KAISER PERMANENTE

Type 2 Diabetes Screening and Treatment Guideline

Last guideline approval: February 2024

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.

Interim Update September 2024

- The guideline now advises temporarily holding SGLT-2 inhibitors in patients with genital infections until the infection is resolved.
- Prescribing precautions and monitoring and discontinuation recommendations have been added for GLP-1 agonists.

Major Changes as of February 2024

- Updated algorithm on use of concentrated insulins.
- New sections on determining diabetes type and management of hypoglycemia.
- Expanded content on dietary recommendations and diabetes medications in the elderly.
- More detail on precautions when prescribing SGLT-2-inhibitors.

Prevention

Studies have shown that increasing physical activity and eating a healthy diet can significantly delay the onset of type 2 diabetes, including for patients diagnosed with impaired glucose tolerance. Studies have also shown that the use of metformin can delay the diagnosis of diabetes for patients with impaired glucose tolerance, but there is no evidence that metformin or any other medication leads to long-term better clinical outcomes prior to diagnosis of diabetes.

Screening and Tests

The U.S. Preventive Services Task Force (2021) recommends screening patients who are at **increased risk for diabetes.**

Risk factors for type 2 diabetes include:

- Age of 35 years or older with overweight or obesity
- Consider screening earlier in patients with **certain racial/ethnic backgrounds,** including African American, American Indian/Alaska Native, Asian American, Hispanic/Latino, and Native Hawaiian/Pacific Islander.
- **It is reasonable to have a higher clinical index of suspicion in adults with multiple risk factors** (such as first-degree relative with diabetes, PCOS) and to use clinical judgment or shared decision-making about screening for type 2 diabetes.

If the decision is to screen, consider a frequency of every 3 years using either fasting plasma glucose or HbA1c.

Adults at high risk for atherosclerotic cardiovascular disease (see the KPWA guidelines for primary and secondary prevention of ASCVD) should be considered for screening. While ASCVD itself is not a risk factor for type 2 diabetes, type 2 diabetes is a serious complicating comorbidity in patients with ASCVD. If they elect screening, these patients should be screened every 3 years using either fasting plasma glucose or HbA1c.

Annual screening is recommended for women with a **history of gestational diabetes** (using HbA1c) and for men and women with **impaired fasting blood glucose** (using either fasting plasma glucose or HbA1c).

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

Patients with type 2 diabetes most commonly present as overweight and hyperglycemic, with gradual onset of symptoms such as fatigue, blurred vision, polydipsia, and polyuria. 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.

For test ordering and referral information, see the Diabetes Quick Care Guide.

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.

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
HbA1c	7.0–8.0% [1]
Fasting blood glucose	80–130 mg/dL

[1] Use clinical judgment to determine if a target lower than 7.0% is appropriate for an individual patient. It can be challenging to push a patient's HbA1c levels from just above 7.0% to below 7.0%. There are potential benefits (decreased nonfatal myocardial infarction) and potential harms (hypoglycemia, weight gain, and possible increase in all-cause and cardiovascular-cause mortality) of intensive glucose therapy, especially in patients with known cardiovascular disease. 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."

Lifestyle modifications and non-pharmacologic options

For information on nursing management of patients with type 2 diabetes, see Diabetes Care at KPWA (SharePoint site). For individual nutrition counseling, refer patients to Nutrition Services. Virtual group classes taught by registered nurses and registered dietitians are also available; see Thriving with Diabetes Virtual Group Classes for more information about the four-class series.

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 and snacks.
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 the Living Well With Diabetes: Action plan for healthier eating.

Dietary recommendations

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. Diet and exercise strategies that help to decrease glycemic load and increase insulin sensitivity also decrease hyperinsulinemia, which in turn can help lead to weight loss. Encourage patients to set *behavior change* goals, rather than weight loss goals, to achieve and maintain long-lasting glycemic control.

"Healthy Eating Plate" and "Diabetes Plate"

The Healthy Eating Plate diet is recommended as a model for appropriately limiting carbohydrates while providing a template for nutritional balance. This model recommends filling 50% of the plate with non-starchy vegetables, 25% with protein (limit fatty and highly processed meat), and 25% with whole grains, starchy vegetables and/or fruit. It is highly adaptable to different cuisines, cultures, and food preferences; see Using the Healthy Plate for Any Cuisine for a variety of options, such as Indian, Chinese, and Soul Food. The Diabetes Plate is similar to the Healthy Eating Plate, with recommendations to fill 50% of the plate with non-starchy vegetables, 25% with carbohydrates, and 25% with protein, limit sugary beverages, fruit juice and sweets, and use an 8"–9" diameter plate for portion control.

Other diets

The Mediterranean Diet is an anti-inflammatory and heart-healthy diet that can be layered on top of the Diabetes Plate, as a next step if a patient's diet already has well-balanced meals, appropriate carbohydrate limits, and food fairly well distributed throughout the day. The Mediterranean diet emphasizes fish, beans, nuts, high-fiber whole grains, and olive oil. Similarly, elements of the DASH diet and plant-based diets overlap those of the Mediterranean Diet and can be overlaid on the Diabetes Plate. The DASH diet focuses on whole grains, fruits, vegetables, lean protein, low-fat or fat-free dairy, limited sodium, and avoidance of processed foods.

Timing

The timing of eating can help stabilize appetite and blood glucose. Consuming a meal or balanced snack every 3 to 4 hours is recommended. Prolonged periods without eating increase the risk of overeating later in the day and may increase cravings for simple carbohydrates. Spacing meals and snacks at least 2 hours apart allows time for blood sugar to resolve in between. Dietary fiber also can help blunt post-prandial glycemic response.

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. 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.

Intermittent fasting

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. This pattern is contrary to the limited portions and even food distribution recommended for managing diabetes, which help to reduce glycemic load at meals. Furthermore, intermittent fasting is difficult to sustain and may decrease energy available for physical activity. While some studies have suggested that intermittent fasting may improve insulin sensitivity and decrease hyperinsulinemia, there are conflicting results regarding effects on blood glucose, and it remains unclear whether intermittent fasting improves diabetes risk indicators. See KPWA Weight Management Guideline evidence summary (question 3).

