KAISER PERMANENTE

Type 1 Diabetes Treatment Guideline

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Guidelines are systematically developed statements to assist patients and providers in choosing appropriate health care for specific clinical conditions. While guidelines are useful aids to assist providers in determining appropriate practices for many patients with specific clinical problems or prevention issues, guidelines are not meant to replace the clinical judgment of the individual provider or establish a standard of care. The recommendations contained in the guidelines may not be appropriate for use in all circumstances. The inclusion of a recommendation in a guideline does not imply coverage. A decision to adopt any particular recommendation must be made by the provider in light of the circumstances presented by the individual patient.

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Major Changes as of February 2024

- New guideline sections on:
  - Determining diabetes type
  - Management of hypoglycemia
  - Non-insulin options for patients with insulin resistance and type 1 diabetes
- Expanded content on dietary recommendations

Prevention

While it is possible to use autoantibody and genetic testing to identify patients at increased risk of developing type 1 diabetes, this is currently being done in research settings only. There is emerging evidence for preventing and delaying type 1 diabetes, and for monitoring for pre-clinical disease states.

Screening

Due to low population prevalence, screening for type 1 diabetes in the general population is not recommended. Patients with a first-degree relative with a type 1 diabetes diagnosis can be considered for screening; see Diabetes Trialnet for more information on risk-based screening.

Diagnosis

Diagnosis for an **asymptomatic** patient requires two abnormal test results, which can be from the same test performed on different days, or from different tests performed on either the same day or different days. If only one test comes back abnormal, repeat the abnormal test on a different day. An abnormal result on the repeated test is diagnostic for diabetes.

Diagnosis for a patient **with classic symptoms of hyperglycemia** (i.e., polyuria, polydipsia, weight loss) can be made with a single random plasma glucose result of 200 mg/dL or higher. A repeat measurement is not needed.

Table 1. Diagnosing diabetes

Test	Results	Interpretation
HbA1c	6.5% or higher	Diabetes
	5.7–6.4%	Impaired glucose tolerance [1]
	Lower than 5.7%	Normal
Random plasma glucose	200 mg/dL or higher	Diabetes
	140–199 mg/dL	Impaired glucose tolerance [1]
	Lower than 140 mg/dL	Normal
Fasting plasma glucose	126 mg/dL or higher	Diabetes
	100–125 mg/dL	Impaired glucose tolerance [1]
	Lower than 100 mg/dL	Normal

[1] Impaired glucose tolerance (IGT) is similar to impaired fasting glucose (IFG) but is diagnosed with a confirmed oral glucose tolerance test (OGTT). Both IGT and IFG are risk factors for future diabetes and for cardiovascular disease. They are sometimes jointly referred to as *pre-diabetes*. This guideline recommends avoiding the term *pre-diabetes* because not all patients with IGT and/or IFG will develop diabetes.

Determining diabetes type

Although patients with type 1 diabetes most commonly present with abrupt onset of symptoms and weight loss, type 1 diabetes can occur in patients at any age and weight. Diabetic ketoacidosis is also a frequent initial presentation. Determining if the diabetes diagnosis is type 1 versus type 2 can be challenging. You may be able to definitively diagnose type 1 diabetes with positive antibody tests, but not everyone with type 1 has positive antibodies. If there are symptoms of ketosis, concern for insulin deficiency, or HbA1c > 10, the patient should be on insulin therapy until diagnosis has been established.

Consider islet cell antibody (ICA) **and** glutamic acid decarboxylase antibody (GADA) testing for differential diagnosis in the following patient populations:

- Children and teenagers to distinguish early type 1 from type 2.
- Adults who are not overweight who are not responding well to oral hypoglycemic and lifestyle (diet/exercise) modification.
- Patients with at least one of the following:
    - Normal to low BMI
    - Extreme variability in glucose (SD > 50 mg/dL)
    - Heightened insulin sensitivity
    - Other autoimmune disorders (e.g., Hashimoto's, rheumatoid arthritis)
    - Positive ketones or history of ketoacidosis
    - Primary relative with type 1 diabetes

The following laboratory tests are **not recommended:**

- Fasting C-peptide is not recommended because the test cannot distinguish well between people without diabetes and those with impaired endogenous insulin secretion. C-peptide is released from the pancreas in equimolar amounts to endogenous insulin. Because the amount of endogenous insulin secreted is dependent on a patient's blood glucose level, low or undetectable C-peptide levels may indicate either an inability to produce insulin **or** an absence of insulin secretion due to low blood sugar levels. In the latter case, a person without diabetes would not secrete much C-peptide and would have an abnormal test result.
- Plasma insulin is not recommended as it does not add any additional useful information.

See the Diabetes Quick Care Guide for more information.

