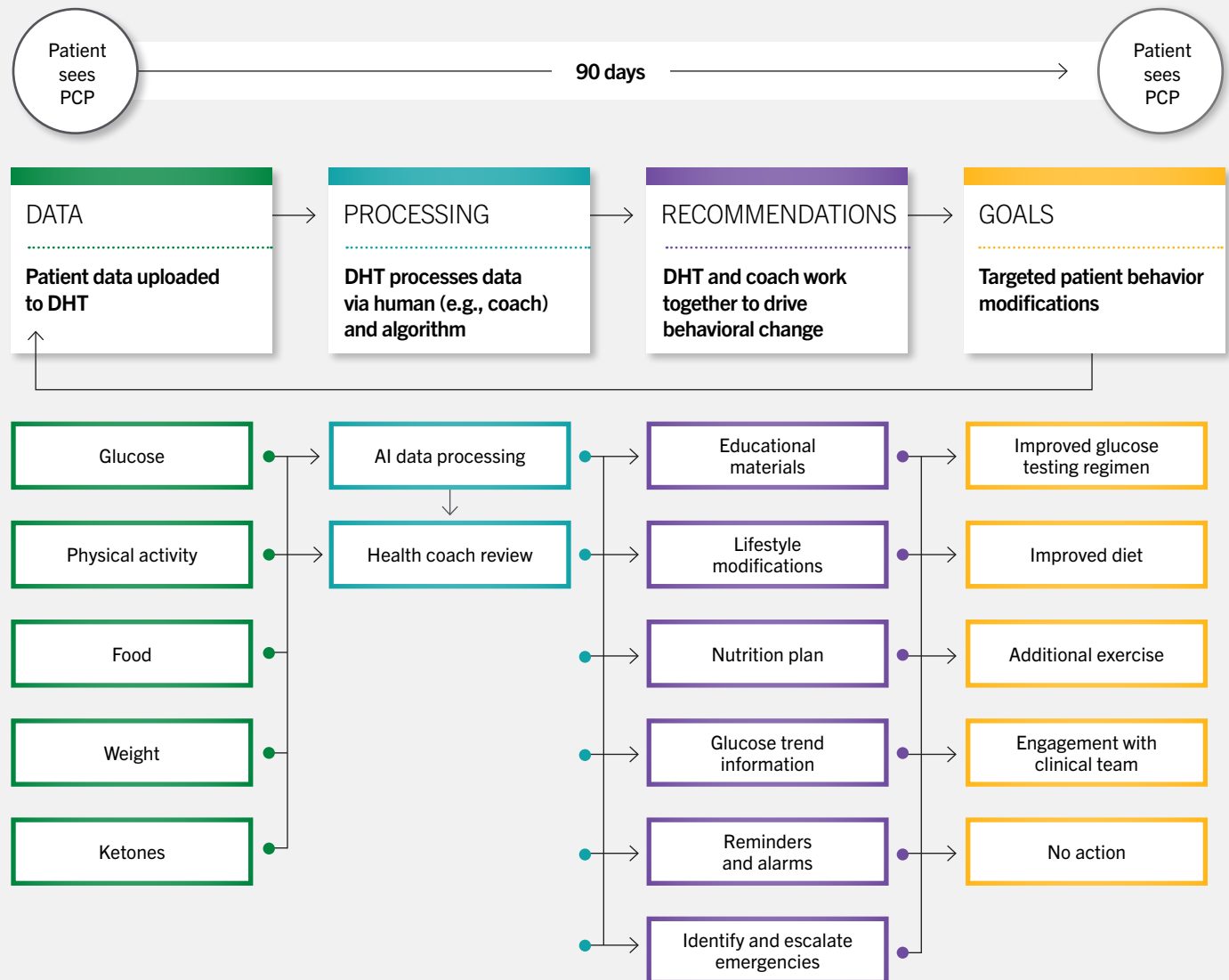
ELEMENTS OF DIGITAL DIABETES MANAGEMENT SOLUTIONS

Notes. PCP = Primary Care Physician, DHT = Digital Health Technology.

Exhibit 6

COMPANY HISTORY AND FUNDING

Company	Year Founded	Public/ Private	Total Funding to Date
DarioHealth	2011	PUBLIC	$238M
Glooko	2010	PRIVATE	$331M
Omada	2011	PRIVATE	$530M
Perry Health	2017	PRIVATE	$26M
Teladoc (Livongo)	2008	PUBLIC[a]	$592M
Verily (Onduo)	2016	PUBLIC[b]	$500M
Vida	2014	PRIVATE	$263M
Virta	2014	PRIVATE	$365M

Notes. [a] Acquired by Teladoc in 2020 for $18.5 billion. [b] Joint venture, 9/2016.

Source: Pitchbook Data, Inc.

and coaching. Some solutions even include clinicians who can act as primary care providers for users. Exhibit 5 lays out the common components of many digital diabetes tools. This report evaluates how these digital diabetes management solutions perform as a supplement to standard care or usual care.

Solutions included in this report were identified through a multistep market analysis. Initial solutions of interest were determined through a scan of the digital diabetes management market using multiple industry-tracking platforms and published literature. This initial set of solutions was reviewed through a detailed solution-by-solution analysis.

To be included in this report, solutions must:

- Connect to a noncontinuous glucose monitor;
- Focus on glucose control as a key outcome;
- Have received investment funding greater than $25 million;

- Replace or augment a care plan overseen by a physician or clinical provider; and
- Be sold primarily to health plans, providers, and/or employers.

The final list of solutions for this report was determined through company meetings, company-submitted data, and detailed solution-by-solution research, as well as input from stakeholders — including health plans, employers, providers, and digital health experts.

Most of the digital diabetes management solutions in this evaluation were founded 5–15 years ago, making them a relatively mature technology in the digital health sector. To date, these companies have each raised between $25 million and $600 million in capital, with a mix of private and public ownership (Exhibit 6).[43]

All the digital solutions reviewed offer a product that connects to a noncontinuous or intermittent blood glucose monitor that transmits data directly to a phone, computer, or electronic medical record for tracking and analysis. This review is focused on the digital solution, including the app, coaching, educational resources, and patient prompts, not the blood glucose

monitors themselves, which are reviewed and approved by the U.S. Food and Drug Administration (FDA). Many solutions are compatible with multiple blood glucose monitors, although some companies require patients to use the blood glucose monitor sent to them by the company.

Of note, many companies are increasingly offering diabetes management solutions that integrate continuous glucose monitors (CGM), which are outside the scope of this report. CGMs provide real-time monitoring of glucose levels via a wearable device that measures subcutaneous interstitial glucose and a reader (usually a smartphone). Although CGM adoption is growing rapidly among people with type 2 diabetes, traditional glucometers remain far more common in the United States at this time.[44] Further, there are currently Medicaid[45] and Medicare[46] coverage restrictions on CGM-devices that limit their access for many people with for type 2 diabetes. Over time, additional evidence will be needed to assess how the integration of CGMs impacts outcomes, including glycemic control, for people using digital diabetes management solutions.

Exhibit 7

HOW DIGITAL DIABETES MANAGEMENT SOLUTIONS WORK

AUTOMATICALLY UPLOADED GLUCOSE DATA

THIRD PARTY APPS AND DEVICES

Steps
6,174

00:00   12:00   24:00

0.0 LB

MANUALLY ENTERED DATA

WEDNESDAY, MAR 6
Summary

Activity
Move **300** CAL
Steps **5,000**
Distance **2.25** MIL

WORKOUTS

WEDNESDAY, MAR 6
Health Specs
Height **5.4** (feet)
Weight **140** (lbs)

Exercise
○ 1 X a week   ○ 5 X a week
○ 2 X a week   ○ 6 X a week
○ 3 X a week   ○ 7 X a week
◉ 4 X a week

THURSDAY, FEB 29
Food Diary
DINNER   514 CAL
Chicken Caesar Salad ▼
Broccoli (1/2 cup)   50
Blueberries (2 cups)   165
SNACKS   260 CAL
Cheddar Puffs (2 oz.)   260

AI ENGINE
- **Data analytics**
- **Clinical guidelines**
- **Behavioral science**
- **User experience**

AUTOMATED GUIDANCE AND SUGGESTIONS

Blood Glucose Reading
Data available for 24 of 24 hours
153 mg/dL   ↓ **4.2%**
Average Glucose
92%   ↑ **2.5%**
Time in Range
228 mg/dL 2:00pm

mg/dL
300
250
200
150
100
50

Current Goal
7 DAYS LEFT
Eat a lean protein 4x/week, for 2 wks
Time to check in: Let us know how things are going?
Check in

Action List
Track Food & Drinks Track 2 more meals
Keep Moving Track 2 more meals
Read Lesson 1 Complete Lesson 1 this week

PERSONALIZED INTERACTIONS WITH CARE TEAM

CLINICIAN

DIABETES EDUCATOR   **HEALTH COACH**

Hi Lisa
Looks like you have been taking more glucose measurements lately. And your numbers are getting better every day.
— Coach Linda

Hi Coach Linda
Yes! I have been trying to take at least five measurements every day. This is really helping me to keep my numbers under control.
— Lisa

Exhibit 8

CATEGORIES OF DIGITAL DIABETES MANAGEMENT SOLUTIONS

Intensity →

Remote Patient Monitoring	Behavior and Lifestyle Modification	Nutritional Ketosis
Glooko	DarioHealth Teladoc (Livongo) Omada Verily (Onduo) Perry Health Vida	Virta
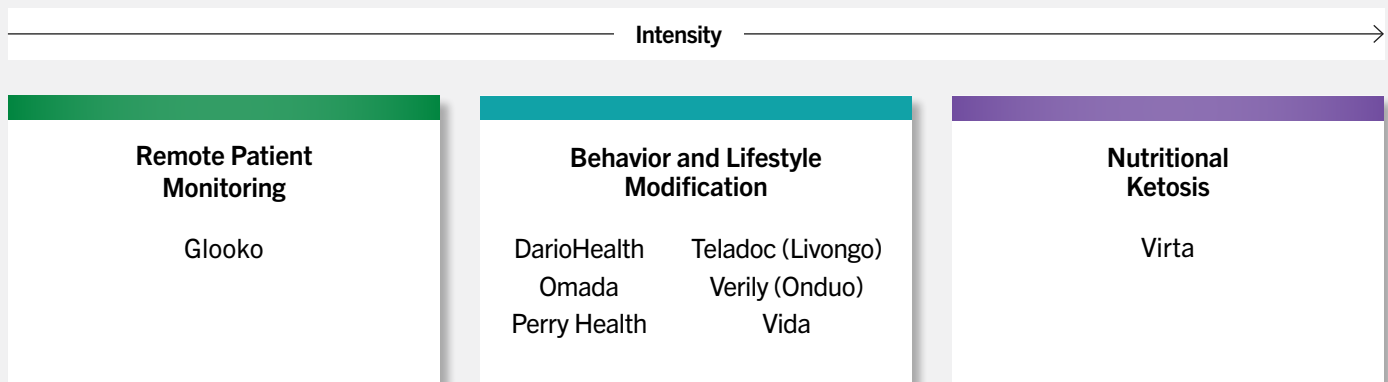
At their core, each of these digital diabetes management solutions facilitates the collection and tracking of patient data, including blood glucose, other biometric readings, and self-reported information (Exhibit 7). These results — whether patient-entered or uploaded through a connected device — are used to track glucose levels over time to inform self-management and/or clinical care teams. The solution then delivers digital nudges or reminders to take actions that align with better glycemic control.

FDA Regulation

The FDA regulates glucometers to ensure that they produce accurate, reliable measures. However, there is no entity that regulates applications that use software and human intervention to guide patients' self-management based on glucose measurements. Companies offering these solutions build and refine proprietary workflows that reflect their clinical approach to optimal diabetes management.

As Exhibit 8 shows, solutions included in this report fall into three categories:

- **Remote patient monitoring** — Enable physicians to support remote patient monitoring of blood glucose, with a goal of improved glycemic control.

- **Behavior and lifestyle modification** — Engage patients with a mix of behavioral, clinical, and lifestyle modification programs in addition to glycemic feedback with a goal of glycemic control and other health improvements.

- **Nutritional ketosis** — Induce a state of ketosis in patients through intensive dietary guidance and monitoring of glycemic and ketone levels with the goal of diabetes remission.

Remote patient monitoring: Remote patient monitoring refers to the collection and transmission of physiological data that are automatically sent from a point of care to a health professional.[47] The Centers for Medicare and Medicaid Services (CMS) started reimbursing for remote patient monitoring in 2018 across a number of disease areas. In 2021, nearly 17% of claims were for diabetes-related diagnoses.[48] There are many companies that offer remote patient monitoring platforms and fall into this category. Glooko's solution is focused on enabling physicians to support remote patient monitoring of blood glucose. Glooko is somewhat unique because of its size and exclusive focus on diabetes management with tailored provider support. Glooko is purchased primarily by healthcare providers, who offer the tool to patients and are reimbursed for their time spent reviewing the data through remote patient monitoring billing codes.

Behavior and lifestyle modification:
Six companies — DarioHealth, Omada, Perry Health, Teladoc (Livongo), Verily (Onduo), and Vida — provide a mix of behavioral, clinical, and lifestyle modification programs, in addition to glycemic feedback. All of these solutions collect additional patient data, such as information on diet, exercise, weight, blood pressure, and mental health. Most solutions in this category offer chronic care management services beyond diabetes, often for hypertension and weight management. Although most of these solutions can facilitate data sharing with a patient's primary physician, the ease of sharing and level of integration with provider systems varies.

Solutions in this category are mainly differentiated by the breadth of the offering, frequency of human versus algorithm-based feedback, and the type or level of providers that are available to enrollees. These solutions are primarily sold to health plans and employers on a capitated (per user per month) basis, often as part of the wellness benefit.

Nutritional ketosis: One solution, Virta, has a specific focus on inducing a state of ketosis in patients through intensive dietary guidance and monitoring of both the patient's glycemic and ketone levels. Ketosis is a metabolic state that occurs when the body burns fat for energy. It relies on greatly restricting carbohydrates

in the diet, which can result in diabetic remission if this highly disciplined diet therapy is followed. Like any highly disciplined diet, following a nutritional ketosis diet and entering sustained ketosis is challenging. However, when successful, literature suggests that the nutritional ketosis diet improves short-term HbA1c.[49,50] The focus of this report is on the digital solution that supports patients as they attempt to achieve nutritional ketosis. Of note, a key distinction of the nutritional ketosis category is its goal of diabetes remission.

All digital diabetes management solutions aim to improve blood sugar management, and many products target additional benefits, such as weight loss, blood pressure regulation, medication adherence, or deprescribing (overview in Exhibit 9). Several companies also promote such benefits as reduced depression and anxiety, improved general function (e.g., lower cholesterol, less pain), and/or patient satisfaction and engagement.

Exhibit 9

HEALTH BENEFITS TARGETED BY DIGITAL DIABETES MANAGEMENT SOLUTIONS

Company	Blood Glucose/ HbA1c Management	Weight Loss/ Body Mass Index Reduction	Blood Pressure Regulation	Medication Adherence or Reduction
DarioHealth	●	●	●	●
Glooko	●		●	
Omada	●	●	●	●
Perry Health	●			
Teladoc (Livongo)	●			
Verily (Onduo)	●	●	●	
Vida	●	●	●	
Virta	●	●	●	●

Notes. Several companies noted other benefits, including reduction in depression and/or anxiety, improved general function (e.g., lower cholesterol, lower pain), and/or patient satisfaction and engagement.

