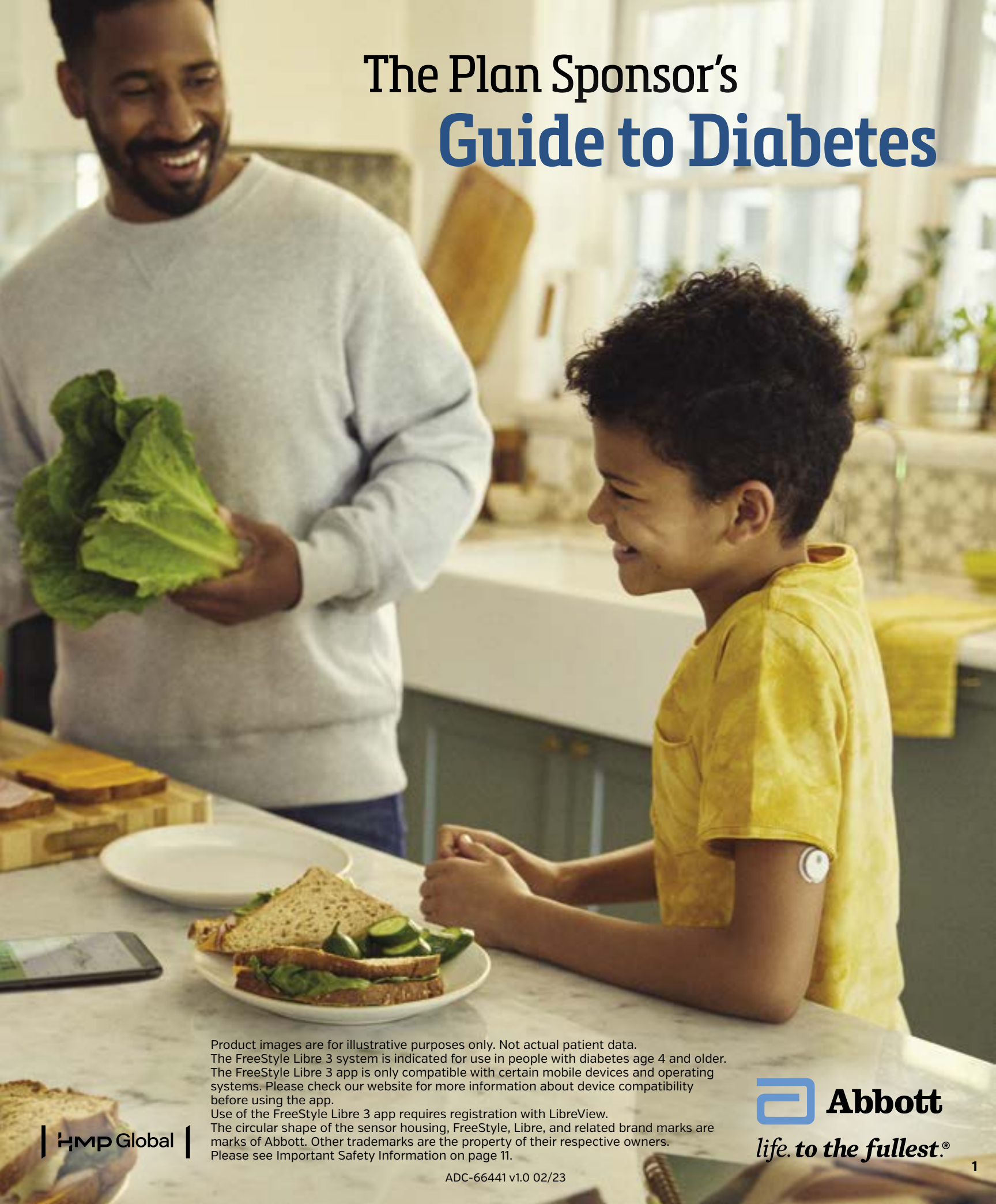


The Plan Sponsor's Guide to Diabetes



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The Plan Sponsor’s Guide to Diabetes

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In the United States, 37.3 million people live with diabetes, representing 11.3% of the population.¹ Managing this complex chronic condition while juggling work, family, and personal obligations can be challenging for many people living with diabetes.²

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Introduction

Over the last decade, the incidence and prevalence of diabetes has increased, and is projected to continue rising. Among US adults aged 18 years or older, there is an incidence of 1.4 million new cases of diabetes.³ During 2001-2020, diabetes prevalence among adults increased significantly from 10.3% in 2001-2004 to 13.2% in 2017-2020.¹