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 (PE63).

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 blood glucose monitoring and control. The following information and help are available:

- Patients at risk for dehydration should stop both SGLT inhibitors and metformin.
- The pamphlet “Living Well with Type 2 Diabetes: Taking care of yourself when you’re sick" is available online and can be ordered (PE338) from the Resource Line; also available in Spanish. Or use SmartPhrase **.chronicdiseasedmtype2sickdayplan**.
- 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 Management of Diabetes in Pregnancy: Standard of Care in Diabetes – 2023.

Bariatric surgery

There is evidence that surgically induced weight loss results in better blood glucose control and less need for diabetic medications than conventional diabetes therapy focused on weight loss through lifestyle changes. Evidence from a large cohort study suggests that failure to sustain blood glucose control is an adverse predictor of diabetes relapse after surgery (Arterburn 2013). See the Bariatric Surgery Quick Care Guide and Clinical Review Criteria: Bariatric Surgery.

Pharmacologic options for glucose control

Metformin

Metformin should be titrated as tolerated. A reasonable initial titration schedule is:

500 mg ½ tab once daily X 7 days;
500 mg 1 tab once daily X 7 days;
500 mg 1 tab twice daily.

This initial titration schedule is now the default in KP HealthConnect. It provides 39 tablets, which equates to a true 30-day supply.

If a patient does not experience any GI side effects after 2–3 days, the dose may be titrated to goal of 1000 mg twice daily more quickly. (The maximum dose is 2000 mg/day).

If a patient develops GI side effects, reduce the dose and reassess. Consider a more conservative titration schedule starting with 500 mg ¼ tab (125 mg) orally once daily; alternatively, consider prescribing the extended-release (XR) formulation for patients who cannot tolerate the dose with regular-release formulation.

Precautions with metformin prescribing:

- **Monitor serum creatinine levels** because the medication is primarily excreted by the kidneys (see Table 4).
- **Reduce metformin dose** to a maximum of 500 mg twice daily in patients with eGFR 30–45.
- **Discontinue metformin dose** in patients with eGFR < 30, or whose eGFR has worsened by 25% or more since the previous reading.
- **Avoid use of metformin** in patients with known binge or excessive alcohol use. Instruct patients to avoid excessive acute or chronic alcohol use.
- **Suspend use of metformin** if a patient is to undergo a surgical procedure or be given iodinated contrast media for a radiological procedure, or has any severe illness. Restart metformin when normal renal function is verified or when severe illness resolves.
- **Metformin should be withheld** in patients with dehydration and/or prerenal azotemia.
- **Monitor B12 level every 2 years** in patients taking metformin who also have neuropathy or anemia. If B12 level is low (< 200 pg/mL), initiate treatment with oral or IM B12. If B12 level is borderline low (200–300 pg/mL), methylmalonic acid levels should be checked. See the Metformin and vitamin B12 deficiency clinical pearl.

A note about diabetes medications in patients aged 65 years and older

The 2023 American Geriatrics Society Beers Criteria provide recommendations for the safe and effective use (e.g., dose adjustments and regular monitoring) of sulfonylureas, insulins, and SGLT-2 inhibitors in elderly patients aged ≥ 65 years or younger patients with other comorbidities.

Sulfonylurea: Strong recommendation (harms, adverse events, and risks clearly outweigh benefits)
- Glimepiride (long-acting) prolonged risk of hypoglycemia based on duration of action
- Glipizide (shorter-acting) best option for patients aged ≥ 65 years to reduce risk of hypoglycemia due to shorter duration of action

Insulin: Strong recommendation
- Short/rapid insulin – using sliding scale without basal insulin increases risk for hypoglycemia

SGLT-2: Weak recommendation (harms, adverse events, and risk may not outweigh the benefits)
- All SGLT-2 (empagliflozin, dapagliflozin) higher risk of urogenital infections and euglycemia diabetes ketoacidosis

Sulfonylureas

- **Glimepiride** remains the preferred sulfonylurea for those aged **< 65 years.** Glimepiride is primarily metabolized by the liver, with renal excretion of active metabolites.

  A reasonable titration schedule for glimepiride is:
  Increase to 2 mg once daily for 1–2 weeks;
  Increase by 2 mg once daily at 1- to 2-week intervals to maximum of 8 mg once daily.

- **Glipizide** is the preferred sulfonylurea for those aged **≥ 65 years** (for kidney toxicity avoidance to avoid excessive prolonged hypoglycemia). Glipizide is metabolized by the liver and primarily excreted in the urine as inactive metabolites, although one of its metabolites may have weak hypoglycemic activity.

  A reasonable titration schedule for glipizide is:
  Adults < 65 years: Starting dose 5 mg daily prior to morning meal. May move to twice-daily dosing and increase based on before-meal response to maximum dose of 40 mg daily.
  Elderly ≥ 65 years: Starting dose 2.5 mg daily prior to morning meal. May move to twice-daily dosing and increase based on before-meal response to maximum dose of 20 mg daily. (If CrCl < 50, reduce dose by 50%.)

  Consider prescribing the extended-release formulation of glipizide for patients who cannot tolerate the regular-release formulation. The most common side effect of sulfonylureas is hypoglycemia. Initiate and titrate with caution in those with chronic kidney disease.

  Titration schedule for extended-release products:
  Adults < 65 years: Start 5–10 mg daily. Maximum dose is 20 mg daily.
  Elderly ≥ 65 years: 2.5–5 mg daily. Maximum dose is 10 mg daily.

Basal insulin

Check fasting blood glucose (FBG) every day and get weekly average. The target is mean FBG of 80–130 mg/dL. For adults over age 65, a higher target (140 mg/dL) may be considered. For a new start, use the Insulin SmartRx in KP HealthConnect to choose the syringe or pen needles as well as testing supplies (glucometer start kit, strips, lancets, and sharps container) if desired.

