

Digital Diabetes Management Solutions

HEALTH TECHNOLOGY ASSESSMENT | MARCH 2024



Type 2 diabetes impacts almost one in seven people in the United States and is the most expensive chronic condition, accounting for \$413 billion of healthcare spending annually.¹ Diabetes can lead to significant clinical complications, often requiring high-cost interventions. Given the critical role of patient selfmanagement in diabetes, there has been significant investment (more than \$50 billion²) over the last 15 years in creating digital diabetes management solutions, with patients as the primary users.

Executive Summary

The core objective of these solutions is to support improved glycemic control through tracking of blood glucose, paired with additional education and support.

These solutions employ both digital and human interventions to drive improved self-management using three broad approaches:

Remote patient monitoring — Enable physicians to support remote patientmonitoring of blood glucose levels.

Behavior and lifestyle modification — Integrate 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 and monitoring of patient's glycemic and ketone levels. *A key distinction of this category is its goal* — *diabetes remission.*

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 patients achieve diabetes remission.³

Included Solutions

Solutions included in this report were identified through a multistep market analysis. The eight diabetes solutions included in this review met criteria for product design, outcomes of interest, funding levels, replace or augment a care plan overseen by a clinician, and sell primarily to health plans, providers, and/or employers. The solutions are DarioHealth, Glooko, Omada, Perry Health, Teladoc (Livongo), Verily (Onduo), Vida, and Virta.

Stakeholder Engagement

PHTI solicits input and advice from a diverse set of stakeholders, including patients, health plans, employers, providers, digital health developers, and

investors. During the assessment process, PHTI partnered with clinical advisors, experts in health technology assessment, and health economists. PHTI also provided all companies included in the report with an opportunity to meet, share data, and understand our methodology and approach.

PHTI Analysis

PHTI's analysis has two main components — clinical effectiveness and economic impact.

Clinical Effectiveness: The clinical analysis relies on a systematic literature review to understand the impact on health outcomes, user experience, and health equity. The literature review screened more than 1,100 pieces of evidence;

three companies (DarioHealth, Omada, and Virta) also submitted a combined 120 clinical references. Of these, 69 articles were analyzed for findings on the primary outcome of glycemic control, secondary health outcomes (cardiovascular risk factors, body weight, patient-reported outcomes, use of medication, etc.), user experience, and health equity. As described in the ICER-PHTI Assessment Framework for Digital Health Technologies, the evaluation reviews 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 also seeks to clarify which populations stand to benefit the most from using the technology.

SUMMARY OF PHTI EVALUATION OF DIGITAL DIABETES MANAGEMENT SOLUTIONS

What is the goal Improv of the technology?	ved glycemic control for adults with ty continuous glucometer with digital rer	pe 2 diabetes, achieved throu ninders, education, and behav	gh improved self-ma vioral coaching.	inagement using						
Which categories are included?	Remote Patient Monitoring Glooko	Behavior and Lifestyle I DarioHealth Tela Omada Veril Perry Health Vida	Modification doc (Livongo) y (Onduo)	Nutritional Ketosis Virta						
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?	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 insulin; or 2 People who are able to complete nutritional ketosis interventions										
How can purchasers achieve be	etter value? Reg cor	larly analyze outcomes and tie Deploy solutions to more diverse Reward acts to clinical performance and high-risk populations generat								
Where are there opportunities f	for further innovation?	Evolve solutions to ac GLP-1s, continuous gl on underserved popu	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.							

Economic Impact: The economic analysis modeled estimates of 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. 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.

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. The evidence showed that improvements in glycemic control for patients using digital diabetes management solutions were minimal and short-term. 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 1) people with higher starting HbA1c who are newly starting insulin, and 2) 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.

Remote patient monitoring and behavior and lifestyle modification solutions as a category delivered small incremental benefits (0.23–0.60 percentage point reduction in HbA1c) when compared with usual care. These solutions have the potential for stronger clinical benefits in populations with higher starting HbA1c levels who are newly starting insulin. These small benefits are accompanied by an increase in total health spending over 1-3 years because the cost of the solution exceeds the savings from improved clinical outcomes. The analysis found that 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 commercially enrollees in Year 1.

Exhibit 19 PHTI CATEGORY-LEVEL RATINGS FOR DIGITAL DIABETES MANAGEMENT SOLUTIONS

- Positive
 Moderate
 Negative
- Higher Evidence Certainty O 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	C	Results: Clinically meaningful reduction in HbA1c sufficient to achieve remission in some patients ^e Evidence Certainty: Lower	0	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.

Nutritional ketosis solutions are more likely to achieve clinically meaningful benefits in glycemic control, including remission in patients who can maintain the rigorous requirements of therapy, compared with other digital diabetes management solutions. These solutions produced 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. Most studies are focused on patients with lower starting blood glucose levels, suggesting that solutions are being tested in less complex patient populations, rather than among individuals who are at highest risk for diabetes-related complications. Published results should be reviewed carefully before generalizing across populations.

Next Steps for Stakeholders

Purchasers

- Require data analysis and transparency.
- Align payment for solutions with their clinical performance, including financial performance guarantees in contracts.
- Focus the deployment of solutions to patients with the highest HbA1c levels.

Innovators

- Clinical evidence generation is critical to support adoption.
- Sustainability of clinical benefits is central to a solution's impact.
- Provider acceptance and engagement matters.
- Contract for results.

Providers

- Performance of solutions may vary by subpopulation.
- Diabetic remission is a worthy goal that may be supported with effective digital solutions.
- Be aware that many digital health solutions are cost-additive.

About the Peterson Health Technology Institute (PHTI)

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.

Accessing PHTI's Full Report

You can access the full report <u>here</u>.



These findings are based on the criteria set forth in the Assessment Framework and the currently available evidence. Please see the full PHTI report for complete assessment, methods, and recommendations.

¹ Parker, Emily, Janice Lin, Troy Mahoney et al., "Economic Costs of Diabetes in the U.S. in 2022," *Diabetes Care* 47, no. 1 (January 2024): 26–43, doi: 10.2337/dci23-0085. ² Including mergers, acquisitions, and other investments.

³ American Diabetes Association, "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.