The workplace can significantly impact an employee's diabetes management. Diabetes can result in severe financial and health burdens, impacting an employee's mental health. Insurers, plan sponsors, and employers play a significant role in improving diabetes management and preventing complications, resulting in positive outcomes for members.⁴

In addition to financial burdens, an educational gap must be filled regarding the importance of diabetes management for plan members. Incorporating positive interventions such as expanding access to continuous glucose monitoring (CGM), novel diabetes medications, and collecting patient

data through digital diabetes care products, optimizes diabetes management. For instance, the incorporation of CGM and reimbursement for its use has improved several primary outcomes, including a decrease in work absenteeism from 5.8% to 2.9% of adults with diabetes (type 1, type 2, and secondary forms of diabetes) in a 12-month prospective observational multicenter real-world study performed from 2016 to 2018.⁴

This guide aims to provide a practical plan for sponsors to deliver a comprehensive environment for plan members with diabetes, helping to reduce financial costs and improve comparative health outcomes.

Diabetes Basics

WHY DOES DIABETES OCCUR?

Diabetes is a complex chronic condition requiring ongoing management including, glycemic control and risk reduction strategies.⁵ Various genetic and environmental factors can result in the progressive loss of pancreatic β -cells, or the

increased cell resistance to insulin, clinically leading to hyperglycemia.⁶ High glucose levels in the blood can lead to complications such as nerve damage, kidney damage, heart attacks, strokes, peripheral vascular disease, cataracts, and loss of vision if left untreated.⁷

Ongoing diabetes lifestyle modification and disease management education are vital to preventing and/or reducing acute and long-term complications. Substantial evidence is available to advocate for a variety of interventions which enhance diabetes outcomes.⁵

TYPES OF DIABETES

Several organizations provide clinical guidance on diabetes management, such as the American Diabetes Association (ADA), the Association of Diabetes Care and Education Specialists (ADCES), the Juvenile Diabetes Research Foundation (JDRF), and the American Association of Clinical Endocrinology (AACE). According to the ADA, there are various types of diabetes.

DIABETES IN THE USA

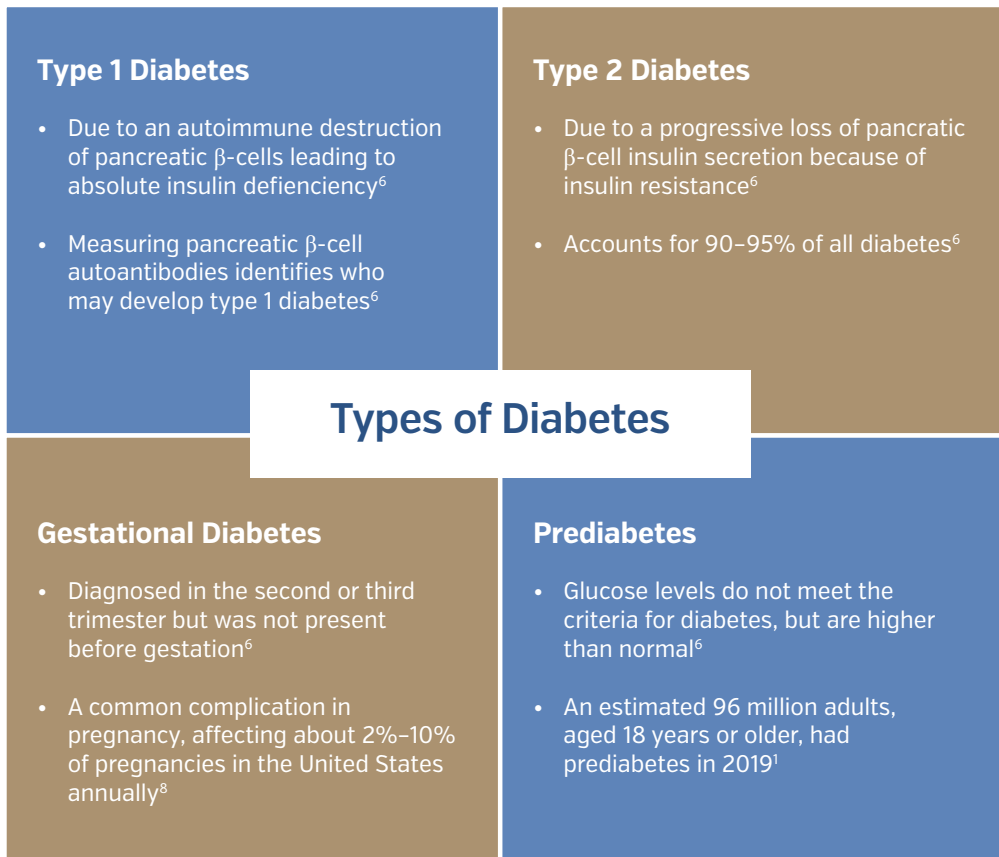
37.3 million people in the United States are living with diabetes, which equals about 11.3% of the country's population.¹ In the past years, overall incidence of type 1 and type 2 diabetes has significantly increased. These numbers rose from 2017-2020 across sex and are expected to continue rising. The crude prevalence of total diabetes in men and women were 15.4% and 14.1% respectively.¹