Treatment

Primary Care clinicians manage diabetes care—including overall plans of care and annual reviews of care—for all patients with diabetes, with help as needed from the Diabetes Team (use REF DIABETES). Consultation with an endocrinologist is recommended and may be coordinated by the Diabetes Team. Routine care (e.g., refills, labs) can continue in Primary Care.

Risk-reduction goals

Cardiac risk reduction is the most important management issue for patients with diabetes.

Table 2. Selected cardiac risk factors and goals for risk reduction for patients with diabetes

Risk factor	Goal
Blood pressure	Lower than 140/90 mm Hg
LDL cholesterol	Lower than 100 mg/dL
Hemoglobin A1c (HbA1c)	Lower than 7.0% [1]
Fasting blood glucose	80–130 mg/dL

[1] While a target HbA1c of lower than 7.0% is ideal, it may not be achievable for all patients. Any progress should be encouraged. For frail elderly patients, a target HbA1c of 7.0–9.0% is reasonable. For additional guidance and decision-making support, see the KP National Diabetes Guideline, table 6, "Recommended SMGB Targets to Achieve A1C Goal."

Glucose control goals

Table 3. Ideal glucose targets	
Timing	**Target** [1]
Before meals	80–130 mg/dL
2 hours post meals	160 mg/dL
Bedtime	80–130 mg/dL
3 a.m.	80–130 mg/dL

[1] Evaluate for hypoglycemia. Regardless of whether the target is met, it is important to ask patients about hypoglycemia occurring at any time of day or night.

Lifestyle modifications and non-pharmacologic options

For information on nursing management of patients with type 1 diabetes, see Diabetes Care at KPWA (SharePoint site). All patients diagnosed with type 1 diabetes should be referred to Nutrition Services.

Assessment of current diet

Brief assessment questions for patients

1. Ask open-ended questions to help identify typical diet patterns. Examples: “Take me through a typical day of what you eat.” “What is a common breakfast (lunch, dinner) that you eat?”
2. Ask for approximate times of meals, snacks, and dosing of insulin.
3. Assess reported patterns for
   - Skipped meals
   - Prolonged periods between meals (> 4 hrs)
   - Basic composition of meals (carbohydrates, protein, vegetables)
   - Patterns of food distribution (Is food concentrated into 1 or 2 large meals? Does the patient graze all day with no distinct meals?)
4. Assess readiness to change. Ask patients if they have control over the food in their house. Do they do the grocery shopping? Do they cook/prepare the food themselves? Ask if they’re interested in making lifestyle changes.
5. Consider 1 or 2 potential goals for improving dietary patterns.
   - Goals should meet patients where they are and provide guidance to make 1 or 2 ***behavioral*** modifications that are culturally appropriate. (Note: Improved HbA1c, improved blood glucose, and weight loss are outcomes rather than goals.)
   - Set 1 or 2 SMART goals that are **S**pecific, **M**easurable, **A**chievable, **R**elevant/realistic, and **T**ime-restricted. See Living Well With Diabetes: Action plan for healthier eating.

Dietary recommendations

For patients with type 1 diabetes, carbohydrate counting is the best way maintain in-target glucose values. Kaiser Permanente Washington offers several resources to help patients with meal planning, including “Ready, Set Start Counting,” as well as “Sample meals for carbohydrate counting” and “Carbohydrate examples for sick days” (Resource Line order numbers PE404 and PE343, respectively), as well as more detailed carbohydrate counting information on Healthwise.

A note about weight management and diet

Weight loss is very difficult for patients with insulin resistance and hyperinsulinemia. While weight management has been correlated with glycemic control, weight loss is an outcome of goal-driven behavior change rather than a goal itself in the context of diabetes management. Encourage patients to set *behavior change* goals, rather than weight loss goals, to achieve and maintain long-lasting glycemic control.

When patients with type 1 diabetes are making changes to their eating habits and/or physical activity, they should work with their RN or provider to ensure that their insulin doses are adjusted accordingly.

Matching insulin to carbohydrate intake

In type 1 diabetes, the primary dietary goal is to match insulin to carbohydrate intake, typically by establishing an insulin to carbohydrate ratio (ICR) in conjunction with carbohydrate counting, which allows for flexibility in the diet. Some patients with type 1 diabetes can take a simplified approach, assigning a set insulin dose based on usual meal portions and composition. This approach is appropriate for patients who have little variation in their diet, cannot easily calculate accurate insulin needs using ICR, and/or have difficulty estimating carbohydrate values of foods. Referral to a registered dietitian or certified diabetes care and education specialist (CDCES) is recommended to help with carbohydrate counting and to assess/address additional nutritional needs. Coordination with an RN or provider is recommended to help establish and adjust insulin dosing.

Timing

The **timing** of both eating and insulin injections can help stabilize appetite and blood glucose. In type 1 diabetes, patients need to take insulin before each meal and allow enough time between the injection and eating the meal for the insulin to begin working—typically 15–20 minutes for rapid-acting insulin.