Source: Public information (websites, marketing materials, company-provided public information, etc.).

Privacy and Security

All of the digital diabetes management solutions in this report are designed to work across multiple settings to achieve their goals:

1) The home or other location where a patient uses their noncontinuous glucometer

2) The app or platform that the solution provides

3) A healthcare provider that supplies the solution with diagnostic or management information.

In 2022, the National Institute of Standards and Technology (NIST) undertook a special review of how to secure remote patient monitoring systems that cross these three domains.

Privacy

By definition, patient data move across the three digital settings described above. As a result, patient privacy in remote monitoring programs like those covered in this report can be compromised through what the NIST calls "problematic data actions." These include data distortions (wrong or misleading data are stored or used), insecurity (lapses in data security), reidentification (information that is meant to be anonymous becomes identified), or unanticipated revelation (private information inadvertently exposed to unauthorized audiences). To mitigate these risks, there are systematic categories of actions to ensure that data are identified, controlled, and protected, which are described in depth within the NIST framework. It is important to read each solution's privacy policy, as it may permit deidentified use by third parties. Regardless, solutions that are sold directly to health plans or providers are governed by HIPAA rules through business associate agreements. This means that solutions must follow a well-established set of rules that govern disclosure of identifiable personal health information.

Security

Security differs from privacy in terms of the types of threats that emerge when security is compromised. According to the NIST cybersecurity risk taxonomy for remote patient monitoring, the highest risks specific to remote patient monitoring-based programs include clinician misdiagnosis (if data are altered inappropriately leading to inaccurate diagnosis), incomplete/incorrect patient escalations (critical patient event is missed due to changes in the data stream), process disruption due to ransomware (normal operation is prevented or data lost), or systematic disruption due to component compromise (a part of an overall solution does not work). All of these are relevant to the digital diabetes management solutions included in this report. Similar to the privacy domain, cybersecurity measures to mitigate these risks are described in more detail within the NIST framework.

Purchasers evaluate the privacy and security risks of digital solutions in the context of their procurement processes, and then again as they go live. Given that solutions in this category inherently work across multiple settings, deeper integration of these solutions across other environments multiplies the potential for privacy or security breaches. Data transfers between systems can also create security vulnerabilities. To the extent that data feeds from digital diabetes management solutions are being transmitted from the companies to health plans or providers, they may face additional risks. Although there is no perfect solution, there are multiple risk mitigation frameworks available — including and beyond NIST — to ensure that these solutions do their part to protect both patients' and providers' data and systems.

Clinical Effectiveness

Two of the most important questions for payers, providers, and patients considering using any digital health technology are "how well does it work?" and "for whom does it work?" In more technical terms, these questions seek to identify the specific clinical benefits associated with using a solution in one or more subpopulations. As described in the ICER-PHTI Assessment Framework for Digital Health Technologies, the evaluation begins with a review of the technologies' clinical effectiveness to understand how the solutions perform on both primary and secondary clinical endpoints of interest, and how long those benefits persist. It is also important to clarify which populations stand to benefit the most from using the technology.

Methodology and Approach

The evaluation approach for the clinical assessment included the following steps:

- Define the intervention of interest;

- Generate a list of outcome measures (including appropriate metrics and comparators);

- Conduct a systematic search of the scientific literature and gray literature using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines;

- Evaluate additional data and articles submitted by the companies being evaluated; and

- Assess risk of bias across all relevant articles based on quality of design, methods, and analysis.[c]

A detailed methodology for and results of the systematic literature review is included in Appendix A.

Evidence Standards: When reviewing clinical effectiveness literature, the first task is to determine whether the body of research includes the minimum evidence necessary to assess an outcome, based on the level of risk that the technology presents to a user. The interventions in this report qualify as Tier 3a: Professionally Directed Preventive and Therapeutic Health Management, according to the Assessment Framework, because they are a form of preventive behavior management used in consultation with a medical professional. The solutions have low to moderate risk to patients, as they augment usual care and rely on FDA-approved glucometers. The Tier 3a minimum and best evidence standards (see call-out box) guided the clinical effectiveness review.

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ICER-PHTI Assessment Framework Tier 3a Evidence Standards

The evidence standards for Tier 3a: Professionally Directed Preventive and Therapeutic Health Management are calibrated based on the function of the solutions in the category and the risk to patients of poor performance.

Minimum Evidence Requirements are high quality observational or quasi-experimental studies with an appropriate comparator and relevant patient outcomes. Outcomes may include patient reported outcomes, engagement with the healthcare system, or clinical data.

Best Evidence Requirements are randomized controlled trials (RCT) demonstrating clinical efficacy. Study may be conducted in a selected population. Surrogate outcomes and short-term follow-up may be acceptable.

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[c] Risk of bias analysis was performed using the NOS method for observational studies and ROB2 for interventional studies.

Intervention and Comparators: All of the assessed solutions incorporate data collection from noncontinuous blood glucose monitoring associated with a mobile or web application to guide therapeutic workflows. The therapeutic workflows themselves vary considerably, including information in the form of nudges or reminders, targeted nutritional advice, behavioral cues, and/or clinical intervention by a range of provider types.

Per the Tier 3a minimum evidence standards, studies should include an appropriate comparator to show outcomes for users of the digital solution and how those outcomes compare with other treatment options. In most cases, the relevant comparators for digital diabetes interventions include regular monitoring using a nonconnected blood glucose meter, which are generally referred to in this report as "usual care." Comparators to usual care are particularly important to differentiate the impact of digital diabetes management solutions because usual care often results in improvements in glycemic control.

Risk of Bias: Literature included in the clinical effectiveness review was assessed for risk of bias, which varies based on study design. This assessment used the Cochrane Collaboration Risk of Bias in Randomized Trials Version 2 (RoB2)[51] and the Newcastle-Ottawa Scale (NOS)[52] to assess the risk of bias in interventional and observational studies, respectively. Labels used for risk of bias ratings from both scales were matched for ease of interpretation in the report (low, moderate, high).

> **" It is vital for patients to get into that 'control zone.' If a patient has an 8 [% HbA1c] and is only getting down to 7.7, cardiovascular risk is still growing."**
>
> — Dr. Ami Bhatt, Chief Innovation Officer of American College of Cardiology

Outcome Measures: The primary measure of clinical effectiveness in our analysis is glycemic control, most often measured by HbA1c, but also including measures of blood glucose and time-in-range (of appropriate blood glucose levels). Even within this outcome set, there are important distinctions: Diabetes patients with HbA1c above 9% are considered much higher risk than those with HbA1c below 8%.[53] The ADA recommends maintaining a HbA1c below 7%, and a large body of literature[54] finds that intensive glycemic control is beneficial, particularly due to reducing the risk of microvascular complications.

This assessment also reviewed for numerous additional outcome measures, including secondary health effects, patient reported outcomes, changes in healthcare-related utilization, and demographics of the study population, as well as evidence about the technology's impact on heath equity, user experience, and adherence. The full set of outcome measures was informed by the International Consortium for Health Outcomes Measurement (ICHOM) diabetes set.[55]

Clinically Meaningful Benefits: Clinical advisors worked with the evaluation team to provide context regarding the selection of HbA1c as the primary indicator of interest and the clinical impact of various levels of HbA1c reduction. Although many articles report "statistically significant" results, their magnitudes may not be sufficient to change the trajectory of disease, reduce long-term health risks, or produce changes in healthcare utilization and spending.

To establish an agreed upon level of difference that would be "clinically meaningful" in the context of treatment plans, prognosis, complications, and patient quality of life, clinicians and standards bodies often define a "minimal clinically important difference" (MCID) for important measures. In the diabetes context, the commonly used threshold for HbA1c MCID is 0.5% pt.[56] Clinical advisors for this assessment agreed that changes at or below this magnitude are unlikely to be viewed as clinically meaningful and would not be sufficient to change patient prognosis or care plans. For example, the highest doses of commonly used diabetic drugs result in the following average reductions in HbA1c: metformin (1.09% pt), sulfonylureas (1.00% pt), and GLP-1 receptor agonists (1.24% pt).[57] In this report, we use the MCID threshold of 0.5% pt to assess clinically meaningful differences when comparing between group differences in HbA1c (intervention vs. comparator).

Durability: Given that type 2 diabetes is a chronic disease, it is also important to understand the durability or lasting effect of clinical improvements. Ability to assess the durability of clinical effects may be limited by the length of the study design and duration of follow-up.

Health Equity: Evidence on the impact of digital diabetes management solutions on health equity was considered on two dimensions:

1) Accessibility and Inclusivity — Whether the diabetes management solution is culturally and linguistically appropriate, has a low barrier to entry

for digital literacy, instills or exacerbates implicit biases, and is adaptable to meet the usability needs of health disparity populations; and
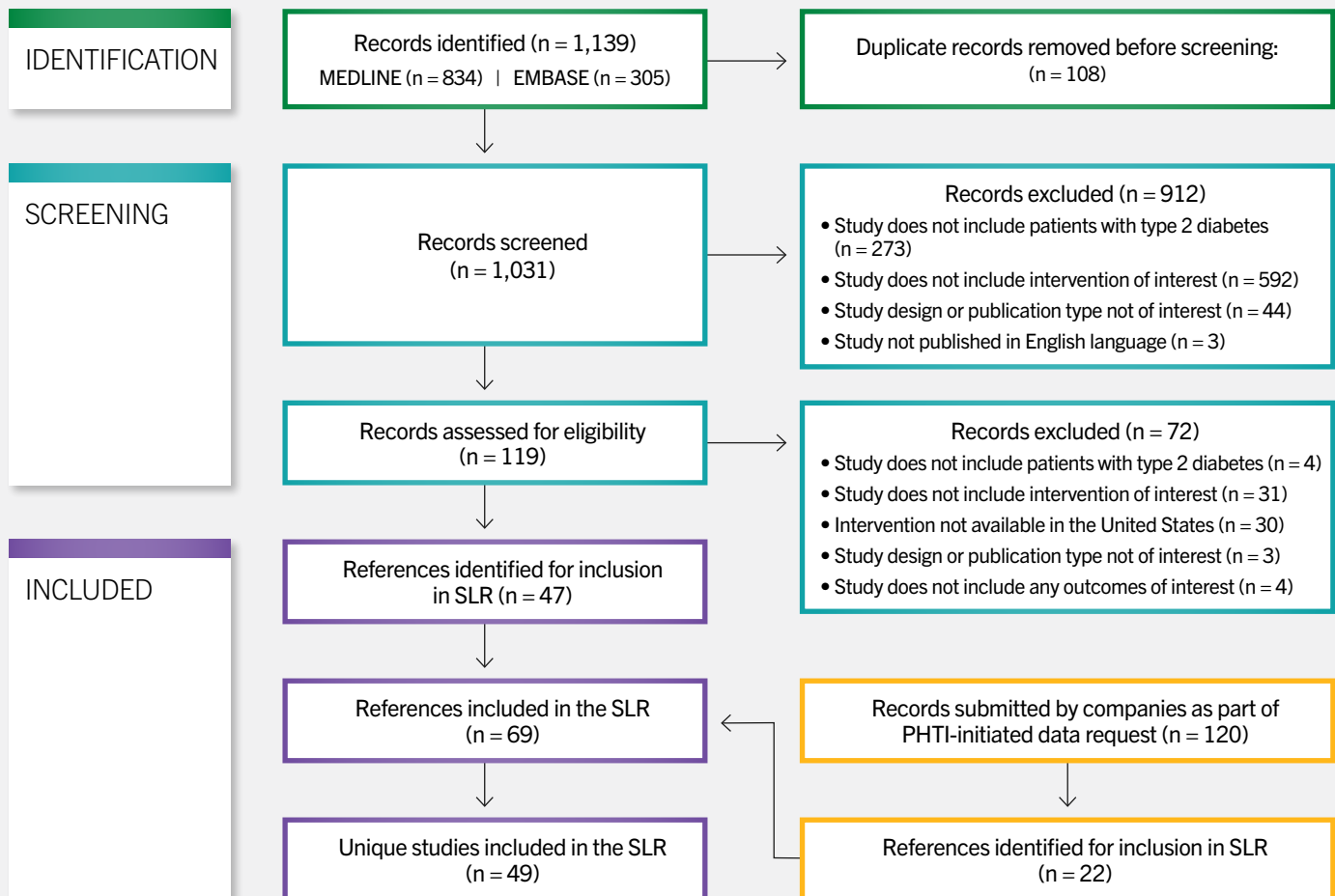
2) Access — Whether the solution is available/distributed across different patient subpopulations and geographic areas (e.g., rural vs. urban, socio-economically diverse communities).

Both categories are important, as they may be related to and/or directly impact the clinical effectiveness of a given solution. For instance, some solutions may require users to have a compatible mobile

device, while others invest to ensure their platforms remain compatible with older devices, and still others may send users a compatible device if they do not own one. Similarly, some solutions may permit users to engage with the platform both synchronously and asynchronously, allowing them to upload their data once they access wi-fi; without this, patients in broadband deserts would be less likely to upload their information in a timely manner and, thus, may have lower engagement with the solutions.

Exhibit 10

PRISMA DIAGRAM OF SYSTEMATIC LITERATURE REVIEW (SLR) AND COMPANY-PROVIDED DATA

IDENTIFICATION

Records identified (n = 1,139)
MEDLINE (n = 834) | EMBASE (n = 305)

Duplicate records removed before screening:
(n = 108)

SCREENING

Records screened
(n = 1,031)

Records excluded (n = 912)
- Study does not include patients with type 2 diabetes (n = 273)
- Study does not include intervention of interest (n = 592)
- Study design or publication type not of interest (n = 44)
- Study not published in English language (n = 3)

Records assessed for eligibility
(n = 119)

Records excluded (n = 72)
- Study does not include patients with type 2 diabetes (n = 4)
- Study does not include intervention of interest (n = 31)
- Intervention not available in the United States (n = 30)
- Study design or publication type not of interest (n = 3)
- Study does not include any outcomes of interest (n = 4)

INCLUDED

References identified for inclusion in SLR (n = 47)

References included in the SLR
(n = 69)

Records submitted by companies as part of PHTI-initiated data request (n = 120)

Unique studies included in the SLR
(n = 49)

References identified for inclusion in SLR
(n = 22)

The systematic literature review (SLR) using online databases identified 1,139 relevant scientific records that met the search parameters using PICOTS (population, intervention, comparators, outcomes, timing, and setting/study design) criteria (Prospero Registry). Complete details of the PICOTS criteria are described in Table 3 of Appendix A. Each record was screened for inclusion based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Checklist [see Appendix B], resulting in 47 articles.

Additionally, three of the companies under review (DarioHealth, Virta, and Omada) submitted a combined total of 120 clinical references that were also screened, resulting in an additional 22 articles that were included in the clinical analysis, for a final combined total of 69 articles stemming from 49 unique studies [see Appendix C for complete list of articles]. Of note, Perry Health also submitted clinical findings but did not provide citations or references.

Records excluded from the systematic literature review were those that did not target type 2 diabetes patients (e.g., prediabetes), those about unrelated interventions, or those that had a study design that did not meet the criteria for eligibility. Forty-one of the 69 articles were assessed for study quality and risk of bias using standardized approaches (25 abstracts/posters and three meta-analyses were not rated). Among articles with interventional trial designs, three had high risk of bias, four had moderate risk of bias, and six had low risk of bias. Among articles with observational trial designs, 20 had poor ratings and eight had fair ratings [see Appendix D for detailed risk of bias tables].