DIABETES RELATED COMPLICATIONS

Diabetes-related complications account for a large portion of morbidity and mortality in patients with diabetes. Understanding the prevalence and risk of developing acute and chronic complications, can help with management of diabetes, leading to less health care costs and decreased morbidity and mortality.⁹

The prevalence of acute and chronic complications in 2019 was 13.3% and 73.1%, respectively.¹⁰ The most common acute complications are infections (54.4%), metabolic abnormalities (22.3%) and myocardial infarction (7.6%). The most common chronic complications are endocrine (20.9%), cardiovascular disease (19.7%), neurological symptoms (16.5%), renal (14%), and ophthalmic (5.2%).¹⁰

Acute and chronic complications were more likely to be diagnosed among patients with Medicaid or Medicare coverage, chronic comorbidities, uncontrolled HbA1c, and/or patients who were overweight or obese.¹⁰



Workplace Impact of Diabetes

DIABETES IMPACT ON DRUG PLAN COSTS

Diabetes inflicted a considerable financial burden on society due to its increased prevalence over a decade. The global financial burden in 2017 was \$760 billion and is expected to increase to \$845 billion by 2045.¹¹

Additionally, increase in costs caused by diabetes medications in the US represents 43% of the total medical burden. This consists of \$15 billion for insulin products, \$15.9 billion for other antidiabetic medications, and \$71.2 billion in prescription medications used for treating diabetes complications.¹²

DIABETES IMPACT ON THE EMPLOYER

Employees with type 2 diabetes cost employers an estimated \$7,000 annually per capita, due to reduced productivity and missed work.¹³ Productivity costs for patients with diabetes were 13.3% higher, and medical costs were double (\$11,354 vs \$5,101), compared to employees without diabetes. Drug plan spending for employees with type 2 diabetes is three times the amount of all other drug claims (\$4,182 vs \$1,189). Employees with diabetes, aged 18-34 years, had higher short term disability leaves.¹³

There are several indirect costs associated with diabetes including, work absenteeism, presenteeism, inability to work, and premature death. A study has shown that employees with type 2 diabetes had 4.2 excess days lost compared to those without diabetes.¹³ Another study shows that people with diabetes have a 3.1% higher rate of becoming unemployed and receiving disability payments, compared to employees without diabetes.¹²

DIABETES IMPACT ON THE EMPLOYEE

Out-of-pocket (OOP) health care costs are the expenses for services that are paid by patients or their families, as opposed to those paid or reimbursed by insurance. High OOP costs can cause financial hardships and increased debts, leaving the employee with less money for necessities and unable to follow the treatment plan for diabetes.¹⁴ According to Dr Ana Stankovic, chief medical officer of United Healthcare, "This only scratches the surface of the dilemma. A tremendous burden is placed on employees to manage their diabetes in the face of comorbidities and high costs."



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“A tremendous burden is placed on employees to manage their diabetes in the face of comorbidities and high costs” ~Ana Stankovic, MD

The growth in OOP costs continues to outpace increases in workers' wages, and while many employer plans cover a significant portion of health costs, the payments made by enrollees have increased significantly over the last decade. Employees with families, using large employer coverage, pay more than a third of the total cost of care in the form of premiums and OOP costs.¹⁵

DIABETES IMPACT ON MENTAL HEALTH

There is a multitude of barriers for patients with diabetes to achieve glycemic control. A largely overlooked obstacle is mental health

complications. A person with diabetes experiences high levels of social and emotional complications, which are linked with poor glycemic control, decreased diabetes self-care, and impacted diabetes literacy.¹⁶

Depression

Depression is a highly prevalent illness, especially in chronic illness such as diabetes. Lifetime rates of depression in patients with type 2 diabetes are between 24% and 29%, affecting diabetes outcomes and poorer diabetes control.¹⁷⁻¹⁹ Recognizing and treating depression in patients with diabetes may help avoid adverse health-related

outcomes including mortality, hospitalizations, diabetes-related complications, disability, health-care costs, medical symptom burden, and a decreased quality of life.²⁰

Diabetes Distress

Diabetes distress is considered one of the most important mental health concerns in persons with diabetes. Thirty-eight to forty-five percent of adults with diabetes report moderate levels of diabetes distress.^{20,21} Stress associated with resolving work issues and diabetes management is a major source of diabetes distress.²² “Its important to note,” says Dr Stankovic, “That with stress, anxiety and depression comes a poor performance in diabetes control!”