Weight-based dosing strategy:

- Start with 0.2 units/kg once daily at bedtime and adjust by 4–10 units per week.
- Reassess fasting and daytime BG once a dose of 0.6 units/kg of a longer-acting insulin is achieved.

Note: If insulin is over 0.6 units/kg, evaluate the need for daytime basal or mealtime insulin. If glucose is dropping > 50 points between daytime and fasting, evaluate the need for mealtime insulin.

Treat-to-target strategy:

- Initial dose of 10 units basal insulin at bedtime.
- If FBG is higher than 130 mg/dL, increase bedtime insulin dose by 1 unit.
- If FBG is higher than 180 mg/dL, increase bedtime insulin dose by 2 units.
- Continue increasing bedtime insulin dose by 1–2 units at a time until FBG is in the target range.
- If FBG is lower than 80 mg/dL, decrease bedtime insulin dose by 2 units.
- If FBG is 50–70 mg/dL, decrease bedtime insulin dose by 4 units.
- Continue decreasing bedtime insulin dose by 2–4 units at a time until FBG is in the target range.
- Insulin 70/30 can be a cost-effective option when the need to intensify and eating patterns support safe use.

If HbA1c is higher than 7.0% and blood glucose checks before lunch, dinner, and bedtime are indicating a steady rise in blood glucose throughout the day, the patient very likely needs daytime insulin therapy.

Sodium-glucose cotransporter-2 (SGLT-2) inhibitors

Empagliflozin (Jardiance) is the preferred formulary SGLT-2 inhibitor at KPWA. While the PA criteria was removed in March 2023, patients may still have a cost share. Use of **half-tablet empagliflozin 25 mg daily** instead of 10 mg tablets helps to reduce patient costs and avoid coverage gaps.

When initiating SGLT-2 inhibitors, consider waiting until HbA1c is within 2% of goal to help ensure tolerability and effectiveness. Benefits from the cardiorenal protection associated with these agents are based on value from long-term administration. SGLT-2 inhibitors generally only lower HbA1c by 0.5–1.0%. Using agents with greater glucose-lowering capabilities (e.g., metformin and/or insulin) may help patients feel better faster.

Do **NOT** start medication	• Patients with significant renal impairment with eGFR < 20 mL/min, have end stage renal disease (ESRD), and/or on dialysis • Patients at high risk for developing diabetic ketoacidosis (DKA) • Patients with type 1 diabetes • Patients with active lower limb infections • Patient with heavy alcohol use
Consider the risks versus benefits before starting medication	• Evaluate endogenous insulin production/adequacy prior to initiation of SGLT-2 inhibitors to minimize the risk of euglycemia ketoacidosis. • Patients with low intake of carbohydrates, such as a ketogenic dietary approach, as this may increase the risk for euglycemia ketoacidosis • Patients with an eGFR between 20 and 30, may start SGLT-2 inhibitor but require monitoring within 1–2 weeks as transient decline in eGFR is common. See Table 4, Monitoring for medication effectiveness and adverse effects, for more information. • Patients with chronic or recurring genitourinary infections (fungal and bacterial) or a history of prior amputations • Patients with immobility, incontinence, chronic diarrhea, inability to maintain hygiene
Hold the medication	• 3 days prior to procedures requiring patients to be NPO or have reduced dietary intake (see Preoperative Evaluation Practice Resource) • Active urinary tract infections (UTI), genital infections, or yeast infections until resolution • Active limb infections until healing is complete • Illness that may result in dehydration (e.g., vomiting or diarrhea)

Ertugliflozin and canagliflozin in any combination with other diabetes agents are **not** recommended and remain non-formulary. Canagliflozin is of particular concern among patients with prior history of amputations or concerns about bone density. While dapagliflozin also remains non-formulary, it is the preferred alternative for patients with a contraindication, intolerance, or failure of empagliflozin.

For more information on SGLT-2 inhibitors, see the Diabetes Quick Care Guide.

Non-preferred options that can be considered in patients at high hypoglycemia risk where cost is an issue

- **Acarbose:** alpha-glucosidase inhibitor (generic available)
  May have some cardiovascular benefit in those with impaired glucose tolerance. Generic, low risk of hypoglycemia.
  - Start 25 mg t.i.d. with first bite of food, can increase up to 100 mg t.i.d.
  - Predominant side effects include flatulence and diarrhea, which lead to low adherence in most patients.
- **Pioglitazone:** thiazolidinedione (generic available)
  Generic, non-preferred agent (use caution with patients with liver disease or heart failure), low risk of hypoglycemia.
  - Start with 15 mg daily, increase up to 30 mg daily.
  - Significant side effects include weight gain, edema, increased risk of congestive heart failure. Contraindicated in patients with active liver disease.
  - Other concerns include increased risk of bone loss and osteoporotic fracture in women, and a potential increase in the risk of bladder cancer.
- **DPP-4s:** E-Consult Pharmacy for new starts or if questions.

Concentrated insulin

For patients requiring insulin between 1 unit/kg/day and 250 units/day, consider **U-200 insulin**.

For patients who require > 250 units insulin daily, consider **U-500 insulin**; consultation with the Diabetes Team is recommended before switching to U-500 insulin.

Consider referral to Chronic Disease Management for patients using any concentrated insulin.