This body of literature included evidence about primary and secondary outcomes, including: HbA1c (42 articles); blood glucose levels (33 articles); proportion of in/above/below glucose range (17 articles); medication use (eight articles); diabetes treatment satisfaction (four articles); patterns of use (18 articles); and self-efficacy, knowledge, and behaviors (eight articles) [see Appendix E for HbA1c articles, Appendix F for blood glucose articles, Appendix G for articles on additional health outcomes, and Appendix H for articles on user experience outcomes].

This body of evidence is sufficient to understand the primary outcomes of interest for digital diabetes management solutions — their impact on glycemic control. It also provides information on many of the secondary outcomes, although questions remain about user experience, health equity, and durability of effects. Despite this evidence being sufficient for our assessment, we note with concern that there were relatively few high-quality, low risk of bias articles with many participants after a decade plus of research and development invested into these solutions.

The subsequent report sections review the evidence for key outcomes of interest, provide solution-specific analysis, describe the impact of the technologies on health equity and user experience, and identify evidence gaps (on the performance of these tools) that ought to be addressed by future research.

Primary Outcome: Glycemic Control

In clinical practice, there are many ways to measure glycemic control. They include directly measuring the quantity of glucose in the blood at a single point in time, which can fluctuate depending on what a patient ate, the time of day, or the equipment used. Given these variations, HbA1c is the most widely used measurement for both clinicians and patients because it serves as a superior measurement of glycemic control over time. HbA1c was the most reported outcome of glycemic control identified in the systematic review and the most common way companies evaluate the efficacy of their digital solutions.

There were 24 articles summarizing interventional studies and 18 articles summarizing observational studies that assessed HbA1c. Of these, 10 studies had a comparator available for analysis, meeting at least the minimum standards of evidence. Notably, the number of participants across interventional studies was relatively low, ranging from 14 to 349, with a mean of 150. The quality of the comparative HbA1c articles was variable: three with low risk of bias, four with moderate, one with high, and three that could not be rated [see Appendix I]. Exhibit 11 includes an overview of the 10 studies that have a comparator available for analysis.

The 10 studies with comparators show that HbA1c improved over time for both users of digital solutions and those receiving usual care [see Appendix E]. Patients who received the digital diabetes management intervention achieved improvements of 0.63% pt to 3.2% pt in HbA1c. Patients who received usual care showed HbA1c improvements between 0.28% pt to 2.0% pt, although two articles found that HbA1c actually increased by 0.2% pt–0.4% pt under usual care. Because patients receiving usual care generally achieve a reduction in HbA1c, this assessment focuses on the between-group differences in HbA1c to isolate the incremental benefits of digital diabetes management solutions compared with usual care.

Blood Glucose Findings

Out of the 33 articles on blood glucose, one observational and four interventional articles included a usual care comparator group. Minimum evidence standards were met in all five comparator articles, but three of the articles were rated as having a high risk of bias. Overall, their findings showed improvements (not always statistically significant) in blood glucose over time in both the usual care and the digital intervention groups [see Appendix F].

HbA1c Improvements With Digital Solutions Compared to Usual Care

Of the 10 studies comparing HbA1c changes from baseline in digital intervention to usual care groups, five examined remote patient monitoring, four examined behavior and lifestyle modification, and one examined nutritional ketosis (reporting on one- and two-year follow-ups).

Four out of five studies reported statistically significant between-group differences for HbA1c using remote patient monitoring compared with usual care. Each of these studies found that

people using **remote patient monitoring** had HbA1c reductions of 0.34% pt to 1.2% pt greater than usual care (Exhibit 11). Two studies in this group met the 0.5% pt standard for clinically meaningful difference; they are described below.

One remote patient monitoring study was a randomized trial conducted by Kaiser Permanente, which found that frequent users of digital diabetes management solutions achieved HbA1c reductions of 0.6% pt greater than usual care. This may

represent the "best case" performance when digital diabetes management solutions are linked with highly-integrated delivery models.

One of the largest effect sizes in the remote patient monitoring category was observed in a small cohort of 40 patients who were followed for 10–14 weeks.[58] Notably, the study enrolled patients who were starting insulin for the first time and had the highest average starting HbA1c levels (10.8%) in the analysis. This group achieved HbA1c reductions of 1.2% pt

Exhibit 11

BETWEEN-GROUP COMPARISONS FOR HbA1c

Study Articles (I/O)	Solution	N	Follow-up Duration	Risk of Bias	HbA1c Reduction for Digital Solutions vs. Usual Care[a]
REMOTE PATIENT MONITORING					
Nosrat 2023 (I)	Glooko	195	6 months	NA	0.34*
Greenwood 2015 (I)	Other	90	6 months	Low	0.41**
Nagrebetsky 2013 (I)	Other	14	6 months	Moderate	0.40[b]
Lee 2017 (I)	Other	144	6 months	Low	0.60**[b]
Hsu 2016 (I)	Other	40	3 months	Moderate	1.20*[b]
BEHAVIOR AND LIFESTYLE MODIFICATION					
Thingalaya 2023a (O)	DarioHealth	2,267	6 months	NA	0.23**
Tsang 2013 (O)	Other	226	1 year	NA	0.24*[b]
Yang 2020 (I)	Other	247	3 months	High	0.30**
Amante 2021 (I)	Teladoc (Livongo)	119	1 year	Low	0.37
NUTRITIONAL KETOSIS					
Athinarayanan 2019 (I)	Virta	349	1 year	Moderate	1.30***
		262	2 years		1.20***

Notes. * p<.05. ** p<.01. *** p<.001. (I/O): I = Interventional Study; O = Observational Study; NA = Not Applicable; Insufficient methodological data to assess study quality and risk of bias for conference proceedings. [a] Between group difference in mean change from baseline HbA1c % pt. Values indicate between-group difference in % pt improvements in glycemic control. [b] Calculated value based on data provided in study article.

greater than usual care. This represents a promising but limited use case that suggests digital diabetes management solutions may perform best when targeted to patients with higher starting HbA1c levels who are at critical transition points in their diagnosis and care plan (when behavioral modifications may be more impactful).

For the **behavior and lifestyle modification** category, three studies reported between-group differences in HbA1c, with digital solutions achieving HbA1c reductions of 0.23% pt to 0.37% pt greater than usual care (Exhibit 11). One of the studies is a well-designed RCT that reported 0.37% pt reduction (not statistically significant) in HbA1c under the digital diabetes management solution compared with usual care after 12 months.[59] None of these between-group

differences achieved the 0.5% pt threshold for meaningful clinical benefits used in this report.

Across both the remote patient monitoring and behavior and lifestyle modification categories, despite the variability in study design and quality, the results across all studies are tightly grouped and very consistent. This increases confidence in the reliability of the findings across the body of evidence. Taken together, the data suggest that remote patient monitoring and behavior and lifestyle modification solutions deliver only small incremental benefits to HbA1c relative to usual care, and that effect sizes may be greater for populations with higher starting HbA1c levels.

The performance of the **nutritional ketosis** category — containing one solution, Virta — merits separate

discussion. A single, nonrandomized interventional, intention-to-treat study with one- and two-year follow-ups demonstrated statistically significant HbA1c reductions of more than twice the threshold for clinically meaningful differences. The adjusted between-group effect size was a reduction of 1.3% pt HbA1c at year one (mean starting HbA1c of 7.6%) and 1.2% pt at the two-year follow-up.[60] Notably, this study reported that after two years, 53.5% of participants met criteria for diabetes reversal (HbA1c less than 6.5% and no use of medication other than metformin and an additional 17.6% of patients were in remission, meaning they had HbA1c of less than 6.5% with no diabetes medication.[61]) Details on the study design and generalizability are included below.

Exhibit 12

BETWEEN-GROUP DIFFERENCES IN HbA1c

● RPM   ● Behavior and Lifestyle Modification   ● Nutritional Ketosis
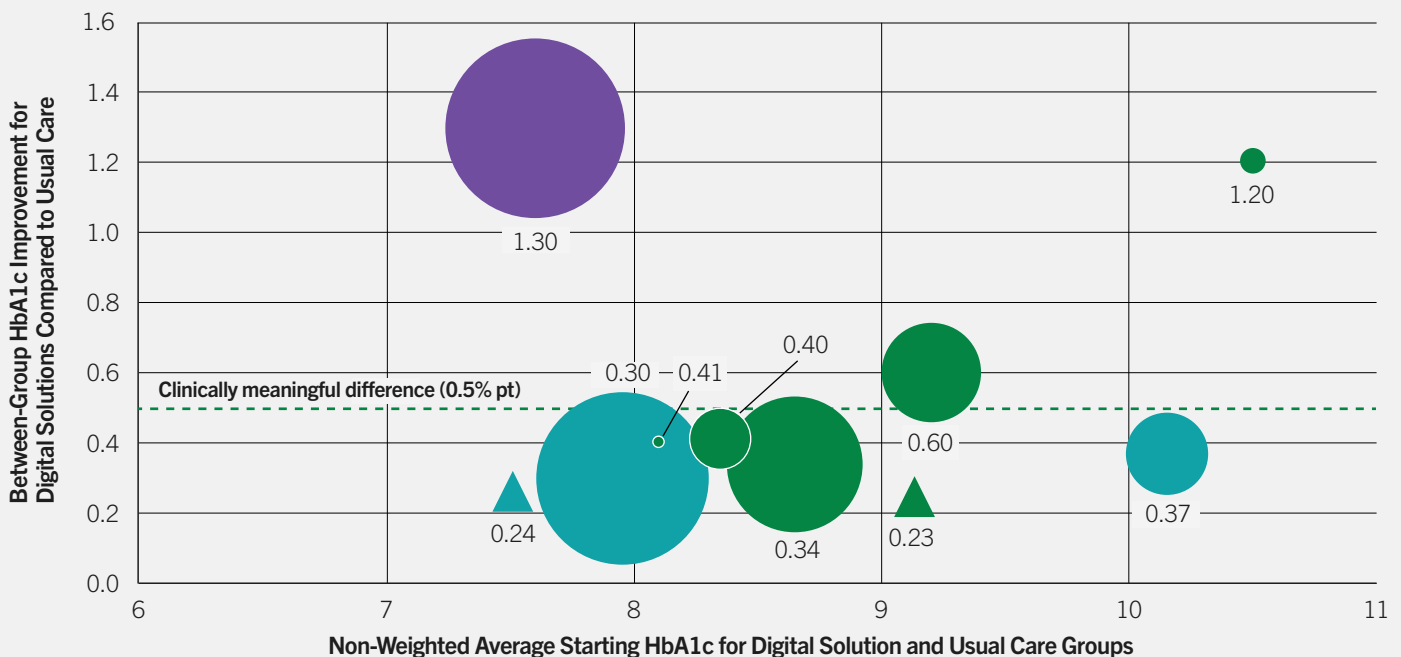
Notes. RPM = Remote patient monitoring. Size of bubbles represent the number of people in interventional studies. Observational studies are depicted with triangles.

Durability of HbA1c Benefits

Across the studies, the duration of the measured interventions ranged from three months to one year, except for nutritional ketosis that included follow-up at two years. Given the chronic nature of type 2 diabetes, these findings speak to a relatively short duration, preventing definitive conclusions about the durability of the observed outcomes. In most cases, it is not possible to conclusively discern whether patients can sustain their HbA1c and other outcomes after the study ends. Further, it is unclear whether the incremental benefits of digital technologies relative to usual care erode over time, as patients experience reminder fatigue, lack of habit formation, and lack of integration with other tools used to manage their care.

One of the behavior and lifestyle modification articles is from a well-designed RCT consisting of a six-month digital diabetes management solution, followed by six months of usual care. The benefit of the digital diabetes management solution that was seen at six months disappeared by 12 months.[62] Only the nutritional ketosis category included a long-term follow-up study that revealed diminishing, but still clinically meaningful (i.e., greater than 0.5% pt) between-group differences in HbA1c control in year two.

Although most of the studies were not designed to examine durability of intervention effect, additional evidence suggests that patients generally struggle to maintain intensive HbA1c control over longer periods of time. A 2019 study published in the *New England Journal of Medicine* analyzed intensive diabetes management intervention with long-term follow-up.[63] This study randomized participants to a usual care group that maintained HbA1c at a level of 8–9% and an intensive therapy group that achieved high glycemic control (1.5% pt improvement in HbA1c over usual care). Following the end of the intervention, HbA1c levels between the groups immediately began to converge, reaching only 0.2–0.3% pt HbA1c difference after three years, and no difference between groups after four years. Further, the study found that long-term clinical benefits of reduced cardiovascular events and mortality did not accrue from temporary HbA1c control. **In other words, people with diabetes must sustain blood glucose control permanently to achieve health benefits.** Therefore, the value of a diabetes intervention is dependent on long-term, rather than short-term maintenance of HbA1c control.

With the exception of nutritional ketosis, there is no evidence of sustained effects for digital diabetes management solutions relative to usual care after the intervention period is complete, which is consistent with the *New England Journal of Medicine* study's findings. Unless remission is achieved, this category's impact will likely diminish with time, including with sustained use, and there is no evidence to suggest long-term benefit.

Secondary Health Outcomes

Additional health outcomes captured included body weight (13 articles), blood pressure (10 articles), body mass index (five articles), high-density lipoprotein (11 articles), low-density lipoprotein (11 articles), total cholesterol (10 articles), triglycerides (nine articles), and waist circumference (two articles) [see Appendix G for detailed outcomes]. Despite the importance of these secondary health outcomes for long-term risks for people with diabetes, these articles reported no significant changes in body mass index, low-density lipoprotein, total cholesterol, or waist circumference.

Evidence for weight loss and blood pressure effects was limited. Four out of 13 studies reported significant between-group differences in body weight. One of the studies focused on the benefits of adding health coaching to a digital diabetes management solution.[64] Another single study reported statistically significant differential changes from baseline in systolic blood pressure at one year: both groups got slightly worse, but more so for usual care (0.90 mmHg) compared with the intervention (0.31 mmHg).[65]

Another goal of successful diabetes management is improved adherence to prescribed medications, which is important to support glycemic control in people with diabetes. Most digital diabetes management solutions include prompts that remind users to take their medicine. Few articles reported on medication adherence, and generally found that digital solutions helped improve medication adherence among users. While improved medication adherence should improve overall performance of glycemic control, these results were not sufficient to produce clinically meaningful benefits, as described above.

Taken together with the company-submitted data, the evidence does not indicate that either the **remote patient monitoring** or **behavior or lifestyle modification category** produces clinically meaningful improvements on any secondary health outcomes, relative to usual care.

Introduction

Technology
Context

Clinical
Effectiveness

Economic
Impact

Summary
Ratings

Next
Steps

By contrast, the **nutritional ketosis** category produced superior results in secondary health effects, including statistically significant improvements in blood glucose, weight loss, blood pressure, cholesterol and liver profiles compared with usual care after two years. In addition, as a result of remission, findings showed that patients were able to reduce glycemic control medication use (except for metformin) from 55.7% to 26.8%, including a 62% reduction in insulin use and 100% stoppage of sulfonylureas, a common oral diabetes medication.[66] Findings for nutritional ketosis are promising and would benefit from more rigorous study designs to explore the generalizability of results to more diverse patient populations.