Diabetes Stigma

Another mental health concern that can develop with a chronic disease, such as diabetes, is diabetes stigma. Diabetes stigma refers to negative feelings such as blame, judgment, identity concerns, and feelings of being treated differently than others who do not have diabetes.²² Ultimately, diabetes stigma can result in diabetes distress in an employee's work life, leading to poor management and glycemic control.²²

Managing Diabetes

LIVING WITH DIABETES

According to an initiative performed by the ADA to see how it felt for patients living with diabetes, a diagnosis of diabetes is the start of a lifelong relationship with healthcare professionals, healthcare systems and change in lifestyle.²³ In addition to the existing life stressors, the individual now faces a new demanding condition. For some people, the diagnosis of diabetes can be a shock. Many people with diabetes describe it as more than a full-time job. There is considerable pressure to learn and apply the complex management tasks, adding to the emotional burden of the disease.²³

CAREGIVER CHALLENGES

Caregivers can play a crucial role in providing long-term care to patients with diabetes mellitus. A caregiver is a person who provides long-term care to help meet the needs of the patient. A caregiver can be a relative, spouse, adult child, or friend. The high burden on caregivers lead to various physical and mental health problems such as depression, headaches, and insomnia. According to studies, 66.7% of caregivers experience both objective and subjective effects when caring for diabetes mellitus patients.²⁴

INTEGRATION OF CROSS FUNCTIONAL HEALTH CARE TEAMS

Successful management of diabetes should be through a patient-centered collaborative multidisciplinary team. This approach will require a close working relationship between the patient and the healthcare professionals involved in management plan. The cross functional team may include physicians, nurse practitioners, physician assistants, nurses, dietitians, exercise specialists, pharmacists, dentists, podiatrists, and mental health professionals.²⁵

Additionally, complications and comorbidities are a major concern in diabetes management; prompt and appropriate referrals should be arranged to prevent complications from occurring. Clinicians such as optometrists, dietitians, and mental health professionals are only a few examples of referrals.

DIABETES EDUCATORS

Evidence supports the direct correlation between health literacy and diabetes outcomes.²⁶ Persons with diabetes and poor health literacy are more likely to have poor glycemic control, less self-management, and decreased communication with their providers.²⁶ Diabetes educators have an important role in improving self-management and glycemic control, significantly affecting quality of life, and reducing the risk of complications. Diabetes educators can likely yield positive clinical results through the utilization of developed

tools for assessing diabetes-specific numeracy, educational materials, and ensuring effective communication.²⁶

GLUCOSE LEVELS

Importance of Checking Blood Glucose Levels

Regularly checking blood glucose levels is important for persons with diabetes as it helps ensure that blood sugar levels are stable, and in a healthy range.²⁷

The ADA recommends for patients on intensive insulin to self monitor blood glucose (SMBG) at least 4 times per day to achieve good metabolic control.²⁸ There is debate over optimal frequency and timing of SMBG for those with type 2 diabetes mellitus (T2DM) not taking insulin.²⁹ Unfortunately, according to a retrospective cross-sectional study performed on patients with type 1 diabetes in Sweden, less than 50% of persons performed SMBG frequently, due to various reasons.²⁸ Thirty percent of patients were not aware of recommended guidelines for SMBG measurements, while 70% of patients were aware of guidelines but only about 40% followed them.²⁸ Additionally, pain from the measurement has been reported by 14 % of patients, and 50% of patients reported not remembering and/or lack of time as main reasons for not performing more frequent SMBG measurements.²⁸ Therefore, there is an unmet need for further supporting SMBG and development of glucose monitoring devices.²⁸ Traditional blood glucose monitors do not capture fluctuations in glucose levels and trends, which does not allow for ease of adjusting insulin and lifestyle.

Different Ways to Monitor Glucose Levels

There are different methods to monitor glucose levels: determining the glycated hemoglobin A1c (HbA1c), SMBG before and after meals with a glucometer and using a continuous glucose monitoring system (CGMS).