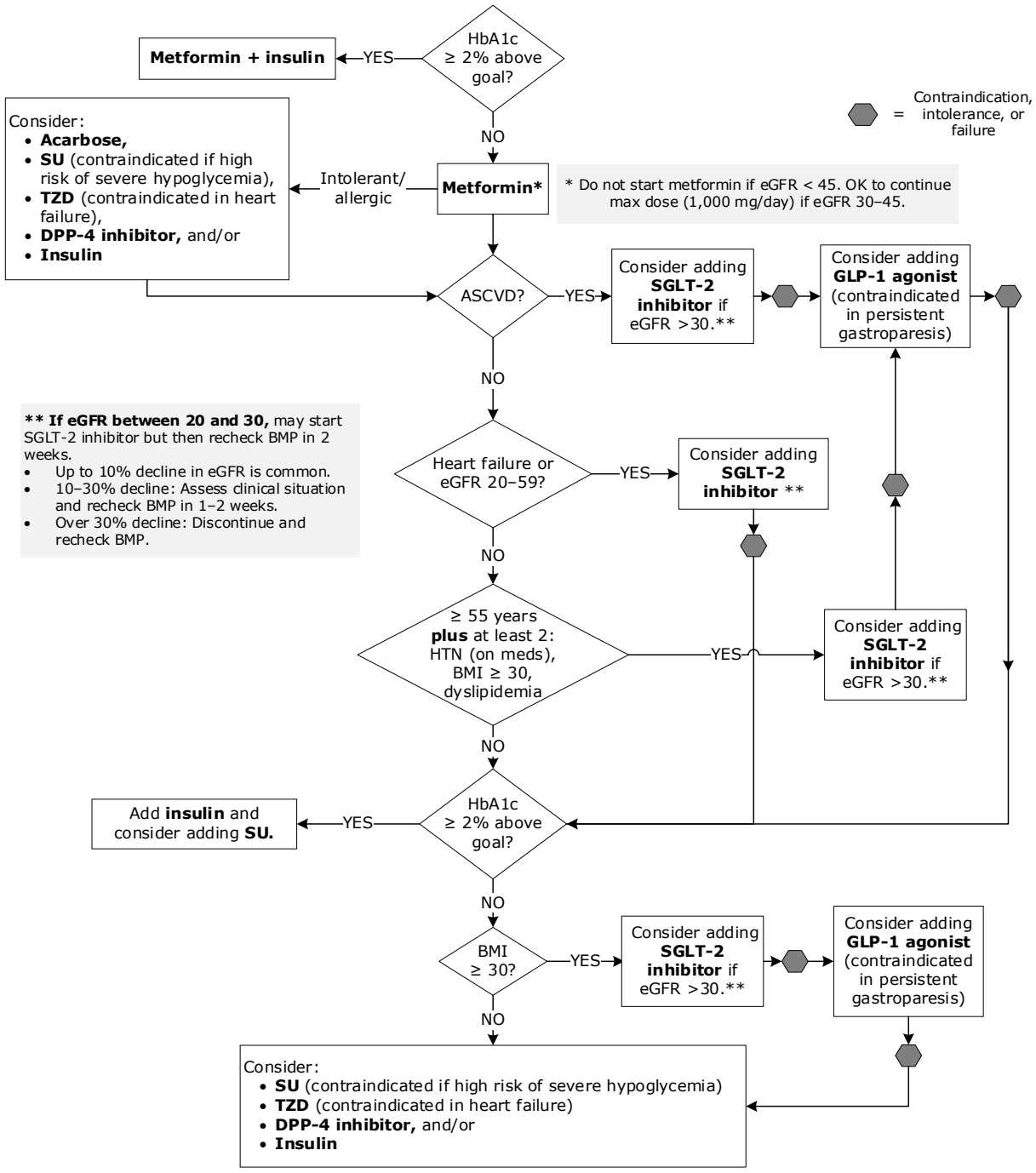
U-200 maximum single dose in one injection is 160 units (0.8 mL). Adjustments can be made in increments of 2 units.

U-500 maximum single dose in one injection is 250 units (0.5 mL). Adjustments can be made in increments of 5 units.

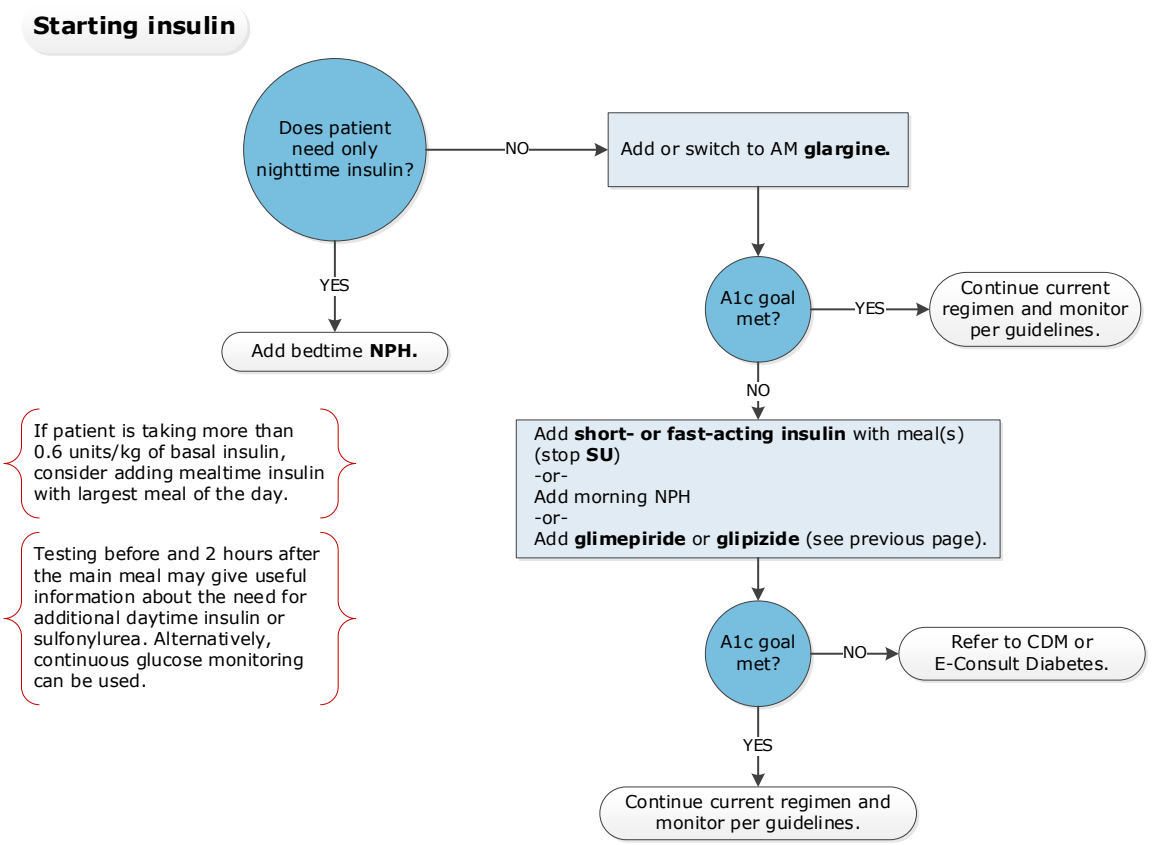
See Concentrated Insulin Start algorithm, p. 12.