Solution-Specific Analysis

The following section reviews the evidence on the performance of individual solutions compared with the performance of the diabetes management solution categories assessed above. The solution-specific evaluations include literature from the SLR, as well as solution-specific information identified via internet research. Four companies — DarioHealth, Omada, Perry Health, and Virta — submitted company-specific information for this assessment [see Appendixes C-1 and C-2 for a full list of company-specific clinical references].

Not all solutions in this report have clinical data that meets the inclusion standards based on the assessment methodology. Given the similarity of approaches across the behavior and lifestyle modification solutions and the consistency of clinical outcomes across the fully body of evidence, it is fair to assume that companies without solution-specific data perform in line with the rest of the category. However, purchasers and users will have to make their own assumptions about performance. Some companies indicated that they were making product updates that may impact the results.

Exhibit 13

RISK OF BIAS FOR COMPANY EVIDENCE

Count of Solution-Specific Evidence Included in SLR

No qualifying evidence for **Perry Health, Verily (Onduo)** or **Vida.**
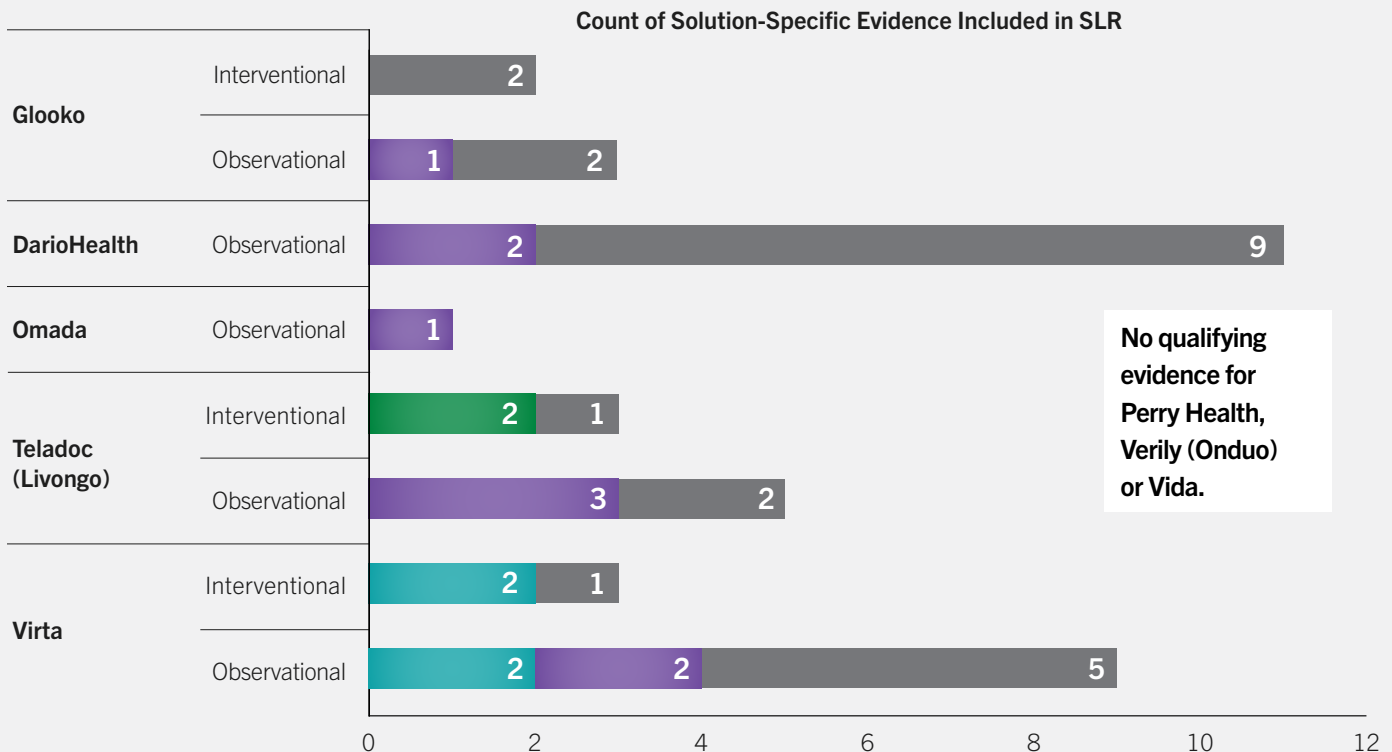
Notes. NA = Not Applicable; Insufficient methodological data to assess study quality and risk of bias for conference proceedings. The ROB2 and NOS were used to assess interventional and observational articles, respectively. See Appendix A for detailed risk of bias assessment methodology.

From 120 company-submitted references, 22 met the PICOTS criteria and were reviewed along with 15 SLR references related to the solutions in this report. Of these 37 references, only 15 could be evaluated for risk of bias (the remaining 22 references were abstracts or posters). As shown in Exhibit 13, nine had a high risk of bias, four were rated as moderate risk of bias, and two had a low risk of bias. Details on risk of bias for individual studies can be found in Appendix D.

Glooko: Glooko did not submit data for this assessment. From the literature scan, five total publications were reviewed for Glooko, including four conference abstracts and one retrospective publication[67] that had a high risk of bias. Of these, three pieces of evidence had comparators to usual care, and one was a RCT that used Glooko's platform in addition to coaching compared with usual care.[68] The latter study yielded an HbA1c reduction of 0.34% pt more than usual care,[69] which is in line with the remote patient monitoring category performance described above.

DarioHealth: DarioHealth provided 42 references that were reviewed in addition to evidence from the SLR. Eleven total references met the PICOTs criteria. Only one poster reported between group differences in HbA1c, with the Dario intervention reporting 0.23% pt greater decline in HbA1c compared with the matched non-user

cohort.[70] Among patients with a starting HbA1c above 9%, they had a 0.47% pt greater decline than patients whose starting HbA1c was 9% or lower. This supports the conclusion that people with higher starting HbA1c may benefit more from digital diabetes management solutions. DarioHealth also shared several conference posters and abstracts that suggest there were no significant differences in solution effect between rural/non-rural populations and across racial/ethnic groups. Additionally, in a poster presentation describing a retrospective matched cohort study, Dario users had a 23.5% lower all-cause inpatient hospitalization rate compared with non-users.[71]

Teladoc (Livongo): Teladoc (Livongo) did not submit data for this assessment. The SLR included eight publications on the Teladoc (Livongo) solution, including three high-quality interventional studies that had a low risk of bias. The studies included a well-designed crossover RCT that compared usual care from a diabetes Center of Excellence with Livongo's solution integrated into the center's workflow for six months, and then the patients from one group crossed over to the other. The groups that received the Livongo solution in either six-month period saw a statistically nonsignificant reduction in HbA1c of 0.4% pt compared with usual care. However, the Livongo solution group did not demonstrate a benefit over usual care after 12 months

in this mixed-effects study design.[72,73] These solution-specific results are consistent with the performance profile seen at the category level for behavior and lifestyle modification solutions, including the finding that benefits from digital diabetes management solutions diminish over time. Beyond HbA1c results, the other two interventional articles focused on varying the amount/intensity of coaching delivered in the Livongo program;[74] these results generally indicated that more coaching or provider intervention was beneficial.

Omada: Omada provided 23 references for this evaluation. Omada's solution targets population-level care for several chronic conditions, including diabetes, hypertension, and musculoskeletal care. Many of the clinical articles submitted by Omada focused on diabetes prevention for a prediabetes population, which is beyond the scope of this assessment. One relevant study for type 2 diabetes was examined. This was a single-armed, nonrandomized trial that demonstrated improvement of 0.8% pt HbA1c among a self-selected group of participants from an online health community; however, there was no comparator and the study had a high risk of bias.[75] This result is consistent with the absolute longitudinal reductions in HbA1c identified for the category of behavior and lifestyle modification. Additionally, a microsimulation analysis found Omada users had overall reductions of 0.9% Hba1c on average within 6 months.[76]

Vida: While the SLR did not include any studies on Vida, a broad search of solution-specific evidence identified two single arm, retrospective studies of Vida's solution. These studies showed an absolute decrease of 0.81% pt and 1.35% pt HbA1c from baseline among Vida users. The applicability of both studies was limited by methodological characteristics, most notably a lack of a usual care comparison group and likely selection bias. Nonetheless, the longitudinal improvements in HbA1c in these studies are consistent with the evidence included in the SLR and suggest that Vida performs in line with the behavior and lifestyle modification category.

Perry Health and Verily (Onduo): The SLR did not yield any studies that met inclusion criteria for Perry Health or Verily (Onduo). Perry Health submitted a variety of information describing their product but no clinical publications. Perry Health's submissions did include two clinical claims without sources and the results could not be verified. Verily (Onduo) did not submit any solution-specific data; however, given similarities in solution design, these solutions are likely to perform in line with the rest of the behavior and lifestyle modification category.

Virta: Twelve of the 55 publications reviewed for Virta were relevant for this evaluation, including multiple articles derived from a single longitudinal cohort study.[77,78] As noted above, this nonrandomized, interventional, intention-to-treat study with one- and two-year follow-ups demonstrated significant HbA1c reductions of more than twice the clinically meaningful

threshold. The between-group effect size was a reduction of 1.2% pt[79] HbA1c after two years. More importantly, after two years, 71.1% of users achieved HbA1c levels below the 6.5% threshold for diabetes, either taking no diabetes drugs or only metformin.[80] These Virta participants saw considerable reductions in their prescription drug use and also reported significant improvements in weight, blood pressure, and cholesterol levels.

These results suggest that compared with people using other digital diabetes management solutions, those who complete the nutritional ketosis intervention are more likely to achieve clinically meaningful benefits in glycemic control, including remission, and those benefits may be more durable. Although

this study had a larger sample size and longer duration than the rest of the literature, it has a moderate risk of bias because of concerns regarding selection and comparability of cohorts. Specifically, because participation was not randomized, the intervention arm of the study was likely to attract participants who were more willing to make the intensive dietary changes required for nutritional ketosis. As such, results may not be broadly attainable for all people living with type 2 diabetes and real-world participation and success rates may be lower than those seen among the study population. Notably, Virta's data suggest comparable impact on HbA1c across racial and ethnic backgrounds and patients who reside in areas of socioeconomic disadvantage.

Two Key Questions Remain for Virta's Solutions

1) Who can follow a program of nutritional ketosis?

Several articles support the durability of Virta's effects among the 83% of study participants who completed the program. This suggests that patients who are willing to participate in and complete nutritional ketosis programs can achieve significant health benefits. However, because the study designs were nonrandomized, they are likely to suffer from selection bias, from attracting participants who are most willing to follow the program and most likely to see improvement without any intervention. The significant dietary changes required for nutritional ketosis may not be achievable for all people living with type 2 diabetes.

2) Is this solution relevant for people with low socioeconomic status or of different racial or ethnic backgrounds?

This topic is under-researched and deserves additional attention. One study found statistically meaningful reductions in HbA1c across all socioeconomic levels,[81] yet preliminary results from another study on user engagement suggests that age, race, and HbA1c level may differentially influence the use of Virta.[82] These preliminary results ought to encourage future study designs that allow for adequately powered subgroup analyses and that control for these and other relevant covariates in analyzing patient outcomes. This would expand the evidence about how users experience this category of solutions, as well as the solutions' track record in reaching groups who can most benefit from these interventions.

User Experience

Eighteen articles reported information on patterns of use, including four interventional and 14 observational study designs. Use of digital diabetes management programs decreased over time across all articles, including those within the remote patient monitoring and the behavior and lifestyle modification categories. Most follow-up time periods ranged from weeks to a year, with a few exceptions for multiyear follow-up periods described above [see full details in Appendix H].

A separate set of articles that included outcomes for self-efficacy, knowledge, and self-management behaviors showed marginal impacts, with few studies reporting significant between-group differences. Some studies demonstrated benefits in blood glucose testing and general self-care behaviors with the digital diabetes management solutions,[83] while others showed nonsignificant or mixed results,[84] with limited durability over time.[85] Of note, one study found a significant increase in self-management skills among patients using a digital solution in conjunction with health counseling, but not among patients using the digital solution alone nor those receiving usual care.[86]

Health Equity

Diabetes disproportionately affects certain racial and ethnic groups and low-income individuals who are more likely to experience barriers to high-quality healthcare and to have higher starting HbA1c levels. As such, digital diabetes management solutions could improve health equity by targeting the solutions to these groups that would benefit most from improved management:

- **Diverse populations with high disease prevalence** — The burden of type 2 diabetes disproportionately affects people who are lower income, have limited health literacy, and come from Black or Hispanic backgrounds.

- **Patients with high starting HbA1c levels** — As described above, diabetes complications are more serious for people with starting HbA1c levels of greater than 9%. Further, given that the clinical evidence suggests that these digital diabetes management solutions may have a greater impact on patients with high HbA1c levels, prioritizing this group could have more meaningful impact.

- **People with limited access to diabetes care** — People who live in rural or underserved areas that may have less access to regular, high-quality, in-person diabetes care. While this review did not uncover specific evidence related to this subgroup, remote management solutions could be particularly helpful to those with more limited access to in-person care.

The ability to conduct a detailed analysis of how digital diabetes management solutions impact health equity was constrained by the available evidence. Unfortunately, most studies were not designed or statistically powered for detailed subgroup analysis. Given that the studies did not produce population-specific evidence, we considered more indirect measures of health equity by looking at the inclusion criteria, demographic composition, and demographically related findings across all studies.

Unfortunately, demographic characteristics of study participants are sparsely reported across the 69 articles [see Appendix J]. Only 14 articles reported on one or more sociodemographic characteristics, namely geographic location (seven articles), educational background (10 articles), employment status (six articles), and internet access (one article). Only 24 articles reported race/ethnicity, with the vast majority of these including primarily white patient populations in the study. It is regrettable and inadequate that these studies do not reflect the demographic mix of people living with diabetes.

Two articles reported on patient engagement by race/ethnicity. One reported significantly higher engagement by white participants than Black participants[87] and the other reported no significant differences between white participants and those of other racial and ethnic backgrounds.[88] It is imperative that further research be conducted to determine whether patient engagement and clinical outcomes for digital diabetes management solutions are comparable across diverse populations.

Of the 42 articles that report on HbA1c, only 12 articles had participants with average starting HbA1c levels above 9%, suggesting these solutions are often being deployed to populations with lower blood glucose levels.

Based on the available research, there is no compelling evidence that digital diabetes management solutions are being used to address health disparities or deployed to patients with higher starting HbA1c levels who suffer the most serious consequences from diabetes.

Of note, DarioHealth, Omada, Perry, and Virta all supplied additional information on health equity and accessibility, much of it informed by user data. The data suggest that these companies are making efforts to understand variations in the use of their solutions and to improve such areas as accessibility, cultural competency, and equitable access. Ongoing analysis and publication of these findings would help fill an existing data gap.

Given the characteristics, prevalence and seriousness of this disease, combined with the associated health access challenges, ongoing research and evidence generation about the health equity effects of these solutions and their potential for positive impact should be a priority.

A Note on Safety

There were limited data on adverse events in the body of evidence. Some studies, such as the one conducted using Virta, did report the absence of safety and adverse events in the intent-to-treat population attributed to the intervention. Even without evidence of harm, a Tier 3a intervention still has potential risk that may arise from incorrectly used glucometers, misinterpretation of results, or suboptimal clinical support. That said, because these diabetes management solutions augment standard care approaches or provide clinical oversight, these potential risks may be addressed in treatment.