HbA1c is considered the gold standard in diabetes management. It is recommended to test HbA1c twice a year for patients who have achieved glycemic control, and four times per year in uncontrolled cases or when a change of therapy is needed.³⁰ Unlike time in range, HbA1c represents an average glucose level and does not show glycemic variability and hypoglycemia. Self-monitoring with a glucometer is the most frequently used method to perform real-time blood glucose measurement. With the glucometer, glucose monitoring is performed

“It is critical to integrate diabetes educators into cross-functional teams when managing diabetes with other complex conditions”

~Ana Stankovic, MD

in real-time, giving information on glycemic control and its fluctuations. A newer technique recently developed is CGM, which provides a complete picture of the glucose profile.³⁰ According to Dr Kim Carmichael, endocrinologist and professor of medicine at Washington University, “In terms of continuous glucose monitoring, there has been no question that most patients have much better care and markedly lower risk for hypoglycemia.”

Glucose Targets

According to the ADA, the recommended glucose targets for most people with diabetes are listed below:

Hemoglobin A1C: <7% (53mmol/mol)

Time in Range for general population: TIR> 70%³¹

Time in Range

Recently, time in range is another metric being used in collaboration with A1C to assess glucose levels. Time in range is a patient-centered metric, defined as the percent of time glucose levels within target (70-180 mg/dL).³² It was estimated that a type 1 or type 2 individual of the general population should spend more than 70% of a day in target range.³³ It was reported that every 10% change in time within range resulted in a 0.8% change in HbA1c.³³

Benefits of Glucose Monitoring Devices

There are several options of CGM devices: therapeutic and non-therapeutic. CGMSs provide software that allows results to be accessed by healthcare providers (HCPs) and patients for educational and treatment purposes.³⁴ CGM devices are associated with improved glycemic control and reductions in hypoglycemia.^{33,35} Data from randomized controlled trials show that the primary outcome of reducing A1C levels and episodes of hypoglycemia were met.^{36,37} A real-world observational study shows improvements in primary outcomes such as HbA1C levels, patient-reported outcomes such as treatment satisfaction when comparing CGM with BGM levels, and reductions in acute complications.³⁸

The use of CGM devices allows for more thorough tracking of glucose levels for newly diagnosed diabetes, which decreases the frequency of using traditional glucose monitors.³⁸ Additionally, CGM is a cost-effective approach to managing diabetes and maintaining healthy glucose levels.³⁹ Dr. Carmichael adds that “In addition to being a cue motivator for better overall control, it allows people to better monitor during changes in daily patterns, such as exercise, sleep, and nutritional intake.”



“CGM is a cost-effective approach to maintaining diabetes and maintaining healthy glucose levels” ~Kim Carmichael, MD

TYPE 2 DIABETES GLUCOSE LOWERING MEDICATIONS

In conjunction with lifestyle modifications, there are a multitude of pharmacologic therapies used to treat type 2 diabetes and keep patients under glycemic control. The ADA provides medication recommendations which are used by clinicians to make informed decisions on individualized management approaches according to patients’ glycemic trends.³⁹

Based on the AACE guidelines, diabetes mellitus therapy should be individualized based on level of glycemia and the presence of comorbidities, complications, and access. Metformin is often the preferred initial therapy. Other agents may be appropriate as first line or in addition to metformin.

First line medications: Metformin

Second line medications: Sodium-Glucose Cotransporter-2 (SGLT2) Inhibitors, Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs), Dipeptidyl Peptidase-4 (DPP-4) Inhibitors, Thiazolidinediones, Sulfonylureas, and Insulin.

Innovation in Diabetes Management

NOVEL DIABETES MEDICATIONS

Advances in diabetes treatment has created a broader range of treatment options to meet patients’ diverse needs thereby, improving adherence and reducing complications such as stroke, cardiac events, and death. In Dr Carmichael’s experience, “In most instances, novel diabetes medications have had a significant benefit for my individual patients regarding risk of hypoglycemia, improvement in long-term end-organ outcomes, as well as weight management. Many of the newer medications provide “convenience” features such as once daily or once weekly administration, and extensive pharmacy data have proven that this improves compliance.”

While current treatments focus on lowering blood glucose, recent innovative treatment approaches target multiple pathophysiological

pathways present in type 2 diabetes. The innovative treatment goals are delaying disease progression and decreasing treatment failure. Some innovative treatment include⁴⁰

- Mounjaro (Tirzepatide) is the first dual GIP/GLP-1 receptor agonist which means it works on the glucosedependent insulinotropic polypeptide (GIP) receptors and GLP-1 receptors. Mounjaro can be used as a single therapy or with other diabetes medicines including metformin, sulfonylureas or SGLT2 inhibitors.
- Omarigliptin a long acting DPP-4 Inhibitor
- DGAT has been associated with insulin sensitization, reduction in liver triglycerides, and weight loss
- Dapagliflozin, a highly selective SGLT2 Inhibitor