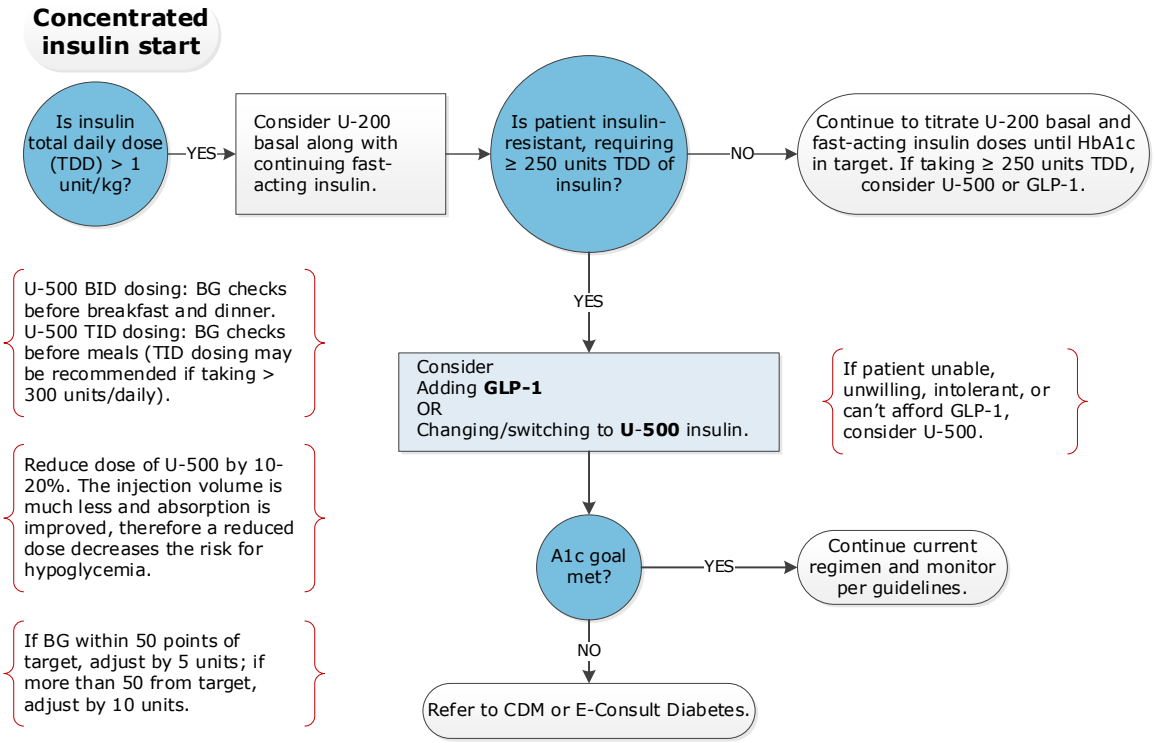
Type 2 diabetes treatment algorithm

See Think Preferred (staff SharePoint site) for specific product recommendations.



Type 2 diabetes treatment: when to consider longer-acting or concentrated insulin





Additional pharmacologic options to consider in consultation with the Diabetes Team

Basal insulin

For patients with type 2 diabetes who need intensive insulin schedules (which typically include both basal insulin and pre-meal boluses of rapid-acting insulin) or who experience recurrent hypoglycemia with other longer-acting insulins, glargine is preferred, similar to the way patients with type 1 diabetes are managed (see “Recommended physiologic insulin replacement schedule” in the Type 1 Diabetes Treatment Guideline).

Glucagon-like peptide-1 (GLP-1) receptor agonists

GLP-1s are used as adjuncts to diet and exercise to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes and established ASCVD. If patients develop persistent symptoms of gastroparesis—regardless of level of severity—discontinue use. Other GLP-1–containing formulations—such as **tirzepatide** (GLP-1/GIP)—are non-formulary, non-preferred agents at this time.

GLP-1 agonists are associated with an increased risk of gastrointestinal side effects (e.g., nausea, diarrhea, vomiting).

- For most patients, toleration of the GI side effects of GLP-1 agents requires acclimation to therapy by starting with subtherapeutic doses and titrating up to more effective doses.
- Good adherence is essential to prevent side effects and improve tolerance.

Average weight loss with GLP-1 agonists is modest and depends on the specific agent used.

- **Liraglutide:** 5 lb. loss in the liraglutide group compared to placebo at 3 years.
    - Note: SGLT-2 inhibitors also achieve about 3–5 lb. weight loss compared to placebo at 2–4 years.
- **Semaglutide:** 7–15 lb. weight loss at 68 weeks compared to placebo.

Do **NOT** start medication	• Pregnancy or breastfeeding • Patients with history of gastroparesis, intestinal obstruction • Patients with a personal or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2 (MEN2)
Consider risks versus benefits before starting medication	• Existing GI disease or at risk for dehydration • At risk for pancreatitis, gallbladder, or biliary tract diseases • At risk for diabetic retinopathy complications • At risk for hypoglycemia with concurrent insulin or sulfonylurea. Consider reduction or discontinuation of sulfonylurea, and reduction in insulin as applicable. Monitor closely.