- Meals and snacks should be at least 2 hours apart to allow time for blood glucose to come down in between.
- Insulin doses should be at least 3 hours apart to avoid “stacking” insulin, which can lead to hypoglycemia.
- Meals that are low in carbohydrates and high in fat/protein may delay gastric emptying, potentially requiring an adjustment to the timing of dosing before and/or after the meal. Patients should identify patterns in their response to such meals to assess how to adjust the timing of their insulin doses.
- With prolonged or intense exercise, food and insulin adjustments may be necessary to avoid hypoglycemia and ensure adequate fuel for exercise.

Popular diets that are *not* recommended

Ketogenic (“keto”) diet

This very low-carbohydrate diet is not recommended. Although it does reduce glycemic load and blood glucose, it is not well balanced and can have negative health effects. Extreme limits of carbohydrates, by default, result in increased dietary fat and/or protein, which can lead in turn to increased risk of elevated cholesterol, renal stones, and gout. In type 1 diabetes, this can also lead to an unpredictable pattern of delayed hyperglycemia. On a ketogenic diet, the body prioritizes protein as a fuel for gluconeogenesis, limiting what is available for tissue repair. The initial rapid weight loss (about 10–12 pounds over the first 2 weeks) associated with keto diets is largely due to depleted glycogen stores and the associated water loss. The depleted glycogen results in fatigue and decreased ability to exercise efficiently, while increasing the risk for severe, prolonged, and repeated hypoglycemia in patients taking insulin.

Intermittent fasting

Intermittent fasting is not recommended for patients with type 1 diabetes. This diet trend has several variations and often includes skipping meals or fasting 1 or 2 days per week, which typically results in excessive hunger and large food portions at the next meal. There is not enough research or evidence to support this strategy in type 1 diabetes, which requires a complex insulin regimen with injections several times per day. Type 1 diabetes management requires bolus injections not only at mealtimes, but potentially at other times of the day (e.g., before

bed, or with stress, increased physical activity, or caffeine consumption). Hypoglycemia needs to be treated appropriately with fast-acting carbohydrates, even if the patient is in a “fasting window.”

Physical activity

For patients who have been inactive, recommend slowly working up to at least 30 minutes of moderate physical activity per day. If they are unable to be active for 30 minutes at one time, suggest accumulating activity in 10- to 15-minute sessions throughout the day.

Foot care

For patients at very high risk or increased risk of developing foot ulcers, recommend daily foot care. The pamphlet “Diabetes: Healthy feet and shoes” is available online and can be ordered from the Resource Line (PE063).

Foot-ulcer risk definitions:

- Patients at **very high risk** are those with a previous foot ulcer, amputation, or major foot deformity (claw/hammer toes, bony prominence, or Charcot deformity).
- Patients at **increased risk** are those who are insensate to 5.07 monofilament at any site on either foot or who have bunions, excessive corns, or callus.
- Patients at **average risk** are those with none of the aforementioned complications.

Encourage patients to check their feet regularly. If the patient or a family member cannot perform the patient’s foot care, encourage the patient to find someone who can provide assistance.

Sick-day management

Patients experiencing acute illnesses need to be extra vigilant about glucose monitoring and control. The following information and help is available:

- The pamphlet “Living Well with Type 1 Diabetes: Taking care of yourself when you’re sick" is available online and can be ordered (PE337) from the Resource Line, or use SmartPhrase **.dmtype1sickdayplan**.
- Pharmacy staff can help with selecting sugar-free cold medicines and cough syrups.

Contraception and preconception counseling

Preconception counseling should be provided to all female diabetic patients of childbearing age, as the risk of maternal-fetal complications is higher in the setting of uncontrolled blood glucose. Patients desiring conception should achieve an HbA1c < 6.5% prior to pregnancy and be offered preconception counseling. If a patient does not wish to conceive or is not at HbA1c target, contraception should be discussed. For more information, refer to the CDC U.S. Medical Eligibility Criteria for Contraceptive Use, 2016. For more information about contraceptive choices, refer to the Management of Diabetes in Pregnancy: Standard of Care in Diabetes – 2023.

Pharmacologic options for blood glucose control

The long-term goal of insulin treatment is to prevent complications by maintaining blood glucose levels as close to normal as possible.

The aggressiveness of therapy should be individualized based on HbA1c goals and the patient’s ability to engage in self-management. Selected populations may have better clinical results with less aggressive regimens (e.g., very young children, older adults, people with a history of severe hypoglycemia, and those with limited life expectancies or comorbid conditions).

Recommended physiologic insulin replacement schedule

Insulin management for type 1 diabetes typically includes basal insulin such as glargine and rapid-acting insulin such as aspart or lispro. Consider using the SmartPhrases **.dmsimplescale** and **.dmsophscale** (“sophisticated”) for rapid-acting insulin dosing instructions.