DIGITAL DIABETES CARE

Digital health technology has been rapidly developing to help people manage their diabetes. Patients and caregivers should consider digital care an asset in managing glucose levels, daily life habits, and mental health burden.⁴¹

Wristbands, belts, patches, and smartphones can help measure various factors of diabetes. Pre-clinical conditions and lifestyle modification can be watched such as, a patient's activity and calorie consumption. It can also help in blood glucose measurement, medication adherence, and management of complications.⁴²

Digital care is also used as a clinical decision-making tool for HCPs and provides the ability to communicate regularly with patients and monitor their glycemic data remotely.⁴²

Managing Diabetes in the Workplace

DIABETES AND WORKPLACE SAFETY

There is a high prevalence of diabetes in the US, and many of such Americans are part of the workforce. According to the ADA: "Any person with diabetes, whether insulin [treated] or non-insulin [treated], should be eligible for any employment for which he/she is otherwise qualified."⁴³ As a result of amendments to the Americans with Disabilities Act, which became effective on January 1st of 2009, all persons with diabetes are considered to have a "disability" and are exempt from discrimination.⁴³

WORKPLACE DIABETES PROGRAMS

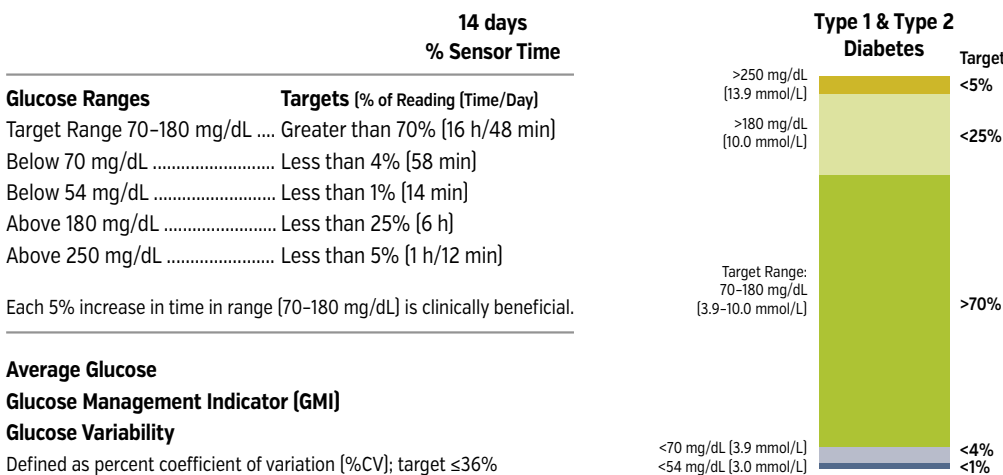
To reduce the number of patients undiagnosed with diabetes, the ADA and the U.S. Preventive Services Task Force recommend screening adults aged 45 years or older and younger adults with risk factors such as being overweight, having hypertension, or family history of diabetes.⁴⁴

The workplace should promote diabetes educational programs, focusing on information, interactive tools, and activities to improve employee adherence to medication, reduction in chronic complications, and other primary outcomes.

ACCOMMODATING EMPLOYEES WITH DIABETES

In the workplace, employers should provide the accommodations employees with diabetes need every day to manage their diabetes. "Although employees are responsible for their diabetes care," Dr Carmichael notes, "Employers need to be aware of their particular requirements, including opportunities for self-monitoring of glucose, ability to take insulin and other medications on time." Some employees may prefer a private location to administer and store their diabetes management supplies whenever feasible.⁴³ Dr Carmichael also states, "Individuals at the workplace, including supervisors and coworkers, should be aware of the signs and symptoms of hypoglycemia as well as having shown knowledge regarding nutritional and medical management." Employers can fulfill this accommodation by providing access to employees through vending machines, healthy snacks, and water. Furthermore, programs and resources such as exercise programs and stress management can be made available.⁴³