Hold the medication	• Acute illness with nausea/vomiting
	• For planned procedures:
	  ○ Hold daily formulations within 24 hours of surgery.
	  ○ Hold weekly formulations within 7 days of surgery (may resume after surgery).
	  ○ See KPWA Preoperative Evaluation Practice Resource.

Restarting GLP-1 treatment after interruption	• Re-titration from lowest dose is needed when:
	  ○ Daily dosing: If patients miss > 3 days of GLP-1 agonist therapy
	  ○ Weekly dosing: If patients miss ≥ 2 weeks of therapy

When to discontinue GLP-1 therapy for diabetes	• Consider discontinuing GLP-1 therapy for patients without comorbid diabetes complications if HbA1c is not improving within 3 months of receiving a therapeutic dose and/or patient is unable to tolerate therapeutic doses of the GLP-1 agent. • Continue therapy if achieving at least 0.5% reduction in HbA1c and/or at least 5% weight loss.

Commercial criteria for type 2 diabetes coverage for preferred GLP-1 receptor agonists

For patients with type 2 diabetes:

- Currently on maximum tolerated dose of metformin (or contraindication, intolerance, or failure of maximum tolerated doses of metformin), and **contraindication, intolerance, or failure of an SGLT-2 inhibitor** (empagliflozin preferred) after a trial of at least 3 months duration, with
    - History of clinical atherosclerotic cardiovascular disease (ASCVD), ***or***
    - Age ≥ 55 years *plus* two or more of the following: hypertension (on medication), obesity (BMI ≥ 30), or dyslipidemia

-OR-

- With hemoglobin A1c (HbA1c) within 2% of A1c goal ***and*** all of the following:
    - Clinically significant weight gain while on insulin therapy or BMI ≥ 30 prior to insulin therapy
    - Contraindication, failure, or intolerance to maximum tolerated dose of metformin
    - **Contraindication, failure, or intolerance, to achieve A1c goal with an SGLT-2 inhibitor** (empagliflozin preferred) after trial of at least 3 months duration

-OR-

- Contraindication, failure, or intolerance of maximum tolerated doses of metformin, insulin,* **and an SGLT-2 inhibitor** (empagliflozin preferred)

*Note: Previously documented severe hypoglycemia would be considered an intolerance or contraindication to insulin therapy. Severe hypoglycemia includes hypoglycemia resulting in seizures, loss of consciousness, or needing help from others.

For more information on GLP-1 receptor agonists, see the Diabetes Quick Care Guide.

Continuous subcutaneous insulin infusion (insulin pumps or infusion pods)

There is evidence to support the use of insulin pumps for a subset of patients with type 2 diabetes.

Motivated patients with type 2 diabetes who are having difficulty controlling their blood glucose 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 to acquire and maintain use of a pump.

Note that the Diabetes Team sees patients with diabetes who are using or considering insulin pumps and places orders for all insulin pumps and supplies. 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 those patients' overall diabetes plans of care and annual reviews of care.

Continuous glucose monitoring (CGM) systems

CGM systems allow the patient to get real-time blood glucose readings automatically. Data is transmitted to a receiver, which can be a Smart Phone, a handheld device called a reader (for Libre devices), or a handheld receiver (for Dexcom CGMs).

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:

- Meglitinides—repaglinide (Prandin), nateglinide (Starlix)
- Amylinomimetics—pramlintide (Symlin)
- Dopamine agonists—bromocriptine (Cycloset)
- Bile acid sequestrants—colesevelam

There is **no high-quality evidence** to determine the effect on blood glucose control of any of the following:

- Chromium
- Cinnamon
- Vanadium

Chronic Disease Management Support

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

When to refer to Chronic Disease Management (CDM):

- HbA1c ≥ 8% on insulin or diabetes medication that requires titration
- Patients experiencing urgent concerns
  - New insulin start
  - Frequent or severe hypoglycemia
  - Recent diabetes-related hospitalization (e.g., DKA or HSS)
  - Recent UC visit with excessive hyperglycemia
  - Requiring insulin conversion
  - New medication starts requiring insulin adjustments (steroids, GLP-1s)
  - Average home glucose ≥ 200

Do not refer:

- Patients with HbA1c < 8% unless there are safety issues
- Patients with gestational diabetes or type 2 diabetes who become pregnant
- Patients who are not residing in the state of Washington or are planning to be out of state for an extended period

Note: **For HbA1c < 8%, metformin titration or SGLT-2 inhibitor initiation can be managed in Primary Care.**

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 for anyone using a sulfonylurea or insulin, as both of these medications can cause hypoglycemia.

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.

Self blood glucose monitoring

Table 3. Self blood glucose monitoring (SBGM)
Note that for patients with diabetes, SBGM is useful only if they are testing and using the information to make changes to their diabetes self-management plans.

Eligible population	Recommendations
Patients on lifestyle changes and/or metformin only	• These patients are not at risk for hypoglycemia.[1] **It is reasonable for them not to do SBGM.** • Changes to therapy can be made based on HbA1c values every 3 months. • Some patients may find that SBGM helps them see the effect of particular food items or exercise on their blood glucose, thus helping them stay motivated with lifestyle changes.

Patients on sulfonylureas and/or insulin	• These patients may develop hypoglycemia. It is advisable that they do SBGM when they "feel funny" to confirm whether or not their symptoms are due to hypoglycemia.
	• If patients are using treat-to-target approaches, especially if using insulin (for example, titrating their dose of bedtime longer-acting insulin until they reach a fasting blood glucose target of 120 mg/dL), then testing the fasting blood glucose (FBG) once a day is advisable.
	  ○ Once patients achieve their FBG target, there is no need to continue testing every morning if they feel well and their HbA1c stays below their target range.
	  ○ However, if such patients are at their FBG target but their HbA1c is still above target, then testing before and 2 hours after their main meal may give useful information about the need for additional daytime treatment (with sulfonylurea or insulin).