Clinical Effectiveness Ratings

Using the evidence-rating matrix from the ICER-PHTI Assessment Framework, the body of evidence for both remote patient monitoring and behavior and lifestyle modification technologies delivers moderate to high certainty. The evidence meets both minimum and best evidence standards. While the risk of bias varies across articles, each category includes one or more well-designed, comparative studies. Most importantly, the study results that are statistically significant (regardless of risk of bias) are tightly clustered, which enhances the reliability of the findings.

The comparative net health benefit for glycemic control consistently shows a small, positive benefit for patients using digital diabetes management solutions, compared with usual care. Taken together, the evidence certainty and net health benefit result in a "Comparable or Incremental" rating[d] for clinical effectiveness in **remote patient monitoring** and **behavior and lifestyle modification.** Solution-specific evidence varies, as described above. Because all of these solutions deliver similar interventions to patients, it is likely that their performance will be comparable to that of the rest of the category. Additional evidence generation is needed, however, to both validate and differentiate the performance of individual technology solutions in these categories.

For the **nutritional ketosis** category, specifically for Virta, there is a low to moderate level of evidence certainty based on a single large, long-term trial with a moderate risk of bias. However, the clinical results at both one- and two-year follow-ups demonstrate substantial comparative net health benefits of the intervention relative to usual care, as well as to other solutions included in this assessment. This produces an overall clinical effectiveness rating of "Comparable or Better"[e] for Virta.

It would be beneficial to further substantiate these initial promising results to meet the best evidence standard for a Tier 3a intervention by conducting studies that randomize patients to the intervention group. This would limit the risk of selection bias given the intervention's reliance on strict patient compliance with a ketosis diet. Further evidence generation should also focus on broader populations, including more-diverse groups and those with higher starting HbA1c, who stand to benefit the most from improved glycemic management.

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[d] This corresponds to a C+ in the ICER Evidence Rating Matrix™.

[e] This corresponds to a C++ in the ICER Evidence Rating Matrix™.

Economic Impact

The economic impact on purchasers of digital diabetes management solutions depends on the price of the digital solution and how it affects patterns of healthcare utilization and spending for patients who use them. People with diabetes have higher overall levels of healthcare spending, which increases with higher levels of HbA1c.[89] As a result, there is potential to reduce healthcare system spending if patients with diabetes achieve meaningful benefits in glycemic control that result in reductions in medication use, outpatient services, hospitalizations, and testing supplies.

Careful assessment of the economic impact of these technologies must balance the incremental health benefits and cost savings that these solutions deliver against the price paid to companies for the solution. If digital diabetes management solutions could improve glycemic control enough to result in healthcare savings that exceed the cost of the product, they would deliver both clinical and economic benefits.

Budget Impact Model Methodology

While there are many methods to estimate the savings impacts of healthcare interventions, to create comparability across digital diabetes categories, this analysis uses a budget impact approach to estimate net healthcare spending impacts on payers. The budget impact model estimates the expected one- and three-year change in total healthcare spending from implementing digital diabetes management solutions for eligible participants. The model accounts for the number of people who could be eligible for digital diabetes interventions, the gross reduction in expected healthcare spending resulting from improved glycemic control for patients enrolled in these programs, and the net impact on health system spending once such savings are offset by spending on the diabetes management solutions.

It assumes a 25% adoption rate among eligible users.

Based on the clinical effectiveness results above, the budget model estimates the impact of digital diabetes solutions on healthcare spending for people with type 2 diabetes in three scenarios: 1) those using remote patient monitoring solutions, 2) those using behavior and lifestyle modification solutions within a general adult type 2 diabetes population, and 3) those using digital diabetes solutions targeted specifically to insulin users. This section also describes the potential for long-term budget impact associated with diabetes remission under nutritional ketosis.

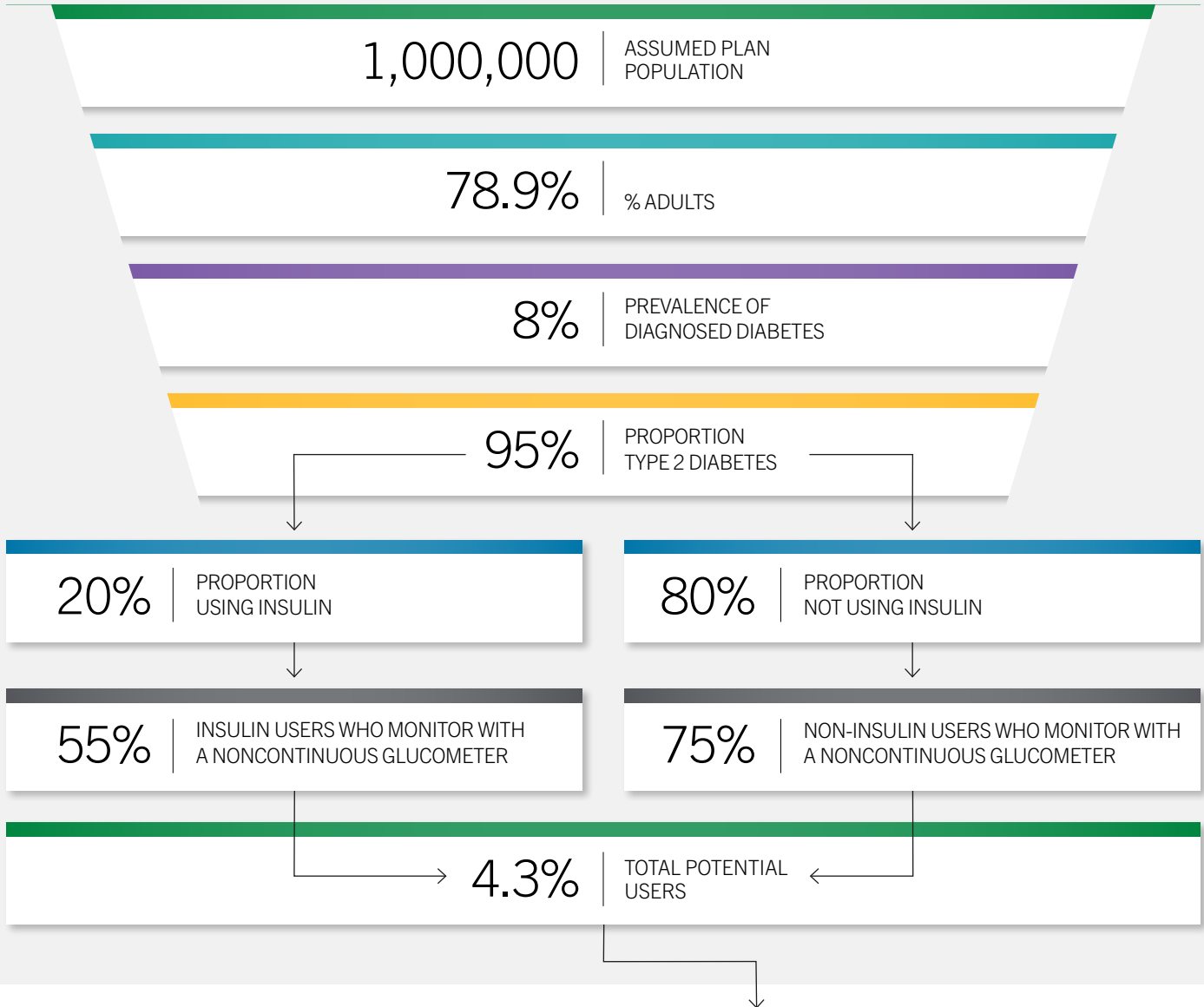There are three primary components of the budget impact:

1) Eligible population — The total number of patients who may qualify for a digital diabetes management solution, if broadly implemented;

2) Savings from health improvements — The changes in healthcare spending that result from improved glycemic control under usual care and digital diabetes management solutions; and

3) Technology price — The price paid to a digital health technology company (under a capitated agreement) or to a provider (under remote patient monitoring reimbursement).

These components come together to estimate the net impact on healthcare spending for a given user of a digital diabetes management solution. To scale estimates, the model calculates changes in spending across a hypothetical one-million-member plan. This is used to calculate the total change in spending across all digital diabetes solution users in the plan, and the overall per member per month impact of that spending across all enrollees in the plan.

Budget Impact Model Results

Eligible Population: The model estimates the number of adults with type 2 diabetes who are recommended to use a glucometer (insulin users and nonusers) across commercial, Medicare, and Medicaid coverage. After accounting for adults with diagnosed diabetes across payers, it is estimated that 20% of all patients with type 2 diabetes[90, 91] rely on insulin, and approximately 55% of insulin users self-monitor their blood glucose levels using a noncontinuous glucometer.[92] Of the remaining people with type 2 diabetes who do not use insulin, an estimated 75% perform regular self-monitoring.[93] Based on these assumptions, the proportion of people who could be clinically eligible to participate in digital diabetes

Exhibit 14

ESTIMATING THE ELIGIBLE POPULATION FOR DIGITAL DIABETES MANAGEMENT SOLUTIONS

Hypothetical Million-Member Commercial Health Plan

1,000,000 | ASSUMED PLAN POPULATION

78.9% | % ADULTS

8% | PREVALENCE OF DIAGNOSED DIABETES

95% | PROPORTION TYPE 2 DIABETES

20% | PROPORTION USING INSULIN

80% | PROPORTION NOT USING INSULIN

55% | INSULIN USERS WHO MONITOR WITH A NONCONTINUOUS GLUCOMETER

75% | NON-INSULIN USERS WHO MONITOR WITH A NONCONTINUOUS GLUCOMETER

4.3% | TOTAL POTENTIAL USERS

Population	Commercial	Medicare	Medicaid
Adults[94]	78.9%	99.2%	48.7%
Prevalence, diagnosed diabetes[95]	8.0%	25.4%	14.6%
Proportion, type 2 diabetes[96]	95.0%	95.0%	95.0%
Proportion using insulin[97, 98]	20.0%	20.0%	20.0%
Insulin users who use a noncontinuous glucometer[99]	55.0%	55.0%	55.0%
Proportion not using insulin who use a noncontinuous glucometer[100]	75.0%	75.0%	75.0%
TOTAL ELIGIBLE POPULATION FOR DIGITAL DIABETES MANAGEMENT	**4.3%**	**17.0%**	**4.8%**

management programs is as much as 4.3% of people with commercial insurance, 17% of those with Medicare, and 4.8% of those with Medicaid (Exhibit 14).

Savings From Health Improvements

The model estimates the impact of digital diabetes management solutions' total healthcare spending for insured adults with type 2 diabetes who are enrolled in commercial insurance, Medicare, or Medicaid.[101] For people with starting HbA1c above 7%, researchers have found that each point (1% pt) decrease of HbA1c is associated with a linear 1.7% decrease in total cost of care (including all healthcare costs, not just diabetes).[102]

The budget impact model applies this spending reduction assumption to the between-group differences in HbA1c between individuals receiving usual care and those enrolled in a digital diabetes management program, as reported in the clinical literature. For reductions in HbA1c that are less than 1%, we take a pro rata reduction in cost based on the 1.7% for a 1% reduction.

For the people with type 2 diabetes who use remote patient monitoring solutions, the incremental HbA1c reduction ranged from 0.23% pt to 0.60% pt. One study with a 24-week follow-up for patients using Glooko compared with usual care found between-group differences of 0.34% pt HbA1c. Using this study, the incremental health savings from HbA1c reductions with remote patient monitoring is estimated at $100 per user per year in commercial insurance, $144 per user per year in Medicare, and $114 per user per year in Medicaid.

For the people who use behavior and lifestyle modification solutions, the incremental HbA1c reduction was 0.37% pt using Teladoc (Livongo) compared with usual care. Based on average spending for people with type 2 diabetes, this would reduce annual healthcare spending for users by approximately $109 in commercial insurance, $157 in Medicare, and $125 in Medicaid.

As described above, one study found larger between-group differences (1.2% pt HbA1c) for users who were newly beginning insulin. For this population, the model estimates that users of digital diabetes management solutions could achieve gross healthcare savings of $354 per year in commercial insurance, $508 per year in Medicare, and $406 per year in Medicaid (Exhibit 15).

Exhibit 15

ANNUAL HEALTHCARE SAVINGS FROM IMPROVED HBA1C COMPARED WITH USUAL CARE

		Commercial	Medicare	Medicaid
Total Healthcare Spending for People With Type 2 Diabetes[103]		$17,335	$24,889	$19,911

		Incremental health savings from HbA1c reduction, per user per year		
REMOTE PATIENT MONITORING	Between-group difference in HbA1c	Commercial	Medicare	Medicaid
Low HbA1c Benefit[104]	0.23%	$68	$97	$78
Middle HbA1c Benefit[105]	0.34%	$100	$144	$114
High HbA1c Benefit[106]	0.60%	$177	$254	$203
BEHAVIOR AND LIFESTYLE MODIFICATION[107]	0.37%	$109	$157	$125
NEW INSULIN USERS	1.20%	$354	$508	$406

Technology Price: To assess the expected net spending impact, the model offsets the price of the digital diabetes management solution from the healthcare savings.

Digital solutions for remote patient monitoring are typically sold to healthcare providers who then bill insurance via current procedural terminology (CPT) codes that reimburse them for their time spent reviewing patient data. In Medicare, providers can bill $1,155 or more annually for remote patient monitoring services[108,109] assuming one month of setup, 12 months of device supply and monitoring, and 12 months of care management. Annual billing for remote patient monitoring is estimated at $2,102 in commercial coverage and $809 in Medicaid. These figures represent increased costs to health plans, employers, and enrollees in the form of higher provider billing. This becomes revenue to the providers who often purchase remote patient monitoring solutions for their practices.

For behavior and lifestyle modification, company-submitted data and published[112] pricing information were used to estimate an average monthly solution price of $64 per user per month or $768 per user per year. This average price is used to estimate the budget impact (Exhibit 17). Actual prices charged by specific solution vendors or negotiated by particular purchasers may vary and would impact these results.

Supplies

- People with diabetes who self-monitor their blood glucose need testing supplies, including a glucometer (which can last for several years), and disposable single-use lancets for finger pricks and test strips for collecting blood samples.

- People with diabetes who use insulin test their glucose an average of three times per day, while those who do not use insulin typically test once a day.[110]

- The cost of test strips and lancets is estimated at $0.32[111] per use of strip and lancet in commercial insurance or approximately $178 per year, across both insulin and noninsulin users.

- Most health insurers cover diabetes testing supplies.

- Some digital diabetes management solutions include the testing supplies in their pricing, especially in the behavior and lifestyle modification and nutritional ketosis categories.

- Given these facts, our analysis excludes any shifting of this testing supply cost from the net cost savings. This is because these costs are incurred with or without the digital solution. Therefore, the shifting of these costs, if any, from usual care to the digital solution does not represent actual savings from usual care.

Understanding Digital Product Prices

Many digital diabetes management solutions report estimates of their impact on total healthcare spending for users, but these numbers must be interpreted carefully. Typically, companies report gross savings, without "netting out" the cost of their solution. Further, most estimates also reflect total healthcare savings from diabetes management generally, rather than reporting the incremental savings that accrue from digital solutions relative to usual care. This is a critical distinction, given that most patients achieve HbA1c reductions and the associated cost savings under usual care scenarios. To understand the actual incremental value that digital solutions offer, purchasers need to assess performance above and beyond what patients are likely to achieve through self-management in usual care settings.