- While a once-daily glargine dose can be given at any time of day, administration in the morning is preferable. Some patients may require two doses of glargine daily.
- For patients who can’t tolerate glargine due to hypoglycemia or variability of basal requirements, insulin degludec once daily is an option.

- Patients should review their glucose patterns every 3–7 days and adjust insulin doses as needed. Insulin doses of greater than 50 units should be split into two separate injections, given at different sites.

Non-insulin agents in patients with type 1 diabetes and insulin resistance

For type 1 patients with insulin resistance who present with type 2 diabetes metabolic symptoms, consider use of insulin-sparing agents in consultation with the Endocrinology (REF Diabetes) Team.

The medications most commonly considered are metformin and GLP-1s (requires Prior Authorization). The Diabetes Team will use the following criteria, suggested by KPWA Endocrinology, for this small population to determine if the patient eligible for GLP-1s:

- Currently on metformin or tried/failed/intolerant
- Type 1 diagnosis
- Insulin resistance defined as two or more of the following:
    - BMI > 30
    - Total daily dose of insulin > 80 units
    - Family hx of type 2 diabetes
    - Evidence of NAFLD (Fibrosure scores F1 or greater, evidence on US or diagnosis in chart)
    - Fasting triglyceride levels > 400
    - PCOS
    - CAD/CVD

Self-management

All patients should engage in the following self-management activities:

- Consider use of continuous glucose monitoring (CGM) for all patients with type 1 diabetes. If patient declines or cannot use CGM, recommend monitoring blood sugar before breakfast (fasting), before lunch, before dinner, and before bed to identify a pattern. More frequent monitoring may be necessary to assess appropriateness of mealtime insulin dosing.
- Counting and recording carbohydrates.
- Recalling and recording possible influencing factors for specific blood glucose readings.
- Adjusting insulin doses in response to given glucose patterns.
- Coordinating attention to diet, exercise, and insulin therapy.
- Responding appropriately to hypoglycemia.

Insulin adjustments in response to planned variations in eating or exercise patterns

Diet—Calculate the carbohydrate content of the meal, and adjust the insulin dose based on the carbohydrate ratio that was prescribed (e.g., 1 unit for each 15 g of carbohydrate). The actual ratio of insulin units to grams of carbohydrate may vary in individuals from 1 unit/5 g of carbohydrate to 1 unit/20 g of carbohydrate.

Exercise—Insulin requirements may change by up to 50% during periods of exercise. Patients should monitor their glucose level before, during, and after exercise to determine the effects on their glucose levels. If the effects of the exercise are predictable, insulin doses can be adjusted.

Stress—Whether due to physical injury, infection or illness, iatrogenic use of steroids, or psychological factors, stress causes an increase in hormones that antagonize insulin (and thus increases glucose unless adjustments are made). Although stress usually causes glucose to rise, some people become more agitated and active during stress, leading to a drop in glucose.

Continuous subcutaneous insulin infusion (insulin pumps and pods)

Motivated patients with type 1 diabetes of at least 6 months' duration who are having difficulty with glucose control and experiencing frequent hypoglycemia with conventional intensive insulin regimens may be considered for insulin pumps. For more information, see Clinical Review Criteria: Insulin Pump. Patients with Medicare coverage must meet both the clinical review criteria **and** Medicare requirements in order to acquire and maintain use of a pump.

Note that the Diabetes Team sees patients with diabetes who are using or considering insulin pumps. The Insulin Pump Program can provide device training and consultation, at which time a care plan can be established to assist Primary Care with ongoing management. Primary Care retains responsibility for implementing those patients' overall diabetes plans of care and annual reviews of care.

Continuous glucose monitoring (CGM) systems

Consider a CGM system for individuals with type 1 diabetes (requires Prior Authorization). Although several FDA-approved CGM systems are available, evidence from randomized controlled trials has not shown significant benefit except in specific situations, such as patients who have well-documented frequent and/or severe hypoglycemia despite best-practice management.

CGM is a useful tool for consideration when people are testing blood glucose with traditional finger pokes frequently and are also on a basal/bolus insulin regimen. Note that when using a CGM, routine finger sticks are not required, testing blood glucose with a fingerstick ***is*** required when prompted by the device. It is also important to check blood glucose with a fingerstick if the CGM system numbers do not match symptoms. Anytime a member suspects hypoglycemia, a fingerstick should be used to collect a blood sample for testing. For CGM criteria and ordering information, see the Diabetes Quick Care Guide.

Pharmacologic options that are *not* recommended

The following pharmacologic options are **not recommended or not on the formulary;** consider consultation with the Diabetes Team.