Patients on basal insulin and pre-meal rapid-acting insulin	• These patients should do SBGM 3–4 times daily if they are using the information to adjust how much rapid-acting insulin they take before the meal. • They may also want to test 2 hours after their main meal or under other circumstances where they want to know the effect of food, exercise, or stress on their blood glucose levels.

[1] Several studies have shown that improvement in HbA1c is almost identical whether patients test their blood glucose or not (Poolsup 2009).

Periodic monitoring of medication effectiveness and adverse effects

Table 4. Monitoring for medication effectiveness and adverse effects

Eligible population	Test	Frequency
Effectiveness and adverse effects		
Patients being treated with GLP-1 receptor agonists	Weight	Monthly for the first 3 months. Continue monitoring every 3 months thereafter.
	Hydration Blood pressure Creatinine	Monitor hydration status, weight, blood pressure every month for the first 3 months, then every 3 months thereafter.
	HbA1c	At 3 months ensure at least 0.5% HbA1c reduction.
	Blood glucose monitoring Hypoglycemia [1]	More frequent monitoring is recommended with starting and adjusting/ changing doses.
	Creatinine	Baseline and annually thereafter for most patients.
Adverse effects		
Patients being treated with metformin	Serum creatinine/eGFR	Annually if eGFR is 60 or lower **or** Twice a year if eGFR is 45 or lower.
Patients being treated with metformin with neuropathy or anemia	Vitamin B12	Every 2 years.
Patients being treated with SGLT-2 inhibitors [2]	Estimated glomerular filtration rate (eGFR)	Monitor at baseline and at 3 months and 6 months after starting therapy.
	Urinalysis	May be useful in rare cases where SGLT-2 abandonment is suspected by not routinely recommended.

[1] Especially if taking sulfonylureas or insulin.

[2] **If eGFR is between 20 and 30,** may start SGLT-2 inhibitor but then recheck BMP in 2 weeks.
- Up to 10% decline in eGFR is common.
- 10–30% decline: Assess clinical situation and recheck BMP in 1–2 weeks.
- Over 30% decline: Discontinue and recheck BMP.

Periodic monitoring of conditions and complications

Table 5. 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	Albumin/creatinine ratio [1] and Estimated glomerular filtration rate (eGFR)	At least 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 and lipodystrophy [4]	Examine insulin injection sites or infusion set insertion sites.	At every in-person visit in Primary Care.

[1] The albumin/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 more than 30 mcg/mg. Two positive tests, ideally 3–6 months apart, are diagnostic for microalbuminuria.

[2] See “Foot care” in the “Lifestyle modifications and non-pharmacologic options” section for foot-ulcer risk definitions.

[3] Annual screening is not recommended because the benefits of more frequent screening are marginal: For every 1,000 persons 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 and lipodystrophy can interfere with efficient insulin absorption.

Recommended immunizations

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

Table 6. Recommended immunizations for patients with diabetes	
Immunization	**Frequency**
Influenza	• Annually by the end of October. • Injectable vaccine recommended. Avoid LAIV (FluMist).
Pneumococcal polysaccharide	• For adults ages 19 to 64 years, one dose PCV20. • Age 65 years and older, if previously received PCV13, PCV23 or both, give 1 dose PCV20 at least 1 year later
Hepatitis B	• Three-dose series for ages 19 to 59 years. • Ages 60 years and older, depending on risk.
RSV	• Shared decision-making in adults ages 60 years and older. • Diabetes is considered a chronic underlying condition that increases the risk for severe RSV disease.
All other routine adult immunizations per CDC guidance.	

Comorbidities

Depression screening

Screen for depression 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 or type 2 diabetes who have hypertension (BP > 140/90 mm Hg).
- Patients with type 2 diabetes aged 55 or older who have elevated albumin to creatinine ratio **and** additional cardiovascular risk factors.

For patients with type 2 diabetes at high risk of ASCVD or with heart failure or chronic kidney disease, consider use of SGLT-2 inhibitor after metformin to reduce cardiorenal events.

See the ASCVD primary prevention and secondary prevention guidelines 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 Association of Clinical Endocrinology Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm – 2023 Update (Samson 2023)

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)

Pharmacologic Approaches to Glycemic Treatment of Type 2 Diabetes: Synopsis of the 2020 American Diabetes Association's Standards of Medical Care in Diabetes Clinical Guideline (Doyle-Delgado 2020)

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 type 2 diabetes, what is the safety and effectiveness of plant-based diet compared to Mediterranean and DASH diets or other diet approaches in achieving and maintaining weight loss and remission of diabetes?

   There is insufficient published evidence to determine that plant-based diet is equivalent or superior to the Mediterranean or DASH diets in improving glycemic control in patients with diabetes, achieving and maintaining weight loss, or achieving remission of diabetes. The literature search did not identify any randomized controlled trials (RCTs) that directly compared plant-based diet head-to-head with the Mediterranean or DASH diets in the management of patients with type 2 diabetes. The majority of published studies and systematic reviews on plant-based diet were conducted among patients without diabetes and mainly focused on examining the effect of the plant-based or vegan diet on reducing body weight, blood pressure, and cholesterol, and/or the primary prevention of type 2 diabetes.

2. In adult patients with diabetes, does the use of sodium glucose cotransporter-2 (SGLT-2) inhibitors increase the risk for diabetic ketoacidosis 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.

3. 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).

4. 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.

5. 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.

6. 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.

7. 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.

8. In the African American population with type 2 diabetes, what interventions/strategies or programs are effective in improving their glycemic control with the aim of reducing the disparities in HbA1c levels between them and white adults with diabetes?

Moderate-quality evidence from earlier systematic reviews of RCTs and nonrandomized studies (Smalls 2015, Walker 2013) suggests that community interventions are effective in reducing HbA1c in African Americans.

Effective community interventions, approaches, and delivery methods include nutritionist educators, nurse educators, using a curriculum-based approach, using problem-solving with the patient, culturally tailoring the intervention, and using mobile device software. One systematic review (Small 2015) indicated that the use of community health workers was not more effective than other approaches.