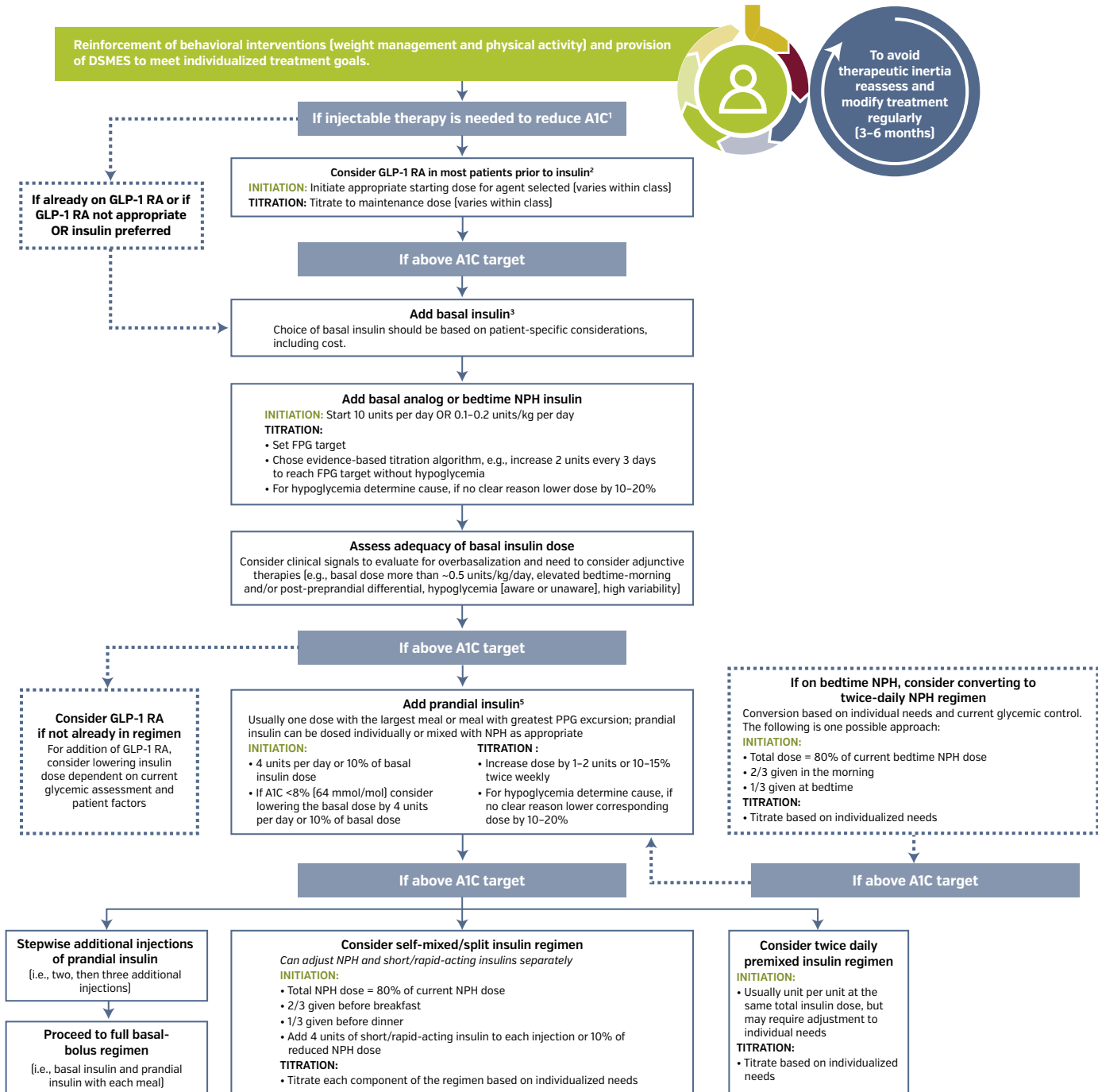
Figure 1. Clinical Targets for Continuous Glucose Monitoring



ADA; 6. Glycemic targets: standards of medical care in diabetes-2021. *Diabetes Care*. 2021;44(Suppl 1):S73-S84. **Republished with permissions.**

“Employers need to be aware of opportunities for employees to self-monitor glucose levels”
 ~Kim Carmichael, MD

Figure 2. Algorithm for Glucose Lowering Medication in Type 2 Diabetes



1. Consider insulin as the first injectable if evidence of ongoing catabolism, symptoms of hyperglycemia are present, when A1C levels (>10% [86 mmol/mol]) or blood glucose levels (≥300 mg/dL [16.7 mmol/L]) are very high, or a diagnosis of type 1 diabetes is a possibility.
2. When selecting GLP-1 RA, consider: patient preference, A1C lowering weight-lowering effect, or frequency of injection. If CVD, consider GLP-1 RA with proven CVD benefit. Oral or injectable GLP-1 RA are appropriate.
3. For patients on GLP-1 RA and basal insulin combination, consider use of a fixed-ratio combination product [IDegLira or iGlarLixi].
4. Consider switching from evening NPH to a basal analog if the patient develops hypoglycemia and/or frequently forgets to administer NPH in the evening and would be better managed with an AM dose of a long-acting basal insulin.
5. If adding prandial insulin to NPH, consider initiation of a self-mixed or premixed insulin regimen to decrease the number of injections required.