- Amylinomimetics—pramlintide (Symlin)
- Inhaled insulin (Afrezza) —rapid-acting insulin

Chronic Disease Management Support

Chronic disease management (CDM) is a population health improvement program offered to KPWA members by nursing and pharmacy services. The goal of the program is to promote evidence-based practice and improve health care outcomes. Patients work with an RN or clinical pharmacist for an average of 3–6 months to gain better control of their chronic disease.

When to refer to Chronic Disease Management:
Refer all patients with type 1 diabetes—regardless of their HbA1c—to Chronic Disease Management; use **REF Chronic Disease Management**.

Do ***not*** refer:

- Patients who are not residing in the state of Washington or are planning to be out of state for an extended period
- Patients on insulin pumps should be referred to REF DIABETES.
- Pregnant patients should be referred to OB/GYN for escalation to maternal fetal medicine.

See the Diabetes Quick Care Guide for more information.

Follow-up and Monitoring

Hypoglycemia

Many people with diabetes are at risk of hypoglycemia; additionally, there is a risk that they may not be aware of their hypoglycemia episodes (i.e., “hypoglycemia unawareness”). Hypoglycemia prevention is a high priority in diabetes care. Ask about symptomatic hypoglycemia and review glucose monitoring data for “hidden” hypoglycemia at every visit.

Hypoglycemia definitions

- Hypoglycemia: Glucose level less than 70 mg/dL with or without symptoms
- Clinically significant hypoglycemia: Glucose level less than 54 mg/dL
- Severe hypoglycemia: Altered mental and/or physical functioning that requires assistance of another person, irrespective of the glucose value.

For more information about management of hypoglycemia, see the Diabetes Quick Care Guide.

Periodic monitoring of conditions and complications

Table 4. Periodic monitoring of conditions and complications

Condition/complication	Tests	Frequency
Elevated blood pressure	BP taken with appropriate size cuff using optimal technique.	Every visit.
Blood glucose control	HbA1c and Self-monitored glucose	HbA1c every 3 months until the target level is reached; thereafter, patient should be monitored at least every 6 to 12 months. Self-monitored glucose should be reviewed by clinician at each diabetes assessment.
Foot ulcers	Physical exam focused on ankle reflexes, dorsalis pedis pulse, vibratory sensation, and 5.07 monofilament touch sensation performed by a provider qualified to determine the level of risk for foot ulcers.	Patients at **very high risk** [2] should be screened in person in Primary Care at least once every 3 months. Patients at **increased risk** [2] and **average risk** [2] should be screened annually.
Kidney health	Microalbumin/creatinine ratio [1] and Estimated glomerular filtration rate (eGFR).	Annually.
Retinopathy	Dilated eye exam by a trained eye services professional **or** Nondilated digital photography followed by a comprehensive exam for those who test positive.	Patients **with** evidence of retinopathy should be screened annually. Patients **without** evidence of retinopathy should be screened every 2 years. [3]
Electrolyte and chemistry abnormalities	Serum creatinine **and** Serum potassium.	At least annually.
Lipohypertrophy or lipodystrophy [4]	Examine insulin injection sites or infusion set insertion sites.	At every in-person visit in Primary Care.
Autoimmune conditions	Screen for autoimmune conditions (thyroid and celiac disease).	Thyroid hormone levels (TSH with reflex) annually. Celiac screening (TTG/IgA) every 5–10 years or if symptomatic.

1 The microalbumin/creatinine ratio test can identify patients with microalbuminuria by giving a quantitative estimate of protein loss that correlates with 24-hour urinary protein measurements. Test results are expressed in micrograms of urinary albumin per milligram of urinary creatinine (or A:C ratio). A positive test is greater than 30 mcg/mg. Two positive tests, ideally 3–6 months apart, are diagnostic for microalbuminuria.

2 For foot-ulcer risk definitions, see “Foot care.”

3 Annual screening is not recommended because the benefits of more frequent screening are marginal: For every 1,000 people screened annually (instead of every second year), one additional case of proliferative diabetic retinopathy and one additional case of clinically significant macular edema will be detected.

4 Lipohypertrophy or lipodystrophy can interfere with efficient insulin absorption.

Recommended immunizations

Source: CDC Recommended Adult Immunization Schedule by Medical Condition and Other Indications (2023)

Table 5. Recommended immunizations for patients with diabetes	
Immunization	**Regimen**
Influenza	• Annually by the end of October (all populations). • Injectable vaccine recommended for patients with diabetes; avoid LAIV (FluMist).
Pneumococcal polysaccharide (PCV20)	• For adults aged 19 to 64 years, 1 dose PCV20. Diabetes is considered a risk factor for community-acquired pneumonia, invasive pneumococcal disease, and pneumonia-related hospitalization. • For adults aged 65 years and older who have **not** previously received pneumococcal polysaccharide vaccine, give 1 dose PCV20 (all populations). • For adults aged 65 years and older who have previously received PCV13, PCV23, or both: Vaccinate per routine CDC recommendations.
Hepatitis B	• Three-dose series for aged 19 to 59 years (all populations). • For patients with diabetes aged 60 years and older who have **not** previously had the vaccine, shared decision-making is recommended. Diabetes is considered a risk factor for hepatitis B; adults with diabetes have twice the likelihood of acquiring acute hepatitis B.
RSV	• Shared decision-making in adults aged 60 years and older (all populations). • Diabetes is considered a risk factor for severe RSV disease.
All other routine adult immunizations per CDC guidance.	