Moderate-quality evidence from another systematic review (Cunningham 2018) suggests that of diabetes self-management education (DSME) has a positive effect on reducing HbA1c in African Americans. However, there is insufficient evidence to determine the most effective setting, structure, content, contact hours, and type of provider delivering the education.

Moderate-quality evidence from a recent systematic review and meta-analysis (Anderson 2022) suggests that telehealth interventions delivered by telephone calls, text messages, web-based portals, and virtual visits that mainly delivered DSME, are effective at improving glycemic control among African American patients with diabetes.

The evidence on the impact of using of peer support on improving glycemic control in African Americans is mixed.

- One RCT (Presley 2020) found that targeted community-based DSME with and without peer support improved glycemic control among low-income, African American adults with poorly controlled type 2 diabetes.
- One systematic review (Smalls 2015) indicated that community health workers visiting homes of individuals with type 2 diabetes to deliver DSME was not more effective that other community intervention approaches.
- The PLEASED trial (Tang 2015) found no significant effect of using peer support to sustain improvements achieved in a short-term DSME program for African American adults with type 2 diabetes.
- An RCT (Heisler 2019) examined the effect of enhancing peer coaching with individually tailored interactive web-based educational tools (iDecide) among African American, low-income adults with diabetes and poor glycemic control. The results showed significant improvements in glycemic control through peer support with or without using interactive web-based educational tools.

There is insufficient evidence to determine the effect of using technology in improving glycemic control in African Americans.

9. In the Hispanic/Latino population with type 2 diabetes, what interventions/strategies or programs are effective in improving their glycemic control with the aim of reducing the disparities in HbA1c levels between them and white non-Hispanic adults with diabetes?

The most effective evidence-based method(s) for improving glycemic control among the U.S. Hispanic/Latino population include:

- Community health worker (CHW) Interventions
- Diabetes self-management education (DSME)
- Use of health information technology (HIT) in DSME
- Intensive glucose-lowering therapy.

Different programs were also identified and reviewed, including Project Muse and the Emory Latino Diabetes Education Program (ELDEP).

The overall results of the published studies, meta-analyses, special programs, or projects evaluating and implementing different strategies for improving glycemic control among Hispanics/Latinos with diabetes mellitus are as follows:

- Several studies showed that community health worker (CHW) interventions (Palmas 2015, Duggan 2014, Pérez-Escamilla 2015, Carrasquillo 2017) were effective in reducing HbA1c levels in Latino/Hispanic patients with poorly controlled type 2 diabetes. The components of the interventions varied between studies, but overall, they were culturally and health-literacy tailored and delivered by trained and supervised bilingual and (in some studies) bicultural community health workers. In some trials the CHW intervention was integrated as part of a broader intervention that included medication management by health care providers.
- The effects of CHW interventions on HbA1c varied between studies and were more pronounced among patients with poorer glycemic control and in trials with longer duration (≥ 12 months). The highest effect size was observed in the DIALBEST intervention (Pérez-Escamilla 2015), which showed a 0.85% reduction in HbA1c at 12 months that was sustained for 6 months post–intervention period.
- DSME was effective in reducing HbA1c levels in Hispanic/Latino patients with diabetes (Ferguson 2015, Ricci-Cabello 2014, Attridge 2014).
- DSME interventions were more effective in reducing HbA1c when they: were provided in conjunction with primary care, were delivered face-to-face in a group format by community health workers or nurses, incorporated dietitians and community peer educators, were culturally tailored, had more contact times (e.g., >10 times), and were delivered over a longer period (≥ 6 months).
- Studies relying primarily on telephone or telemedicine in delivering DSME did not show significant improvement in glycemic control. It was, however, found to be associated with a small improvement in glycemic control when incorporated with interventions provided by the educators to monitor patient data, have personalized video sessions with the educator, and/or send messages to the providers.
- The use of health information technology (Heitkemper 2017) may not be of much use among Hispanics/Latinos who do not regularly use computers and text messages in their daily life. Heitkemper and colleagues concluded that it would take time and resources to train and support these non-users before implementing health information technology in the Hispanic/Latino group.
- Intensive glucose-lowering therapy (Saremi 2015) may be more effective in lowering HbA1c among the Hispanic/Latino population with poor glycemic control compared to non-Hispanic whites.
- Analysis of the results of Project MUSE (Saremi 2015) suggests that enhanced primary care services provided to high-risk underserved patients with diabetes may improve their glycemic control and reduce the racial/ethnic disparities in HbA1c levels.
- One meta-analysis (Anderson 2022) suggests that telehealth interventions delivered by telephone calls, text messages, web-based portals, and virtual visits that mainly delivered DSME may be effective at improving glycemic control among Black and Hispanic diabetes patients.

10. In the American Asian population with type 2 diabetes, what interventions/strategies or programs are effective in improving their glycemic control with the aim of reducing the disparities in HbA1c levels between them and white adults with diabetes?

    The published studies identified by the literature search were conducted in Asia and their results might not be applicable to Asian Americans.

11. In the Native Hawaiian and Pacific Islander (NHPI) population with type 2 diabetes, what interventions/strategies or programs are effective in improving their glycemic control with the aim of reducing the disparities in HbA1c levels between them and white adults with diabetes?

    There is a lack of large RCTs or meta-analyses of RCTs investigating interventions for managing diabetes and improving glycemic control in NHPIs. The published literature consisted of relatively small RCTs or pilot studies on the management of diabetes in NHPI communities.

    The limited published studies do not provide sufficient evidence on benefit of the interventions evaluated for improving glycemic control among Hawaiians and Pacific Islanders.

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Guideline Development Process and Team

Development process

The Type 2 Diabetes Screening and 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.

Team

The Type 2 Diabetes Screening and Treatment Guideline development team included representatives from the following specialties: endocrinology, family medicine, internal medicine, nursing, nutrition services, pharmacy, and population care.

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