Change in Overall Spending

For **remote patient monitoring** (Exhibit 16), based on the middle estimates of HbA1c benefit as described above and 25% participation in a million-member plan:

- For commercial insurance, the net impact on total healthcare spending is a $2,002 increase per user per year. The technology would increase total spending by $21.3 million per year, or $1.77 per member per month.

- For Medicare, the net impact on total healthcare spending is $1,011 per user per year. The technology would increase total spending by $43.0 million, or $3.58 per member per month.

- For Medicaid, the net impact on total healthcare spending is $723 per user per year. The technology would increase total spending by $8.6 million per year or $0.72 per member per month.

In the **behavior and lifestyle modification** category (Exhibit 17), based on the estimates described above for HbA1c improvement achieved relative to usual care and a 25% participation assumption in a million-member plan:

- For commercial insurance, the net impact on total healthcare spending is $484 per user per year. The technology would increase total spending by $5.1 million per year, or $0.43 per member per month.

- For Medicare, the net impact on total healthcare spending is $513 per user per year. The technology would increase total spending by $21.8 million, or $1.82 per member per month.

- In Medicaid, the net impact on total healthcare spending is $574 per user per year. The technology would increase total spending by $6.9 million per year, or $0.57 per member per month.

Exhibit 16

REMOTE PATIENT MONITORING: NET CHANGE IN HEALTHCARE SPENDING

	Commercial	Medicare	Medicaid
Per User Per Year (Diabetes RPM Users Only)	$2,002	$1,011	$723
Total Spending Increase Per 1M Enrollees*	$21.3M	$43.0M	$8.6M
Per Member Per Month (All Enrollees)*	$1.77	$3.58	$0.72

* Assuming 25% of eligible people shift to RPM from usual care, the middle estimate for HbA1c improvement, providers bill the maximum RPM reimbursement per year, and no test strips are included with the solution.

Exhibit 17

BEHAVIOR AND LIFESTYLE MODIFICATION: NET CHANGE IN HEALTHCARE SPENDING

	Commercial	Medicare	Medicaid
Per User Per Year (Diabetes Behavior and Lifestyle Modification Users Only)	$484	$513	$574
Total Spending Increase Per 1M Enrollees*	$5.1M	$21.8M	$6.9M
Per Member Per Month (All Enrollees)*	$0.43	$1.82	$0.57

* Assuming 25% of eligible people shift to digital diabetes management from usual care and digital solutions include all test strips and lancets.

For the targeted application of digital diabetes management solutions to new insulin users, the budget impact is more favorable because there are greater savings associated with better HbA1c control (1.2% pt compared with usual care) and it targets a much smaller number of eligible enrollees. The model assumes that digital solutions would be offered to all insulin users, although it could be even more narrowly targeted to an incident population who is newly diagnosed with diabetes. If limited to only people with diabetes who are using insulin and self-monitoring their blood glucose, the eligible population shrinks to 0.7% of commercial coverage members and 2.6% of Medicare enrollees. Assuming a $64 per month charge for the digital solution, the net impact on total healthcare spending would be an increase of $239

in commercial, $162 in Medicare, and $322 in Medicaid. Because this approach has a more-targeted set of patients, total spending per million members is estimated at a lower level of $0.4 million in commercial, $1.1 million in Medicare, and $0.6 million in Medicaid in year one.

Given these stronger clinical meaningful benefits and attainment of MCID, more-targeted investment in these solutions could be potentially worthwhile to support. For example, if these solutions could achieve a 1.6% pt HbA1c reduction relative to usual care, they would start to be cost-saving for Medicare beneficiaries. However, solutions would need to demonstrate that new insulin users are able to sustain these health benefits over time to justify continued spending on the solution.

Three-Year Spending Impact

There are limited data on durability of the glycemic control achieved by digital diabetes management solutions, but the literature suggests these solutions lose efficacy over time.[113] The model assumes a 30% annual reduction in HbA1c control achieved by these interventions after the first year. By the third year, this virtually eliminates any expected health savings. If users remain enrolled in these solutions as clinical efficacy diminishes, then costs continue to accrue to payers. This underscores the importance of payers monitoring to ensure that payments for digital solutions are limited to active users.

Exhibit 18 shows three-year spending estimates for digital diabetes solutions, assuming that 25% of eligible users participate in the program, but that clinical efficacy declines annually by 30%.

Exhibit 18

THREE-YEAR NET SPENDING IMPACT OF DIGITAL DIABETES MANAGEMENT SOLUTIONS FOR A ONE-MILLION-MEMBER PLAN

	Commercial	Medicare	Medicaid
Remote Patient Monitoring	$65.6M	$138.9M	$28.1M
Behavior and Lifestyle Modification	$17.3M	$72.6M	$23.0M
Insulin Users	$2.1M	$8.6M	$3.0M

* Assuming 25% of eligible people shift to digital diabetes management from usual care.

Taken together, according to the clinical evidence available, digital diabetes management solutions in the remote patient monitoring and behavior and lifestyle modification categories are found to increase total health spending because the cost of the solution exceeds the

savings from improved clinical outcomes. These solutions are more promising for people with newly diagnosed diabetes who are beginning self-monitoring of their glucose, as well as those with higher starting blood glucose — for whom more-significant improvements in HbA1c

are more likely. For these targeted populations, purchasers can expect improved clinical performance with some increase in spending, although digital solutions must demonstrate that outcomes can be sustained over multiple years.

Nutritional Ketosis

The body of research on nutritional ketosis is smaller but offers insight into how digital solutions can achieve diabetes remission, which has a greater impact on health outcomes and spending. Virta's study reported larger HbA1c improvements (1.3% pt) at one year than any of the other interventions included in this report and showed lasting durability with a two-year HbA1c improvement of 1.2% pt over usual care.

Further, because 72% of Virta users achieve HbA1c levels below the 6.5% threshold for diabetes, the budget savings associated with Virta's clinical benefits are likely to outperform the linear assumption of 1.7% savings per 1% pt reduction in HbA1c used elsewhere in this model. Virta users who achieve HbA1c below 6.5% benefit from lower utilization of prescription drugs, including insulin, metformin, and other oral medications. Preliminary research also suggests that these users experience lower inpatient and emergency department visits, supply costs, and outpatient visits.[114] If Virta users can sustain their health improvements, the potential annual healthcare savings continues to accrue. However, more rigorous research is needed to substantiate these findings and their long-term impact on spending.

Virta's higher potential for cost savings must be considered in the context of its more intensive approach and much higher price. While negotiated prices with insurers may vary, Virta's listed price for 2021–22 was $2,868 in year one and $2,580 in year two.[115] Virta's own analysis from the same time period estimates annual savings in the first year of $3,094, which (if achieved) would result in savings to payers of $226 per user.[116] Virta's evidence also finds that users experience even more healthcare spending reductions in subsequent years, which could produce additional savings for payers. These clinical savings estimates could not be independently validated for this report.

Actual savings realized by payers could be consistent with or different from these company-produced estimates, depending on the portion of members who can sustain nutritional ketosis, the associated spending reductions from improved health, and the durability of those benefits. A key to effective contracting for Virta will be to ensure that negotiated prices are tied to attainment of promised clinical benefits and that real-world performance is on par with that found in the study population.

Out-of-Pocket Costs

While digital diabetes management solutions increase health plan budgets, and thereby premiums to employers and individuals, they may result in lower out-of-pocket costs for patients. Today, many digital solutions are offered to patients through the wellness benefit with no required cost-sharing. Particularly for behavior and lifestyle modification solutions that shift testing supply costs from the medical benefit to the capitated product price, people who use these solutions may have reduced cost-sharing for their supplies. However, remote patient monitoring solutions can increase patient out-of-pocket spending, depending on how their health plan applies deductibles and cost-sharing to those services.

Additional Costs and Benefits

Although some digital diabetes management solutions provide users with connected glucometers as part of their pricing models, the model does not offset these costs from the product price. While digital health companies incur these costs, not all patients need a new glucometer, so the provision of a new glucometer does not directly reduce expected health plan spending for these members.

Importantly, deployment of these solutions across health plan members or provider groups also consumes attention and resources (time and money). The budget model does not capture these additional costs associated with the introduction of a new technology into payer and provider systems. Furthermore, the model does not account for the time that users invest engaging with digital technologies.

Limitations

A key assumption in the model is the 1.7% linear savings reduction from a 1% pt HbA1c improvement across all payer types. This estimate was based on a study that used a commercial claims dataset for people with starting HbA1c levels above 7%. Other estimates of savings from improved glycemic control find the savings are higher in commercial populations than in Medicare, for which healthcare spending is less sensitive to improvements in HbA1c.[117] As a result, this budget impact model may overestimate savings in Medicare relative to those in commercial insurance.

While other studies estimate higher health savings from HbA1c improvements, these studies have several limitations. First, many studies assume that individuals who reduce their HbA1c — for instance, from 8% to 7% — will have annual spending patterns that are similar to the population with a lower starting HbA1c.

However, studies that track patients who actually reduce their blood glucose levels find that, while spending goes down, it still exceeds that of the cohort who had a lower starting HbA1c.[118]

One actuarial analysis on the impact of diabetes management solutions estimated a much larger reduction in healthcare spending equal to 9% in commercial insurance and 5% in Medicare. However, in this simulation, patient HbA1c levels went down by 1% pt with an accompanying 10mm/hg drop in blood pressure and improvements in cholesterol. This highlights the potential for better budget impact performance, if digital diabetes management solutions can produce both incremental HbA1c improvements and blood pressure and cholesterol benefits compared with usual care — none of which was found in the clinical literature for these solutions.

If we were to use this enhanced savings assumption in the model for all users, the cost of digital diabetes management in commercial insurance would effectively break even ($15 per user per year) in year one and still remain cost-increasing over three years as clinical benefits erode over time. In Medicare, using this assumption, digital diabetes management solutions would increase costs by $209 per user per year in year one and would continue to increase in future years. In Medicaid, first year per user costs would be $36 and would increase rapidly in future years.

Summary Ratings

Digital diabetes management solutions in the remote patient monitoring and behavior and lifestyle modification categories do not deliver meaningful clinical benefits, and they increase healthcare spending relative to usual care. Nutritional ketosis solutions hold promise for diabetes remission.

Based on evidence from a range of studies, digital management solutions consistently demonstrate that they help patients achieve small reductions in HbA1c beyond what they would achieve with usual care, but the evidence rarely reported improvement that exceeded commonly used thresholds for meaningful clinical benefit. Further, evidence suggests that such small benefit will reduce over time. After accounting for the average price of these products, these solutions increase net healthcare spending for purchasers because the small estimated savings are less than the cost of the solution.

There are two important exceptions to these summary findings:

1) People with higher starting HbA1c who are newly starting insulin are likely to experience greater benefits from the use of these technologies; and 2) nutritional ketosis, as offered by Virta, has the potential to deliver more dramatic and durable clinical benefits — including diabetes remission and deprescribing — for those who can adhere to the intensive change in diet.

The first exception underscores the importance of patient selection. Patients with uncontrolled diabetes who are trying to make large, relatively rapid shifts in their glycemic control in collaboration with their providers may better utilize the feedback loops

Exhibit 19

PHTI CATEGORY-LEVEL RATINGS FOR DIGITAL DIABETES MANAGEMENT SOLUTIONS

● Positive   ● Moderate   ● Negative
● Higher Evidence Certainty   ○ Lower Evidence Certainty

	Clinical Effectiveness		Economic Impact[a]		Summary Rating[b]	
Remote Patient Monitoring Glooko	●	**Results:** Small but not clinically meaningful reduction in HbA1c **Evidence Certainty:** Higher	●	Net increase in spending — current provider reimbursement exceeds cost savings from avoided care	●	Current evidence does not support broader adoption
Behavior and Lifestyle Modification DarioHealth, Omada, Perry Health, Teladoc (Livongo), Verily (Onduo), Vida[c]	●	**Results:** Small but not clinically meaningful reduction in HbA1c[d] **Evidence Certainty:** Higher	●	Net increase in spending — current solution pricing exceeds cost savings from avoided care	●	Current evidence does not support broader adoption
Nutritional Ketosis Virta	○	**Results:** Clinically meaningful reduction in HbA1c sufficient to achieve remission in some patients[e] **Evidence Certainty:** Lower	○	Initial net increase in spending with potential for long-term savings	●	Evidence supports broader adoption with ongoing evidence generation

Source: PHTI, Digital Diabetes Management Solutions Assessment, March 2024. See full PHTI report on digital diabetes management solutions for complete assessment, methods, and recommendations.

[a] Economic impact for remote patient monitoring based on standard provider reimbursement using remote patient monitoring (RPM) codes. Economic impact for behavior and lifestyle modification category assumes a $64 per user per month product price.

[b] Summary rating reflects the combination of clinical and economic results.

[c] Not all solutions have clinical data that meet the inclusion standards for this report. Based on the similarity of approaches and the consistency of clinical outcomes across the category, it is fair to assume that companies without solution-specific data perform in line with the category. Purchasers and users will have to make their own assumptions about performance.

[d] Potential for improved and meaningful clinical benefits in populations with higher starting HbA1c who are newly starting insulin.

[e] Key questions for nutritional ketosis involve generalizability of evidence and adherence rates among real-world users.

and support that these technologies provide. These focused use-cases could be important places to start for developing more effective technologies.

The second exception, nutritional ketosis, rests upon the potential of this solution category in achieving diabetic remission. With this goal, the higher upfront effort and spending appears to deliver longer-term health benefits and associated cost savings, which continue to accrue over time. Virta is building an evidence base that includes multi-year follow-up, and we encourage more research on patient characteristics that are predictive of program completion.

These findings are based on the criteria set forth in the Assessment Framework and the currently available evidence.

Remote patient monitoring and behavior and lifestyle modification solutions showed small incremental benefits (0.23–0.60% pt reduction in HbA1c) compared with usual care. However, they also are likely to increase total health spending. An estimated 4.3% of all people enrolled in commercial coverage and up to 17% of all Medicare beneficiaries could be eligible for these solutions. However, remote patient monitoring solutions are estimated to increase annual spending by $2,002 per user in commercial coverage and $1,011 per active Medicare beneficiary, and $732 per Medicaid beneficiary. Behavior and lifestyle modification solutions increase annual spending by $484 per user per year in commercial coverage, $513 per Medicare user, and $574 per Medicaid user.

Nutritional ketosis solutions are more likely to achieve clinically meaningful benefits in glycemic control — including diabetes remission — with greater health benefit durability compared with other digital diabetes management solutions.

In terms of impact to health equity, the literature shows no compelling evidence to suggest that these solutions are being used to address health disparities or create access for patients without standard care options. Most studies are focused on patients with lower starting blood glucose levels, rather than individuals who are at highest risk for diabetes-related complications. Published results should be reviewed carefully before generalizing across populations.

Next Steps

Recommendations for Purchasers

As discussed above, the current available evidence for remote patient monitoring and behavior and lifestyle modification diabetes management solutions suggests only small incremental benefits to HbA1c levels and a higher overall cost of care, compared with usual care. As a result, the current evidence base reviewed in this report does not support broader adoption of these solutions by purchasers on the basis of their clinical or economic performance.