Comorbidities

Depression screening

Screen for depression by using the Annual Mental Health Questionnaire. Evidence suggests that patients with depression are less likely to be adherent to recommended management plans and less likely to be effective at self-management of diabetes.

See the Depression Guideline for additional guidance. Patients with major depression can be treated in Primary Care or offered a referral to Mental Health and Wellness for counseling and/or drug therapy.

ASCVD prevention

Risk-reduction measures to consider include smoking cessation, blood pressure control, statin therapy, ACE inhibitor or angiotensin receptor blocker (ARB) therapy, and antiplatelet therapy. ACE inhibitor or ARB therapy should be included for patients with type 1 diabetes who have hypertension (BP > 140/90 mm Hg). See the ASCVD guidelines for primary prevention and secondary prevention for details.

Blood pressure management

- The target is to treat all adults—including those with diabetes—to a blood pressure of below 140/90 mm Hg. How far below 140/90 mm Hg depends on the patient's clinical circumstances and overall ASCVD risk.
- **The target for adults with diabetes has changed from below 130/80 mm Hg to below 140/90 mm Hg.** Diabetes alone does not qualify a patient for a systolic blood pressure goal of less than 130 mm Hg.
- A systolic blood pressure goal of 130 mm Hg or lower is recommended for adults who
    - Have 10-year ASCVD risk of 10% or higher
    - Have chronic kidney disease
    - Are age 75 or older

Evidence Summary

As part of our improvement process, the Kaiser Permanente Washington guideline team is working towards updating our clinical guidelines every 2–3 years. To achieve this goal, we are adapting evidence-based recommendations from high-quality external guidelines, if available and appropriate. The external guidelines must meet several quality standards to be considered for adaptation. They must: be developed by a multidisciplinary team with no or minimal conflicts of interest; be evidence-based; address a population that is reasonably similar to the KPWA population; and be transparent about the frequency of updates and the date the current version was completed.

In addition to identifying the recently published guidelines that meet the above standards, a literature search was conducted to identify studies relevant to the key questions that are not addressed by the external guidelines.

External guidelines meeting KPWA criteria for adaptation/adoption

American Diabetes Association. Management of Diabetes in Pregnancy: Standards of Care in Diabetes-2023. (ElSayed 2023)

Management of Individuals With Diabetes at High Risk for Hypoglycemia: An Endocrine Society Clinical Practice Guideline (McCall 2023)

American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan - 2022 Update (Blonde 2022)

International Consensus on Risk Management of Diabetic Ketoacidosis in Patients with Type 1 Diabetes Treated With Sodium-Glucose Cotransporter (SGLT) Inhibitors 2019 (Danne 2019)

National Institute for Health and Care Excellence. Diabetes in pregnancy: management from preconception to the postnatal period. Published: 25 February 2015 Last updated: 16 December 2020

Key questions for the 2024 Guideline update

1. In adult patients with diabetes, does the use of sodium glucose cotransporter-2 (SGLT-2) inhibitors increase the risk for diabetic ketoacidosis (DKA) compared with dipeptidyl peptidase-4 (DPP-4) inhibitors or any other antihyperglycemic medication?

   The literature search identified several qualitative and quantitative systematic reviews on the risk of diabetic ketoacidosis (DKA) associated with the use of SGLT-2 inhibitors in patients with diabetes types 1 and 2.

   - **For type 2 diabetes:** Two systematic reviews and meta-analyses of RCTs (Liu 2021, Alkabbani 2021) and one systematic review and meta-analysis of RCTs and observational studies (Colacci 2022) showed an increased risk of DKA with SGLT-2 inhibitors in type 2 diabetes compared with placebo or other antidiabetic drugs. On the other hand, another systematic review and meta-analysis (Donnan 2019) and an earlier, industry-funded meta-analysis (Monami 2017) showed no increased risk in DKA with SGLT-2 inhibitors in type 2 diabetes compared with placebo or other antidiabetic drugs. This lack of increased risk may be due to insufficient power of the meta-analyses due to the small number of studies included in the systematic reviews conducted before publication of the larger two trials. In addition, DKA is a rare adverse event, and the numbers of reported cases in the RCTs that mainly include a healthier population are limited and may be too small to provide sufficient power to detect significant differences, as opposed to the population-based cohort studies that include large numbers of individuals in the general population receiving usual care.