ADA Professional Practice Committee; 9. Pharmacologic approaches to glycemic treatment: standards of medical care in diabetes-2022. *Diabetes Care*. 2022; 45 [Supplement_1]: S125-S143. **Republished with permissions.**

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US Diabetes Policy Landscape

A FRAMEWORK FOR DIABETES STRATEGY FOR THE USA

A framework for diabetes management must be put in place to prevent high costs, enable self-management, provide appropriate evidence-based care, and provide medication and digital care to all.⁴⁴ According to Dr Stankovic, "The current coverage and policy design for novel medications and digital diabetes care in the US follows ADA guidelines, peer reviewed literature, and are covered according to medical necessity."

UNITED STATES CLINICAL PRACTICE GUIDELINES FOR THE PREVENTION AND MANAGEMENT OF DIABETES

The ADA publishes comprehensive, evidence-based clinical guidelines for diabetes care and prevention efforts. They are intended to support decision making by providing recommendations informed by the best available evidence; however, ultimately a therapeutic individualized plan is made between the patient and health care team.

Health insurance plans can utilize these guidelines to create programs to reduce the risk of developing diabetes and, make a framework for accessibility and coverage of diabetes care.

COVERAGE AND ACCESS

The prevalence of health insurance coverage in patients aged 18-64 years in 2009 was 83.1% for newly diagnosed diabetes. There are different types of health insurance coverage for patients with diabetes in the USA: 13.6% from Medicare coverage, 58.3% from private insurance coverage, 19.4% from Medicaid, and 4% through military benefits. For patients with private insurance coverage, preferred provider organizations (PPOs) were more prevalent than health maintenance organizations (HMOs).⁴⁵ According to Dr Carmichael, the coverage of diabetes supplies under the pharmacy benefit or the medical benefit could affect the pre-authorization process, copays, availability of supplies and cost'. Additionally, in Dr Stankovic's experience, there is a benefit of easier access when switching from manual to smart prior authorization.

On July 18, 2021, Medicare was able to qualify for CGM coverage, which was an unnecessary barrier to access effective technology for diabetes care.⁴⁶ Coverage and access to programs, treatments, and medical care devices vary widely by age, diabetes type, clinical criteria, and plan. According to Dr. Carmichael's experience, "Benefit plan coverage on patient access to novel diabetes medications and continuous glucose monitoring has chronically been variable, inconsistent and changing. Consequently, patients may go without the supplies for a duration of time until I can update the prescriptions and sometimes then have to work on pre-authorization for the new medication or device." ■

"Benefit plan coverage on patient access to novel diabetes medications and continuous glucose monitoring has chronically been variable"
~Kim Carmichael, MD



Plan Sponsor Checklist

For plan sponsors who want to address diabetes management, here is a useful checklist:

WORKPLACE SUPPORT

- Is your workplace environment supportive of employees with diabetes?
- Is your workplace environment supportive of caregivers of employees with diabetes?
- Does your workplace avoid diabetes stigma?
- Does your workplace help provide a supportive work environment to help improve employees' mental health such as depression, diabetes distress and diabetes burnout?
- Does your workplace accommodate the needs of employees with diabetes?

WORKPLACE PROGRAMS

- Do your programs support employees who are at risk of type 2 diabetes or in the prediabetes stage?
- Do you offer programs to support employees in the management of obesity?
- Do you offer employee diabetes screening programs?
- Do you offer programs that promote employees' mental health when dealing with diabetes?
- Do your programs provide education on diabetes management?

BENEFIT PLAN DESIGN

- Does your benefit plan offer or cover digital diabetes care products?
- Does your benefit plan cover continuous glucose monitoring (CGM)?
- Does your benefit plan offer full vision care and recommend annual eye exams?
- Does your benefit plan cover preventative and complication-related management care?
- Does your benefit plan provide access to a full range of medications required to manage diabetes?

At this time, FreeStyle Libre 3 is not currently eligible for Medicare reimbursement, and Medicaid eligibility may vary by state.

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IMPORTANT SAFETY INFORMATION

FreeStyle Libre 2 and FreeStyle Libre 3 systems: Failure to use FreeStyle Libre 2 or FreeStyle Libre 3 systems as instructed in labeling may result in missing a severe low or high glucose event and/or making a treatment decision, resulting in injury. If glucose alarms and readings do not match symptoms or expectations, use a fingerstick value from a blood glucose meter for treatment decisions. Seek medical attention when appropriate or contact Abbott at 855-632-8658 or <https://www.FreeStyle.abbott/us-en/safety-information.html> for safety info.

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