For purchasers with existing contracts for these solutions or purchasers who are interested in these solutions for other reasons, we suggest a tailored, data-driven approach below. As solutions continue to evolve and the evidence base expands, purchasers may need to update their approach to contracting.

Nutritional ketosis solutions are more likely to achieve clinically meaningful benefits in glycemic control, including diabetes remission. As a result of this promising performance, the evidence supports broader adoption of these solutions with ongoing evidence generation to strengthen and validate the evidence about clinical benefits and confirm the budget impact.

For purchasers who are contracting with the digital diabetes management solutions included in this report, we offer the following recommendations:

1) Require data analysis and transparency — Purchasers should contractually require data and analysis of digital solution's performance in their own member population at regular intervals. This should include a clear method of reviewing evidence in key areas of clinical impact (including HbA1c), as well as user engagement, program completion rates, and key predefined clinical outcomes or utilization changes.

2) Align payments and performance — We recommend that purchasers use these additional performance data to ensure that payments are tied to successful results. This may include increasing the portion of contracts at risk and/or including claw back clauses for overpayments. These provisions should be balanced with significant payments for solutions that achieve meaningful targets, at price levels that both reward the solution provider and lower the overall cost of care.

3) Refocus performance guarantees on patients with the highest HbA1c — As discussed above, people with higher starting HbA1c who are newly starting insulin are likely to experience greater benefits from the use of these technologies. Populations that have high HbA1c are also more likely to be low-income and disproportionately Black and Hispanic. While some contracts with digital solutions include performance guarantees, they are often not focused on specific subpopulations. Purchasers should define meaningful clinical and economic impact targets that emphasize success in these important subpopulations who may be more likely to benefit from the solution.

Recommendations for Innovators

When these tools were first built, they responded to decades of evidence that diabetes self-management and education programs could help patients improve their outcomes. After more than 15 years of adoption, testing, and evidence generation, this report found that the digital diabetes management solutions have not generated the hoped for levels of improvement in health outcomes or cost efficiency. However, the information, data and know-how that this sector has acquired is valuable, and should be leveraged toward better performance going forward.

The next generation of diabetes management solutions must aim for clinically meaningful glycemic control. This is the key goal for all diabetes management, and the implementation of new technology solutions must be proven to have a positive impact on the health of patients and a reduction in overall healthcare spend. The increasing use of GLP-1 medications and CGMs represent important opportunities for review and innovation. Given the promising performance of nutritional ketosis solutions, this category also merits further testing. Development of new solutions should focus on these key themes:

1) Sufficient evidence generation is critical — As companies and investors commercialize solutions, we recommend that they set aside capital to invest in generating evidence of performance that can prove the clinical and economic benefits of the technology to providers and patients. To be valuable to the market, this research should compare solution performance to usual care over longer periods of time and across more diverse populations. This does not mean that full RCTs are necessary or appropriate for all technologies. However, it does mean that partnerships with healthcare researchers must find the right balance of rigor and speed, to sufficiently demonstrate how new technology solutions perform relative to usual care.

2) Sustainability is central to clinical impact — Diabetes is a chronic condition that requires persistence in self-management—temporary improvements will not result in long-term health benefits or savings. We recommend that companies expand the length of follow-up in their studies to understand the durability of any clinical effects their solutions can deliver. Diabetes solutions must address old habits and reminder fatigue and deliver a user experience that sustains engagement and creates lasting behavior changes to support durable health benefits.

3) Provider acceptance and engagement matters — A strong patient and provider relationship is an important part of effective chronic condition management. Innovators need to help purchasers of digital health solutions better understand how a solution integrates into or complements patient care, and providers' ongoing chronic condition management. Within the technology solution, this may include the bi- or uni- directional sharing of data, clinical results, or notes on management.

4) Contract for results — Purchasers are increasingly seeking digital technology solutions that are prepared to put their fees at risk based on delivering successful health results and economic savings. Outcome-based contracts and performance guarantees will become increasingly common as purchasers re-evaluate their digital health stack.

Recommendations for Providers

Under usual care, most patients can lower their HbA1c through traditional forms of self-monitoring and care management. In terms of new digital solutions, this report found that **remote patient monitoring and behavior and lifestyle modification** solutions showed small incremental benefits (0.23–0.60% pt reduction in HbA1c) when compared to usual care. In comparison, common diabetes drugs — such as metformin, sulfonylureas, or GLP-1 receptor antagonists — can produce median HbA1c improvements of 1% pt or greater.[119] When considering whether to recommend digital solutions to patients, providers should be aware that:

1) Performance may vary by sub-population — Specifically, the evidence suggests that patients with high HbA1c (>9%) who are initiating insulin for the first time may benefit the most from these digital solutions. Combined with supplementary support, education, and self-management, it is important for these patients to establish successful behaviors and habits from the start. Further, these populations are more likely to be low-income and disproportionately Black and/or Hispanic.

2) Diabetes remission is a worthy goal that may be supported with effective digital solutions — While more modest improvements in managing diabetes can improve health and generate savings, full diabetes remission is a viable health outcome that has much more significant and lasting benefits. The evidence reviewed in this assessment indicates that nutritional ketosis solutions are more likely to achieve clinically meaningful benefits in glycemic control — including diabetes remission — than usual care. A challenge with this approach is that it requires patients to maintain an intensive ketogenic diet, which can be difficult for patients to achieve and sustain long-term. Given the potential of this approach, providers should consider these solutions to determine feasibility, and the patients that may be most likely to achieve this highly beneficial health outcome and associated cost savings.

3) Be aware that many digital health solutions are cost-additive — Because these digital health solutions complement (rather than substitute for) usual care, they represent an additional cost. Furthermore, these solutions can be labor intensive for provider practices to set-up and document for reimbursement, and effort from the provider and patient is required for implementation. As a result, providers should be cautious when considering the patient benefits weighed against the spending impact of these programs. The solution's overall economic implications should be assessed based on its ability to eliminate or generate material savings in other aspects of the healthcare provided. The overall objective must be to improve health and lower overall net spending.

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Appendix E

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Appendix I

Between Group Comparisons for Glycated Hemoglobin Levels (HbA1c) by Solution Category

Appendix J

Baseline Patient Demographic Characteristics

To access all appendices, please visit https://phti.com/assessment/digital-diabetes-management-tools/#appendices.

References

1. Centers for Disease Control and Prevention (CDC). "National Diabetes Statistics Report," accessed February 8, 2024. https://www.cdc.gov/diabetes/data/statistics-report/index.html

2. CDC, "Type 2 Diabetes," accessed February 9, 2024. https://www.cdc.gov/diabetes/basics/type2.html#:~:text=Type%20 2%20diabetes%20most%20often,adults%20are%20also%20 developing%20it

3. CDC, "National Diabetes Statistics."

4. Lin, Ji, Theodore Thompson, Yiling Cheng et al. "Projection of the Future of Diabetes Burden in the United States Through 2060," *Population Health Metrics* 16, no. 9 (June 2018). https://doi.org/10.1186/s12963-018-0166-4

5. Health People 2030, "Diabetes," accessed February 21, 2024. https://health.gov/healthypeople/objectives-and-data/ browse-objectives/diabetes

6. Institute for Health Metrics and Evaluation, "Global Diabetes Cases to Soar from 529 Million to 1.3 Billion by 2050." June 22, 2023. https://www.healthdata.org/news-events/newsroom/news-releases/ global-diabetes-cases-soar-529-million-13-billion-2050

7. CDC, "Preventing Diabetes-Related Amputations," April 7, 2023. https://www.cdc.gov/diabetes/library/features/amputations.html

8. CDC, "Chronic Kidney Disease (CKD)," December 30, 2022. https://www.cdc.gov/diabetes/managing/diabetes-kidney-disease. html

9. CDC, "Heart Disease," June 20, 2022. https://www.cdc.gov/diabetes/library/features/diabetes-and-heart. html

10. Juarez, Deborah T., Roy Goo, Sheri Tokumaru et al., "Association Between Sustained Glycated Hemoglobin Control and Healthcare Costs," *American Journal of Pharmacy Benefits* 5, no. 2 (April 2013): 59–64. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3874271/

11. Bahman, Tabaei P., Renata E. Howland, Jeffrey S. Gonzalez et al., "Impact of a Telephonic Intervention to Improve Diabetes Control on Health Care Utilization and Cost for Adults in South Bronx," *Diabetes Care* 43, no. 4 (April 2022): 743–750. https://doi.org/10.2337/dc19-0954

12. Wagner, Edward H., Nirmala Sandhu, Katherine M. Newton et al., "Effect of Improved Glycemic Control on Health Care Costs and Utilization," *JAMA* 285, no. 2 (January 2001): 182–189. https://doi.org/10.1001/jama.285.2.182

13. Sherwani, Shariq, Haseeb A. Khan, Aishah Ekhzaimy et al., "Significance of HbA1c Test in Diagnosis and Prognosis of Diabetic Patients," *Biomarker Insights* 11, (July 2016):95–104. https://journals.sagepub.com/doi/10.4137/BMI.S38440

14. American Diabetes Association (ADA), "2022 National Standards for Diabetes Self-Management Education and Support," *Diabetes Care* 45, no. 2 (February 2022): 484–494. https://diabetesjournals.org/care/article/45/2/484/140905/2022- National-Standards-for-Diabetes-Self

15. ADA, "American Diabetes Association Releases 2023 Standards of Care in Diabetes to Guide Prevention, Diagnosis, and Treatment for People Living with Diabetes," December 12, 2022. https://diabetes.org/newsroom/american-diabetes-association- 2023-standards-care-diabetes-guide-for-prevention-diagnosis- treatment-people-living-with-diabetes

16. ADA, "International Experts Outline Diabetes Remission Diagnosis Criteria," August 30, 2021. https://www2.diabetes.org/newsroom/press-releases/2021/ international-experts-outline-diabetes-remission-diagnosis-criteria

17. Parker, Emily D., Janice Lin, Troy Mahoney et al., "Economic Costs of Diabetes in the U.S. in 2022," *Diabetes Care* 47, no.1 (November 2023): 26–43. https://doi.org/10.2337/dci23-0085

18. ADA, Statistics About Diabetes, January 30, 2023. https://diabetes.org/about-diabetes/statistics/about-diabetes

19. CDC, "National Diabetes Statistics."

20. Rowley, William R., Clement Bezold, Yasemin Arikan et al., "Diabetes 2030: Insights from Yesterday, Today, and Future Trends," *Population Health Management* 20, no. 1 (February 2017): 6–12. https://doi.org/10.1089/pop.2015.0181

21. UK Prospective Diabetes Study (UKPDS) Group, "Intensive Blood-Glucose Control with Sulphonylureas or Insulin Compared with Conventional Treatment and Risk of Complications in Patients with Type 2 Diabetes (UKPDS 33)," *Lancet* 352, no. 9131 (September 1998): 837–853. https://doi.org/10.1016/S0140-6736(98)07019-6

22. Cheng, Ssu-Wei, Chih-Yuan Wang, and Yu Ko, "Costs and Length of Stay of Hospitalizations Due to Diabetes-Related Complications," *Journal of Diabetes Research* 2019, no. 1 (September 2019): 2363292. https://doi.org/10.1155/2019/2363292

23 ADA, "Understanding A1c," February 2023.
    https://diabetes.org/about-diabetes/a1c

24 Sherwani, "Significance of HbA1c," 95–104.

25 Shetty, S, Kristina Secnik, and Alan Oglesby, "Relationship of
    Glycemic Control to Total Diabetes-Related Costs for Managed
    Care Health Plan Members with Type 2 Diabetes," *Journal of
    Managed Care Pharmacy* 11, no. 7 (September 2005):
    559–564.
    https://doi.org/10.18553/jmcp.2005.11.7.559

26 Mayo Clinic, "A1c Test," December 2022.
    https://www.mayoclinic.org/tests-procedures/a1c-test/about/
    pac-20384643

27 CDC, "All About Your A1c," September 2022.
    https://www.mayoclinic.org/tests-procedures/a1c-test/about/
    pac-20384643

28 Mayo Clinic, "Hypoglycemia," November 2023.
    https://www.mayoclinic.org/diseases-conditions/hypoglycemia/
    symptoms-causes/syc-20373685

29 UKPDS Group, "Intensive Blood-Glucose Control," 837–853.

30 Chiou, Shang-Jyh, Yen-Jung Change, Chih-Dao Chen et al.,
    "Using Patient Profiles for Sustained Diabetes Management
    Amont People with Type 2 Diabetes," *Preventing Chronic
    Disease* 20, no. 1 (March 2023).
    http://dx.doi.org/10.5888/pcd20.220210

31 Lage, Maureen J., and Kristina S. Boye, "The Relationship
    Between HbA1c Reduction and Healthcare Costs Among
    Patients with Type 2 Diabetes: Evidence from a U.S. Claims
    Database," *Current Medical Research and Opinion* 36, no. 9
    (September 2020):1441–1447.
    https://doi.org/10.1080/03007995.2020.1787971

32 ADA, "Standards of Care in Diabetes — 2023 Abridged
    for Primary Care Providers," *Clinical Diabetes* 41, no. 1
    (January 2023): 4–31.
    https://doi.org/10.2337/cd23-as01

33 CDC, "Your Diabetes Care Team," April 2023.
    https://www.cdc.gov/diabetes/library/features/diabetes_care_team.
    html

34 Davis, Jody, Amy Hess Fischl, Joni Beck et al., "2022 National
    Standards for Diabetes Self-Management Education and
    Support," *Diabetes Care* 45, no. 2 (February 2022): 484–494.
    https://doi.org/10.2337/dc21-2396

35 Tenderich, Amy, "Use of Blood Glucose Meters Among
    People with Type 2 Diabetes: Patient Perspectives,"
    Diabetes Spectrum 26, no. 2 (May 2013): 67–70.
    https://diabetesjournals.org/spectrum/article/26/2/67/31924/
    Use-of-Blood-Glucose-Meters-Among-People-With-Type

36 Spencer-Bonilla, Gabriela, Valentina Serrano, Catherine Gao et
    al., "Patient Work and Treatment Burden in Type 2 Diabetes: A
    Mixed Methods Study," *Mayo Clinic Proceedings: Innovations,
    Quality & Outcomes* 5, no. 2 (April 2021): 359–367.
    https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8105508/

37 Focus groups, February 2024.

38 Siminerio, Linda, Ann Albright, Judith Fradkin et al., "The
    National Diabetes Education Program at 20 Years: Lessons
    Learned and Plans for the Future," *Diabetes Care* 41, no. 2
    (February 2018): 209–218.
    https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5780052/

39 CDC, "What is the National DPP?" February 2024.
    https://www.cdc.gov/diabetes/prevention/what-is-dpp.htm

40 Chrvala Carole, Dawn Sherr, and Ruth Lipman. "Diabetes
    Self-Management Education for Adults with Type 2 Diabetes
    Mellitus: A Systemic Review of the Effect on Glycemic Control,"
    Patient Education and Counseling 99, no. 6 (June 2016):
    926–943.
    https://doi.org/10.1016/j.pec.2015.11.003

41 Rock Health Digital Health Venture Funding Database,
    2011–2024.

42 PitchBook Data, Inc.

43 PitchBook Data, Inc.

44 Perez-Nieves, Magaly, Rattan Juneja, Ludi Fan et al., "Trends
    in U.S. Insulin Use and Glucose Monitoring for People with
    Diabetes: 2009–2018," *Journal of Diabetes Science and
    Technology* 16, no. 6 (November 2022): 1428–1435.
    https://doi.org/10.1177/19322968211028268

45 ADA, "Health Equity and Diabetes Technology: A Study of
    Access to Continuous Glucose Monitors by Payer, Geography
    and Race Executive Summary," accessed January 30, 2024.
    https://diabetes.org/sites/default/files/2023-09/ADA-CGM-
    Utilization-White-Paper-Oct-2022.pdf

46 Medicare, "Continuous Glucose Monitors," accessed
    January 30, 2024.
    https://www.medicare.gov/coverage/therapeutic-continuous-
    glucose-monitors

47 Tang, Mitchell, Carter Nakamoto, and Ariel Stern, "Trends
    in Remote Patient Monitoring Use in Traditional Medicare,"
    JAMA Internal Medicine 182, no. 9 (August 2022):
    1005–1006, doi:10.1001/jamainternmed.2022.3043.