   - **For type 1 diabetes:** Two meta-analyses (Li 2019, Musso 2019) that examined the safety and efficacy SGLT-2 inhibitors showed an increased risk of DKA. One (Li 2019) demonstrated that the risk was dose-dependent, and the other (Musso 2019) showed that the risk increased among patients receiving multiple daily injections and in those on continuous subcutaneous infusion.

   - Due to the low rate of events with SGLT-2 inhibitors, no subgroup analysis could be performed in the meta-analyses to examine the differences in risk between individual SGLT-2 inhibitors (e.g., canagliflozin,

empagliflozin, and dapagliflozin), or to identify patient characteristics or factors that may increase their risk of DKA.

- Lower-quality evidence from observational studies (Fralick 2021, Zhao 2023) suggested several factors that may increase the risk of developing DKA associated with the use of SGLT-2 inhibitors, including: prior DKA, prior diagnosis of hypoglycemia, duration of type 2 diabetes longer than 7.625 years, insulin dose reduction or cessation, baseline hemoglobin HbA1C > 10%, major operation, baseline bicarbonate < 18 mmol/L, current drinking, delirium, prior intracranial hemorrhage, acute STEMI, acute infection, use of digoxin, and dementia.

  Additional predisposing conditions (Musso 2020) include: inability or unwillingness to monitor ketone bodies, excessive illicit drug use, very low carbohydrate or ketogenic diet, pregnancy, SGLT-2 inhibitor dose, insulin pump use, and late-onset autoimmune diabetes of adulthood. The precipitating factors listed in Musso 2020 include: vomiting, volume depletion or dehydration, acute infection or illness of any sort, hospitalization for surgery or acute serious medical illness, acute volume depletion or dehydration, vigorous or prolonged exercise, insulin pump or infusion site failure, and travel with disruption in usual schedule or insulin regimen.

2. In diabetic patients with euglycemic diabetic ketoacidosis, what is the optimal treatment/management to normalize fluid-volume status, hyperglycemia, electrolytes, and ketoacidosis?

   There is no published evidence from RCTs to provide an evidence-based strategy for the management of euglycemic diabetic ketoacidosis (DKA).

   The published guidelines, consensus statements, and reviews on the management of euglycemic DKA recommend following the usual protocol for the management of DKA, aiming at the restoration of normal extracellular fluid volume and tissue perfusion, resolution of ketoacidosis, correction of electrolyte imbalances and hyperglycemia, and the diagnosis and treatment of coexistent illness. These recommendations are mainly based on consensus.

   There is no new evidence that would change the recommendations of published guidelines and consensus statements on the management of DKA.

   Two published protocols based on the same principles were proposed for mitigating DKA risk patients with Type 1 Diabetes on adjunctive treatment with SGLT Inhibitors: the STICH strategy (Garg 2018) and the STOP DKA protocol (Goldenberg 2019).

3. For diabetes mellitus patients with insulin resistance, what is the comparative safety and efficacy of human regular U-500 insulin versus insulin degludec U-200, insulin lispro U-200, and glargine U-300?

   The literature search did not identify any trials that compared the safety and efficacy of human regular U-500 insulin versus insulin degludec U-200, insulin lispro U-200, or glargine U-300 in patients with diabetes mellitus with insulin resistance.

   The only published trial to date comparing one concentrated insulin preparation versus another that was identified by the literature search was the CONCLUDE trial (Philis-Tsimikas 2020), which compared insulin degludec U-200 head-to-head versus insulin glargine U-300 in insulin-treated adult patients. Its results showed no significant difference between the two treatment groups in the rate of overall symptomatic hypoglycemia during the maintenance period.

   The rates of nocturnal symptomatic and severe hypoglycemia (secondary endpoints) were significantly lower with degludec U-200 compared with glargine U-300. However, interpretation of secondary endpoints when the primary endpoint is not statistically significant is controversial.

4. In pregnant women with diabetes, what is the effect of using continuous glucose monitoring on the outcomes of pregnancy?

The use of continuous glucose monitoring (CGM) as an adjunct to self-monitored blood glucose (SMBG) versus SMBG alone was studied in four RCTs published between 2008 and 2018 with a total of 609 women. The trials focused on women with type 1 diabetes and used CGM as an adjunct to SMBG.