48 Card, Alex, "Realizing the Potential of Remote Patient
    Monitoring," *Definitive Healthcare,* February 2023.
    https://www.definitivehc.com/sites/default/files/resources/pdfs/
    Realizing-the-potential-of-remote-patient-monitoring_.pdf

49 Tinguely, Delphine, Justine Gross, and Christophe Kosinski, "Efficacy of Ketogenic Diets on Type 2 Diabetes: A Systematic Review," *Current Diabetes Report*s 21, no. 32 (2021). https://doi.org/10.1007/s11892-021-01399-z

50 Veazie, Stephanie, Kathryn Vela, and Mark Helfand, "Evidence Brief: Virtual Diet Programs for Diabetes," *Department of Veterans Affairs,* August 2020. https://www.ncbi.nlm.nih.gov/books/NBK563523/

51 Higgins Julian P.T., Jelena Savović, Matthew J Page et al., eds, "Chapter 8: Assessing Risk of Bias in a Randomized Trial," in *Cochrane Handbook for Systematic Reviews of Interventions* version 6.4, updated August 2023. https://training.cochrane.org/handbook/current/chapter-08

52 Wells, G.A., B. Shea, D. O'Connell et al., "The Newcastle-Ottawa Scale (NOS) for Assessing the Quality of Nonrandomised Studies in Meta-Analyses," Ottawa Hospital Research Institute*,* no date. https://www.ohri.ca/programs/clinical_epidemiology/oxford.asp

53 ADA, "Understanding A1c."

54 UKPDS Group, "Intensive Blood-Glucose Control," 837–853.

55 International Consortium for Health Outcomes Measurement (ICHOM), "Patient Centered Outcome Measures," accessed January 30, 2024. https://connect.ichom.org/patient-centered-outcome-measures/diabetes/

56 National Institute for Health and Care Excellence (NICE), "Type 2 Diabetes in Adults: Management," updated June 29, 2022. https://www.nice.org.uk/guidance/ng28

57 Feingold, Kenneth R, "Oral and Injectable (Non-Insulin) Pharmacological Agents for the Treatment of Type 2 Diabetes," in *Endotext,* eds. Kenneth R. Feingold, Bradley Anawalt, Marc Blackman et al. Dartmouth: MDText.com. updated August 26, 2022. https://www.ncbi.nlm.nih.gov/books/NBK279141/#:~:text=If%20one%20averages%20the%20effect,%2D1%20receptor%20agonists%201.24%25

58 Hsu, William C., Ka Hei, Karen Lau, Ruyi Huang et al., "Utilization of a Cloud-Based Diabetes Management Program for Insulin Initiation and Titration Enables Collaborative Decision Making Between Healthcare Providers and Patients," *Diabetes Technology & Therapeutics* 18, no. 2 (February 2016): 59–67, doi:10.1089/dia.2015.0160.

59 Amante, Daniel, David Harlan, Stephenie Lemon et al., "Evaluation of a Diabetes Remote Monitoring Program Facilitated by Connected Glucose Meters for Patients with Poorly Controlled Type 2 Diabetes: Randomized Crossover Trial," *JMIR Diabetes* 6, no. 1 (March 2021): e25574, doi:10.2196/25574

60 Athinarayanan, Shaminie J., Rebecca N. Adams, Sarah J. Hallberg et al., "Long-Term Effects of a Novel Continuous Remote Care Intervention Including Nutritional Ketosis for the Management of Type 2 Diabetes: A 2-Year Non-randomized Clinical Trial. Clinical Trial," *Frontiers in Endocrinology* 10, no. 1 (June 2019): 348, doi:10.3389/fendo.2019.00348.

61 Athinarayanan, "Novel Continuous Remote Care Intervention," 348

62 Amante, "Diabetes Remote Monitoring Program, e25574.

63 Reaven, Peter, Nicholas Emanuele, Wyndy Wiitala et al., "Intensive Glucose Control in Patients with Type 2 Diabetes — 15-year Follow Up," *New England Journal of Medicine* 380, no. 23 (June 2019):2215–2224. https://www.nejm.org/doi/full/10.1056/NEJMoa1806802

64 Bollyky Jennifer B., Dena Bravata, Jason Yang, et al., "Remote Lifestyle Coaching Plus a Connected Glucose Meter with Certified Diabetes Educator Support Improves Glucose and Weight Loss for People with Type 2 Diabetes," *Journal of Diabetes Research* 2018, 3961730. https://doi.org/10.1155/2018/3961730

65 Lee, Jun Yang, Carina Ka Yee Chan, Siew Siang Chua, et al., "Telemonitoring and Team-Based Management of Glycemic Control on People with Type 2 Diabetes: a Cluster-Randomized Controlled Trial," *Journal of General Internal Medicine* 35, no. 1 (January 2020): 87-94 https://pubmed.ncbi.nlm.nih.gov/31512187/

66 Hallberg, Sarah, Amy McKenzie, Paul Williams et al., "Effectiveness and Safety of a Novel Care Model for the Management of Type 2 Diabetes at 1 Year: An Open-Label, Non-Randomized, Controlled Study," *Diabetes Therapy* 9, no. 2 (April 2018): 583–612. https://doi.org/10.1007/s13300-018-0373-9

67 Offringa, Reid, Tong Sheng, Linda Parks et al., "Digital Diabetes Management Application Improves Glycemic Outcomes in People with Type 1 and Type 2 Diabetes," *Journal of Diabetes Science and Technology* 12, no. 3 (May 2018): 701–708. https://doi.org/10.1177/1932296817747291

68 Nosrat, S., V. Myers, E. Nykaza et al., "The Impact of Remote Patient Monitoring on Glycated Hemoglobin for Type 2 Diabetes: A Randomized Controlled Trial," *Diabetes Research and Clinical Practice* 197, no. S1 (March 2023):110315. https://doi.org/10.1016/j.diabres.2023.110315

69 Nosrat "Impact of Remote Patient Monitoring," 110315.

70 Thingalaya, Nita, David Kerr, Praveen Kumar Potukuchi et al., "Impact of Digital Diabetes Solution on Glycemic Control in Adults with Type 2 Diabetes Mellitus in the United States — A Retrospective Cohort Study," *Diabetes* 72, no. S1 (June 2023): 962–P. https://doi.org/10.2337/db23-962-P

71 Wilson, Laura, Daniel Malone, Praveen Potukuchi et al., "Comparison of All-Cause Healthcare Resource Utilization Rates Between Patients with Type 2 Diabetes Who Use a Digital Diabetes Solution Versus Non-Users: A 12-Month Retrospective Cohort Study," (poster, Annual Meeting of the Professional Society for Health Economics and Outcomes Research, May 7–10, 2023, online).

72 Amante, "Diabetes Remote Monitoring Program," e25574.

73 Bollyky, "Remote Lifestyle Coaching," 3961730.

74 Amante, "Diabetes Remote Monitoring Program," e25574.

75 Wilson-Anumudu, F, Ryan Quan, Cynthia Castro et al., "Early Insights from a Digitally Enhanced Diabetes Self-Management Education and Support Program: Single-Arm Nonrandomized Trial," JMIR Diabetes 6, no. 1 (January-March 2021), doi:10.2196/25295.

76 Chen, Fang, Carolyn Jasik, Timothy Dall, et al., "Impact of a Digitally Enhanced Diabetes Self-Management Program on Glycemia and Medical Costs," The Science of Diabetes Self-Management and Care 48, no.4 (August 2022): 258-269. https://doi.org/10.1177/26350106221100779

77 Athinarayanan, "Novel Continuous Remote Care Intervention," 348.

78 Hallberg, "Effectiveness and Safety," 583–612.

79 Athinarayanan, "Novel Continuous Remote Care Intervention," 348.

80 Athinarayanan, "Novel Continuous Remote Care Intervention," 348.

81 McKenzie, Amy, and Shaminie Athinarayanan, "837-P: Improved Outcomes across Socioeconomically Advantaged and Disadvantaged Communities — A Real-World Study," Diabetes 72, no. S1 (June 2023): 837-P. https://doi.org/10.2337/db23-837-P

82 Shaw, Ryan, Q Yang, A Barnes et al., "Self-Monitoring Diabetes with Multiple Mobile Health Devices," Journal of the American Medical Informatics Association 27, no. 5 (May 2020): 667–676. https://doi.org/10.1093/jamia/ocaa007

83 Greenwood, Deborah, Shelley Blozis, Heather Young et al., "Overcoming Clinical Inertia: A Randomized Clinical Trial of a Telehealth Remote Monitoring Intervention Using Paired Glucose Testing in Adults with Type 2 Diabetes," Journal of Medical Internet Research 17, no.7 (July 2015): e178, doi: 10.2196/jmir.4112.

84 Lee, "Telemonitoring and Team-Based Management," 87–94.

85 Mora, Pablo, Ann Buskirk, Maureen Lyden, et al., "Use of a Novel, Remotely Connected Diabetes Management System Is Associated with Increased Treatment Satisfaction, Reduced Diabetes Distress, and Improved Glycemic Control in Individuals with Insulin-Treated Diabetes: First Results from the Personal Diabetes Management Study," Diabetes Technology and Therapeutics 19, no. 12 (2017), Doi: 10.1089/dia.2017.0206

86 Holmen, Heidi, Astrid Torbjørnsen, Astrid Klopstad Wahl et al., "A Mobile Health Intervention for Self-Management and Lifestyle Change for Persons with Type 2 Diabetes, Part 2: One-Year Results from the Norwegian Randomized Controlled Trial RENEWING HEALTH," JMIR Mhealth and Uhealth 2, no. 4 (2014): e57, doi:10.2196/mhealth.3882

87 Shaw, "Self-Monitoring Diabetes," 667–676.

88 Gershoni, Tamar, Marilyn Ritholz, David Horwitz et al., "Glycemic Management by a Digital Therapeutic Platform across Racial/Ethnic Groups: A Retrospective Cohort Study," Applied Sciences 13, no.1 (December 2023): 431. https://doi.org/10.3390/app13010431

89 Boye, Kristina, Maureen Lage, and Vivian Thieu. "The Association Between HbA1c and 1-Year Diabetes-Related Medical Costs: A Retrospective Claims Database Analysis," Diabetes Therapy 13, no. 2 (February 2022): 367–377. https://doi.org/10.1007/s13300-022-01212-4

90 Cefalu, William, Daniel Dawes, Gina Gavlak et al., "Insulin Access and Affordability Working Group: Conclusions and Recommendations," Diabetes Care 41, no. 6 (May 2018): 1299–1311. https://doi.org/10.2337/dci18-0019

91 CDC, "National Diabetes Statistics."

92 Perez-Nieves, "Trends in U.S. Insulin Use," 1428–1435.

93 Young, Laura, John Buse, Mark Weaver et al., "Glucose Self-Monitoring in Non-Insulin-Treated Patients with Type 2 Diabetes in Primary Care Settings," JAMA Internal Medicine 177, no. 7 (2017): 920–929, doi:10.1001/jamainternmed.2017.1233.

94 CDC, "National Diabetes Statistics."

95 Estimated based on Milliman, "The Cost and Quality Gap in Diabetes Care: An Actuarial Analysis," January 2012, and CDC, "National Diabetes Statistics." https://www.milliman.com/-/media/milliman/importedfiles/uploadedfiles/insight/health-published/cost-quality-gap-diabetes.ashx

96 CDC, "Type 2 Diabetes."

97 Cefalu, William, Daniel Dawes, Gina Gavlak et al., "Insulin Access and Affordability Working Group: Conclusions and Recommendations," *Diabetes Care* 41, no. 6 (May 2018): 1299–1311.
https://doi.org/10.2337/dci18-0019

98 CDC, "National Diabetes Statistics."

99 Perez-Nieves, "Trends in U.S. Insulin Use," 1428–1435.

100 Young, "Glucose Self-Monitoring," 920–929.

101 Fitch, Kathryn, Kosuke Iwasaki, and Bruce Pyenson, "The Cost and Quality Gap in Diabetes Care: An Actuarial Analysis." *Milliman Client Report,* January 30, 2012.
https://www.milliman.com/-/media/milliman/importedfiles/uploadedfiles/insight/health-published/cost-quality-gap-diabetes.ashx

102 Lage, "Relationship Between HbA1c Reduction," 1441–1447.

103 Fitch, "Cost and Quality Gap."

104 Thingalaya, "Impact of Digital Diabetes Solution," 962–P.

105 Nosrat, "Impact of Remote Patient Monitoring," 110315.

106 Lee, Min-Kyung, Kwang-Hyeon Lee, Seung-Hyun Yoo et al., "Impact of Initial Active Engagement in Self-Monitoring with a Telemonitoring Device on Glycemic Control Among Patients with Type 2 Diabetes," *Scientific Reports* 7, no. 1 (June 2017): 3866.
https://doi.org/10.1038/s41598-017-03842-2

107 Amante, "Diabetes Remote Monitoring Program," e25574.

108 Centers for Medicare & Medicaid Services (CMS), "License for Use of Current Procedural Terminology, Fourth Edition," accessed February 2024.
https://www.cms.gov/medicare/physician-fee-schedule/search

109 CMS, "License for Use."

110 Zhuo, Xiaohui, Ping Zhang, and Thomas Hoerger, "Lifetime Direct Medical Costs of Treating Type 2 Diabetes and Diabetic Complications," *American Journal of Preventive Medicine* 45, no. 3 (September 2013): 253–261.
https://doi.org/10.1016/j.amepre.2013.04.017

111 Merative, Micromedex Redbook, December 2023.

112 Whaley, Christopher M., Jennifer Bollyky, Wei Lu et al., "Reduced Medical Spending Associated with Increased Use of a Remote Diabetes Management Program and Lower Mean Blood Glucose Values," *Journal of Medical Economics* 22, no. 9 (September 2019): 869–877.
https://doi.org/10.1080/13696998.2019.1609483

113 Amante, "Diabetes Remote Monitoring Program," e25574.

114 Zhang, Amy, Wendy de Heer, Lisa Izuierdo et al., "Analysis of Type 2 Diabetes Reversal Cost Savings," Virta Health, 2023.
https://assets.virtahealth.com/docs/Virta_Health_T2D_Reversal_Cost_Savings_Analysis.pdf

115 2021–22 list price data for employers and health plans submitted to PHTI by Virta.

116 Zhang, "Type 2 Diabetes Reversal Cost Savings."

117 Fitch, "Cost and Quality Gap."

118 Lage, "Relationship Between HbA1c Reduction," 1441–1447.

119 Feingold, "Oral and Injectable."