- There were some variations between the studies in the population included, CGM systems used, primary outcomes measured, and the overall results.
- One study included only women with type 1 diabetes (CONCEPTT [Feig 2017]) and three included women with types 1 and 2 diabetes (Murphy 2008 [UK], Secher 2013 [Demark], Voormolen 2018 [GlucoMOMS, Dutch]). However, the numbers of women with type 2 diabetes in each study were small (35%, 20%, and 27%, respectively).
- CGM protocols varied between the studies, from intermittent use at intervals throughout pregnancy to daily use.
- Two studies used older-generation masked (also known as retrospective or professional) CGM sensors, and two used rtCGM, which was used intermittently rather than continuously throughout pregnancy in one of the two studies.
- The CGM systems used in all four trials were from a single manufacturer (Medtronic Guardian REAL-Time, MiniMed Minilink, iPro2, or CGMS Gold).
- Compliance with CGM study protocols was low. Some researchers attributed this to the lower patient engagement with sometimes complex monitoring protocols, or to patient dissatisfaction with the CGM device itself.
- None of the trials compared CGM used alone versus fasting and postprandial SMBG.
- None of the published trials evaluated the impact of using CGM on long-term outcomes when used during pregnancy in women with diabetes.
- All studies examined the impact of using CGM only on short-term maternal and perinatal/neonatal outcomes and had mixed results. One study (Murphy 2008) showed a reduction in birth weight and macrosomia, and lower third-trimester HbA1C. CONCEPTT (Feig 2017) also found a small but statistically significant difference in HbA1C in pregnant women who used CGM versus those who did not. It also found a statistically significant lower incidence of LGA status, a reduction in neonatal hypoglycemia, a 1-day reduction in hospital length of stay, and fewer neonatal intensive care admissions. On the other hand, another study (Secher 2013) found no benefits in HbA1C, severe hypoglycemia, or large-for-gestational-age status. The GlucoMOMS study (Voormolen 2018) also found no difference in the risk of the primary endpoint of macrosomia between the two groups.

The overall results of the published trials suggest that the use of CGM in adjunct with self-reported glucose monitoring leads to significant improvements in maternal glycemic control (measured by HbA1c levels as a surrogate marker), and a reduction in the risk of pre-eclampsia. In the neonate, the maternal use of CGM was found to reduce the incidence of hypoglycemia and reduce the rate and duration of NICU or admission.

There is insufficient evidence to determine the impact of CGM on other outcomes, including the need for caesarean section and the incidence of pregnancy-induced hypertension, miscarriage, increased birthweight, and neonatal mortality or stillbirth.

There is insufficient evidence to make a recommendation on the use of CGM in pregnant women with type 2 diabetes.

There is insufficient evidence to recommend the use of CGM alone without meter glucose testing.

5. In pregnant women with diabetes using continuous glucose monitoring, what is the recommended time in range target, and what is its impact on maternal and fetal outcomes?

CGM time in range (TIR) endorsed by *The International Consensus on TIR* * (Battelino 2019) can be used for the assessment of glycemic outcomes in people with type 1 diabetes, but it does not specify the type or accuracy of the device or need for alarms and alerts.

TIR can be used for assessment of glycemic outcomes in people with type 1 diabetes, but it does not provide actionable data to address fasting and postprandial hypoglycemia or hyperglycemia.

*Target range 63–140 mg/dL (3.5–7.8 mmol/L): TIR, goal > 70%
Time below range (< 63 mg/dL [3.5 mmol/L]), goal < 4%

Time below range (< 54 mg/dL [3.0 mmol/L]), goal < 1%
Time above range (>140 mg/dL [7.8 mmol/L]), goal < 25%

Moderate-quality evidence suggests that the rate of achieving TIR goal > 70% in pregnant women using CGM is low.

Reaching CGM TIR target is associated with improvement in maternal and neonatal outcomes.

The CONCEPTT pregnancy trial (Feig 2017) showed that between the group of pregnant women using CGM versus the control group, the differences in time in target, hyperglycemia, and glucose variability became apparent in the late gestation period.

- Achieving the time in range target at 34 weeks was associated with a lower risk of preterm birth.
- Achieving the time above range target at 24 weeks was associated with a lower risk of LGA.
- Achieving the time above range target at 34 weeks was associated with a lower risk of both LGA and preterm birth.
- On the other hand, achieving the time below range target at 24 weeks was associated with an increased risk of neonatal hypoglycemia and NICU admission.

A Swedish observational study (Kristensen 2019) showed that a high percentage of time in target in the second and the third trimesters was associated with lower risk of large-for-gestational-age newborns.

There is limited data on the optimal TIR or its benefits in pregnant women with type 2 diabetes or gestational diabetes.

6. In diabetic patients on dialysis treatment, what are the benefits and harms associated with the use of continuous glucose monitoring? What is the recommended target time in in range?

There is insufficient published evidence to determine the safety and effectiveness of CGM on improving glycemic control in patients with diabetes receiving kidney dialysis.

There is insufficient evidence to determine the clinical utility of CGM in patients with diabetes or in patients with diabetes receiving kidney dialysis.

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Guideline Development Process and Team

Development process

The Type 1 Diabetes Treatment Guideline was developed using an evidence-based process, including systematic literature search, critical appraisal, and evidence synthesis. For details, see Evidence Summary and References.

This edition of the guideline was approved for publication by the Guideline Oversight Group in February 2024.

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